

**Can clinical audit, an intervention to influence medical practice,
improve the diagnosis of smear negative tuberculosis in three Latin
American countries?**

Full Name of Author: - Kamran Siddiqi

Submitted in accordance with the requirements for the degree of
PhD

The University of Leeds
Nuffield Centre for International Health and Development
Institute of Health Sciences and Public Health Research

September 2006

I confirm that the work submitted is my own and that appropriate credit has been
given where reference has been made to the work of others.

This copy has been supplied on the understanding that it is copyright material and
that no quotation from the thesis may be published without proper
acknowledgement.

**PAGE
MISSING
IN
ORIGINAL**

Acronyms

AFB	Acid Fast Bacilli
ARI	Acute Respiratory Infections
ARIMA	Auto-Regressive Integrated Moving Average
CASP	Critical Appraisal Skills Programme
CHD	Coronary Heart Disease
CI	Confidence Interval
CME	Continuing medical education
CMF	Clínico Medico Familia
CPD	Continuing professional development
CRD	Centre for Reviews and Dissemination
DOTS	Directly Observed Therapy
EPOC	Effective Practice and Organisation of Care
GP	General Practitioner
HCW	Health Care Workers
HIV	Human Immunodeficiency Virus
HV	Havana Vieja
IMCI	Integrated Management of Childhood Illnesses
LAM	Latin American
LR	Likelihood Ratio

LT	Las Tunas
MoH	Ministry of Health
NGO	Non-Governmental Organisation
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence
NTP	National Tuberculosis Control Programme
OR	Odds Ratio
ORS	Oral Rehydration Salt
PHC	Primary Health Care
PTB	Pulmonary Tuberculosis
QA	Quality Assurance
RCT	Randomised Control Trials
RR	Relative Risk
SD	Standard Deviation
SHC	Secondary Health Care
SN TB	Smear Negative Tuberculosis
SR	Sintomáticos Respiratorios
STD	Sexually Transmitted Diseases
TB	Tuberculosis
TPS	Tuberculosis Prediction Score
WHO	World Health Organisation

Abstract

Background

Clinical audit is an intervention designed to improve the quality of clinical care. Although well established in high income countries, there is little research evidence for its effectiveness in resource poor settings.

Aims and objectives

I aimed to evaluate the effectiveness of clinical audit in influencing clinical practice in providing diagnostic care for patients with suspected TB.

Methods

A total of 26 health centres were recruited in total in Cuba, Peru and Bolivia. Clinical audit was introduced to improve the diagnostic care for patients attending with suspected TB. Standards were based on the WHO and TB programme guidelines relating to the appropriate use of microscopy, culture and radiological investigations. At least two audit cycles were completed over two years. Improvement was determined by comparing performance between two six-month periods pre-and-post intervention. Qualitative methods were used to ascertain facilitating and limiting contextual factors influencing change among health care professionals' clinical behaviour, following the introduction of clinical audit.

Results

I found a significant improvement in 11 out of 13 standards in Cuba, two out of six in Bolivia and two out of five standards in Peru. Barriers to quality improvement included conflicting objectives for clinicians and TB programmes, poor coordination within the health system, and patients' expectations of illness and health services.

Conclusions

Clinical audit may drive improvements in the quality of clinical care in resource poor settings. It is likely to be more effective if integrated within local TB programmes. I recommend developing and evaluating an integrated model of quality improvement including clinical audit.

Contents

Acknowledgements.....	ii
Acronyms.....	iii
Abstract.....	v
Contents.....	i
Tables.....	xv
Figures.....	xviii
Chapter 1 Influencing change in professional practice in health care.....	3
1.1. Introduction.....	3
1.2. Theoretical models.....	5
1.2.1. Classical theories/models of change.....	6
1.2.1.1. Learning theory.....	6
1.2.1.2. Social cognition theory.....	7
1.2.1.3. Trans-theoretical model.....	8
1.2.1.4. Diffusion of innovations.....	9
1.2.1.5. Linear implementation model.....	11
1.2.2. Planned change theories/models.....	11
1.2.2.1. A conceptual framework.....	12
1.2.2.2. Planning framework for the interventions.....	12
1.2.2.3. Ottawa Model of Research Use.....	13
1.3. Interventions to improve professional practice.....	14
1.3.1. Audit and feedback.....	15
1.3.1.1. Introduction.....	15
1.3.1.2. Summary of the evidence.....	16
1.3.1.3. Limitations of studies.....	17
1.3.1.4. Barriers to change.....	18
1.3.1.5. Future implications.....	19
1.3.2. Continuing medical education (CME).....	28
1.3.2.1. Introduction.....	28
1.3.2.2. Summary of the evidence.....	28
1.3.2.3. Limitations of the current evidence.....	28
1.3.2.4. Barriers to change.....	29
1.3.2.5. Future Implications.....	29

1.3.3.	Educational materials.....	38
1.3.3.1.	Introduction.....	38
1.3.3.2.	Summary of the evidence	38
1.3.3.3.	Limitation of the studies	39
1.3.3.4.	Barriers to change.....	39
1.3.3.5.	Future implications	39
1.3.4.	Local consensus processes.....	43
1.3.4.1.	Introduction.....	43
1.3.4.2.	Summary of the evidence	43
1.3.4.3.	Limitations of the studies.....	43
1.3.4.4.	Barriers to change.....	44
1.3.4.5.	Future implications	44
1.3.5.	Local opinion leaders.....	46
1.3.5.1.	Introduction.....	46
1.3.5.2.	Summary of the evidence	46
1.3.5.3.	Limitations of the studies.....	46
1.3.5.4.	Barriers to change.....	47
1.3.5.5.	Future implications	47
1.3.6.	Educational outreach	49
1.3.6.1.	Introduction.....	49
1.3.6.2.	Summary of the evidence	49
1.3.6.3.	Limitations of the studies.....	54
1.3.6.4.	Barriers to change.....	54
1.3.7.	Reminders	54
1.3.7.1.	Introduction.....	55
1.3.7.2.	Summary of the evidence	55
1.3.7.3.	Limitations of studies	56
1.3.7.4.	Barriers to change.....	57
1.3.8.	Marketing.....	57
1.3.8.1.	Summary of the evidence	57
1.3.9.	Patient mediated interventions.....	57
1.4.	Barriers to Implementation	58
1.4.1.	Health care staff and providers	58
1.4.1.1.	Provider and staff knowledge/skills deficits.....	58
1.4.1.2.	Provider and staff psychological barriers	59

1.4.2.	Organisational barriers.....	60
1.4.3.	Resources barriers.....	60
1.4.4.	Patient psychological barriers and preferences.....	61
1.5.	Synthesis of studies	61
1.5.1.	Interventions likely to be effective	61
1.5.2.	Interventions likely to produce mixed results.....	61
1.5.3.	Interventions likely to produce no effect	61
1.5.4.	Interventions about which not enough is known	62
1.6.	Methodological limitations	62
1.7.	Research implications	62
Chapter 2	Influencing change in professional practice in health care: what works in developing countries?.....	63
2.1.	Introduction	63
2.1.1.	Deficiencies in the quality of service provision	63
2.1.1.1.	Causes of these deficiencies	63
2.1.2.	Gap between evidence and practice.....	64
2.1.2.1.	Constraints to implementing evidence into practice.....	65
2.1.2.2.	Actions required.....	65
2.2.	Aims and Objectives	66
2.3.	Methods.....	66
2.3.1.	Sources.....	66
2.3.2.	Search strategy.....	66
2.3.3.	Critical Appraisal.....	67
2.4.	Results.....	67
2.4.1.	Interventions	68
2.4.1.1.	Audit and feedback	68
2.4.1.2.	Education and training.....	114
2.4.1.3.	Local consensus development	116
2.4.1.4.	Educational outreach	116
2.4.1.5.	Local opinion leaders.....	116
2.4.1.6.	Educational materials.....	117
2.4.1.7.	Mass media, Marketing, Reminders and Patient mediated interventions.....	117
2.4.1.8.	Multiple strategies	117
2.5.	Discussion	117
2.5.1.	Limitations of the review.....	117

2.5.2.	Facilitators and barriers to change	118
2.5.3.	Policy implications	120
2.5.4.	Research gaps	120
2.6.	Conclusion.....	121
Chapter 3	Clinical diagnosis of smear negative pulmonary tuberculosis in developing countries: A review of the evidence	122
3.1.	Introduction	122
3.2.	Aims and objectives	123
3.3.	Methods.....	123
3.4.	Results	124
3.4.1.	Diagnostic indicators for smear negative tuberculosis	125
3.4.1.1.	Demographic indicators.....	125
3.4.1.2.	Clinical indicators.....	125
3.4.1.3.	Radiological indicators	126
3.4.1.4.	Sputum concentration	128
3.4.1.5.	Tuberculin test	128
3.4.1.6.	Other laboratory markers.....	129
3.4.2.	Diagnostic drug trials.....	129
3.4.3.	Diagnostic algorithms.....	130
3.5.	Discussion	133
Chapter 4	Aims and Objectives	144
4.1.	Objectives.....	144
Chapter 5	Methods.....	146
5.1.	Phase 1	146
5.1.1.	Critique of study designs to assess effectiveness	146
5.1.1.1.	Observational studies.....	147
5.1.1.2.	Quasi-experimental designs.....	147
5.1.1.3.	Randomised trials	151
5.1.2.	Methods used in Phase 1.....	153
5.1.2.1.	Justification of study design	154
5.1.2.2.	Settings and Participants.....	156
5.1.2.3.	Intervention.....	157
5.1.2.4.	Outcomes	160
5.1.2.5.	Analysis	161
5.1.2.6.	Anticipated difficulties with the design.....	162
5.2.	Phase 2	165

5.2.1.	Theoretical framework.....	165
5.2.1.1.	Macro theories	165
5.2.1.2.	Middle-range theories.....	166
5.2.1.3.	Epistemological theories.....	166
5.2.1.4.	Broad research orientation.....	168
5.2.2.	Methods used in phase 2.....	169
5.2.2.1.	Critique of study designs	169
5.2.2.2.	Choosing an appropriate design.....	171
5.2.2.3.	Selected research design.....	172
5.2.2.4.	Anticipated methodological problems in phase 2.....	179
5.3.	Conclusion.....	180
Chapter 6	Description of the three Latin American countries	183
6.1.	Peru..	183
6.1.1.	Geography, politics and population.....	183
6.1.2.	Major health problems	184
6.1.3.	Health reforms and organisation.....	185
6.1.4.	TB and its control	186
6.2.	Bolivia.....	190
6.2.1.	Geography, politics and population.....	190
6.2.2.	Major health problems	191
6.2.3.	Health reforms and organisation.....	192
6.2.4.	TB and its control	193
6.3.	Cuba.....	193
6.3.1.	Geography, politics and population.....	193
6.3.2.	Major health problems	194
6.3.3.	Health reforms and organisation.....	195
6.3.4.	TB and its control	196
Chapter 7	Study sites	198
7.1.	Peru..	198
7.1.1.	Study sites and TB indicators	198
7.1.2.	Current service provision in selected sites.....	198
7.1.2.1.	Structure.....	198
7.1.2.2.	Process	198
7.2.	Bolivia.....	204
7.2.1.	Study sites and TB indicators	204

7.2.2.	Current service provision in selected sites.....	204
7.2.2.1.	Structure.....	204
7.2.2.2.	Process.....	206
7.3.	Cuba.....	209
7.3.1.	Study sites and TB indicators.....	209
7.3.2.	Current service provision in selected sites.....	209
7.3.2.1.	Structure.....	209
7.3.2.2.	Process.....	213
Chapter 8	Implementation of clinical audit.....	215
8.1.	Peru.....	215
8.1.1.	Development of the audit committee.....	215
8.1.2.	Selection of the criteria and standards.....	215
8.1.3.	Data collection.....	216
8.1.4.	Issues related to data collection, collation, analysis and validation.....	218
8.1.5.	Problem analysis, recommendations and action planning.....	218
8.2.	Bolivia.....	224
8.2.1.	Development of the audit committee.....	224
8.2.2.	Selection of the criteria and standards.....	224
8.2.3.	Data collection.....	228
8.2.4.	Issues related to data collection, collation, analysis and validation.....	228
8.2.5.	Problem analysis, recommendations and action planning.....	232
8.3.	Cuba.....	232
8.3.1.	Development of the audit committee.....	232
8.3.2.	Selection of the criteria and standards.....	233
8.3.3.	Data collection.....	239
8.3.4.	Problem analysis, recommendations and action planning.....	239
Chapter 9	Results of the clinical audit.....	240
9.1.	Peru.....	240
9.1.1.	Clinical audit.....	240
9.1.1.1.	Standard 1.....	242
9.1.1.2.	Standard 2.....	244
9.1.1.3.	Standard 3.....	247

9.1.1.4.	Standard 4a and 4b.....	249
9.1.1.5.	Summary.....	252
9.1.2.	Themes from qualitative interviews conducted in Peru	253
9.1.2.1.	Shared goals (lack of support from the TB programme).....	253
9.1.2.2.	Health professionals' views on patients' perspective	254
9.1.2.3.	Lack of resources.....	256
9.1.2.4.	Communication.....	257
9.1.2.5.	Poverty.....	258
9.1.2.6.	Frequent changes in policies and personnel	258
9.1.2.7.	Differential treatment towards healthcare professionals	259
9.1.2.8.	Participatory leadership	261
9.1.2.9.	Safe environment.....	262
9.1.2.10.	Stigma about TB.....	263
9.1.2.11.	No blame culture.....	264
9.2.	Bolivia.....	264
9.2.1.	Clinical audit.....	264
9.2.1.1.	Standard 1	266
9.2.1.2.	Standard 2	268
9.2.1.3.	Standard 3	269
9.2.1.4.	Standard 4	271
9.2.1.5.	Standard 5	272
9.2.1.6.	Standard 6	275
9.2.1.7.	Summary.....	276
9.2.2.	Analysis of the qualitative interviews conducted in Bolivia	277
9.2.2.1.	Facilitating factors	277
9.2.2.2.	Limiting factors	282
9.3.	Cuba.	287
9.3.1.	Havana-Audit.....	287
9.3.1.1.	Standard 1	289
9.3.1.2.	Standard 2	291
9.3.1.3.	Standard 3	292
9.3.1.4.	Standard 4	293
9.3.1.5.	Standard 5	294

9.3.1.6.	Standard 6	295
9.3.1.7.	Standard 7	297
9.3.1.8.	Standard 8	298
9.3.1.9.	Summary	299
9.3.2.	Las Tunas-Audit	299
9.3.2.1.	Standard 1	300
9.3.2.2.	Standard 2	303
9.3.2.3.	Standard 3	304
9.3.2.4.	Standard 4	305
9.3.2.5.	Standard 5	307
9.3.2.6.	Summary	308
9.3.3.	Analysis of the qualitative interviews conducted in Cuba..	309
9.3.3.1.	Facilitating factors	309
9.3.3.2.	Limiting factors	314
9.4.	Conclusions	316
Chapter 10	Discussion	320
10.1.	Methodological limitations of this study.....	320
10.1.1.	External validity of the results.....	320
10.1.2.	Lack of controls	321
10.1.3.	Defining and measuring the impact of audit.....	322
10.1.4.	Issue of clinical significance and statistical significance ...	323
10.1.5.	Differentiation between intervention and research activity.....	324
10.1.6.	Failure to capture variations in individual health centres...	324
10.1.7.	Limited potential for improvement.....	325
10.1.8.	The data collection system and its influence on outcomes	325
10.1.9.	Time series and modelling.....	326
10.1.10.	Limited information about changes during intervention ...	326
10.2.	Summary of results	327
10.2.1.	Peru	327
10.2.1.1.	What went well?	327
10.2.1.2.	What went wrong?.....	328
10.2.2.	Bolivia.....	328
10.2.2.1.	What went well?	329

10.2.2.2.	What went wrong?.....	329
10.2.3.	Cuba.....	330
10.2.3.1.	What went well?.....	330
10.2.3.2.	What went wrong?.....	331
10.2.4.	Similarities and differences across the three countries.....	331
10.2.5.	Clinical audit and the TB programme	333
10.2.6.	Guidelines.....	334
10.2.7.	Selection of criteria.....	336
10.2.8.	Cost-effectiveness of audit	339
10.2.9.	Systems and resources to support implementation of evidence.....	340
10.3.	Research implications	342
10.3.1.	Evaluation of clinical audit.....	343
10.3.2.	Evaluating complex interventions - examples from the literature	345
10.3.2.1.	MRC framework for developing and evaluating complex interventions.....	345
10.3.2.2.	An integrated quantitative and qualitative approach.....	348
10.3.2.3.	Process evaluation in RCTs of complex interventions	349
10.3.2.4.	Standardising complex interventions.....	350
10.3.2.5.	The stepped wedge trial design.....	350
10.3.2.6.	Qualitative evaluation.....	351
10.3.2.7.	Systems approach	351
10.3.2.8.	Realistic evaluation.....	352
10.3.3.	Recommendations for future research	353
Chapter 11	Conclusions.....	355
References	358
Appendix 1	380
Appendix 2	384
Appendix 3	385

Tables

Table 1.1: Some resources for research evidence in concise form (systematic reviews)	4
Table 1.2: Interventions influencing change in professional behaviour through education and quality assurance.....	15
Table 1.3: Reviews of audit and feedback.....	20
Table 1.4: Reviews of CME.....	30
Table 1.5: Reviews of educational materials.....	40
Table 1.6: Some recent studies of local consensus process.....	45
Table 1.7: Some recent studies of local opinion leaders	48
Table 1.8: Principles of educational outreach or “academic detailing”.....	49
Table 1.9: Some recent studies of educational outreach.....	51
Table 2.1: Some examples demonstrating deficiencies in quality of care in developing countries	64
Table 2.2: Inclusion and exclusion criteria.....	67
Table 2.3: Interventions designed to influence change in professional behaviour through education and quality assurance.....	69
Table 2.4: Studies examining the influence of various interventions on changing professional practice in developing countries	71
Table 2.5: Reasons for poor prescribing habits among physicians in developing countries	119
Table 3.1: Search strategy.....	124
Table 3.2: TPS using multivariate predictors.....	132
Table 3.3: Post-test probability of TB given the prevalence of smear negative TB in three different settings	133
Table 3.4: Summary of studies reviewed	136
Table 3.5: Appraisal of included studies.....	139
Table 5.1: Steps in an audit cycle.....	157
Table 5.2: Table used for scoring each criterion against four factors.....	158
Table 5.3: Template table for problem analysis.....	160
Table 5.4: Strategies for implementing change after feedback.....	160
Table 5.5: Selecting the appropriate study design for the research question	171
Table 5.6: Methods of investigation in a case study.....	174
Table 5.7: Methods used for collecting evidence for case studies	174
Table 6.1: TB indicators for the three LAM countries.....	187

Table 6.2: Population indices of the three Latin American countries adopted from World Health Report.....	188
Table 7.1: TB indicators from participating health centres from Canto Grande district in Lima, Peru (2002).....	201
Table 7.2: A general overview of the service provision at the participating study sites in the three countries (2002).....	202
Table 7.3: Critical points in the SR patient’s journey through the health systems in the selected sites	203
Table 7.4: TB indicators from participating health centres in Cochabamba, Bolivia (2002)	205
Table 7.5: Health facilities at the participating health centres in Cochabamba, Bolivia (2002)	206
Table 7.6: TB indicators from the participating health zones in Cuba (2002).....	211
Table 7.7: Health facilities at the participating health zones in Cuba (2002).....	212
Table 8.1: Audit committee in Lima, Peru	216
Table 8.2: Agreed criteria (standards) in Lima, Peru	217
Table 8.3: Recommendations after the first audit cycle	218
Table 8.4: The process of standard setting in Lima, Peru.....	219
Table 8.5: Data handling issues in Lima, Peru.....	221
Table 8.6: Problem analysis after the first data collection	222
Table 8.7: Recommendations and action planning.....	223
Table 8.8: Audit committee in Cochabamba, Bolivia	224
Table 8.9: Agreed criteria and standards in Cochabamba, Bolivia	225
Table 8.10: A systematic assessment of the selected audit criteria in Cochabamba, Bolivia	226
Table 8.11: Issues with data collection for each standard in Cochabamba, Bolivia.....	229
Table 8.12: Recommendations after the first feedback in Cochabamba, Bolivia.....	232
Table 8.13: Audit committees in Havana and Las Tunas, Cuba	233
Table 8.14: Selected criteria and standards in Havana and Las Tunas, Cuba	234
Table 8.15: A systematic process of selecting audit criteria in Havana and Las Tunas, Cuba	236
Table 8.16: Recommendations of the audit committee after the feedback in Cuba.....	239
Table 9.1: <i>Absolute</i> difference between the mean proportions of the first and the last quarter for all standards in Lima, Peru.....	241

Table 9.2: <i>Absolute</i> difference between the mean proportions in the first and the last quarter: a sub-analysis of standard 2.....	245
Table 9.3: <i>Absolute</i> difference between the mean proportions in the first and the last quarter of standards 4a, 4b and their combination	250
Table 9.4: <i>Absolute</i> difference between the mean proportions of the first and the last audit cycle for all standards in Cochabamba, Bolivia	266
Table 9.5: <i>Absolute</i> difference between the mean proportions in the first and the last audit cycles for standards 4 and 5, and their combination	274
Table 9.6: <i>Absolute</i> difference between the mean proportions of the first and the last six-month data collection period for all standards in Havana, Cuba	288
Table 9.7: <i>Absolute</i> difference between the mean proportions of the first and the last six-month data collection period for all standards in Las Tunas, Cuba.....	300
Table 10.1: Results and inferences in the three Latin American countries.....	332

Figures

Figure 1.1: The diffusion of innovations	10
Figure 1.2: Linear implementation model	12
Figure 1.3: Ottawa Model of Research Use	14
Figure 1.4: An integrated approach between information, change and monitoring.....	16
Figure 2.1: Number and types of studies for each intervention.....	69
Figure 3.1: WHO algorithm for diagnosing TB in poorly-resourced countries	131
Figure 5.1: Fish bone diagram for problem analysis.....	159
Figure 5.2: A multiple case study design.....	173
Figure 6.1: Map of Peru	184
Figure 6.2: A comparison of the annual incidence of TB (per 100,000) of the three Latin American (LAM) countries.....	187
Figure 6.3: A comparison of the annual incidence of smear positive TB (per 100,000) in the three LAM countries.....	187
Figure 6.4: Map of Bolivia.....	190
Figure 6.5: Map of Cuba	194
Figure 7.1: A Patient's journey through the health system in Canto Grande, Lima	200
Figure 7.2: A typical SR patient's journey through the health system in the participating centres in Bolivia.....	208
Figure 7.3: A typical SR patient's journey through the health system in the participating centres in Cuba	214
Figure 9.1: A comparison of trends for all standards in Lima, Peru	241
Figure 9.2: <i>Relative</i> difference between the mean proportions (95%CI) of the first and the last quarter for each standard in Lima, Peru	242
Figure 9.3: Trend line over two years showing the proportions (95%CI) of patients meeting standard 1 for all health centres in Lima combined	243
Figure 9.4: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last quarter for standard 1 in each health centre in Lima, Peru	244
Figure 9.5: Trend line over two years showing the proportions (95%CI) of patients meeting standard 2 for all health centres in Lima combined	246

Figure 9.6: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last quarter for standard 2 in each health centre in Lima, Peru	246
Figure 9.7: Trend line over two years showing the proportions (95%CI) of patients meeting standard 3 for all health centres in Lima combined	248
Figure 9.8: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last quarter for standard 3 in each health centre in Lima, Peru	249
Figure 9.9: Trend line over two years showing the proportions (95%CI) of patients meeting standard 4a for all health centres in Lima combined	250
Figure 9.10: Trend line over two years showing the proportions (95%CI) of patients meeting standard 4b for all health centres in Lima combined	251
Figure 9.11: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last quarter for standard 4a in each health centre in Lima, Peru	252
Figure 9.12: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last quarter for standard 4b in each health centre in Lima, Peru	252
Figure 9.13: A comparison of trends for all standards in Cochabamba, Bolivia.....	265
Figure 9.14: <i>Relative</i> difference between the mean proportions (95%CI) of the first and the last cycles for each standard in Cochabamba, Bolivia.....	265
Figure 9.15: Trend line over two years showing the proportions (95%CI) of patients meeting standard 1, for all health centres in Cochabamba combined	267
Figure 9.16: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 1 in each health centre in Cochabamba, Bolivia	267
Figure 9.17: Trend line over two years showing the proportions (95%CI) of patients meeting standard 2 for all health centres in Cochabamba combined	268
Figure 9.18: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 2 in each health centre in Cochabamba, Bolivia	269
Figure 9.19: Trend line over two years showing the proportions (95%CI) of patients meeting standard 3 for all health centres in Cochabamba combined	270
Figure 9.20: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 3 in each health centre in Cochabamba, Bolivia	271

Figure 9.21: Trend line over two years showing the proportions (95%CI) of patients meeting standard 4 for all health centres in Cochabamba combined	272
Figure 9.22: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 4 in each health centre in Cochabamba, Bolivia	272
Figure 9.23: Trend line over two years showing the proportions (95%CI) of patients meeting standard 5 for all health centres in Cochabamba combined	274
Figure 9.24: <i>Absolute</i> difference between the mean proportions (95% CI) of the first and the last audit cycle for standard 5 in each health centre in Cochabamba, Bolivia	275
Figure 9.25: Trend line over two years showing the proportions (95%CI) of patients meeting standard 6 for all health centres in Cochabamba combined	276
Figure 9.26: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 6 in each health centre in Cochabamba, Bolivia	276
Figure 9.27: A comparison of trends for standards 1 to 4 in Havana, Cuba...	287
Figure 9.28: A comparison of trends for standards 5 to 8 in Havana, Cuba...	288
Figure 9.29: <i>Relative</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for each standard in Havana, Cuba	289
Figure 9.30: Trend line showing the proportions (95%CI) of patients meeting standard 1 for all health centres in Havana combined	290
Figure 9.31: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 1 in each health centre in Havana, Cuba	290
Figure 9.32: Trend line showing the proportions (95%CI) of patients meeting standard 2 for all health centres in Havana combined	291
Figure 9.33: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 2 in each health centre in Havana, Cuba	291
Figure 9.34: Trend line showing the proportions (95%CI) of patients meeting standard 3 for all health centres in Havana combined	292
Figure 9.35: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 3 in each health centre in Havana, Cuba	293
Figure 9.36: Trend line showing the proportions (95%CI) of patients meeting standard 4 for all health centres in Havana combined	293
Figure 9.37: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 4 in each health centre in Havana, Cuba	294

Figure 9.38: Trend line showing the proportions (95%CI) of patients meeting standard 5 for all health centres in Havana combined	295
Figure 9.39: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 5 in each health centre in Havana, Cuba	295
Figure 9.40: Trend line showing the proportions (95%CI) of patients meeting standard 6 for all health centres in Havana combined	296
Figure 9.41: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 6 in each health centre in Havana, Cuba	296
Figure 9.42: Trend line showing the proportions (95%CI) of patients meeting standard 7 for all health centres in Havana combined	297
Figure 9.43: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 7 in each health centre in Havana, Cuba	298
Figure 9.44: Trend line showing the proportions (95%CI) of patients meeting standard 8 for all health centres in Havana combined	298
Figure 9.45: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 8 in each health centre in Havana, Cuba	299
Figure 9.46: A comparison of trends for all standards in Las Tunas, Cuba ...	301
Figure 9.47: <i>Relative</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for each standard in Las Tunas, Cuba.....	301
Figure 9.48: Trend line showing the proportions (95%CI) of patients meeting standard 1 for all health centres in Las Tunas combined.....	302
Figure 9.49: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 1 in each health centre in Las Tunas, Cuba.....	303
Figure 9.50: Trend line showing the proportions (95%CI) of patients meeting standard 2 for all health centres in Las Tunas combined.....	303
Figure 9.51: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 2 in each health centre in Las Tunas, Cuba.....	304
Figure 9.52: Trend line showing the proportions (95%CI) of patients meeting standard 3 for all health centres in Las Tunas combined.....	305
Figure 9.53: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 3 in each health centre in Las Tunas, Cuba.....	305
Figure 9.54: Trend line showing the proportions (95%CI) of patients meeting standard 4 for all health centres in Las Tunas combined.....	306

Figure 9.55: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 4 in each health centre in Las Tunas, Cuba.....	306
Figure 9.56: Trend line showing the proportions (95%CI) of patients meeting standard 5 for all health centres in Las Tunas combined.....	307
Figure 9.57: <i>Absolute</i> difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 5 in each health centre in Las Tunas, Cuba.....	308
Figure 9.58: A comparison of <i>absolute</i> improvement in all criteria across all the three Latin American countries	317
Figure 9.59: A comparison of <i>relative</i> improvement in all criteria across all the three Latin American countries	317
Figure 10.1: Medical Research Council framework for evaluating complex interventions	347
Figure 10.2: Realistic Evaluation.....	352

Introduction

This section of the thesis provides a summary of the existing literature on the effectiveness of interventions aimed at influencing clinical practice including clinical audit. It also presents a brief introduction of smear negative tuberculosis and summarises outcomes of recent attempts to improve its diagnosis. It is subdivided as follows:

1. The first chapter provides a brief theoretical background to interventions aimed at influencing clinical practice, and reviews the researched literature on the evidence of their effectiveness.
2. The second chapter presents a systematic review of the literature on the effectiveness of interventions aimed at influencing clinical practice in resource-poor settings.
3. The third chapter gives a brief background to smear negative tuberculosis and systematically reviews the literature on the effectiveness of interventions aimed at improving the diagnosis of smear negative tuberculosis.

The background to the intervention and the clinical condition, along with the three literature reviews help in understanding the context of the aims and objectives of this study presented in the following chapter.

Chapter 1 Influencing change in professional practice in health care

1.1. Introduction

“The innovator makes enemies of all those who prospered under the old order and only lukewarm support is forthcoming from those who would prosper under the new”

Machiavelli

The last two decades have seen an increasing desire on the part of policy makers, managers and authorities for influencing change in health professionals' behaviour and practice (Bauchner, Simpson & Chessarre, 2001). There have been three main interlinked drivers behind this movement:

- Quality improvement
- Getting research into practice
- Cost pressures

Significant variations among different geographical areas in the provision of health care were first demonstrated nearly 30 years ago (Wennberg & Gittelsohn, 1973). A vast amount of literature has since accumulated, highlighting variations in service provision in almost every aspect of health care (Steinberg, 2003). This has led many health services, especially among developed countries, to focus their efforts on quality improvement (Thomson, 1998).

Authorities, policy makers and professionals have accepted the need for change to improve quality in health care provision. This international phenomenon has resulted in many initiatives such as evidence-based medicine, accreditation, accountability, total quality management, risk management, managed care, organisational development and leadership enhancement. These schemes have varied in their focus from changing professional behaviour to changing organisations, and from self-regulation to external quality assurance. However, quality improvement initiatives often demand health professionals provide the 'right' care for the 'right' people at the 'right' first time and in the 'right' amount (International society for quality in health care, 2003). Therefore, influencing change in health professionals' practice and behaviour is the underlying mechanism behind the majority of quality improvement initiatives.

It is also acknowledged that despite huge advances in health care achieved through research, and a significant body of evidence available on ‘what works’, relatively little has been put into practice by health professionals (Eddy, 1982). There is a common belief among health professionals and policy makers that health might be better if only we were able to better apply what we have learned through research into practice (Lenfant, 2003). Unacceptable delays in the implementation of research findings often result in suboptimal care for patients (Haines & Jones, 1994) e.g. lemon juice was shown to be effective in preventing scurvy as early as 1601, but wasn’t adopted as a preventative strategy until 1795 by the British navy, and until 1865 by the merchant navy (Mosteller, 1981). Similar delays in the adoption of research evidence into practice have resulted in poor clinical care in managing hypertension, orthopaedic surgery, myocardial infarction, asthma and gastroenteritis in children (Haines & Jones, 1994).

Access to sources of evidence and/or systematic reviews has improved due to a number of national and international initiatives (Table 1.1). However, adaptation of research findings into clinical practice requires a much more complex multifaceted approach (NHS CRD, 1999). This often requires a change in behaviour on the part of the relevant health professional, in order to replace less effective practices by those shown to be more effective. This emphasis on change in professional practice in order to provide health care consistent with the evidence is likely to improve quality of care and reduce variations in service provision.

Table 1.1: Some resources for research evidence in concise form (systematic reviews)

Bandolier
Clinical Evidence
Cochrane Library
Effective Health Care bulletins
National Institute of Health and Clinical Excellence
National Health Service (NHS) Cost and Effectiveness Reviews

In order to develop effective interventions to change professional practice, a conceptual model is needed that explains the behaviour change process and provides a rationale for developing intervention strategies (Cohen, Halvorson & Gosselink, 1994). This chapter aims to provide an overview of the effectiveness of various interventions designed to influence professional practice and behaviour in health care. The first part discusses various underlying models of behaviour change and the

second part summarises the current evidence on the effectiveness of these interventions. The concluding part highlights major constraints and barriers encountered in implementing such change.

It must be emphasised at this point that changing professional practice is not the only mechanism to improve quality and get research into practice. A number of other initiatives work by changing organisational, resource and financial management. This review focuses only on interventions aimed primarily at influencing health professionals' behaviour; these are generally based on various models of behaviour change. This will help to give the background to the aims and objectives of this thesis.

1.2. Theoretical models

Despite efforts to improve professional performance, there has been a recognised lack of understanding of all the determinants of change in clinicians' behaviour. Absence of such a theoretical base for conceptualising behaviour change compounds delay in the adoption of desired professional behaviour. No single unifying theory of health professionals' behaviour change has been developed which has been applicable and proven in practice (Smith, 2000).

T. Lawrence defines behavioural-change strategy as (Lawrence, 1999):

“a dynamic process, developing and evolving through a number of definable stages, and drawing on a range of identifiable psychological processes to initiate and support the desired outcome”

A number of theoretical models have been described to predict professional behavioural change. Such models have been developed and widely tested in altering consumers' attitudes towards products in the marketing and advertising worlds. In health care, the focus has mostly remained on health-enhancing (healthy eating etc.), health protective (smoking cessation, condom use etc.) and sick-role behaviours (compliance with medical regimes) of patients and the general public (Conner & Norman, 1996). In recent years, researchers have realised that such behavioural and psychological theories can also help in understanding the determinants of professional behaviour change. Interventions without a theoretical underpinning are likely to omit psychological processes central to professional behaviour change and thereby fail to optimise their effectiveness (Norman, 1995). However, very rarely have such models been field-tested and often studies evaluating interventions designed to influence professional behaviour fail to use the theoretical basis of the intervention. These models can be broadly classified into two categories (Graham & Logan, 2004):

- Classical theories/models of change (also referred to as descriptive or normative)
- Planned change theories/models

1.2.1. Classical theories/models of change

These theories are considered to be passive models as they provide a description of the change process. Here I will discuss five such theoretical models that have been widely described in relation to change in professional behaviour.

- Learning theory
- Social cognition theory
- Diffusion of innovations
- Trans-theoretical model
- Linear implementation model

1.2.1.1. Learning theory

Two types of learning theories may be applicable to clinical behaviour change.

- Adult learning theory
- Cognitive learning theory

1.2.1.1.1. Adult learning theory

According to adult learning theory, learning is a process in which behavioural capabilities are changed as the result of previous experience (Skinner, 1953). When the response is rewarded, it reinforces a particular type of behaviour. This behaviour becomes habitual when responses are reinforced repeatedly, and extinction of learned habit occurs when the response is not rewarded or punished (Chauhan et al, 2003). According to behaviourists, the focus needs to be on observable behaviour and the understanding of how learners' response patterns change over time as they encounter different stimuli (Williamson, Gunderman, Cohen & Frank, 2004). People learn from forming connections between stimuli and responses. When results are favourable, these connections become stronger and when consequences are adverse, the links become weaker.

If we apply this to professional practice, clinicians are likely to adopt practices that result in positive outcomes as compared to those that result in negative consequences. Change in professional practice is also likely to follow if the professional perceives the outcomes as desirable. Most educational strategies to improve professional behaviour are based on this theory. Learners learn to respond correctly to a question from their instructor. If they respond correctly, the

educational strategy has succeeded, while if the response is incorrect, further education is given until the correct answer becomes a fixed behaviour(Williamson et al, 2004). It is expected that this fixed behaviour will result in a change in practice as soon as the clinician makes a connection between the stimuli and the outcome. This is also applicable to interventions that provide feedback on outcomes and performance to the health professionals.

Adult learning theory is often considered to be too simplistic as knowledge is regarded from an external, objective perspective. Behaviourists are more interested in observable behaviour and do not attempt to understand the dynamics in the minds of learners. Too many complex processes take place that cannot be explained solely by this theory.

1.2.1.1.2. Cognitive learning theory

Cognitive theorists are more interested in the processes in the minds of the learners(Piaget, 1970). They tend to focus on information patterns and ways in which different ideas and concepts fit together in the minds of learners. This theory is also sensitive to the way different factors that alter those patterns, facilitate or detract from learners' abilities to use their knowledge in solving problems. Cognitivists are interested in how acquired knowledge transfers to new situations. Application of a cognitive perspective in designing educational interventions to influence clinicians places a greater emphasis on relating instruction to the existing knowledge and experience of the clinician. An interactive training model based on problem solving techniques is an example of cognitive learning theory.

1.2.1.2. Social cognition theory

Social cognition theory (also previously known as social learning theory) is the most widely applied and recognized theory to understand and influence health-related behavioural change. It originated from consumer research, as a study of how people process social information and apply this to social situations. Bandura applied this concept to understand health related behaviour, for the first time, and highlighted the social context in which health behavioural change and its related cognitive processes take place(Bandura, 1986). According to this theory, personal reaction to a perceived or actual threat of disease/illness and the processes that lead to any action taken, or not taken, depend on the social context(Whitehead, 2001).

Social cognition models to explain and understand behavioural change in health care professionals have not been developed or evaluated. Professional behaviour is usually shaped by professionals' beliefs, attitudes and intentions. Belief of the perceived balance of benefits against costs, perception about the attitudes of important others and self-belief in one's ability to adopt new practice would

constitute important cognitive processes in such a model. Four models are generally discussed in relation to health related behaviour change(Ogden, 2003).

- Theory of reasoned action
- Theory of planned behaviour
- Health belief model
- Protection motivation theory

Social cognitive models are, at best, a description of how a certain process might work, rather than how something does work. They are not solutions themselves. They can predict certain behavioural processes but do not guarantee desirable change.

1.2.1.3. Trans-theoretical model

Prochaska and DiClemente presented a transtheoretical model, which identifies preparatory psychological changes that precede behavioural change(Prochaska & DiClemente, 1983). This model has been widely applied in numerous health promotion interventions e.g. smoking cessation, condom use etc. According to it, a person passes through the following stages of psychological change processes during a given behaviour change.

- Pre-contemplation phase
- Contemplation phase
- Preparation phase
- Action phase
- Maintenance phase

There is little evidence that these postulated stages of change generate desired behavioural change. However, this model has been used to design interventions aiming for change in health related behaviour e.g. anti-smoking strategies. In the first stage, pre-contemplation, very basic information about research-based recommendations would be sufficient to facilitate change to the contemplation stage. In this interactive period, more information can be provided explaining potential benefits to patients if the recommendations were to be adopted. In the next stage, the preparation stage, health professionals can acquire skills of accessing sources of evidence. If this stage goes well, it will be followed by action. Desired behaviour can be maintained, perhaps through regular reminders and feedback.

There has been some criticism of this model. Some have argued that there is a logical flaw in distinguishing between the different stages. The “arbitrary time

periods” are artificial and in reality, there would be considerable overlap between these stages(Norman, 1995). In addition, this model gives a description of cognition during behaviour change but does not demonstrate cognition-changing techniques and their link to behaviour change outcomes.

1.2.1.4. Diffusion of innovations

The diffusion of innovation theory, originated from the social sciences, points out that the uptake and dissemination of an innovation depends on numerous influences, which correlate with the rate of spread of a change(Roger, 1995). In health care, these influencing factors can be clustered as follows(Berwick, 2003):

- Perceptions of the innovation
- Characteristics of the people who adopt the innovation, or fail to do so
- Contextual factors, especially involving communication, incentives, leadership, and management

1.2.1.4.1. Perception of innovation

An innovation that is perceived to be beneficial to the adopter is likely to be adopted at a faster pace. Similarly, compatibility with the beliefs and values of the innovator is another positive attribute of an innovation. A simple innovation is likely to be taken up better than a complex one. If the innovator feels that the innovation can first be adopted at a smaller scale before using it at a larger scale, he will be more tempted to try it (trialability). Similarly, an opportunity to observe others doing it is likely to persuade people to adopt innovations (observability).

1.2.1.4.2. Characteristics of individuals who may adopt an innovation

The curve in Figure 1.1 defines adopter categories, based on the rapidity with which people take up innovations plotted against time. These are innovators, early adopters, early majority, late majority and laggards. This postulates that the rate of spread of an innovation is related to the personalities of the people considering adoption of an innovation.

In health care, innovators are clinicians with a special interest in the topic who either have been involved in the research themselves, or have been part of developing national guidance. The early adopters are usually professionals who put themselves forward for local implementation committees, and serve as local opinion leaders. The early majority consist of the vast number of clinicians who would adopt an innovation, if it had the characteristics described in the previous paragraph. Late adopters will only adopt something new, when it becomes the new status quo. Laggards in health care are the clinicians usually referred to as traditionalists or “old

school”, who would air their opposition, and sometimes even persuade others not to adopt the innovation.

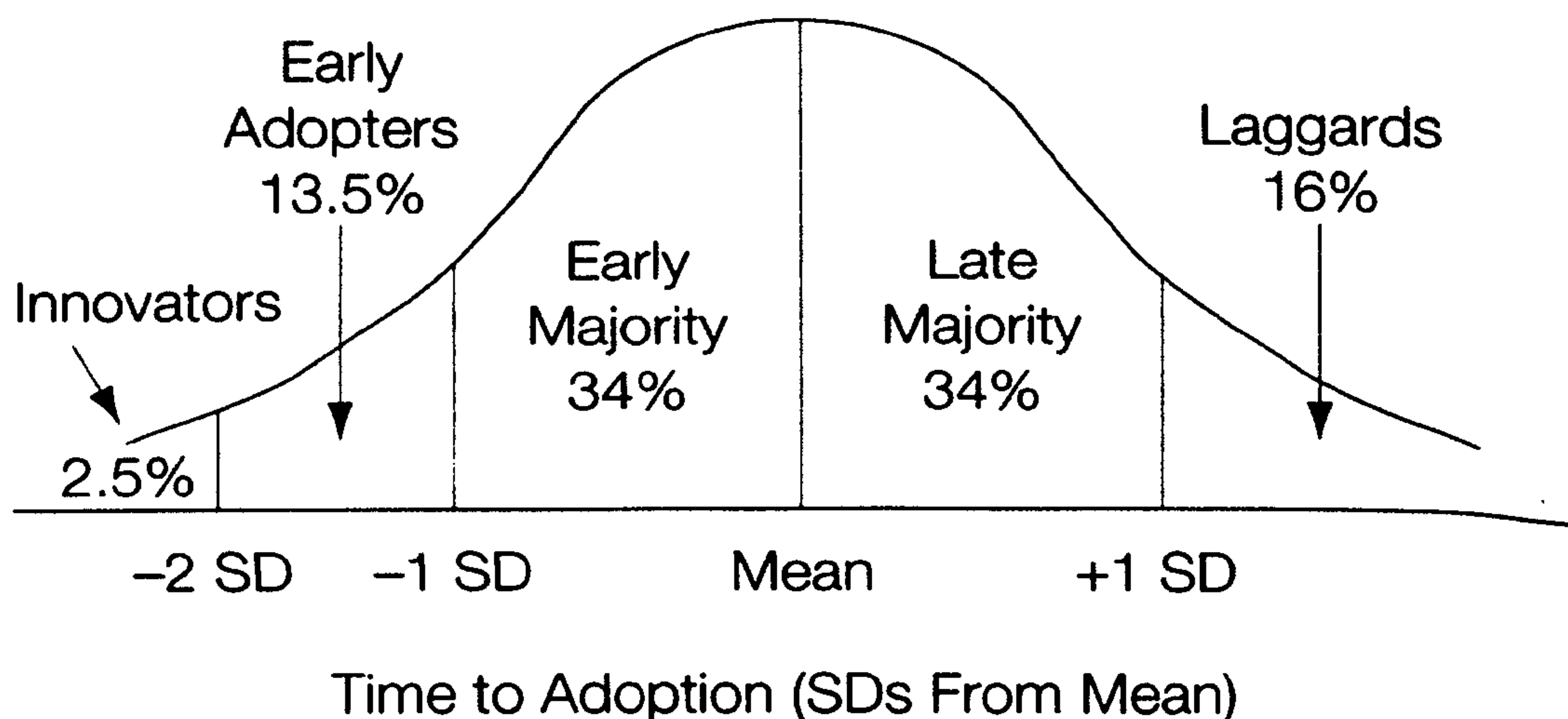


Figure 1.1: The diffusion of innovations

1.2.1.4.3. Contextual factors

These refer to the organisational factors that influence the rate of adoption of an innovation by either providing a favourable environment, or by discouraging innovation. In health care settings, an organisation that fosters research and development is likely to have a positive influence. On the other hand, organisations with a strong blame culture can discourage health professionals from adopting innovations.

A recent systematic review demonstrates how the above model can be applied to the adoption of innovations in health care organisations, and summarises the evidence supporting this model (Greenhalgh et al, 2004). This review provides a useful list of the attributes of innovations that are likely to be successful in adoption. It highlights the importance of contextual influences and the networks under which health care professionals operate. It also demonstrates the characteristics of organizations that encourage and inhibit innovation. A similar review evaluated literature on the adoption of innovations in health care and came up with a list of 50 determinants that influence the rate of adoption (Fleuren, Wiefferink & Paulussen, 2004). In the following paragraph, I summarise a paper that uses some of these determinants to describe a behaviour change model that is applicable to general practitioners.

1.2.1.4.4. A model of behaviour change among general practitioners

A study of general practitioners' reasons for recent changes in their prescribing behaviour concluded that numerous factors influence this behaviour (Armstrong, Reyburn & Jones, 1996). Three models of change emerged that have important implications for the design and evaluation of interventions aimed at behaviour change. These models do not challenge the above-mentioned theories but build upon some the determinants of change behaviour indicated above as follows:

- The *accumulation model* argues that when evidence exceeds a certain threshold behaviour change, is triggered. The volume of evidence and the agency advocating it determines the weight of evidence.
- The *conflict model* suggests that behaviour is changed by a surprise or a challenge posed by a critical event. It may be possible to stimulate such challenges through appropriate educational interventions.
- The *continuity model* promotes interventions to sustain change and suggests that doctors who constantly update their practice, and are sensitive to outside influences, are likely to maintain a behavioural change.

1.2.1.5. Linear implementation model

Lomas suggests that change in professional behaviour is a result of a linear interaction between the research evidence and the environment that the health professionals are practicing in (Lomas, 1993b). The author argues that behaviour change takes place in stages. The availability of credible information through dissemination "predisposes" physicians to consider changing their practice. Subsequently, local implementation activities assist in the change process by "enabling" and subsequently "reinforcing" the desired behaviour change (Figure 1.2). However, this model has only limited appeal due to its failure to incorporate complexity in adoption of the evidence.

1.2.2. Planned change theories/models

Classic theories/models are informative and help in identifying the determinants of change behaviour. However, they are less useful in designing interventions to change behaviour. Planned change models, on the other hand, present a set of concepts that explain how planned change may occur (Graham & Logan, 2004). The main aim of these theories is to alter social systems and predict how contextual factors might interact to bring about a behavioural change process. Some of these models are summarised below.

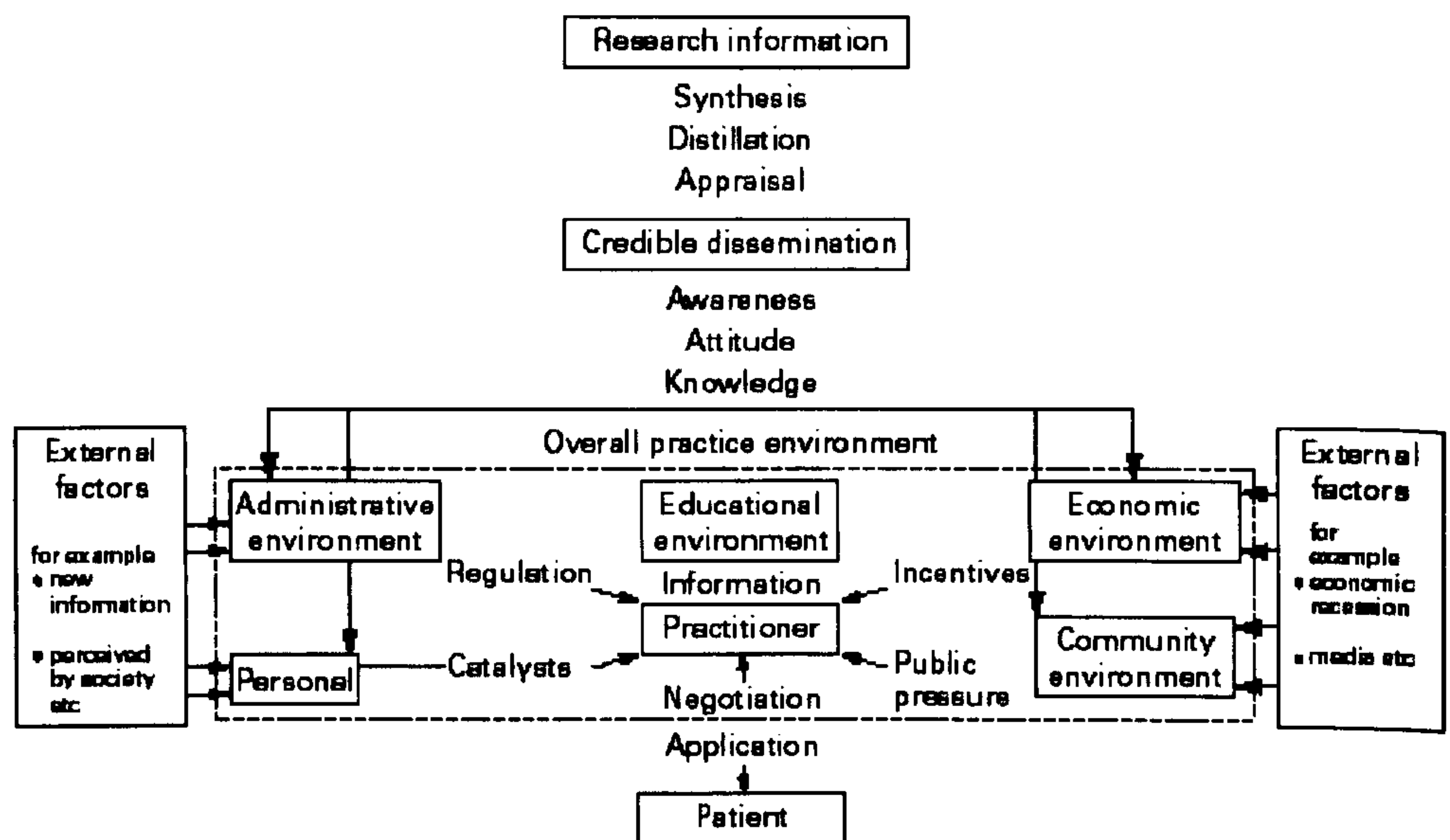


Figure 1.2: Linear implementation model

Adapted from (Lomas, 1993b)

1.2.2.1. A conceptual framework

According to this framework, successful implementation of research findings is a function of the nature of the *evidence*, the *context* of implementation and mechanism of *facilitation* (Kitson, Harvey & McCormack, 1998). The strength of the evidence is judged on the basis of quality of the research, professional consensus and patients' preferences. Similarly, the context in which change is implemented depends on the culture of learning, leadership and improving performance through continually measuring performance. Facilitation of the change process largely depends on the characteristics, role and style of the facilitator.

This model was recently revised by the same group (Rycroft-Malone et al, 2002). The revised model acknowledges that the evidence should be well conceived, designed and executed. The context should be characterised by decentralised decision-making, transformational leadership and reliance on multiple sources of information on performance. This framework provides guidance for health professionals in planning, implementing and tracking their own strategies for change.

1.2.2.2. Planning framework for the interventions

Any intervention based on the above theories should be linked into a comprehensive planning framework in order to be effective in meeting its objectives (NHS CRD, 1999). *Social marketing* and *Precede-Proceed* are such frameworks, and have been used in implementing change in professional behaviour.

According to the *social marketing* framework, success is viewed as likely only when the needs, perceptions and requirements of the target group are identified and

met, through the design and implementation of appropriate interventions(Kotler, 1984). It consists of six stages. The first stage entails planning, involvement of the target group and assessing availability of resources for the intervention. Stage two involves selection of the relevant channels and materials for intervention. The structure of the intervention is specified along with division of the target group into more homogeneous sub-groups. Stage three involves developing and piloting interventions with the target audience in order to determine their relevance, comprehensibility, and likely impact. Stages four and five are implementation and evaluation, where effectiveness is assessed in terms of whether and how the intervention is meeting its objectives. In the final stage, feedback helps in refining the intervention.

The *Precede-Proceed* model outlines the steps required to be in place before an intervention, and gives guidance on how to implement and subsequently evaluate the intervention(Green & Kreuter, 1980;Green & Kreuter, 1991). The *Precede* stages are concerned with problem specification, and identification of factors that influence the implementation of the intervention. These are classified as predisposing (beliefs, attitudes and perceptions), enabling (resources, skills and facilities) or reinforcing factors (incentives, positive feedback etc.). They are rated in terms of their importance and amenability to change. The *Proceed* stage is concerned with implementation and evaluation of the intervention. This stage analyses the extent to which behavioural change takes place after implementing a given strategy, and its influence on the predisposing, enabling and reinforcing factors.

1.2.2.3. Ottawa Model of Research Use

This model offers a comprehensive framework with elements that are likely to enhance the uptake of research into practice in a sustainable way(Logan & Graham, 1998). Elements include consideration of evidence-based innovations, potential adopters, the practice environment, interventions to promote the transfer of knowledge into practice, process of adoption of the innovation and the outcomes resulting after adoption. The following is a list of steps to guide implementation of this model(Logan & Graham, 1998) (Figure 1.3).

- Getting started
- Clarifying the innovation
- Assessing the innovation, potential adopters and the practice environment for barriers and support
- Selecting and monitoring the implementation of interventions

- Monitoring the adoption
- Evaluating the outcomes

Ottawa Model of Research Use

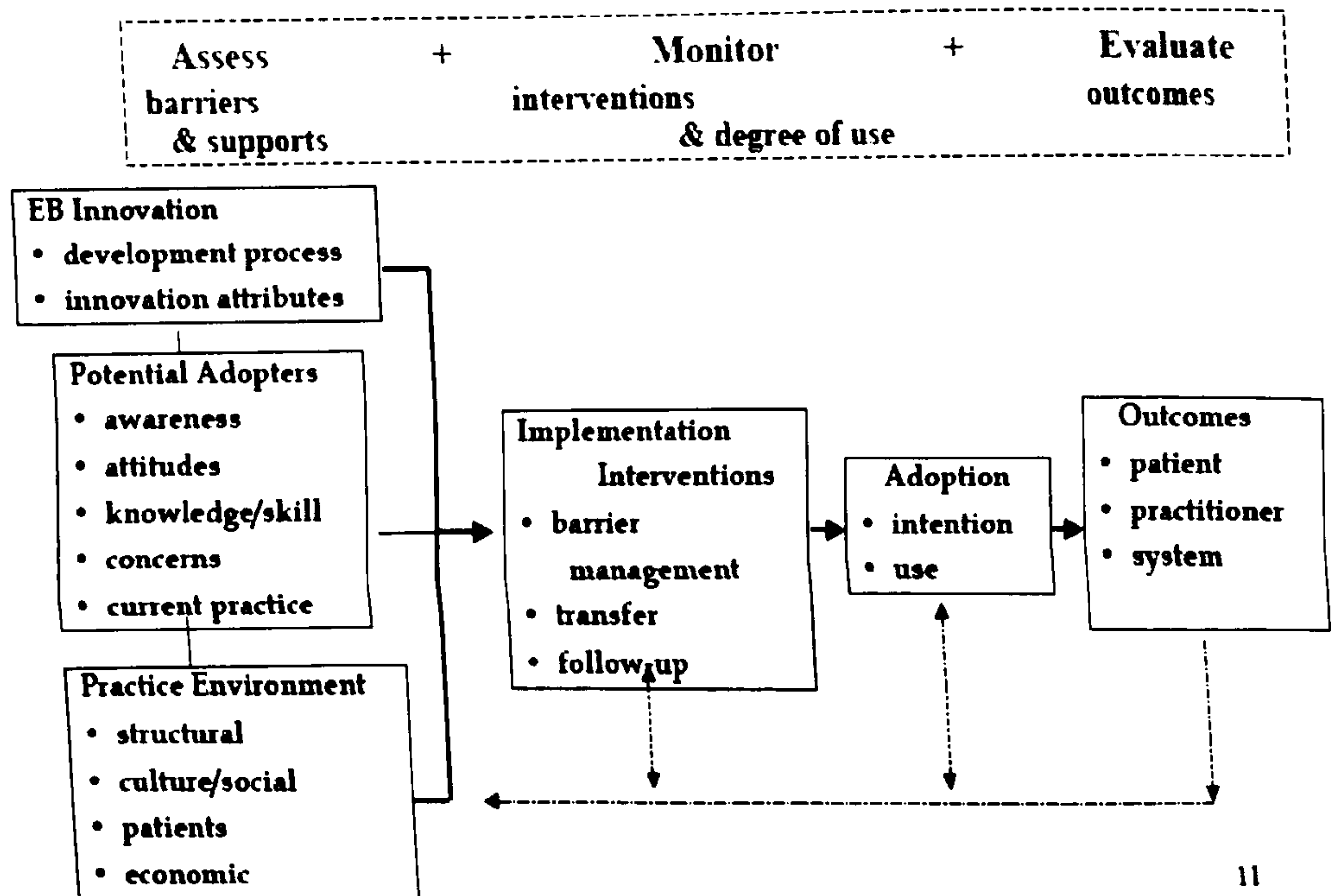


Figure 1.3: Ottawa Model of Research Use

1.3. Interventions to improve professional practice

The previous section presented the theories behind professional behaviour change. This section introduces some of the key strategies used to influence this change, providing an overview of published systematic reviews on interventions to improve professional practice (Table 1.2). These include reviews published so far by the Effective Practice and Organisation of Care (EPOC) Cochrane Review Group and the NHS Centre for Reviews and Dissemination (CRD)(Sheldon & Chalmers, 1994;Mowatt, Grimshaw, Davis & Mazmanian, 2001). It also includes reviews identified through the Medline and Embase databases between 1966 and 2003. The Cochrane Library was searched again in June 2006 to check for any updates on the key Cochrane reviews included in this chapter. Each subsection provides a summary of the evidence of effectiveness of the relevant intervention, followed by a description of the limitations of the retrieved literature, and barriers identified in implementing each intervention. Only those interventions that are based on education and quality assurance are examined in this section. Other interventions based on financial incentives and organisational changes are beyond the scope of this review. I have also excluded mass media interventions that target the public to increase health service utilisation.

Table 1.2: Interventions influencing change in professional behaviour through education and quality assurance

Audit and feedback
Local consensus development
Educational materials
Continuing medical education
Educational outreach
Local opinion leaders
Marketing
Reminders
Patient mediated interventions

1.3.1. Audit and feedback

Clinical audit is defined as an ongoing process to improve the quality of health care through the ongoing critical examination of current performance against agreed standards, leading to the identification and utilisation of opportunities for bringing performance closer to that standard.

1.3.1.1. Introduction

Audit is widely used as a strategy to influence professional practice as it appears logical that healthcare professionals would be likely to modify their practice if given feedback about variations in their clinical performance compared to that of their peers or from accepted guidelines (Jamtvedt et al, 2003). Audit has been adopted in many western countries including the UK over the last decade (Johnston et al, 2000). It has been argued that an approach integrating clinical audit and continuing education, based on guidelines and standards derived from systematic reviews can bridge the gap between evidence and practice (Haines & Jones, 1994). This assumes a logical relationship between information, monitoring and changing practice (Figure 1.4). This approach however has been criticised by other authors as rather simplistic and does not capture the complexity involved in the change process (Kitson et al, 1998). Concerns have been raised about the effectiveness of clinical audit on both sides of the Atlantic, ever since it was adopted as national policy.

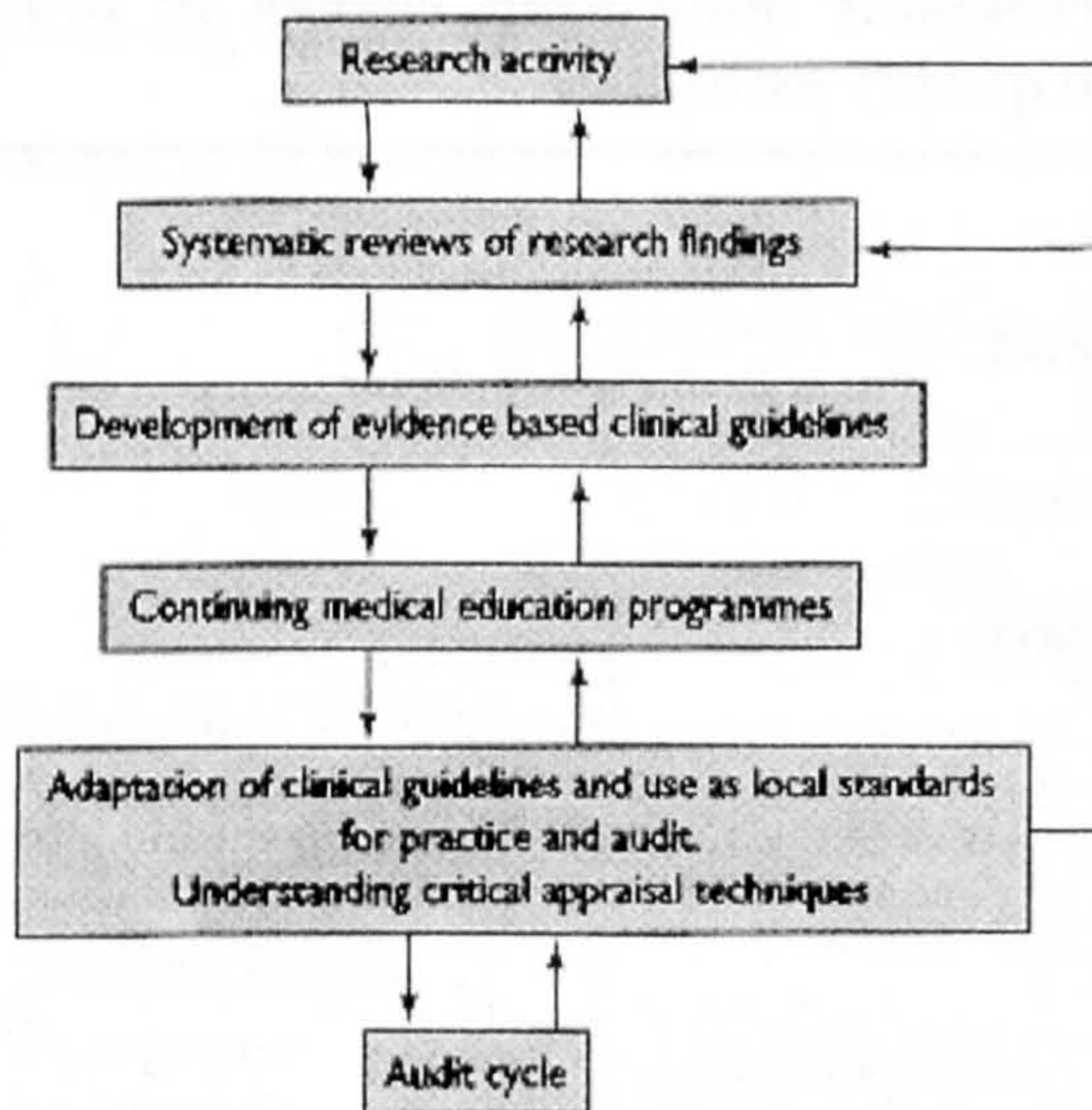


Figure 1.4: An integrated approach between information, change and monitoring

Adapted from (Kitson et al, 1998)

1.3.1.2. Summary of the evidence

This section provides a summary of 17 systematic reviews conducted between 1991 and 2003 including studies from 1966 to 2002 (Table 1.3). All reviews focused on examining the effect of audit and feedback, (alone or in combination with other educational strategies) on the practice of health care professionals and on patient outcomes. Four reviews were restricted to Randomised Controlled Trials (RCTs) only, two to systematic reviews, and the rest included non-randomised before and after controlled studies in addition to RCTs. 12 reviews included studies examining practicing physicians in primary or secondary care and five reviews covered all health care providers. Five reviews examined studies aimed at specific diagnostic (3) or preventative (2) care provision while the others included all studies irrespective of their target behaviour.

Audit and feedback produces a mixed effect on professional performance. Reviews included in this section have shown small to moderate improvement subsequent to performance feedback when used alone in comparison to no intervention and in comparison with other interventions. Multifaceted interventions targeting different barriers to change are far more likely to be effective than a single intervention. Performance feedback is likely to be more successful as part of a multifaceted strategy, and if it is given near the decision time. Similarly, feedback accompanied by physicians' trust in the process is likely to bring improvement in clinicians' behaviour. Feedback improves diagnostic test ordering behaviour and preventative care delivery, where prior educational strategies have established positive attitudes towards desired behaviour among physicians. Clinical audit was

more effective in improving care in situations where baseline compliance was poor. Active feedback of clinical performance comparing it to other clinicians' performance is likely to be effective. Changes in health care outcomes often lag behind the change in the performance of health care professionals due to several other factors influencing these outcomes.

1.3.1.3. Limitations of studies

Systematic reviews are not immune from publication bias. Despite authors making efforts to discover unpublished literature from developing countries, the majority of the studies included in reviews were from the UK and the US. Trials included in the systematic reviews were found to be of variable quality. Many studies failed to clarify their randomisation methods, blinding of the outcomes assessment procedure and completeness of their follow up (Jamtvedt et al, 2003). Analysis in the majority of studies was at patient level, despite randomisation based on physicians or health care provider units. This unit of analysis error results in overestimation of the effect size. Similarly, trials only assess change during and shortly after the interventions. Therefore, despite many trials, the long-term sustainability of improvement in clinicians' behaviour is still not known. Studies included in the reviews are based on voluntary participation of health care professionals, possibly creating a *Hawthorne* effect. Optimal performance of these motivated professionals can also give rise to 'ceiling effect' (where scope for further improvement is limited). Heterogeneity prevented many reviewers from performing meta-analyses. However, few reviews included studies of high quality according to specified criteria.

An updated Cochrane review conducted in April 2006 on audit and feedback included 118 studies (Jamtvedt et al, 2006). It also concluded that audit and feedback can change professional behaviour but its effect is usually small to moderate. The influence of audit and feedback is more likely to be large when baseline performance is low, and when health professionals are actively involved in implementing change.

All reviews showed variations in the effect of feedback on professional practice. However, reviewers were unable to prove or refute prior hypotheses on the role of various personal or organisational factors in explaining such variations. One such hypothesis is that differences in motivation could explain some of the observed variation in the effectiveness of audit and feedback across the included studies, but reviewers were unable to assess the influence of this factor (Jamtvedt et al, 2003).

1.3.1.4. Barriers to change

Researchers have hypothesized many barriers to the successful implementation of audit, often based on qualitative surveys of health care providers. However, very few researchers have attempted to prove or refute these hypotheses. One systematic review divides these barriers into the following categories(Johnston et al, 2000):

1.3.1.4.1. Physicians' attitude

Health professionals' attitude towards audit and feedback is one of the major determinants of its success. Audit is perceived by some physicians as a waste of time and a distraction from clinical responsibilities. Often physicians consider audit as a restriction to their clinical freedom and find it difficult to judge their peers' performance according to set standards. A threat to professional freedom often creates a negative attitude among physicians towards clinical audit and performance feedback. Physicians' lack of recognition of the need for improvement in their current performance also leads to failure of strategies based on feedback.

1.3.1.4.2. Lack of resources

A lack of resources is likely to de-motivate clinicians from adopting improved practices. Dedicated staff and funding are expected to help in conducting audit on a routine basis. A reliable health information system is also essential to make measure performance against standards. Lack of physicians' time and competing interest such as clinical care are unhelpful in implementing audit.

1.3.1.4.3. Lack of expertise in project design and analysis

Many studies have reported obstacles, which are imposed by a lack of expertise in audit methods. Lack of skills in project management, standard setting, data collection and designing audit tools can make the whole exercise useless. A successful audit also requires leadership skills to execute it according to a common vision based on agreed aims and objectives.

1.3.1.4.4. Poor team dynamics

A dysfunctional team without well-defined roles and responsibilities can also impede the success of audit. Lack of commitment, well-defined objectives, conflict among staff, fear of loss of confidentiality and failure to involve important stakeholders and generate ownership among professionals can all influence its success.

1.3.1.4.5. Organisational impediments

A lack of good relationships between managers and clinicians, with clear lines of authority and accountability is a recognised barrier to implementing audit. In

addition, the lack of organisational structures and procedures allowing clinicians to implement changes subsequent to performance feedback is likely to make physicians lose motivation for change.

1.3.1.5. Future implications

The majority of reviews advocate targeted and tailored use of audit and feedback where it is likely to overcome barriers for change. However, more studies are required with better designs. Ideal studies would have large sample sizes to avoid unit of analysis errors. Better reporting of the study methods, targeted behaviours, characteristics of participants and interventions is also essential in future studies. Future research should identify the optimal duration and frequency of audit and feedback to sustain improvement (Bordley et al, 2000). Such studies should also incorporate behaviour change models in designing interventions and evaluate their effectiveness rigorously over prolonged periods.

Table 1.3: Reviews of audit and feedback

Study	Focus	Inclusion criteria				Outcomes	Period	Results	Conclusions
		Study type	Participants	Intervention	Outcomes				
(Mugford, Banfield & O'Hanlon, 1991)	Role of performance feedback in changing clinical practice	RCTs, controlled trials and use of historical controls in before-and-after studies	Physicians	Active and passive feedback of comparative information from statistical system	Not specified	Not specified	At least 30 out of 36 studies included, showed some improvement in clinical performance subsequent to feedback. However, evidence is insufficient to define good formats for performance feedback	Feedback is likely to be effective as part of a multifaceted strategy and if provided close to the decision making progress	
(Davis, Thomson, Oxman & Haynes, 1992)	Impact of educational materials on physicians performance and health care outcomes	RCTs	50% were practicing physicians	Performance feedback provided to practicing physicians	Objective determination of health care professionals' behaviour and health care outcomes	1977-1991	In 12 out of 23 studies performance feedback had a positive effect on physicians' behaviour	Interventions using practice-enabling strategies consistently improve physician performance and, in some instances, health care outcomes	

<p>(Buntinx, Winkens, Grol & Knottnerus, 1993)</p>	<p>Effectiveness of feedback and reminders on diagnostic and preventative care in ambulatory care</p>	<p>RCTs, controlled trials, before-and-after studies</p>	<p>Physicians in ambulatory care</p>	<p>Feedback compared to reminders</p>	<p>Rate and cost of test ordering and compliance with the guidelines of preventative medicine</p>	<p>1983-1992</p>	<p>27 studies included. 8 evaluated the impact of interventions on reducing tests/costs: 2 of 2 RCTs assessing reminders and 5 of 6 studies (including 1 of 1 RCT) assessing feedback observed significant reductions. 14 studies evaluated impact of interventions on adherence to guidelines: 5 of 7 studies (including 4 of 4 RCTs) assessing reminders and 5 of 9 studies (including 3 of 4 RCTs) observed significant improvements</p>	<p>Feedback may reduce the utilisation of diagnostic tests, and may improve compliance of doctors to standards. Reminders appear to exert greater improvement other than methods of feedback</p>
<p>(Greco & Eisenberg, 1993)</p>	<p>Effectiveness of interventions designed to change physicians' practice</p>	<p>RCTs and controlled before-and-after studies</p>	<p>Physicians</p>	<p>Performance feedback in comparison to other interventions</p>	<p>Change in physicians' practice</p>	<p>1986-1992</p>	<p>Feedback had a mixed effect on clinical performance</p>	<p>Feedback is likely to be effective if provided near the decision time and accompanied by physicians' trust in the process</p>

<p>(Axt-Adam, van der Wouden & van der Does, 1993)</p>	<p>Interventions aimed at improving laboratory test-ordering behaviour</p>	<p>Not specified</p>	<p>Physicians</p>	<p>Performance feedback in comparison to other interventions</p>	<p>Test-ordering behaviour</p>	<p>1966-1992</p>	<p>Performance feedback given with comparison to peers' performance was more effective than on its own. Active feedback with involvement of health professionals and clear recommendations was more effective than passive feedback. Feedback on performance was relatively more effective than feedback on costs</p>	<p>Considerable variation was found among studies. Overall, the effectiveness of feedback in improving test-ordering behaviour among physicians is not shown to be highly effective</p>
<p>(Wensing & Grol, 1994)</p>	<p>Effectiveness of strategies for implementing changes in primary care focussing on the differences between single and multiple strategies</p>	<p>RCTs, controlled trials, before and after studies</p>	<p>Primary care clinicians</p>	<p>Performance feedback in comparison to the other interventions</p>	<p>Physicians behaviour</p>	<p>1980-1992</p>	<p>Feedback alone shown to be effective in improving physicians performance, but not in all cases. More improvement was observed if combined with educational sessions or peer review. Combining feedback with educational materials and reminders still remains questionable</p>	<p>Combined strategies are more effective than single strategies (although not in all cases) especially when addressing different types of barriers</p>

<p>(Oxman, Thomson, Davis & Haynes, 1995)</p>	<p>Effectiveness of interventions targeting physicians learning and practice might be altered</p>	<p>RCTs and controlled before-and-after studies</p>	<p>Health care providers</p>	<p>Audit and feedback compared to other interventions</p>	<p>Physicians behaviour and health outcomes</p>	<p>1966-1993</p>	<p>In 31 studies of audit and feedback as a single intervention and 15 trials of it in combination, only minimal to moderate effectiveness was observed. Effectiveness varied across the clinical behaviours. Multifaceted approaches were more successful in changing clinical practice and improving health outcomes in some instances</p>	<p>There are no "magic bullets" for improving quality in health care but a number of available interventions, if used appropriately can produce desirable results</p>
<p>(Davis, Thomson, Oxman & Haynes, 1995)</p>	<p>Effect of educational strategies on physicians' performance and health care outcomes</p>	<p>RCTs</p>	<p>50% were practicing physicians or medical residents</p>	<p>Performance feedback in combination or alone</p>	<p>Objective determination of performance of health care professionals in their workplace and health care outcomes</p>	<p>1975-1994</p>	<p>Performance feedback was only effective in 10 out of 24 studies. Feedback was more effective in studies where it was provided in the form of chart review</p>	<p>Widely used short educational interventions and educational materials are not effective if used in isolation. The change in health care outcomes lags behind the change in performance of health care professionals</p>

(Balas et al. 1996)	Effectiveness of physician profiling (peer comparison feedback) on professional behaviour	RCTs	Physicians	Peer comparison feedback	Compliance with clinical standards	Not specified	10 of 12 studies observed significant effects on various clinical procedures; p <0.05 and OR of 1.09 (CI: 1.05-1.14) based on a meta-analysis of 5 trials. Subgroup analyses of studies focusing on test ordering and prescribing were non-significant	Peer comparison alone is unlikely to result in significant quality improvement or cost reduction. There is a need for further evaluation of more substantive feedback and other methods to improve health care quality and control costs
(Davis & Taylor-Vaisey, 1997)	Strategies for implementing guidelines	Systematic reviews (3)	Physicians	Audit and feedback	Adoption of guidelines and patients' outcomes	1990-1996	Audit and feedback are moderately effective and have a mixed effect on the providers behaviour	Audit and feedback are more effective if timed close to the decision making process and is provider specific
(Solomon, Hashimoto, Daltroy & Liang, 1998)	Interventions aimed at improving physicians testing practices	Randomised and non-randomised trials	Physicians	Audit and feedback with and without other interventions	Diagnostic testing practices	1966-1998	7 out of 11 studies assessing the effectiveness of audit and feedback showed significant change in testing behaviour. When combined with other strategies 24 out of 28 studies showed improvement	Feedback on performance was effective in changing testing practices where prior educational strategies had established physicians' positive attitudes towards rational tests ordering

<p>(Wensing, van der & Grol, 1998)</p>	<p>Effectiveness of strategies for implementing changes in primary care; a comparison between single or multiple strategies against no interventions</p>	<p>RCTs and controlled before-and-after studies</p>	<p>Primary care clinicians</p>	<p>Performance feedback in comparison to the other interventions</p>	<p>Physicians behaviour</p>	<p>1980-1984</p>	<p>10 out of 15 studies comparing feedback with no intervention showed it was effective in changing clinical practice. A single strategy with feedback was often more effective than combining it with educational strategies. Combined strategies with at least three types of interventions were found to be highly effective</p>	<p>Single feedback interventions are likely to be more effective than in combination with educational strategies</p>
<p>(Hulscher et al, 1999)</p>	<p>Interventions aimed at improving preventative services delivered by primary care physicians</p>	<p>RCTs, controlled before-and-after studies and interrupted time series</p>	<p>Primary care clinicians</p>	<p>Feedback alone or in combination with other interventions</p>	<p>Measurement of clinicians performance</p>	<p>1966-1995</p>	<p>Feedback alone has not been shown to be effective in improving physicians' performance in five comparisons. However combined with other strategies, small to moderate improvements were observed</p>	<p>Effective interventions to improve preventative services are available. However, more research is required to determine which elements of intervention work in what situations</p>

(NHS CRD, 1999)	Interventions to bring evidence into practice by changing professional behaviour	Systematic reviews (5)	Health professionals	Audit and feedback	Measurement of professional performance or clinical outcomes	1966-1998	Audit and feedback produce a mixed effect on professional performance. Reviews have shown small to moderate improvement when used alone in comparison to no intervention and other interventions	Multifaceted interventions targeting different barriers to change are far more likely to be effective than a single intervention
(Bordley et al, 2000)	Audit and feedback to improve immunisation uptake rates	RCTs, controlled trials, before-and-after studies and interrupted time series.	Health care providers	Audit and feedback	Immunisation uptake rates	1966-1997	12 out of 15 studies found provider feedback beneficial in improving immunisation rates. The effect ranged from -17% to +49%	Eight studies used combined strategies. Only five studies were RCTs, therefore providing only a moderate strength to the evidence
(Stone et al, 2002)	Approaches to promote uptake of adult immunisation and cancer screening services	Randomised and non-randomised trials	Health care providers	Feedback summaries of rates of performance of preventative activities	Uptake of adult immunisation and cancer screening services	1966-1999	Compared to other educational, organisational change and financial incentive based interventions; provider feedback was the most ineffective intervention (OR ranged from 1.10-1.76). Only modest improvement was found in the uptake of mammography	Provider feedback is an ineffective intervention in improving uptake of adult preventative services and must always be used with other interventions

(Jamtvedt et al, 2003)	Audit and feedback on the practice of health care professionals and patient outcomes	RCTs	Health care professionals	Audit and feedback delivered as any summary of clinical performance over a specified period of time presented to the providers with recommendations for action	Objectively measured professional performance or healthcare outcomes	1966-2002	Among 85 studies result varied across from an increase in non-compliance with desired practice of 9% to a decrease of 71%. The baseline non-compliance usually determined the effectiveness of the intervention	Audit and feedback are effective to a small to moderate extent. They are more likely to be effective in situations where compliance is very low. This review support targeted and tailored uses of audit and feedback where it is likely to be practical and overcome barriers for change
------------------------	--	------	---------------------------	--	--	-----------	---	---

1.3.2. Continuing medical education (CME)

CME is an intervention for “transferring knowledge to practicing physicians with an aim to change their practice”(Davis et al, 1992).

1.3.2.1. Introduction

CME has undergone many changes in recent years in terms of its theoretical base, purpose, methodologies and its audience. Continuing professional development (CPD) and CME are used interchangeably and imply a more self-directed approach with interactive learning methods as opposed to more passive, didactic styles of medical teaching(Cantillon & Jones, 1999).

1.3.2.2. Summary of the evidence

This section provides a summary of the systematic reviews covering both styles of medical education. Table 1.4 summarises 13 systematic reviews conducted between 1992 and 2002, including studies published between 1966 and 2000. The educational activities range from teaching rounds, educational meetings, conferences, refresher courses, training programmes, seminars, lectures, workshops and symposia(Davis et al, 1999). The focus of the studies included in these reviews was to assess the effectiveness of CME in influencing health professionals' behaviour and patients' clinical outcomes. Most reviews were restricted to RCTs, but some also included non-randomised controlled studies. The majority of studies in these reviews targeted practicing clinicians; only a few examined the effect of CME in other health care professionals.

CME interventions, which are tailored according to previously identified learning needs of the participants and based on interactive and self-directed learning styles, were more successful than the more traditional, didactic style of large group teaching. Compared to multiple educational strategies, single CME interventions failed to show a significant influence on physicians' behaviour. Practices enabling educational activities, which increase participant activity and provide the opportunity to practice skills in a work environment, were seen to be most effective. This resonates with the principles of adult education theory which describes successful adult education as more learner-centred, interactive, and relevant to learners' needs(Davis et al, 1999).

1.3.2.3. Limitations of the current evidence

Very few reviews acknowledge the unit of analysis error when outcomes are measured in terms of patients, and the unit of randomisation is the clinician resulting in erroneously low p values(Grimshaw, Eccles, Walker & Thomas, 2002). Almost all studies included in the systematic reviews are based on the voluntary

participation of health care professionals in the trials. These usually include motivated individuals, who may have already improved their practice, therefore, creating a '*ceiling* effect' in these studies. Studies often failed to indicate their method of randomisation and details of the interventions used. Due to heterogeneity among participants, settings, targeted behaviours and outcomes, almost no reviewers attempted to perform a meta-analysis of the results. However, some reviews rely on vote counting methods i.e. the number of studies with positive and negative results. Many studies measuring clinical outcomes often choose indicators based on the ease of measurement, rather than health impact. Despite efforts to avoid publication bias, many studies may still have not been included in these reviews because of their negative results.

1.3.2.4. Barriers to change

CME activities which failed to address educational needs of their target audience are often shown to be unsuccessful in the studies included in these reviews(Davis et al, 1999). However, if educational needs assessment relies only on self assessment then practitioners often tend to attend events about things that they already know and usually don't leave their comfort zones(Cantillon & Jones, 1999). Lack of strategies to enable physicians to adopt what has been learned often inhibits change in practice(Davis et al, 1999). A post-course work place facilitating arrangement for problem solving has been proposed to facilitate the desired change. Other limiting factors are personal motivation to change and learning priorities set by the learners themselves(Davis et al, 1999). Physicians often attend CME events with variable levels of motivation to change. These are often superseded by the perceived clinical value of the information, and method of its delivery. Cognitive dissonance between the newly learned knowledge and peers' practice often dictates the level of influence of the knowledge and the practice.

1.3.2.5. Future Implications

Despite a large amount of literature on CME, research gaps exist around factors that facilitate or inhibit effective CME. Researchers often measure change in terms of changed behaviour or clinical outcomes. However, CME effects through a continuum of knowledge, skills, attitude and practice. More research is required to understand what factors influence progression of change along this continuum. The majority of trials have targeted specific preventative and diagnostic testing behaviour. Little has been understood as to how CME influences behaviour in more complex environments such as surgery and psychiatry. More cost-effectiveness studies are also needed with appropriate methods of economic evaluation and analysis(Brown, Belfield & Field, 2002).

Table 1.4: Reviews of CME

Study	Focus	Inclusion criteria				Period	Results	Conclusions
		Study type	Participants	Intervention	Outcomes			
(Davis et al, 1992)	Impact of CME on physicians performance and health care outcomes and attributes of CME that are most effective	RCTs	Clinicians of which 50% were practicing physicians	CME-transferring knowledge to practicing physicians with an aim to change their practice	Objective determination of health care professionals and health care outcomes	1977-1991	Studies using traditional methods of CME to disseminate information showed mixed results. However, studies using more interactive practice enabling interventions had a more positive effect on professional practice and patients outcomes	CME interventions using practice-enabling strategies consistently improve physician performance and, in some instances, health care outcomes. Similarly objective determination of practice and learning needs is an important pre-requisites for effective education
(Wensing & Grol, 1994)	Effectiveness of strategies for implementing changes in primary care focussing on the differences between single and multiple strategies	RCTs, controlled trials, before-and-after studies	Primary care clinicians	Group educational sessions in comparison to the other interventions	Physicians behaviour	1980-1992	Group education alone has been shown to have variable effectiveness in improving physicians' performance. More improvement was observed if combined with other interventions	Combined strategies are more effective than single strategies (although not in all cases), especially when addressing different types of barriers

(Oxman et al, 1995)	Effectiveness of interventions by which the physicians learning and practice might be altered	RCTs and controlled before-and-after studies	Health care providers	Educational conferences, meetings seminars etc. compared to other interventions	Physicians behaviour and patients' health outcomes	1966-1993	Studies in which no explicit effort was made to assess learning needs and facilitate practice change failed to demonstrate an effect. Interventions which were interactive and included other practice rehearsal and practice enabling activities were effective in improving physicians performance	There are no "magic bullets" for improving quality in health care but a number of available interventions if used appropriately can produce desirable results
(Davis et al, 1995)	Review the effect of education strategies on physicians performance and health care outcomes	RCTs	Clinicians of which 50% were practicing physicians	Formal CME programmes in combination or alone	Objective determination of health care professionals' behaviour and health care outcomes	1975-1994	Single day formal CME events produced little effect and six out of seven studies found no effect or results were inconclusive. More positive results were obtained in studies combining more than one educational strategies	Widely used short educational interventions and educational materials are not very effective if used in isolation

(Davis, 1998)	Effectiveness of continuing medical education (CME) and other related educational methods on objectively-determined physician performance and/or health care outcomes	RCTs	Physicians	Educational strategies or interventions	Objectively-determined physician performance and/or health care outcomes	1975-1994	Formal CME educational activities without enabling or practice-reinforcing strategies, had relatively little effect in changing physician performance	CME strategies which do not enable and/or reinforce appear to be less effective in changing physician performance or health care outcomes compared to more interactive interventions
(Wensing et al, 1998)	Effectiveness of strategies for implementing changes in primary care; a comparison between single or multiple strategies against no interventions	RCTs and controlled before-and-after studies	Primary care clinicians	Educational activities in comparison to other interventions	Physicians behaviour	1980-1984	17 comparisons produced variable results. Interventions with positive effect used a combination of strategies and interventions with negative effects used short educational programmes only	Single interventions are unlikely to be effective. Combination of strategies is more effective

(Davis et al, 1999)	Effect of CME on physicians' performance and health care outcomes	RCTs	Clinicians of which 50% were practicing physicians	Didactic and interactive CME interventions	Objective determination of health care professionals' behaviour in their workplace and health care outcomes	1975-1999	Out of 17 interventions tested, nine generated positive changes in professional practice 3 of 4 interventions improved health care outcomes in at least one or more measures. Pooled effect size of these seven studies showed no significant effect of these educational methods on health care outcomes (effect size, 0.34; 95% CI -0.22 to 0.97). However, non-didactic, interactive and mixed educational interventions were associated with a significant effect on professional practice (effect size, 0.67; 95% CI 0.01-1.45)	Interactive CME sessions that increase participant activity and provide the opportunity to practice skills in a work environment are more likely to change professional practice compared to more traditional didactic educational sessions
(Cantillon & Jones, 1999)	Effect of CME on primary care physicians behaviour and factors that facilitate GPs to change with CME	RCTS, non-randomised controlled trials and before-and-after studies	Primary care physicians	Single or multiple educational activities	Change in professional behaviour	1990-1999	Majority of the studies showed beneficial effect in improving GPs clinical behaviour	There is a lack of good quality evaluation studies of CME

(Hulscher et al, 1999)	Interventions aimed at improving preventative services delivered by primary care physicians	RCTs, controlled before and after studies and interrupted time series	Primary care clinicians	CME alone or in combination with other interventions	Measurement of clinicians performance	1966-1995	Four out of five comparisons showed improvement in clinical performance with effect size ranging from -4% to 31%. Biggest improvement was seen where interactive methods were used	Effective interventions to improve preventative services are available. However, more research is required to determine which elements of the intervention work in which situations
------------------------	---	---	-------------------------	--	---------------------------------------	-----------	--	---

<p>(Thomson O'Brien et al, 2001)</p>	<p>Effects of educational meetings and workshops on professional practice and health care outcomes</p>	<p>RCTs and well designed non-randomised controlled studies</p>	<p>Health care professionals</p>	<p>Educational meetings, conferences, workshops</p>	<p>Health care professionals</p>	<p>1966-1999</p>	<p>In 10 comparisons of interactive workshops, there were moderately large effects in six (all statistically significant) and small effects in four (one of which was statistically significant). For interventions that combined workshops and didactic presentations, there were moderately large effects in 12 comparisons (eleven of which were statistically significant) and small effects in seven comparisons (one of which was statistically significant). In seven comparisons of didactic presentations, there were no statistically significant effects, with the exception of one out of four outcome measures in one study</p>	<p>Interactive workshops are likely to produce moderately large changes in professional practice. Didactic educational interventions alone are unlikely to change professional practice</p>
--------------------------------------	--	---	----------------------------------	---	----------------------------------	------------------	--	---

<p>(Smits, Verbeek & de Buissonje, 2002)</p>	<p>Effectiveness of learning in CME in problem based learning improving physicians performance</p>	<p>RCTs and controlled before-and-after studies</p>	<p>Health care professionals</p>	<p>A problem based learning approach adopted for CME</p>	<p>Physicians knowledge, performance, satisfaction and patients' health outcomes</p>	<p>1974-2000</p>	<p>Three studies comparing problem based learning with other educational formats found no evidence of added advantage in improving physicians' knowledge and performance. Three other studies of low quality, comparing problem based learning with no intervention showed limited evidence of improved physicians' performance and knowledge, and patients' health outcomes</p>	<p>Limited evidence for the effectiveness of problem based learning in CME. However, more studies with better design are required</p>
<p>(Brown et al, 2002)</p>	<p>Cost effectiveness of CME</p>	<p>All studies with economic evaluation</p>	<p>Health care professionals</p>	<p>Post registration acquisition of skills or knowledge by health care professionals</p>	<p>Cost-effectiveness of CME</p>	<p>Not specified</p>	<p>Nine studies were of variable quality and used economic terms ambiguously.</p>	<p>The poor quality of studies did not allow any empirical conclusions to be drawn. More studies are required with appropriate methods</p>

(Tu & Davis, 2002)	To examine the impact of educational methods on physicians behaviour in the management of hypertension	RCTs	50% were practicing physicians	Didactic and interactive CME interventions	Objectively-determined physician performance and/or health care outcomes	1966-2000	Two out of three studies showed no significant effect on improving blood pressure control	Reminders were more effective in improving hypertension control than CME and educational materials
--------------------	--	------	--------------------------------	--	--	-----------	---	--

1.3.3. Educational materials

This includes interventions such as printed practice guidelines, manuals, pamphlets, newsletters and audio-visual materials directed solely at health care providers aiming to influence their professional behaviour.

1.3.3.1. Introduction

It has been assumed that health professionals' behaviour can be influenced by simple provision of evidence based information in an accessible form (Freemantle et al, 2000). However, there is a growing concern that the above strategy in isolation may not be able to achieve the desired effect in isolation. Despite the scepticism, printed educational materials are still widely used, at least as a part of passive dissemination strategies to impart current knowledge to clinicians. Familiarity, accessibility and convenience makes it still one of the most commonly used strategies in developed countries to bring evidence into practice. Farmer et al have described four factors which can influence the effectiveness of educational materials (Farmer et al, 2004). These include:

- Characteristics of the intervention including the source of the information, the content and the channel by which it is delivered
- Characteristics of the source including credibility of information, which considers several constructs expertise and knowledge, trustworthiness, and message attributes
- Characteristics of the behaviour that the intervention is trying to change and the content of the printed educational materials tailored to the individual's needs based on behavioural or motivational characteristics
- Characteristics of the organisation and context

1.3.3.2. Summary of the evidence

Table 1.5 provides an overview of seven systematic reviews conducted to assess the effectiveness of printed educational materials in changing professionals' behaviour. It appears that there is a consensus among reviewers that printed educational materials alone are not effective in improving health care professionals' behaviour and subsequently patients' health outcomes. Studies combining the dissemination of educational materials along with other educational strategies, performance feedback, educational outreach etc. have demonstrated effects that are more desirable. The heterogeneity among types of interventions and the results also made it difficult for the reviewers to provide a statistical summary of the effect size shown in various studies (Freemantle et al, 2000).

1.3.3.3. Limitation of the studies

Studies often lacked appropriate primary analysis, presented results poorly and lacked any economic evaluation to make judgements on the cost-effectiveness of such interventions. It has also been argued that many studies examining the effectiveness of printed materials suffer from “the *ceiling* effect” as most of the participants are highly motivated to take part in the study, would have already improved their performance prior to the intervention(Davis et al, 1995).

1.3.3.4. Barriers to change

A number of possible barriers have been hypothesized that can influence the effectiveness of printed educational materials(Farmer et al, 2004). However, more research is needed to evaluate educational materials tailored to overcome these barriers in their specific contexts. These include:

- A mismatch between the clinicians' perceptions of the importance of the information and his previous knowledge
- Assumptions providers make about the source of current knowledge and expertise related to the topic
- Difficulties in applying information in practice
- Lack of readiness to adopt the innovation and for behaviour change

1.3.3.5. Future implications

In conclusion, current evidence does not support the use of printed educational materials in isolation. More research is required to assess the cost-effectiveness and the value of this dissemination strategy tailored to address health care providers' barriers to change.

Table 1.5: Reviews of educational materials

Study	Focus	Inclusion criteria				Period	Results	Conclusion
		Study type	Participants	Intervention	Outcomes			
(Hulscher et al, 1999)	Interventions aimed at improving preventative services delivered by primary care physicians	RCTs, controlled before-and-after studies and interrupted time series	Primary care clinicians	Educational materials alone or in combination with other interventions	Measurement of clinicians' performance	1966-1995	Two out of three RCTs showed no significant improvement in physicians' performance. Biggest improvement (12%) was seen in a study where educational materials were also provided to patients	Effective interventions to improve preventative services are available. However, more research is required to determine which elements of interventions work in what situations
(Davis et al, 1992)	The impact of educational materials on physicians performance and health care outcomes	RCTs	Clinicians of which 50% were practicing physicians	Educational materials provided to practicing physicians with an aim to change their practice	Objective determination of health care professionals' behaviour and patients' health outcomes	1977-1991	5 out of seven studies showed negative or inconclusive results. Only two studies showed educational materials to be as effective as other interventions	CME interventions using practice-enabling strategies consistently improve physician performance and, in some instances, patients' health outcomes. Objective determination of practice and learning needs is an important pre-requisite for effective education

(Davis et al, 1995)	The effect of education strategies on physicians performance and health care outcomes	RCTs	Clinicians of which 50% were practicing physicians	Educational materials and formal CME programmes in combination or alone	Objective determination of health care professionals in their workplace and patients' health outcomes	1975-1994	Educational materials had a positive effect in four and no effect in seven studies. More positive results were obtained in studies combining more than one educational strategy	Widely used short educational interventions and educational materials are not effective if used in isolation. The change in health care outcomes lag behind the change in the performance of health care professionals
(Freemantle et al, 2000)	The effect of printed educational materials in improving physicians behaviour and health care outcomes	RCTs, non-randomised controlled before-and-after trials and interrupted time series	Health care professionals	Printed educational materials vs. no intervention and printed educational materials in combination with other interventions	Health care professionals' behaviour and patients' health outcomes	Not specified	Heterogeneity among the interventions and the results made it difficult to provide a statistical summary. The effect of printed educational materials vs. no intervention ranged from -3% to 243% for improving professional behaviour and -16% to 176% for clinical outcomes. Similarly, beneficial effect from adding other interventions ranged from -11.8% to 93% for professional behaviour and -25% to 75% for clinical outcomes	Printed educational materials alone have either little or no impact on improving professional behaviour and outcomes. Studies examining the beneficial effect of additional interventions show mixed results and more studies are required to determine the real advantage

(Oxman et al. 1995)	Effectiveness of interventions to alter physicians' learning and practice	RCTs and controlled before-and-after studies	Health care providers	Printed educational materials compared to other interventions	Physicians behaviour and patients' health outcomes	1966-1993	The majority of studies failed to shown any beneficial effect of disseminating printed educational materials as the only behaviour change strategy	There are no "magic bullets" for improving quality in health care but a number of available interventions if used appropriately can produce desirable results
(Tu & Davis, 2002)	The impact of educational methods on physicians' behaviour in the management of hypertension	RCTs	Clinicians of which 50% were practicing physicians	Didactic and interactive CME interventions	Objectively-determined physician performance and/or health care outcomes	1966-2000	All three studies showed no significant effect in improving blood pressure control	Reminders were more effective in improving hypertension control then CME and educational materials
(Wensing & Grol, 1994)	Effectiveness of strategies for implementing changes in primary care, focussing on the differences between single and multiple strategies	RCTs, controlled trials, before-and-after studies	Primary care clinicians	Printed educational materials in comparison with the other interventions	Physicians behaviour	1980-1992	Printed educational materials alone had no significant effect on improving physicians' behaviour	Combined strategies are more effective than single strategies (although not in all cases) especially when addressing different types of barriers

1.3.4. Local consensus processes

Local consensus processes are defined as decision-making processes that include participating providers in identifying, prioritising and developing solutions for health problems(Mowatt, Foy, Grimshaw & Sobrevilla, 2004).

1.3.4.1. Introduction

One of the commonest uses of these processes is the development of clinical guidelines(Carter et al, 1995). Many techniques have been developed to avoid biases and conduct the consensus processes systematically. Involvement of local stakeholders is likely to make the decision process more explicit, informed, owned by the local providers and effective in changing their professional practices(BMJ, 1992;Lomas, 1993a). A qualitative survey among providers concluded that the data from clinical trials is likely to become part of routine clinical practice if introduced through local consensus processes(Fairhurst & Huby, 1998). The authors argue that local consensus endorses relevance of the research evidence to routine clinical practice.

1.3.4.2. Summary of the evidence

An earlier systematic review (1993) examined the value of introducing clinical guidelines in improving clinical behaviour of health professionals(Grimshaw & Russell, 1993).This review found positive change in the majority of trials included in the study. However, this review did not distinguish between guidelines introduced following local consensus, from those introduced without this process. A similar non-systematic review described the experience of implementing clinical guidelines in the Netherlands(Grol, 2001a). Clinical guidelines were adhered to in 67% of cases. Nevertheless, compliance was higher in trials where a local consensus process was used for guidelines development. No other systematic reviews were found that exclusively assessed the value of a local consensus processes in improving professional practice. Table 1.6 illustrates a list of studies found from a Medline search that examined the effectiveness of local consensus processes in improving professional practice. Only six studies were found that explicitly evaluated the effectiveness of local consensus processes in improving clinical practice. Only one study was controlled, and the rest were either a time series or before-and-after analysis. All studies indicated benefits of developing local consensus in professionals' adherence to guidelines. However, this evidence is weak due to the poor design of the studies.

1.3.4.3. Limitations of the studies

Despite a number of studies evaluating the effectiveness of guidelines, very few studies made an explicit distinction between the local consensus development

process and general introduction of guidelines. Almost all studies combined the local consensus process with other interventions aiming to improve professional practice, making it difficult to determine the real value of local consensus processes. Similar comparisons between practice guidelines based on local consensus and guidelines developed by national expert committees were also not available. The long-term sustainability of such interventions in maintaining improved performance was only assessed in one study.

1.3.4.4. Barriers to change

In many countries, including the UK, practice guidelines are often developed by national expert committees and subsequently disseminated among local providers. There are often limited opportunities for local adaptation or modification.

1.3.4.5. Future implications

More research is required to assess the extent to which local consensus can be built into such guidelines to control practice variations and enhance local ownership.

Table 1.6: Some recent studies of local consensus process

Study	Method	Participants	Targeted behaviour	Intervention	Results
(Cibere, Sibley & Haga, 2002)	Controlled trial	Specialist clinicians	Adherence to guidelines	Local consensus and feedback vs. local consensus	Adherence to guidelines was significantly greater in the intervention group (consensus and reminder) compared to the control (local consensus only) group (53% vs. 15%; $p = 0.014$)
(Kirkman, Williams, Caffrey & Marrero, 2002)	Before-and-after study	Primary care physicians	Adherence to guidelines for diabetic care	Local consensus and audit and feedback	Improvements were seen in blood pressure measurements (71 vs. 83%; $p = 0.002$), foot examinations (19 vs. 42%; $p < 0.001$), HbA1c measurements (26 vs. 37%; $p = 0.012$), and eye examinations (38 vs. 46%; $p = 0.043$). However, improvements were not sustained over long term suggesting need for organisational support for sustaining improvement
(Pariente et al, 1998)	Before-and-after study	Hospital clinicians	Test ordering	Local consensus	There was a significant reduction in the number of prescriptions for the tumour markers fell by 24% and serum markers orders per prescription (from 1.6 to 1.2). Compliance to the prescription protocol improved, from 65 to 87%. The 6-month cost-savings was at 31,104 French Francs
(Ripouteau et al, 2000)	Before-and-after study	Hospital clinicians	Prescribing habits	Local consensus, feedback and education and reminders	Average number of acetaminophen injections/patient decreased from 6.81 to 2.36, six months after the intervention. Monthly use of acetaminophen injections per 100 patients decreased by 320.9 (95% CI; 192.4-449.4). Annual cost reduction was £15,100
(Causse et al, 1998)	Time series	Hospital clinicians	Prescribing habits	Local consensus and training	The rate of unjustified prescriptions fell below 6%. The cost of antimicrobials fell regularly and the antimicrobial resistance rate fell or remained stable
(Saizy-Callaert et al, 2003)	Time series analysis	Hospital clinicians	Prescribing habits	Local consensus, audit and feedback, education and prescription restriction	This approach reduced antibiotic costs (from US dollars 13.8 in 1997 to US dollars 11 in 2000, $p < 0.001$), contributed to infection control (the prevalence of MRSA and CRP remained stable) and improved the quality of antibiotic prescription. Rates of unjustified prescriptions first fell significantly (from 6 to 0%, $p < 0.001$), then increased significantly (from 0 to 3%, $p < 0.05$) before stabilizing at 3%

1.3.5. Local opinion leaders

Local opinion leaders are health professionals, nominated by their colleagues as 'educationally influential', who are likely to influence their colleagues' professional behaviour(Thomson O'Brien et al, 2000b).

1.3.5.1. Introduction

Diffusion of innovations theory (see page 9) suggests that people can be categorised according to their attitudes towards innovations. According to this theory, if early adopters and innovators achieve a critical mass, they can have a strong influence in accelerating adoption of innovation by the rest (DeCherney, 1999). People in this category, once they acquire the status of an opinion leader, can perform a 'sanctioning function' for the rest of their professional group(Greer, 1988). Similarly, social cognition theory suggests that local opinion leaders can establish norms and appropriate behaviour in a professional group that may play an important role in bringing change in a health professional's practice(Mittman, Tonesk & Jacobson, 1992).

1.3.5.2. Summary of the evidence

The Cochrane collaboration published its review of eight RCTs in 1998 and concluded that opinion leaders, once identified, are likely to influence change in professional practice. However, evidence is lacking on the characteristics of opinion leaders, situations and audiences where such approach is more likely to be effective(Thomson O'Brien et al. 2000b). I identified five more RCTs published since the publication of the above review (Table 1.7). Four trials were conducted in hospitals and one in general practice. Three trials assessed compliance with management guidelines; one study evaluated prescribing behaviour and one change in pre-operative counselling. Three trials used opinion leaders along with other interventions, and demonstrated improved practice against no intervention. Two other trials assessed the added advantage of opinion leaders over other interventions. One trial showed significant improvement in practice, while the other only showed modest change in professional behaviour.

1.3.5.3. Limitations of the studies

Current evidence on the effectiveness of opinion leaders is limited and is of variable quality. There is a lack of consensus on the definition of opinion leaders. Lococ and colleagues describe a wide spectrum of opinion leaders' status and position which creates a methodological difficulty in assessing the effectiveness of opinion leaders by RCTs(Lococ, Dopson, Chambers & Gabbay, 2001). Information on the actual role of opinion leaders in delivering various formal and informal

educational strategies is also limited. Studies have rarely described characteristics of opinion leaders that are likely to be effective.

1.3.5.4. Barriers to change

Opinion leadership often emerges spontaneously during the change process and external nomination or poor identification of opinion leaders is likely to be less effective.

1.3.5.5. Future implications

Opinion leadership has been suggested as a component of a multifaceted process which makes it difficult to examine it in isolation (Lococ et al, 2001). More research is needed to understand the contexts that are likely to be more receptive to opinion leaders.

Table 1.7: Some recent studies of local opinion leaders

Study	Participants	Targeted behaviour	Intervention	Results
(Berner et al, 2003)	Hospital physicians	Compliance with unstable angina management guidelines	Opinion leaders and routine quality assurance vs. routine quality assurance vs. no intervention	5 indicators were used to measure compliance at both patient and hospital level. Statistically significant improvement for the opinion leader group was seen in the use of antiplatelet therapy in both hospital level ($p = 0.01$) and patient level analyses ($p < 0.05$) compared with the other two groups. When analyses were confined to hospitals the opinion leaders' hospitals showed significantly greater change in both antiplatelet (20.2% vs. -3.9%, $p = 0.02$) and heparin therapy (31.0% vs. 9.1%, $p = 0.05$)
(Nilsson et al, 2001)	General practitioners	Prescribing	Educational outreach, feedback, opinion leaders and written materials vs. no intervention	Improved fractional prescribing (favouring diuretics and beta blocking agents) were recorded, with a significant ($p < 0.05$) effect in the intervention group in the hypertension field. In the peptic ulcer/dyspepsia field, the fractional prescribing rates for proton-pump inhibitors decreased from 61.0% to 52.6% in the intervention arm and increased from 68.1% to 76.0% in the control arm (not significant due to low power)
(Heller et al, 2001)	Hospital physicians	Compliance with unstable angina management guidelines	Opinion leaders and performance feedback vs. no intervention	Use of beta-blockers increased significantly in intervention hospitals. However, the change between baseline and follow-up in other indicators did not differ significantly between intervention and control hospitals
(Gifford et al, 1999)	Hospital physicians	Compliance with guidelines for the management of dementia	Opinion leaders, CME and printed educational materials vs. no intervention	Neurologists in the intervention group were more compliant with three of the six recommendations: neuroimaging for patients with dementia only when certain criteria are present (OR 4.1; 95% CI 1.9 to 8.9), referral to the Alzheimer's Association (OR 2.8; CI 1.7 to 4.8), and encouragement of all patients and their families to enrol in the Alzheimer's Association Safe Return Programme (OR 10.8; CI 3.5 to 33.2)
(Guadagnoli et al, 2000)	Hospital physicians	Pre-operative counselling for breast cancer surgery	Opinion leaders and performance feedback vs. performance feedback alone	The proportion of patients who said that their surgeon did not discuss options decreased significantly ($p < 0.001$) from 33% to 17% at intervention hospitals, but this change was not significantly different from the control hospitals

1.3.6. Educational outreach

Educational outreach, often referred to as academic detailing, has been defined as an educational visit by a trained person to a health professional in his/her own settings with the purpose of influencing professional practice(Thomson O'Brien et al, 2000a).

1.3.6.1. Introduction

It was first used to improve physicians' prescribing behaviour and was shown to be useful and cost-effective(Avorn & Soumerai, 1983). Soumerai and colleagues were the first to describe the underlying principles of educational outreach (Table 1.8), and a body of evidence has accumulated since then(Soumerai & Avorn, 1990).

Table 1.8: Principles of educational outreach or “academic detailing”

(1) Conducting interviews to investigate baseline knowledge and motivations for current prescribing patterns
(2) Focusing programmes on specific categories of physicians as well as on their opinion leaders
(3) Defining clear educational and behavioural objectives
(4) Establishing credibility through a respected organizational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues
(5) Stimulating active physician participation in educational interactions
(6) Using concise graphic educational materials
(7) Highlighting and repeating the essential messages
(8) Providing positive reinforcement of improved practices in follow-up visits

1.3.6.2. Summary of the evidence

Educational interventions that enable professionals to address barriers to change and reinforce good practice have been shown to be more effective than didactic educational sessions(Davis, 1998). In a systematic review (including 94 studies) of continuing educational activities to improve professional practice, interventions based on the educational outreach model were shown to be more effective compared to educational materials, seminars and conferences(Davis et al, 1995). A similar review also concluded that educational outreach is moderately effective in improving professional practice and is able to reduce inappropriate performance by 20-50%(Oxman et al, 1995). A Cochrane review published in 1997 including 18 studies compared educational outreach with other interventions alone or in combination with other educational strategies(Thomson O'Brien et al, 2000a).

This concluded that educational outreach is effective in reducing inappropriate professional behaviour by 24-50% when compared to no intervention. However, if combined with other interventions, its effectiveness can improve up to 68%. Maximum benefit is achieved when used along with social marketing interventions. Long-term sustainability of such interventions and the cost-effectiveness of the frequency of visits are not yet known. Outreach visits may be costly, but savings may outweigh costs if targeted at inappropriate prescribing behaviour and the effects are long lasting.

In an overview of systematic reviews on interventions designed to improve professional practice, educational outreach emerged as one of the most effective interventions(Grimshaw et al, 2001).

I found 11 RCTs subsequent to the Cochrane review and their findings are summarised in Table 1.9. All except one targeted primary health care practitioners, and nine out of 11 studies examined prescribing behaviour. Only two trials showed no change in professional behaviour; one used educational outreach alone and the other was conducted with pharmacists. Trials combining educational outreach with other interventions demonstrated greater change in professional behaviour than trials using educational outreach alone. One trial suggests that educational outreach targeted to enable practitioners to improve practice by addressing barriers to change is likely to be successful(Lobo et al, 2002).

Table 1.9: Some recent studies of educational outreach

Study	Participants	Targeted behaviour	intervention	Results
(Zwar, Wolk, Gordon & Sanson-Fisher, 2000)	General practice registrars	Prescribing	20 minute educational outreach visit vs. educational session on an unrelated topic	Significant drop in benzodiazepine prescribing ($p < 0.05$) in both intervention and control groups (from 2.3% to 1.7% and from 2.2% to 1.6% respectively). There was no significant difference between intervention and control ($p = 0.99$)
(Zwar et al, 1999)	General practice registrars	Prescribing	Educational seminars, feedback, guidelines and educational outreach visits in intervention group vs. education related to different topic in controls	Antibiotic prescription rate by the intervention group declined from 25.0 to 23.3 to 19.7 per 100 URTI problems, while the control group increased from 22.0 to 25.0 to 31.7 per 100 URTI problems ($p = 0.002$). Prescribing according to accepted guidelines for tonsillitis/streptococcal pharyngitis increased in the intervention group from 55.6 to 69.8 to 73.0 per 100 problems, but decreased in the control group from 59.6 to 57.5 to 58.5 ($p = 0.05$)
(Watson et al, 2002)	Community pharmacists	Prescribing	Educational outreach vs. continuing professional education vs. written educational materials	There were no significant differences in the proportion of appropriate over-the-counter management of vulvovaginal candidiasis following educational outreach (OR = 1.1; 95% CI 0.52 to 2.45) or continuing professional education (OR = 0.88; 95% CI 0.41 to 1.91)
(Watson et al, 2001)	General practitioners	Prescribing	Educational outreach visits by pharmacists and written guidelines vs. written guidelines vs. no intervention	Practices receiving outreach visits prescribed 1.6% (95% CI 1.4 to 4.7) more of the three recommended NSAIDs than practices that received guidelines only and 2.1% (95% CI 0.8 to 5.0) more than the control practices. No significant differences were observed for the primary outcome measure

<p>(Sirwardena, Rashid, Johnson & Dewey, 2002)</p>	<p>Primary health care teams</p>	<p>Preventative care</p>	<p>Educational outreach, and audit and feedback vs. audit and feedback only</p>	<p>Improvements in pneumococcal vaccination rates in the intervention practices were significantly higher compared with controls in patients with CHD, 14.8% vs. 6.5% (OR = 1.23; 95% CI 1.13 to 1.34) and diabetes, 15.5% vs. 6.8% (OR = 1.18; 95% CI 1.08 to 1.29) but not splenectomy, 6.5% vs. 4.7% (OR = 0.96; 95% CI 0.65 to 1.42). Improvements for influenza vaccination were also usually higher in intervention practices but did not reach statistical significance. The increases for influenza vaccination in intervention vs. control practices were for CHD, 18.1% vs. 13.1% (OR = 1.06, 95% CI = 0.99 to 1.12); diabetes, 15.5% vs. 12.0% (OR = 1.07, 95% CI = 0.99 to 1.16), splenectomy 16.1% vs. 2.9% (OR = 1.22, 95% CI = 0.78 to 1.93); and those over 65 years 20.7% vs. 25.4% (OR = 0.99, 95% CI = 0.96 to 1.02)</p>
<p>(Nilsson et al, 2001)</p>	<p>General practitioners</p>	<p>Prescribing</p>	<p>Educational outreach, feedback and opinion leaders and written materials vs. no intervention</p>	<p>Improved fractional prescribing (favouring diuretics and beta blocking agents) were recorded, with a significant ($P < 0.05$) effect in the intervention group in hypertension field. In the peptic ulcer/dyspepsia field, the fractional prescribing rates for proton-pump inhibitors decreased from 61.0 to 52.6% in the intervention arm and increased from 68.1 to 76.0% in the control arm (not significant due to low power)</p>
<p>(Finkelstein et al, 2001)</p>	<p>General practitioners</p>	<p>Prescribing</p>	<p>Educational outreach and information to patients vs. no intervention</p>	<p>Antibiotic prescribing by General practitioners for children 3 to <36 months old decreased 0.41 antibiotics per person-year (18.6%) in intervention compared with 0.33 (11.5%) in control practices. Among children 36 to <72 months old, the rate decreased by 0.21 antibiotics per person-year (15%) in intervention and 0.17 (9.8%) in control practices</p>

(Freemantle et al, 2002)	General practitioners	Prescribing	Educational outreach vs. no intervention	Significant improvement in prescribing practice (OR = 1.24; 95% CI 1.07 to 1.42), with a 5.2% (95% CI 1.7 to 8.7%) increase in the number of patients treated according to guideline recommendations in intervention practices. Smaller practices responded much more favourably and improved their performance by 13.5% (95% CI 6 to 20.9%) attributable to outreach, while larger practices improved by only 1.4% (95% CI -2.4 to 5.3%, p value for interaction <0.001)
(Bernal-Delgado, Galeote-Mayor, Pradas-Arnal & Peiro-Moreno, 2002)	General practitioners	Prescribing	Educational outreach vs. educational seminars vs. no intervention	The educational outreach group reduced inappropriate Non Steroid Anti-inflammatory Drugs (NSAIDs) prescriptions by 22.5% (95%CI 34.42 to -10.76), compared with a reduction of 9.78% (95%CI -17.70 to -1.86) in the seminar group and an increase of 14.44% (95%CI 5.22 to 23.66) in the control group. The average cost per prescription decreased by 1.91% (95%CI -0.33% to -3.49%) in the educational outreach group, 0.16% (95%CI -0.27% to -2.93%) in the seminar group, and rose by 1.76% (95%CI 0.35% to 3.17%) in the control group
(Lobo et al, 2002)	Primary health care teams	Preventative care	Educational outreach (5 practice visits over a period of 21 months and addressed task delegation, availability of instruments and patient leaflets, record-keeping, and follow-up of routines (practice enabling) vs. no intervention	The difference in change between intervention and control group adjusted for baseline was statistically significant (p < 0.001) for each aspect of organizing preventive care. The largest improvement was found among practice assistants performing preventive tasks

1.3.6.3. Limitations of the studies

So far, most of the trials conducted have studied the influence of educational outreach on prescribing practices of primary care physicians. Limited knowledge is available on its influence on other health care professionals in modifying clinical behaviours other than prescribing.

It has been shown that combining educational outreach with other interventions is more effective. However, there is insufficient evidence on the characteristics within the educational outreach model to make it effective e.g. increasing frequency and duration of visits.

Long-term sustainability of improved performance secondary to educational outreach is not known.

More research is needed to judge its cost-effectiveness compared to other educational and quality assurance interventions.

Educational outreach is a complex intervention to implement. It requires focussed planning, preliminary assessment of educational needs and motivational factors, training educators and establishing their credibility amongst health professionals. It also requires a good rapport between the educator and health professional, in order to establish an interactive dialogue during visits.

1.3.6.4. Barriers to change

In implementing educational outreach, the major barriers to change were patient expectations (such as the perceived desire for a prescription), information management (including the inability to recall specific information) and administrative constraints (such as lack of time)(Thomson O'Brien et al, 2000a). According to one study where pharmacists were used as the educators for general practitioners, pharmacists' and General Practitioners (GPs)' satisfaction with the outreach visits did not necessarily result in prescribing changes. Similarly, GPs' knowledge of the guidelines promoted by the pharmacists did not necessarily transform GPs' professional behaviour. The main barriers to change as judged by the pharmacists were organisational issues, the GPs' scepticism of the evidence presented to them and the doctors' lack of interest in changing their prescribing behaviour(Nazareth et al, 2002).

1.3.7. Reminders

Reminders are defined as any intervention that prompts the health care provider to perform a clinical action(Oxman et al, 1995).

1.3.7.1. Introduction

Reminders work by prompting the doctor to recall information that they already know or would be expected to know, and by presenting information in an accessible, relevant and timely format that can help clinicians to avoid clinical errors (McDonald, 1976). These can be classified into the following three categories:

- Computer generated paper reminders
- Manual paper reminders
- On-screen computer reminders

1.3.7.2. Summary of the evidence

In earlier systematic reviews, reminders were shown to be as effective as feedback in influencing professional practice (Buntinx et al, 1993; Wensing & Grol, 1994; Mandelblatt & Kanetsky, 1995). Another review, specifically looking at computer based clinical decision support systems, concluded that reminder aides can be very effective in improving physicians' performance (Johnston, Langton, Haynes & Mathieu, 1994). However, many studies in this review failed to show their translation into better clinical outcomes.

Reminder systems have been used effectively in increasing physicians' compliance with preventative health care measures. One meta-analysis of RCTs concluded that physician reminder systems in primary care are highly effective in improving tetanus immunisation (OR 2.8; 95 % CI 2.7-2.9) and moderately effective in increasing compliance with cervical screening (OR 1.2; 95 % CI 1.02-1.34). Another non-systematic review of computer generated reminders came to a similar conclusion (Rosser, Jr. & Kleiner, 1995). Studies in this review included a wide range of preventative programmes including breast, bowel and cervical cancer screening, cholesterol screening, and tetanus and influenza immunisation.

One systematic review of 16 RCTs assessed the effectiveness of computer based reminder systems in preventative health in primary care (Shea, DuMouchel & Bahamonde, 1996). Reminders were shown to be effective in improving compliance to vaccinations (OR 3.09; 95% CI 2.39-4.00), breast cancer screening (OR 1.88; 95% CI 1.44-2.45), colorectal cancer screening (OR 2.25; 95% CI 1.74-2.91), and cardiovascular risk reduction (OR 2.01; 95% CI 1.55-2.61). They failed to improve cervical cancer screening (OR 1.15; 95% CI 0.89-1.49) or other preventive care (OR 1.02; 95% CI 0.79-1.32). The combined adjusted OR for all six categories of preventive practices was 1.77 (95% CI 1.38-2.27). Counselling in primary care to bring about change in patients' behaviour is part of many preventative health strategies. One systematic review argues on the basis of many trials that computer

generated or manual reminders are very effective in increasing behaviour counselling and subsequent change in health behaviour(Dickey, Gemson & Carney, 1999). Similar conclusions were reached by another review that assessed the effectiveness of all computer generated interventions (feedback, reminders and educational materials) in changing health behaviour(Revere & Dunbar, 2001).

Hand washing has long been recognised as an effective but often forgotten practice to prevent hospital-acquired infections. A systematic review examining studies of interventions to promote hand washing concluded that strategically placed reminders are more effective in increasing hand washing than educational interventions and performance feedback(Naikoba & Hayward, 2001). Reminders combined with other strategies have been shown to reduce hospital-acquired infection subsequent to improved hand-washing practice.

One systematic review examined strategies to improve cervical and breast screening(Kupets & Covens, 2001). Both computerized and manual reminders were among the most effective strategies. Reminders improved cervical screening by as much as 40% and breast screening by as much as 35%. Of the six studies reviewed, three showed significant improvements in cervical screening, four showed improved breast screening, and five showed improved breast or cervical screening.

In clinical practice other than preventive medicine, the role of reminders in improving professional behaviour is less well established. In a systematic review of strategies to improve blood pressure control, reminders were shown to be effective in improving follow up rate and compliance to hypertension management guidelines but less effective in improving long term blood pressure control(Tu & Davis, 2002). A recent systematic review, examined trials evaluating the effectiveness of various computer generated decision support models in improving prescribing habits(Bennett & Glasziou, 2003). Six out of twelve studies demonstrated generally improved medication management in outpatient settings, with relative rates of improvement from 1.0 to 42. Three out of five studies in in-patient settings also improved prescribing practices among clinicians (Relative Risk [RR] 1.0-2.1). This review suggested that reminders seem to be more effective in improving medication management than feedback. However, one reason for the observed difference might be that reminders are closer to decision making than feedback.

1.3.7.3. Limitations of studies

There has been a lot of interest in assessing the value of computer-generated aids (reminders) in improving professional practice in the last two decades. However, although the evidence for the effectiveness of reminder systems in

preventative clinical practice is strong, the evidence is weak for compliance with practice guidelines for diagnostic and therapeutic management.

1.3.7.4. Barriers to change

A computer generated feedback programme has the advantage of creating screening reminders for each patient and is less reliant on physicians' motivation. However, such strategies are costly, require time and resources for data management and are rarely available in primary care even in developed countries. Often a poor computer interface makes it cumbersome for clinicians to fill in data during consultation (Bennett & Glasziou, 2003). A manual reminder system can be flexible, cheap and easy to use, but is dependant on clinicians' motivation.

1.3.8. Marketing

Marketing interventions involve use of personal interviewing, group discussion (focus groups) or a survey of targeted providers to identify barriers to change and subsequent design of the intervention (Oxman et al, 1995).

1.3.8.1. Summary of the evidence

Researchers assessing the value of various interventions designed to change professional practice have acknowledged that not all interventions work in all circumstances (NHS CRD, 1994; Grimshaw et al, 2001). A strategy successful in one setting may be ineffective in another. Such variable response has been attributed to varying barriers that impede the implementation of change in professional practice. (Reviewers have classified such barriers into many categories) (Grol, 1997; Borbas et al, 2000). The identification of barriers and adoption of strategies to address these is likely to be an effective recipe in changing professional behaviour (Cheater et al, 2004). However, little research has been carried out on tailoring interventions to address barriers identified prior to the implementation of the intervention. In a systematic review, Davies et al identified only 28 out of 160 studies which conducted some form of gap analysis prior to the implementation of the intervention (Davis et al, 1995). 89% of these studies were shown to be effective in bringing professional behaviour closer to that desired.

1.3.9. Patient mediated interventions

These include interventions aimed at changing professional behaviour by seeking information from or providing information directly to patients (e.g. direct mailing to patients, patient counselling delivered by others or clinical information collected from patients and given to providers) (Oxman et al, 1995).

Cohen et al argue that according to the trans-theoretical model proposed by Prochaska and DiClemente (see on page 9), patient mediated interventions can help

in successful transition from the preparation phase to the maintenance phase(Cohen et al, 1994). Most of the research attempting to evaluate the effectiveness of these interventions has been done in preventative medicine and, is therefore, restricted in its generalisability. However, one systematic review found that reminder cards carried by patients, surveys of patients' expectations given to clinicians and letters prompting patients to demand preventative services have resulted in increased service utilisation in a wide range of preventative services e.g. flu immunisation, breast cancer screening, pap smears, bowel cancer screening, cholesterol screening etc.(Cohen et al, 1994). Reviewers also found that these interventions had advantages additional to the reminders directed at clinicians. However, more research is needed to test such interventions in the provision of other health care services, to assess their wider effectiveness.

1.4. Barriers to Implementation

Despite a vast amount of literature on interventions designed to alter professional behaviour, little is known about what impedes the change process. Theorists and researchers have hypothesised a number of determinants, but these theories have rarely been tested and proven. Researchers highlight the importance of understanding the barriers and facilitators prior to development of intervention but in practice interventions are frequently developed and implemented without much regard to these factors(van Bokhoven, Kok & van der Weijden, 2003).

In previous sections, I have identified barriers to implementation from the literature and described these by specific interventions. However, there is a lot of commonality between these barriers, and a summary of these is provided in this section to help researchers and policy makers in designing future interventions. These barriers to change are often determinants for implementing change and their antonyms are often perceived as facilitators for change. Barriers can be related to(Borbás et al, 2000):

- Health care staff and providers
- Organisation
- Resources
- Patients

1.4.1. Health care staff and providers

1.4.1.1. Provider and staff knowledge/skills deficits

Educational materials provided in the form of printed guidelines, algorithms, leaflets, newsletters, desk guides etc. are generally developed and disseminated *en*

masse for a large group of health professionals. Similarly, didactic teaching is also directed towards larger groups of professionals. Both interventions, by virtue of their design, can fail to address individual learning needs and therefore do not engage many professionals in the topic as well as the process (Davis et al, 1999). Physicians often prioritise their learning needs by attending and missing CME events in ways, which do not always relate to their learning needs. Providers' learning is often dependent on how much importance they attach to a particular area in terms of its relevance to their practice based on their previous experiences and the perceived knowledge of their peers (Davis et al, 1999). Objective methods of assessing learning needs must be employed due to a tendency of many professionals to avoid leaving their comfort zones (Cantillon & Jones, 1999).

Implementing educational and quality assurance tools can also generate education needs in itself. Many studies have reported that lack of skills in project management, standard setting, data collection and designing enquiry tools can impede successful implementation of clinical audit. Similarly, identification of opinion leaders can also be a challenging task. Often such leaders emerge spontaneously. However, they often need to be identified and groomed, which in itself can be difficult and may require skills and experience. One danger is the nomination of an opinion leader who is largely "external" to the target group and therefore, has little influence on their professional behaviour.

1.4.1.2. Provider and staff psychological barriers

Health professionals' attitudes towards educational and quality assurance intervention are one of the major determinants of their success. These can be perceived to be a distraction from clinical responsibilities due to complexity (Grol, 1997). Similarly, interventions may be perceived as a threat to physicians' clinical freedom and professional autonomy. A lack of recognition of the need for improvement in their current performance is likely to limit clinicians' receptiveness to such innovations.

Educational outreach or academic detailing is often ineffective if the educator is perceived to have a lower status in a hierarchical health care system than the service provider (Nazareth et al, 2002). The evidence provided by such educators (pharmacists in one study) is often not believed by the clinicians and/or their recommendations are seen as unrealistic. Educational outreach provided through more 'respected' educators is likely to have resource implications.

Manual reminders to prompt physicians to institute appropriate preventative, diagnostic and therapeutic procedures rely on motivation to use these reminders in

their daily practice. Computer generated reminders and prompts are less reliant on the clinicians' motivation but more dependent on provision of other resources.

1.4.2. Organisational barriers

Educational materials, passive performance feedback and didactic educational methods often provide little help in specific difficulties that the professional may face in implementing higher standards of care(Davis et al, 1999). Many such barriers are organisational in nature.

Implementing interventions to change professional behaviour often requires teamwork. Poor team dynamics with ill-defined roles and responsibilities, lack of commitment, ill-defined objectives, conflict among staff, fear of loss of confidentiality and failure to generate ownership among professionals can all influence the success of these interventions.

Lack of a good relationship between managers and clinicians without clear lines of authority and accountability is a recognised barrier to implementing changes subsequent to educational and quality assurance interventions. Quality assurance measures such as clinical audit were often perceived in the UK to be the responsibility only of clinicians, and not managers(Berger, 1998). This perception led to marginal improvement and ultimately necessitated a major policy shift, making such strategies the core responsibility of the chief executive of the health service (clinical governance)(Scally & Donaldson, 1998).

1.4.3. Resources barriers

Almost all interventions have resource implications in terms of the implementation of the intervention itself, and the change it is aimed to produce in the health system because of altering professional behaviour(Davis et al, 1999). For example, protected time is required for professionals to attend educational meetings, read educational materials and take part in audit and feedback as well as resources to implement subsequent changes in the health care system. Dedicated staff and funding is expected to help such strategies in being successful on a routine basis(Cranney et al, 2001).

Educational outreach is attractive due to its innovative nature and effectiveness. However, to establish such a system across all levels of a health care system will require a huge investment and supportive information systems (reminders etc.) to sustain its effectiveness(Thomson O'Brien et al, 2000a).

Similarly, computer generated reminders and prompts, shown to be very effective are highly reliant on computerised patient-data information systems at all levels of health care. Such systems are still not fully implemented in the developed

world, and are likely to impede the implementation of such strategies around the globe for many years to come.

1.4.4. Patient psychological barriers and preferences

Patients' perceived beliefs about antibiotics and other therapeutic forms of management often makes many provider-directed educational interventions including educational outreach ineffective(Thomson O'Brien et al, 2000a). Such measures need to be combined with patient-directed interventions. However, in implementing preventative measures there is a very strong perception among clinicians that patients lack the motivation to change(Cohen et al, 1994). Often such perceptions are false and when dealt with, in the interventions do produce the desired results.

1.5. Synthesis of studies

Based on the above evidence, the educational and quality assurance interventions can be categorised as follows:

1.5.1. Interventions likely to be effective

Multifaceted interventions are likely to be more effective than single interventions. This view is supported by almost all systematic reviews. However, combinations of multiple strategies are more effective where each strategy addresses a different barrier for implementing change.

Despite limitations of the current evidence, there is a consensus that opinion leaders and educational outreach are likely to be the most effective intervention.

1.5.2. Interventions likely to produce mixed results

Audit and feedback is likely to produce mixed effects on improving the performance of health professionals. If instituted in isolation, it is likely to produce mild to moderate changes. However, evidence is accumulating that in situations with poor baseline performance, if followed by change strategy, audit can produce the desired effect. Similarly, CME interventions, which are tailored according to previously identified learning needs of the participants, and based on self-directed learning style, are likely to be more successful than the more traditional, didactic style of large group teaching.

1.5.3. Interventions likely to produce no effect

Printed educational materials are unlikely to be effective if used in isolation. Studies combining the dissemination of educational materials with other educational

strategies, performance feedback, educational outreach etc. have demonstrated better results.

1.5.4. Interventions about which not enough is known

Not enough evidence is available about local consensus, marketing strategies and patient mediated interventions to be able to form conclusions on their effectiveness.

1.6. Methodological limitations

The evidence presented in this section has many common limitations. Despite a number of high quality systematic reviews, publication bias is likely to exist in the current evidence. The majority of Cochrane reviews only include RCTs, often conducted in western countries. Even these reviews, trials were of variable quality, and often not explicit about randomisation procedures and primary analysis. Unit of analysis error was a common issue for the majority of trials included in reviews. Similarly, due to the voluntary participation of health professionals in trials, researchers were unlikely to avoid *Hawthorne* and *Ceiling* effects. Heterogeneity prevented most reviewers from providing statistical summaries of the effect size.

Trials measured the effect either during or shortly after the intervention. There is very little evidence on the long-term effects of these strategies. Similarly, the majority of trials were limited in their focus. Most studies targeted specific clinical behaviours and did not study behaviours that were more complex.

1.7. Research implications

Research implications have been discussed in individual sections. In general, better-designed studies are required to test interventions based on models of change behaviour with better tools to understand and test barriers and facilitators to change. Cost-effectiveness studies are also required to inform and influence policy makers. Impacts on other complex behaviours also need to be tested to develop an in depth understanding of the influence of these interventions.

Future research needs to describe interventions in more detail to determine external validity and to study their long-term effects on sustaining improvement in professional practice.

Chapter 2 Influencing change in professional practice in health care: what works in developing countries?

2.1. Introduction

Influencing change in health professionals' clinical practice is desirable in the developing world mainly due to the realisation of the following two facts:

- Deficiencies in the quality of health care provision
- A wide gap between existing evidence and clinical practice

This chapter describes the health impact of these factors in the developing world and explains how changes in health professionals' clinical practice can be useful in tackling these issues.

2.1.1. Deficiencies in the quality of service provision

In order to address the existing health inequalities between different countries around the globe, all efforts require a clear understanding of the underlying causes and interrelationships. Socio-economic factors have long been established as the main reason for this disparity (WHO, 1980). However, inadequate quality in health care has also been suggested to be responsible for persistent excessive mortality and morbidity in developing countries (Nicholas, Heiby & Hatzell, 1991). An evaluation, in 1991, of primary health care systems in 12 countries identified severe deficiencies in the diagnosis, treatment and counselling of patients in the monitoring and management of child development, immunisation, malaria, diarrhoea and acute respiratory infections (Nicholas et al, 1991). A number of reports since have supported the above claim and have documented major deficiencies in recording, monitoring and optimal management in many health areas (Table 2.1). In these reports, performance has often been measured against the internationally agreed standards of care.

2.1.1.1. Causes of these deficiencies

Poor quality in health care provision in developing countries has been attributed to poor utilisation and access to primary and community health services (Sauerborn, Nougara & Diesfeld, 1989) and an inappropriate focus on inputs and structures rather than the process of care (Reerink & Sauerborn, 1996). However, one of the major causes of poor quality in health care provision is the failure to provide clinical care in accordance with standards shown to be associated with improved health outcomes (Marquez, 2001). For example, it has been shown

that non-adherence to consensus-based clinical guidelines is directly associated with high hospital related mortality in children suffering from diarrhoeal diseases(Walker, Ashley & Hayes, 1988). It is, therefore, desirable that any quality assurance initiative in developing countries should focus itself on attaining and sustaining health care professionals' performance in accordance with agreed standards.

Table 2.1: Some examples demonstrating deficiencies in quality of care in developing countries

Reports	Settings	Health areas	Range of compliance with quality standards (percentage)
(Akel & Hamadeh, 1999)	Primary care	Diabetes	17.8-85.8%
(Arif et al, 1998)	Hospital	Tuberculosis (TB) diagnosis	23%
(Bassili et al, 2000)	Hospital	Asthma and diabetic care in children	39.6-52%
(Behar et al, 2000)	Hospital	Antibiotic prescription	82.2%
(Boonstra et al, 2003)	Primary care	Sexually transmitted diseases (STD)	25-81%
(Campagne et al, 2000)	Radiology	Diagnosing schistosomiasis on bladder ultrasound	80%
(Chareonkul, Khun & Boonshuyar, 2002)	Primary care	Malaria, Diarrhoea and acute respiratory infection	3.3-68.3%
(De Castro, Kopittke, Fuchs & Tannhauser, 1999)	Hospital	Use of antibiotics	39%
(Harrison et al, 1998)	Primary care	Sexually transmitted diseases	37-48%
(Hazra, Tripathi & Alam, 2000)	Voluntary sector health care	General prescriptions	54.4-64.5%
(Heineck, Ferreira & Schenkel, 1999)	Hospital	Pre-operative antibiotic prophylaxis	75%
(Krause et al, 1999)	Primary health care	General prescriptions	59.3%
(Loke, Hwang & Tan, 1997)	Hospital	Thrombolysis in myocardial infarction	68%

2.1.2. Gap between evidence and practice

Health systems in the developing world also need to bridge the gap between existing evidence and current practice. The argument can be made even more strongly for countries with limited resources to put 'what works' into practice(Garner et al, 1998). Ineffective treatments can drain limited resources in the health systems resulting in even more health inequalities.

2.1.2.1. Constraints to implementing evidence into practice

There are a number of constraints to implementing effective health care practices in developing countries. Existing evidence on the common ailments in the developing world is insufficient in quantity and quality (Bhutta, 2003). More than 90% of the current global research funding targets diseases that afflict under 10% of the world's population (Bhutta, 2003). Besides, much of foreign funded research in developing countries pays little attention to ownership, sustainability and the development of national research capacity and is considered as 'semi-colonial' and irrelevant (Costello & Zumla, 2000). A survey of five leading medical journals in 2003 revealed that the frequency of research articles relevant to diseases of poverty was between 0 and 16% (Horton, 2003). Other constraints include (Garner et al, 1998):

- Lack of access to the sources of research information by health care professionals working in primary care health systems, which are already in disarray
- Lack of public accountability, corruption and political motives resulting in public investments into non cost-effective facilities and equipment

Even where evidence is available in the form of agreed guidelines, health care professionals often fail to introduce effective practices in to their own clinical practice due to other organisational and resource constraints.

2.1.2.2. Actions required

World Health Organisation (WHO) calls for its members to focus on strengthening health systems in primary care by the effective use of existing knowledge as well as introduction of new technologies (WHO, 2003b). This call requires action at all levels but urges health systems to focus on bringing existing evidence into practice; and recognises that will often require influencing health professionals' behaviour.

The majority of interventions to influence change in professional practice (see previous chapter) have not been developed and tested extensively in developing countries (Hogerzeil, 1995). Caution must be observed in introducing these interventions in developing countries prior to the establishment of their effectiveness locally or in similar situations. This is because:

The impact of these interventions may vary depending on the effect of different sets of socio-cultural values e.g. conformity and acceptance of authority.

Current evidence from developed countries may also be less relevant in preventative and primary health care in developing countries where the dominant role is often played by non-medical professionals (Marquez, 2001).

However, in such countries existing structures to regulate the public health sector may provide more opportunities to implement quality assurance compared to certain developed countries, where often health care is delivered through a mix of public and private schemes. In addition, due to lack of educational opportunities, health professionals may be more inclined to attend and be influenced by such interventions compared to countries where professionals often feel overwhelmed by the information overload.

2.2. Aims and Objectives

This review summarises and comments on the available evidence of the effectiveness of a variety of interventions to influence change in professional behaviour in developing countries. These interventions are meant to improve care through education and quality assurance. Other interventions, which work through organisational changes, financial incentives or regulatory structures, are beyond the scope of this review. Other objectives include:

- Identify methodological issues relevant to future research in this areas
- Recognise attributes of successful interventions in order to inform future research

2.3. Methods

2.3.1. Sources

I searched (search date 23rd September 03) through standard secondary sources (Table 1.1), Medline (from 1966), Embase (from 1980) and Health Management Information Consortium databases. I also did a limited search in June 2006 using the same search strategy to look for any new evidence that might have since emerged. The results are further discussed in the discussion.

2.3.2. Search strategy

The full search strategy can be found in Appendix 1; this was adapted from the EPOC Cochrane group search strategy for its reviews. I used key words: audit, chart review, feedback, education, information, opinion leaders, outreach, guidelines, algorithm, consensus, reminders and marketing, and combined these with names of the developing countries. The above search strategy was combined with another search tree specifically developed to identify research articles conducted in

developing countries. All language articles were included in the search. Reference lists of other Cochrane reviews from the EPOC group were manually searched for any articles relevant to developing countries. The International Journal of Quality in Healthcare and Health Policy and Planning were also hand searched for relevant articles published in the last 10 years.

2.3.3. Critical Appraisal

All titles were screened for relevance. Inclusion and exclusion criteria were applied to selected articles for the final review (Table 2.2). All articles were appraised using the Critical Appraisal Skills Programme checklist (CASP)(SCHARR, 2004).

The evidence presented in each paper was graded according to the hierarchy of study design for studies of effectiveness adapted from NHS CRD guidance on systematic reviews(NHS CRD, 2001). Data from all articles included in the review were extracted and entered into a pre-designed form.

Table 2.2: Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Target Population	Health care professionals working in hospitals or primary care in low income systems in low and middle income countries (doctors, nurses, midwives, community health workers, pharmacists, etc.)	Health care professionals working in developed countries/high income systems
Interventions	Educational and quality assurance interventions (audit and feedback, education and training, information, consensus development, algorithms and guidelines, opinion leaders and educational outreach)	Interventions that work through change in organisational, financial or regulatory structures
Outcomes	Compliance with quality criteria and standards (processes of care) and/or patient health outcomes	Structures only Patient and provider satisfaction only
Studies	Systematic and non-systematic reviews with quantitative results Randomised controlled trials Controlled trials Non-controlled before-and-after studies	Reviews without appraisal and presentation of the studies included Descriptive studies Case studies
Conditions	All clinical conditions	None

2.4. Results

Out of 3,569 titles retrieved by the first search, 88 relevant articles were selected for detailed study. 46 articles met the inclusion criteria and were

subsequently included in this review. This section summarises the findings, assesses the quality of the evidence and discusses the implications by categorising these according to different types of interventions. Each subsection also compares the evidence reviewed here with current evidence from developed countries reviewed in the previous chapter.

I found only one systematic review (including 28 studies) which examined a variety of interventions tested in developing countries to change clinical behaviour of health professionals (Le Grand, Hogerzeil & Haaijer-Ruskamp, 1999). However, this review was limited to examining change in prescribing behaviour only. The review concluded that the majority of the studies were of poor design and focused on the clinicians' behaviour in the public sector. Almost no studies included in the review mentioned the socio-cultural context in which inappropriate clinical behaviour took place. The majority of studies demonstrated a beneficial effect of these interventions. However, the weakness of the study designs necessitates more rigorous and contextual research in different health settings to draw firm conclusions on the effectiveness of these strategies.

2.4.1. Interventions

Interventions intended to influence the ability of health care professionals to deliver services more effectively and efficiently are classified into the following broad categories:

- Continuing education and quality assurance
- Financial incentives
- Organisational interventions
- Regulatory interventions

This review focuses on the first category in more detail. The interventions included in this review are listed in Table 2.3. Each intervention is described in more detail in the following sections. Due to the potential overlap between various interventions, many studies have evaluated more than one intervention at a time. Only a few researchers have explicitly acknowledged this, and these studies are discussed under a separate section (page 117). Figure 2.1 illustrates number and types of studies for each intervention included in this review.

2.4.1.1. Audit and feedback

Clinical audit has different meanings in different health care systems depending upon the experience, current practice and organisational culture of the respective country (Appendix 2). Clinical audit is defined as an ongoing process to improve the quality of health care through the ongoing critical examination of

current performance against agreed standards, leading to the identification and utilisation of opportunities for bringing practice closer to that standard. Clinical audit has also been referred to as a topic audit in developed countries, in which a review is conducted of a specific care activity (Mancey-Jones & Brugha, 1997). Two examples of sentential event audit (review around a specific event in health care) have also been included in this review.

Table 2.3: Interventions designed to influence change in professional behaviour through education and quality assurance

Audit and feedback
Local consensus development
Education and training
Educational outreach
Educational materials
Local opinion leaders
Mass media
Marketing
Reminders
Patient mediated interventions
Multiple interventions

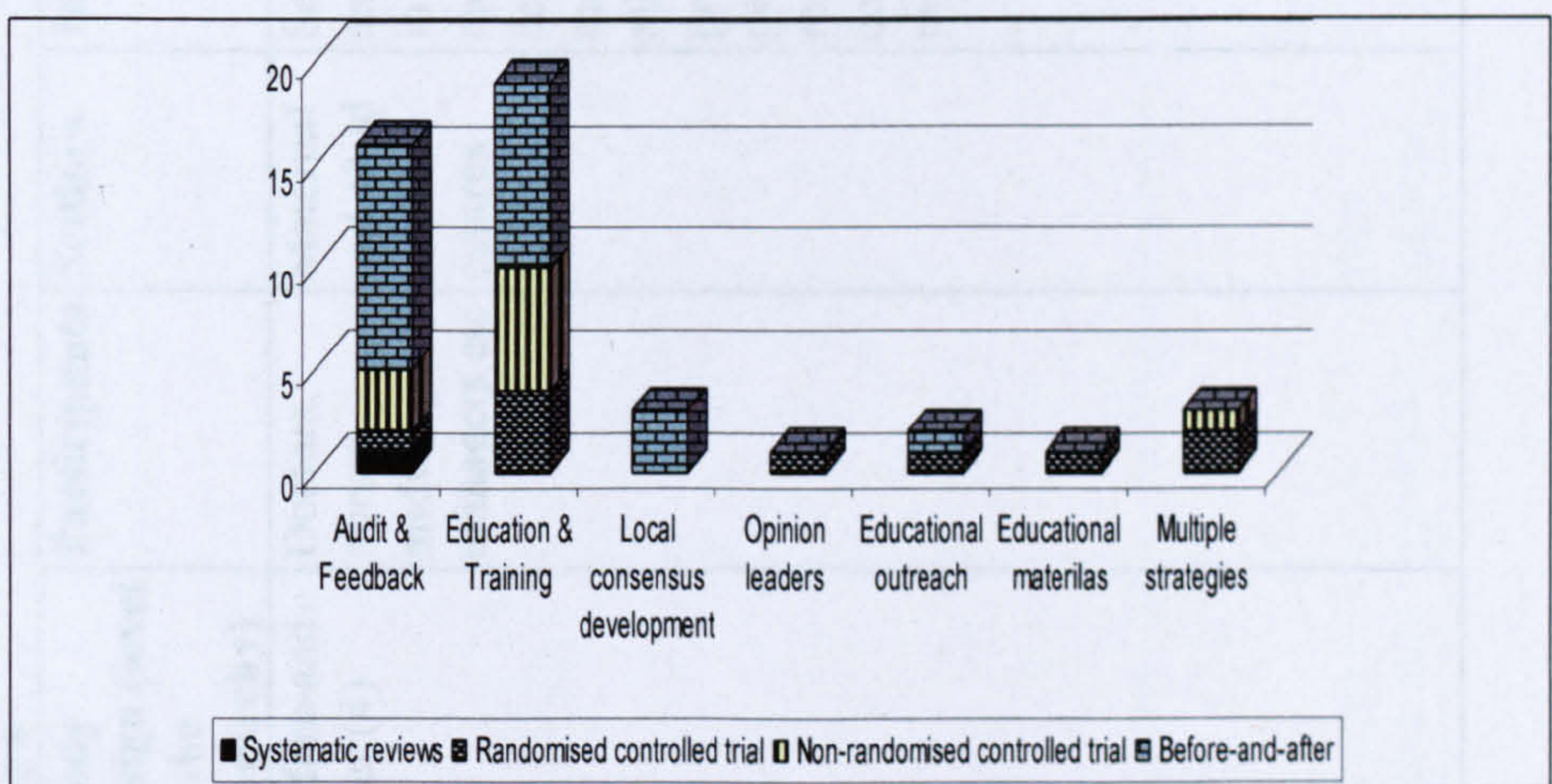


Figure 2.1: Number and types of studies for each intervention

This audit and feedback section reviews 16 studies and includes one non-systematic review, one randomised controlled trial, three controlled trials and 11

before-and-after non-controlled studies (Table 2.4). 10 studies presented audit and feedback conducted in hospitals, four in primary/community care centres and two in services across both primary and secondary care. Four specifically examined physicians' compliance with quality standards and two nurses' compliance. The remaining studies examined compliance and outcomes of the whole unit/service. Six studies related to child and maternal health. Five measured only clinical outcomes while the rest measured compliance against agreed processes. No meta-analyses were conducted due to the heterogeneity observed in the settings, interventions, target populations and measured outcomes.

Table 2.4: Studies examining the influence of various interventions on changing professional practice in developing countries

<i>Audit and feedback</i>									
Country	Study design (level in the hierarchy)	Participants	Settings	Intervention	Outcomes/ Professional behaviour assessment	Results	Methodological issues	Research and practice implications	
Pakistan (Awan, Awan & Akhtar, 1989)	Before-and-after (4)	Doctors, nurses, midwives, managers etc	Maternal and child health centres (12)	Self-appraisal and peer review, in the form of monthly seminars. During these seminars, all centres presented their performance and received comments from peers	Clinical outcomes; crude birth rate, contraceptive use, infant mortality and maternal mortality rates	From 1984 to 1988, compliance with contraceptives increased from 16.2 to 23.3%, crude birth rate decreased from 41 to 29.2, infant mortality rate from 119.9 to 70.2 and maternal mortality rate from 560 to 220	Mortality trends from other parts of the country were not available for comparison. Since these centres were established during the same time period, it is difficult to distinguish if the mortality reduction was a reflection of service provision or self-appraisal and peer-review. The process described in this study also did not include use and development of standards or indicators for quality assurance		

<p>Trinidad and Tobago (Mahabir & Gulliford, 1999)</p>	<p>before-and-after (4)</p>	<p>Doctors</p>	<p>Primary care</p>	<p>Doctors were provided training along with performance feedback (based on surveys). Local input from these clinicians was collected and fed into the development of national guidelines</p>	<p>Clinicians' compliance with the national guidelines in giving appropriate advice, prescribing appropriate treatment, keeping records and controlling of clinical outcomes related to hypertension</p>	<p>Among hypertensives, there was an increase in recording of advice on diet (from 21 to 36% $p < 0.005$) and exercise (from 5 to 19% $p < 0.001$). Use of a combined preparation decreased (from 31 to 6% ($p < 0.001$), use of beta blockers (from 16% to 27% $p < 0.001$) and ACE inhibitors (from 8% to 20% $p < 0.001$) increased. Proportion of adequately controlled hypertensives did not improve significantly (from 51 to 58% $p = ns$)</p>	<p>During this process, the national drug procurement policy changed which may have affected the prescribing behaviour. The study also did not make it clear as to how the local data was fed back to the clinicians. A very modest increase in the recording of non-pharmacological advice (statistically significant but clinically less significant) was observed that may have contributed to lack of improvement in the overall control of hypertension</p>	<p>In this project audit was conducted by an external body, which informed national policy and thereby mobilized change in the health system</p>
--	-----------------------------	----------------	---------------------	---	--	--	--	--

<p>South Africa(Wilson, 1997)</p>	<p>Before-and-after (4)</p>	<p>Doctors, nurses, midwives, managers etc</p>	<p>District maternity service which included a district hospital, village hospitals and mobile clinics</p>	<p>Agreement on a protocol. Case notes analysis of all deaths to look for evidence of any suboptimal care. Intervention included feedback, targeted training, revised protocols and organisational changes</p>	<p>Clinical outcomes; changes in the peri-natal mortality and the proportion of avoidable deaths</p>	<p>Peri-natal mortality decreased by 40% from the peak (p=0.002) and the proportion of avoidable deaths decreased from 18% to nil (p=0.0008)</p>	<p>The deaths were classified as avoidable deaths by the researcher, potentially introducing bias especially in the post intervention survey. Process indicators were not measured during the audit, making it difficult to judge any causal link between intervention and the improvement. The intra-partum mortality was not measured or classified separately, which could have made another objective comparison to avoidable death rates</p>	
-----------------------------------	-----------------------------	--	--	--	--	--	---	--

Yemen(Schultz, 2002)	Before-and-after (4)	Doctors and nurses	Hospital	The audit cycle included collection of base line data, contextualising standards from international guidelines, meetings with staff involving feedback and targeted training, implementing changes and a second data collection	Compliance with asthma management guidelines addressing prescription (inhalers and steroids), advice (peak flow measurement) and patient monitoring (chest examination)	There was improvement in examination of chest (20 to 80%), Peak Expiratory Flow examination (0 to 15%), use of inhaled steroids (0 to 40%), use of antibiotics (40 to 7%) and use of oral steroids (20 to 0%).	The actual figures on improvement were not available from the article and were based on extrapolation from a graph. This audit was conducted on a small sample of case notes and statistical significance was not determined	Such activities can only be sustained if supported by hospital management
----------------------	----------------------	--------------------	----------	---	---	--	--	---

<p>India(Bhara t et al, 2003)</p>	<p>Before-and- after (4)</p>	<p>Doctors</p>	<p>Secondary level hospital</p>	<p>Complete audit cycle</p>	<p>Clinical outcomes including thrombotic events, bleeding events and fatality</p>	<p>Thrombotic risk was reduced from 8.68 per 100pt-yr to 5.12 per 100pt-yr (no p values provided) Non-fatal bleeding events increased from 0.28 to 1.96. Fatal events were reduced from 3.8 per 100pt-yr to none</p>	<p>The post-intervention patient sample included a majority of patients from the pre- intervention survey. Therefore, the patients profile in the post- intervention survey is likely to be different compared with that prior to intervention (more years since anticoagulated, age, early death of patients at higher risk. etc.). Compliance to the International Normal Ratio (INR), a recognised quality assurance indicator for anticoagulation, was not measured</p>	<p>Positive change is likely to be the result of a lot of effort invested in identifying possible problems, finding their solutions and implementing change strategies during the project</p>
---	----------------------------------	----------------	---	---------------------------------	--	--	---	---

<p>South Africa(Campbell. 2001)</p>	<p>Before-and-after (4)</p>	<p>Doctors and Nurses</p>	<p>Hospital</p>	<p>Setting standards for referral of Human Immunodeficiency Virus (HIV) patients from hospital to integrated community-based home care, chart review, focus groups to provide feedback and develop strategies for change, implementing changes and a second chart review</p>	<p>Appropriateness of referral and compliance with the referral guidelines was assessed</p>	<p>No quantitative results given. However, according to the authors, following the intervention the referrals improved and became more compliant with the guidelines</p>	<p>It is difficult to comment on the authors' claim without examining quantitative results</p>	<p>It is likely that any success would have been due to staff involvement in the process, provision of regular feedback and the use of focus groups to develop realistic strategies for change</p>
-------------------------------------	-----------------------------	---------------------------	-----------------	--	---	--	--	--

<p>Lebanon(M ajor et al, 1998)</p>	<p>Before-and- after (4)</p>	<p>Doctors</p>	<p>Primary care health centres</p>	<p>This initiative included feedback to clinicians on their performance, educational materials regarding monitoring to prevent diabetic complications and other educational initiatives to improve compliance</p>	<p>Changes in the recording of clinical information and monitoring diabetics for complications according to agreed guidelines</p>	<p>Improvement in recording of smoking status (11 to 98%), hypertension (9 to 99%), dyslipidaemia (4 to 99%), BMI (nil to 39%), blood pressure (46 to 87%) and foot examination (16 to 92%). No p values provided</p>	<p>Improvement in recording and monitoring clinical information is only a step in the care process to prevent complications in diabetics. This study did not measure if clinicians actually did change their management (as per guidelines) according to the clinical status of the patients</p>	
--	----------------------------------	----------------	--	---	---	---	--	--

South Africa (Brooks et al. 1999)	Before-and-after (4)	Doctors and Nurses	Trauma unit in a hospital	<p>Protocols for universal precautions were agreed. Video recording of the trauma procedures were conducted. Subsequently, feedback of the analysis of video review was given. The trauma procedures were re-recorded following feedback</p>	Compliance with the universal precautions during resuscitation procedures	Improvement in compliance with guidelines (48 to 74% p = 0.007), with specific improvement in the wearing of masks and visors	Video recording in itself can influence professional behaviour and generate bias	
-----------------------------------	----------------------	--------------------	---------------------------	--	---	---	--	--

<p>Thailand(T hamlikitkul, Danchaiviji tr, Kongpattan akul & Ckokloikae w, 1998)</p>	<p>Before-and- after (4)</p>	<p>Doctors</p>	<p>Hospital</p>	<p>Prescribing guidelines and feedback on current performance</p>	<p>Frequency of antibiotic prescriptions, cost of antibiotics, compliance with the guidelines and performance on four indicators of poor antibiotic prescriptions were measured to determine change in prescribing habits</p>	<p>A reduction in antibiotic use (28.2 to 22.1% p<0.001) and the cost of antibiotics (by 20%); A statistically significant reduction in the number of patients receiving inappropriate antibiotics according to five agreed indicators</p>	<p>Despite having no controls, this study tried to exclude other factors that may have influenced clinicians' behaviour</p>	<p>Researchers used a multifaceted approach to provide feedback, which appears to be the main reason for an apparently successful change in prescribing behaviour</p>
--	----------------------------------	----------------	-----------------	---	---	---	---	---

Ghana and Jamaica(Wagaarachchi et al, 2001)	Before-and-after (4)	Doctors, nurses, midwives, managers etc.	Obstetrics units (4) from four different hospitals	One complete audit cycle	Compliance to the 31 agreed quality standards in obstetrics care in the event of five major complications	At least 13 out of 31 criteria showed statistically significant improvement. No deterioration in any criteria was observed. Improvement was seen in recording key information such as parity (76 to 92% p<0.001) and complications in previous pregnancies (34 to 63% p<0.001). Similarly in cases of obstetric haemorrhage more women had cross matching/blood typing(49 to 74% p<0.001) and Hb estimation (84 to 94% p<0.001)	One of the strengths of this study was the use of a multifaceted approach to influence professional behaviour. In addition, bias was reduced by the use of non-medical assistants to assess compliance	The before-and-after design, intrinsic to the audit cycle, cannot be used to demonstrate any causal relationship between audit and change. However a case study of hospitals and its environment can monitor the influence of any external changes that may influence professional practice during this period
---	----------------------	--	--	--------------------------	---	---	--	--

<p>Mozambique (Bugalho & Bergstrom, 1993)</p>	<p>Before-and-after (4)</p>	<p>Doctors, nurses, midwives, managers etc.</p>	<p>Obstetrics unit in a hospital</p>	<p>Sentinel audit (weekly review of all infant and maternal deaths)</p>	<p>Patient outcomes; Intra-partum foetal mortality and hospital based peri-natal mortality</p>	<p>Intra-partum foetal mortality decreased (10.9 to 3.9 p<0.0005) from 1982-1991. The pre-labour foetal deaths increased by 81% and stillbirths increased by 39%. Hospital based peri-natal mortality decreased (85 to 74%) from 1983 to 1985. No reduction in the overall peri-natal mortality was observed</p>	<p>No comparative mortality rates from other parts of the country were given. However, the increase in other unavoidable events and reduction in hospital related events may be able to justify the conclusions</p>	
---	-----------------------------	---	--------------------------------------	---	--	---	---	--

Niger(Kelle y et al. 2003)	Controlled trial (2)	Doctors, nurses, etc.	Community paediatric services	Audit, feedback and self- assessment, including direct observation of a HCW-patient consultation by a peer and performance marked against a 17 point check list. This is followed by self- assessment and a feedback meeting. Health Care Workers (HCW) also provided a 33- point checklist for structural quality standards	Compliance to the standards of care in the management of fever and certain other structural quality indicators	Improvement in assessing fever in the intervention group (52% vs. 40% in control p <0.005). No significant improvement in other indicators in the intervention group (p=0.25)	This variable improvement in indicators may reflect local resource issues and management complexities in dealing with structural improvements. Direct observation was used to assess compliance, potentially biasing behaviour, and a comparison of the providers in the two groups was not available to refute any selection bias	Self- assessment is not cost- neutral, contrary to common belief and does require extra resources
----------------------------------	-------------------------	--------------------------	-------------------------------------	---	---	--	--	--

<p>Ecuador(Hermida & Robalino, 2002)</p>	<p>Controlled trial (2)</p>	<p>Doctors, nurses, midwives, managers etc.</p>	<p>Obstetric and gynaecology departments (each with 20-30 beds) from four hospitals</p>	<p>Complete audit cycle using 11 agreed standards</p>	<p>Compliance with clinical guidelines, patient satisfaction and the level of service utilisation were assessed</p>	<p>In at least eight standards mean compliance with the standards were significantly higher in intervention hospitals than control hospitals. No significant improvement in hospital utilisation and patient satisfaction was seen in the intervention hospitals compared to control hospitals</p>	<p>At baseline, intervention hospitals already had a higher compliance compared to controls. Remarkable improvement was observed in criteria based on structural changes compared to process criteria. This phenomenon was also observed in controls, indicating thereby some external influence on the services during the project other than audit</p>	<p>All resources were mobilised locally except a field coordinator providing technical assistance. Local quality assurance teams and users' committees took an active part in the process</p>
--	-----------------------------	---	---	---	---	--	--	---

<p>Thailand(Moongtui, Gauthier & Turner, 2000)</p>	<p>Controlled trial (2)</p>	<p>HCWs, ward nurses and health care assistants</p>	<p>Casualty department vs. hospital wards (controls)</p>	<p>An audit and peer-feedback programme was developed which included reviewing peer performance (11 times) by using a checklist tool to observe compliance with universal precautions' guidelines. These feedback reports were then posted to all participants</p>	<p>Compliance with the universal precautions both before, during and after the intervention was observed directly by the investigator</p>	<p>The intervention group showed a significantly improved adjusted compliance rate compared with the control group during the intervention period (49.2 to 82.7% vs. 61.5 to 65.8%, in controls $p=0.0001$). However, there was no significant difference in the compliance scores obtained 1 month after the intervention (73.2 and 65.8%, respectively $p=0.4$)</p>	<p>Anonymity was observed during feedback, according to the local organisational culture. HCWs from the causality department may be different in their attitude from those working in other wards, creating a possible selection bias. Moreover, baseline compliance of HCWs in the intervention group was lower compared with controls, leaving more opportunity for improvement. Direct observation, used to measure change in clinical behaviour, is likely to influence the actual behaviour by itself</p>	<p>This highlights the need of sustainable programmes to maintain compliance with improved clinical behaviour</p>
--	-----------------------------	---	--	--	---	---	--	---

<p>Thailand(Ruangkanchanasetr, 1993)</p>	<p>Randomised controlled trial (1)</p>	<p>Doctors (residents and consultants)</p>	<p>Hospital paediatric departments</p>	<p>An educational seminar along with regular audit and feedback. In addition second year residents and consultants also received peer review</p>	<p>Appropriateness of investigation ordering and reduction in the laboratory utilisation cost per patient</p>	<p>Resident's test ordering reduced in the intervention group (3.32 Standard Deviation (SD)+0.78 to 3.27 SD+0.84 intervention group vs. 3.27 SD+0.70 to 3.46 SD+0.99 in the controls p value 0.05). The appropriateness of test ordering improved in residents but failed to reach statistical significance. The over utilisation significantly decreased (26.9 to 17.6) while under utilisation increased (17.7 to 26.0). Consultants' investigation ordering did not improve despite involvement in peer review</p>	<p>Overall, the over utilisation decreased while under utilisation increased, possibly due to cost cutting strategies. The consultants' investigation ordering did not improve, perhaps due to already optimum performance. Since both intervention and controls were working in the same hospital, some cross-contamination may have led to under estimation of the actual results</p>	<p>Due to a remarkable change in the attitude of second year residents, it is argued that there is an added benefit of adding peer review to the process of chart audits and feedback</p>
--	--	--	--	--	---	---	---	---

Developing countries(Mancey-Jones & Brugha, 1997)	Review (non-systematic) of six studies	Doctors, nurses, midwives, managers etc.	Child and maternal health services in developing countries	Peri-natal audits	Peri-natal mortality rate	Three studies showed a statistically significant decline in the peri-natal mortality rate after the introduction of peri-natal audits. On further sub analysis of two of the above three studies show significant reduction in intrapartum foetal deaths. One study in the review showed significant reduction in the deaths due to avoidable factors after the introduction of clinical audit ($p < 0.05$); two did not	This review did not explain any means to avoid publication bias. Due to the absence of controls in the studies, other factors may have confounded the improvement shown in the mortality rates. A comparison with the general trends of mortality in the rest of the country and a description of other changes that took place during that period in the health systems were not given	All studies remarked on the beneficial effects of clinical audit in improving peri-natal care
---	--	--	--	-------------------	---------------------------	--	---	---

Educational Strategies

Country	Study design (level in the hierarchy)	Participants	Settings	Intervention	Outcomes/ Professional behaviour assessment	Results	Methodological issues	Research and practice implications
Guatemala(O'Rourke, 1995)	Before-and-after (4)	Hospital staff and traditional birth attendant (TBA)	Hospital and community settings for obstetrics	Training programme	Standards of management of obstetrics and their complications	The referral rates increased 200%, peri-natal mortality improved and satisfaction scores improved. No p values	This study did not assess compliance with the standards of obstetrics and used surrogate measures to infer causality	

Peru(Salazar-Lindo, Chea-Woo, Kohatsu & Miranda, 1991)	Before-and-after (4)	Doctors and nurses	Primary care	An intense training programme consisting of a seminar series, local workshops and supervisory visits by tutors	Prescribing behaviour	Significant improvement in the use of oral rehydration therapy at health facilities (2.9 to 23.6%, $p = 0.007$) and a reduction of antibiotic prescription for inpatients with diarrhoea (85.7% to 64.8%, $p = 0.025$)		A huge gap between the knowledge acquired and change in actual practice highlighted more room for improvement using other types of interventions
Mozambique(Pisacane, 1985)	Before-and-after (4)	Nurses	Paediatrics department in a hospital	Twice a week half hourly face-to-face educational sessions	Compliance with record keeping, hospital mortality of children with diarrhoea and case fatality ratio	Mortality went down from 8 to 3% ($p < 0.01$) post intervention; Case fatality went down from 30 to 1. Nurses compliance with data collection on 4 indicators increased from 0(0/30) to 70%(24/34); no p values given	However, the evidence is not convincing to assume a causal link between nurses' compliance with the record keeping and the mortality reduction	A controlled design using process indicators related to the direct delivery of care might have helped in establishing authors' conclusion

Nepal(Baral et al, 2001)	Doctors	Teaching hospital	Two educational seminars	Laboratory test (thyroid function test) ordering behaviour	Rational prescribing improved (7.3 to 19.6%) No p values. Only 23% of all doctors attended and their prescribing improved from 6.3 to 66.6%. No p values	The improvement was far greater in clinicians who attended these seminars than in others	
China(Hesket, Zhu & Zheng, 1994)	Doctors, nurses, etc.	Neonatology department in a hospital	Targeted module based training that lasted for 16 weeks	Compliance with the agreed protocols before-and-after the intervention	32% of all practice protocol were met and 55% practice protocols showed improvement after the course		It was considered successful due to its focus on the local educational needs, appropriate teaching materials and establishment of management protocols

<p>Mali(Mallet , Njikam & Scouflaire, 2001)</p>	<p>Before-and-after (4)</p>	<p>Nurses as prescribers' in the</p>	<p>Primary care</p>	<p>Targeted training</p>	<p>Prescribing habits</p>	<p>The mean number of drugs per prescription increased from 2.96 to 3.14 ($p < 0.01$) between the two periods, and the proportion of prescriptions with injections from 29.9 to 36.6% ($p < 0.02$), whereas the proportion of prescriptions with antibiotics decreased from 75.2 to 68% ($p < 0.01$). Correct prescriptions according to standard treatment guidelines were only around 50%, in both the before and after surveys</p>	<p>A non-controlled trial is incapable of addressing these complexities and showing straight causal link</p>	<p>Such ambiguous results highlight the complexity of factors that influence prescribing behaviour</p>
---	-----------------------------	--------------------------------------	---------------------	--------------------------	---------------------------	---	--	--

Zimbabwe(Adamolekun, Mielke & Ball, 1999)	Before-and-after (4)	Nurses and environmental health officers	Rural health centres without doctors	Knowledge workshops on epilepsy diagnosis and management with and without educational leaflets for patients	Compliance with the quality standards of management and diagnosis of epilepsy	74% increase in the new cases in the register with their diagnosis verified by a panel of physicians. Non-compliance among patient reduced from 15.6 to 2.2%	This trial only measured outcomes that make it difficult to tease out the real effect of the intervention. Besides leaflet-campaign could also have influenced the outcome. A subgroup analysis did not have enough power to distinguish this influence from that of the intervention itself	
Solomon Islands(Lucas & Oberli, 1997)	Before-and-after (4)	Doctors and nurses	Hospital	An educational seminar series	Compliance of hospital staff with the local guidelines for ordering and transfusing blood in surgical patients	A 29.7% reduction in the number of units of blood cross matched as a proportion of total admissions and a 30.1% reduction in the number of units transfused per 100 operations after the educational intervention	No p values available to assess statistical significance	Further situation analysis revealed that poor communication was responsible for lack of improvement in one of the indicators measured in the trial

<p>Mexico(Bojalil et al, 1999)</p>	<p>Before-and-after (4)</p>	<p>Doctors</p>	<p>Public (n=49) and private (n=72) primary care health centres</p>	<p>A five-day clinical course with training materials on the management of children with acute respiratory infections (ARI) and diarrhoeal diseases</p>	<p>Compliance with the 10 standards of care (six for diarrhoeal diseases and four for ARI) were assessed using direct observation, interviews and data analysis</p>	<p>The proportion of private physicians who had five or six correct elements out of six increased from 14 to 37%: for public physicians the corresponding increase was from 53 to 73%. In ARI case management, decisions taken on antimicrobial therapy and symptomatic drug use improved in both groups; the proportion of private physicians with at least three correct elements out of four increased from 13 to 42%, while among public doctors the corresponding increase was from 43 to 78%</p>	<p>Recruitment to the trial was on a voluntary basis and an unaccounted number of clinicians dropped out in the middle of the trial. Improvement was comparable in both public and private practitioners despite differences in their average age, experience, workload etc. 77% of private physicians responded and attended the training sessions</p>	<p>This study has been successful in engaging private practitioners. Access to continuing education in private sector is a major issue in developing countries especially in an environment of unregulated drugs control policy and uncontrolled access to false marketing by drug company representatives</p>
------------------------------------	-----------------------------	----------------	---	---	---	--	---	--

<p>Ghana(Smith et al, 2000)</p>	<p>Controlled trial (2)</p>	<p>Traditional birth attendants</p>	<p>Obstetrics services</p>	<p>A course on obstetrics care</p>	<p>The obstetric practices were the target behaviour in this trial but it was only assessed through clinical outcomes</p>	<p>Significant improvement in three out of eight patient outcomes assessed. OR of labour duration > 18 hours 2.57 (CI 1.13-5.81), OR of intrapartum fever 0.30(CI 0.14-0.65) and OR of retained placenta 0.35 (CI 0.13-0.96)</p>	<p>All outcome assessment was based on interviews and was, therefore, subject to information and recall bias. The trial did not have a mechanism to account for maternal deaths or any other adverse events not reported by the interviewee. Since no process measures were observed, causality cannot be attributed entirely to the training received by the traditional birth attendants</p>	
---------------------------------	-----------------------------	-------------------------------------	----------------------------	------------------------------------	---	---	--	--

<p>Guatemala(Flores, Robles & Burkhalter, 2002)</p>	<p>Controlled trial (2)</p>	<p>Doctors, nurses, health visitors, etc.</p>	<p>Primary care</p>	<p>Training materials, exercises, tutors' feedback, occasional telephone calls and field visits to their respective health facility</p>	<p>Compliance to the management guidelines of diarrhoeal diseases assessed by direct observation, interviews, routine data and surveys</p>	<p>The percentage of diarrhoea cases assessed correctly and dehydration cases classified correctly increased by 25% and 27% ($p < 0.05$) respectively more in the intervention group than in the control group, but post-course performance was still only ~60% in the intervention group. Rehydration treatment did not improve. Counselling improved insignificantly</p>	<p>This modest improvement in some of the indicators questions the value of distant training packages (probably cheaper to administer) compared to the traditional face-to-face courses and training</p>
--	-----------------------------	---	---------------------	---	--	--	--

<p>Honduras(Brown et al, 2000)</p>	<p>Controlled trial (2)</p>	<p>Doctors (24)</p>	<p>Hospitals</p>	<p>In-service training programme on interpersonal communications, delivered in three half-day sessions, focussing on socio-emotional communication, problem solving and counselling skills</p>	<p>Pre and post-intervention change in interpersonal communication was assessed by interaction analysis of audio-taped clinical encounters, patient exit interviews, and a self-administered questionnaire for health providers</p>	<p>Intervention resulted in more communication by trained doctors (mean scores of 136.6 vs. 94.4; $p = 0.001$), more positive talk (15.93 vs. 7.99; $p = 0.001$), less negative talk (0.11 vs. 0.59; $p = 0.018$), more emotional talk (15.7 vs. 5.5; $p = 0.021$), and more medical counselling (17.3 vs. 11.3; $p = 0.026$) compared to controls. Patients also communicated more (mean scores of 113.8 vs. 79.6; $p = 0.011$) and disclosed more medical information (54.7 vs. 41.7; $p = 0.002$). Patient satisfaction ratings were higher for trained doctors and providers reported training to be relevant and useful</p>	<p>Possible selection bias and altered clinicians' behaviour due to audio-taping was also possible in this trial</p>	
------------------------------------	-----------------------------	---------------------	------------------	--	---	---	--	--

Nigeria(Kim et al, 1992)	Controlled trial (2)	Nurses	Family planning services	Six weeks of family planning training and a three day counselling workshop	The proportion of scheduled follow up visit	96% of trained nurses scheduled a return visit for their first time method adopter clients compared to 78% by the untrained nurses (p<0.001)	A number of other indicators were also measured by client interviews but those were not an objective measurement to assess change in nurses' professional behaviour	
--------------------------	----------------------	--------	--------------------------	--	---	--	---	--

<p>Mexico(Per ez-Cuevas et al, 1996)</p>	<p>Controlled trial (2)</p>	<p>Doctors</p>	<p>Social Security (IMSS) and Ministry of Health (SSA) primary care health centres</p>	<p>Series of workshops on the use of antibiotics in rhinopharyngitis, printed reminders, feedback on their performance and a review of the clinical notes carried out by a peer review committee on a regular basis</p>	<p>Prescribing habits; The proportion of prescriptions carrying antibiotics for rhinopharyngitis and the proportion of inappropriate antibiotics per prescription were measured</p>	<p>Post-intervention, the percentage of patients receiving antibiotic prescriptions in the IMSS went from 85.2 to 48.1% (p<0.05), in the SSA it went from 68.8 to 49.1%(p<0.05). Similarly, the percentage of the IMSS physicians treating their patients appropriately increased from 30 to 57.7%, and at the 18-month follow-up, it was 54.2%. The SSA study group increased the appropriate use of antibiotics from 35.7 to 46.2%, with this percentage falling to 40.9% after the 18-month follow-up period</p>	<p>The observed improvement tailed down according to an 18-month post intervention follow up survey. It was not clear as to how the physicians were allocated into the intervention and control groups. However, the groups were comparable according to the information provided in the article</p>	<p>Long-term sustainability of the correct prescribing behaviour is questionable unless the intervention is sustained on a regular basis. However, this study highlights that changes in professional behaviour are likely to take place if multiple strategies are employed</p>
--	-----------------------------	----------------	--	---	---	---	--	--

<p>Trinidad and Tobago(Rotter et al, 1998)</p>	<p>Controlled trial (2)</p>	<p>Doctors</p>	<p>Primary care in three different countries</p>	<p>Eight hour two-day training in communication skills</p>	<p>A scoring system based on doctor and patient talk duration, patient satisfaction and doctor's tone was used</p>	<p>More patient talk in the intervention group compared to control after CME (p<0.025). Change in doctor talk also increased in the intervention group but did not reach statistical significance (p<0.072). Patient satisfaction was greater in the intervention group (p<0.066)</p>	<p>Some selection bias is likely as the allocation to the intervention group was based on clinicians' preference. Moreover, doctors were aware of the videotaping of their encounters, which like any other direct observation method can influence professional behaviour. Each trial arm had a small sample of doctors making it difficult statistically to detect clinically significant differences. However, both groups were shown to be similar in their characteristics thereby reducing chances of confounding</p>	
--	-----------------------------	----------------	--	--	--	--	---	--

<p>Zambia(Be xell et al. 1996)</p>	<p>Randomised controlled trial (1)</p>	<p>Doctors</p>	<p>Primary care</p>	<p>Three two-day workshops</p>	<p>Prescribing habits</p>	<p>The average number of drugs per patient decreased from 2.3 to 1.9 (p = 0.005) and the proportion of patients managed with non- pharmacological treatment increased from 1 to 13.2%. More drugs were correctly chosen compared to control health centres (51 to 77% in intervention arm 53 to 62% in control p = 0.03). The proportion of patients prescribed antibiotics decreased (41.2 to 34.2% in intervention and 41 to 42% in control p<0.004) and the proportion of patients adequately managed increased in the intervention health centres(18.8 to 27.8% in intervention and 16.8 to 10.5% in control p<0.02)</p>	<p>The intervention and control groups were both similar in their characteristics reducing the possibility of any other confounding factors</p>	
--	--	----------------	-------------------------	------------------------------------	-------------------------------	--	---	--

<p>South Africa(Harrison et al, 2000)</p>	<p>Randomised controlled trial (1)</p>	<p>Doctors, nurses, health visitors, etc.</p>	<p>Primary care</p>	<p>Training workshops and were provided with sexually transmitted diseases (STD) packs containing guidelines, treatment packs, partner packs, information leaflets and condoms</p>	<p>Compliance with the STD guidelines was observed</p>	<p>Intervention clinics provided better case management than controls: 88 vs. 50% (RR 1.28; 95%CI 1.12-1.47 p < 0.01) received recommended drugs; 83 vs. 12% (RR 2.08; 95%CI 1.53-2.84 p < 0.005) were correctly case managed; 68 vs. 46% (p = 0.06) were adequately counselled; 84 vs. 58% experienced good staff attitude (RR 1.21; 95%CI 0.97-1.5 p = 0.07)</p>	<p>Simulated patients were used to assess improvement, which may have an extra influence on clinical behaviour. The educational component was not assessed separately in this trial, making its actual value difficult to ascertain</p>	
---	--	---	---------------------	--	--	--	---	--

Indonesia(Hadyono et al, 1996)	Randomised controlled trial (1)	Doctors	Primary care	Educational interractional group discussion (IGD), each comprising of six prescribers and six consumers, to counteract cognitive dissonance (CD) that causes doctors to prescribe irrationally despite having the correct knowledge	Prescribing habits	A significant decrease in injection use from 69.5 to 42.3% in the intervention group, compared to a decrease from 75.6 to 67.1% among controls [-18.7% intervention, vs. control reduction, 95% CI -31.1 -6.4%, p < 0.025]. A significant reduction in average number of drugs per prescription from 4.04 to 0.37 drugs prescribed per patient in intervention and from 3.97 to 3.88% in control, overall reduction of 0.28; 95% CI -0.04, -0.52, p < 0.05, indicating that injections were not substituted with other drugs	Some contamination is likely as all prescribers were from the same region	The real value of such intensive intervention needs to be assessed along with its cost implications and feasibility of implementation widely across health systems
---------------------------------	---------------------------------	---------	--------------	---	--------------------	--	---	--

Cuba(Ochoa et al, 1996)	Randomised controlled trial (1)	Doctors randomised in four groups	Primary care	Groups A and B received a refresher course on the management of ARI. In groups A and C, a community programme was introduced in the catchment population meant to educate the public on the value of antibiotics in ARI. Group D was treated as controls	Prescribing habits	The baseline prescription rates for antibiotics were 26%, 20%, 11%, and 19% in areas A, B, C, and D respectively ($p > 0.05$). In the period following the interventions, prescription rates declined by 26% and 63% in areas A and B, while increasing by 2% and 48% in areas C and D. Overall, prescription in the intervention areas A and B combined decreased by 54% (95% CI: 31-69%)	A surprising increase was observed in control group D that indicates other possible factors influencing prescribers' behaviour. Similarly, no apparent reason was given for the ineffectiveness of the community educational programme	The refresher course appeared to work in the short term but such interventions needs to be repeated regularly to sustain improvement	
<i>Consensus development</i>									
Country	Study design (level in the hierarchy)	Participants	Settings	Intervention	Outcomes/ Professional behaviour assessment	Results	Methodological issues	Research and practice implications	
Senegal(Di allo et al, 2002)	Before-and-after (4)	Doctors	Primary care health centres	Local doctors took part in developing algorithms for common illnesses	Prescribing behaviour was assessed by estimating ratio of oral vs. parentral drugs	The ratio between oral vs. parentral drugs before intervention changed to 78.1% and 21.9% post intervention	There was a difference of five years (1991-1996) between the two surveys and many other factors could have potentially changed the practices		

<p>Tanzania(V os et al, 1994)</p>	<p>Before-and- after (4)</p>	<p>Doctors</p>	<p>Hospitals (8)</p>	<p>Developed guidelines for appropriate transfusion after developing a local consensus</p>	<p>The proportion of inappropriate blood transfusions was estimated as per the agreed guidelines</p>	<p>Overall no significant change in the proportion of inappropriate transfusions before- and-after the interventions. In blood transfusion recipients aged < 5 years, a significant reduction in the proportion of avoidable blood transfusions from 52 to 33%; $p < 0.001$</p>		<p>Improvement in children was probably due to focused training on inappropriate transfusion requests in that age group. Two peripheral hospitals that did better in complying with the guidelines instituted regular feedback meetings on blood transfusion requests and made sure that all transfusion requests were duly verified by more than one doctor</p>
---	----------------------------------	----------------	--------------------------	--	--	--	--	--

<p>South Africa (Edwards et al, 1998)</p>	<p>Before-and-after (4)</p>	<p>Doctors</p>	<p>Community hospital</p>	<p>Local clinicians adapted and implemented national guidelines for hypertension. In addition, the health centre withdrew less cost-effective drugs and categorised drugs into those which can be prescribed by consultants only and those that can also be prescribed by other clinicians</p>	<p>A prescription review analysed the prescribing behaviour of clinicians both before-and-after the intervention</p>	<p>No significant change in the proportion of prescriptions of the five most commonly used drugs. The mean blood pressure did not change after the intervention</p>	<p>It appears that the change in the cost was mainly because of the shift of drugs between the same classes, prescription restrictions and withdrawal of certain drugs from the hospital formulary rather than the guidelines itself</p>	<p>Implementation of guidelines alone is not sufficient unless other interventions are implemented to facilitate change in behaviour. In this case, organisational changes helped in forcing doctors to change their behaviour</p>
---	-----------------------------	----------------	---------------------------	--	--	---	--	--

<i>Opinion leaders</i>								
Country	Study design (level in the hierarchy)	Participants	Settings	Intervention	Outcomes/ Professional behaviour assessment	Results	Methodological issues	Research and practice implications
Hong Kong(Hong, Ching, Fung & Seto, 1990)	Randomised controlled trial (1)	Nurses	Hospital wards were divided into three groups (A, B and C)	Group A received a lecture on the guidelines as well as tutorials run by their opinion leaders. Group B received only opinion leader-led tutorials and Group C received the lecture only. Nurses selected their own opinion leaders by using a systematic method	Compliance to the guidelines was observed by estimating mean change in practice score and the proportion of nurses applying correct practices through surveys and direct observation respectively	Significant change in practice mean score (A 5.63; B 4.96; C 3.29; $p < 0.05$) and percentage of nurses with correct practices (30 to 77% in Group A 32 to 64% Group C 25 to 52%; $p < 0.05$)	Assessment conducted by post intervention surveys and direct observation is likely to have recall and observers' bias. Such assessment can also artificially alter clinical behaviour	

Educational outreach

Country	Study design (level in the hierarchy)	Participants	Settings	Intervention	Outcomes/ Professional behaviour assessment	Results	Methodological issues	Research and practice implications
Kenya(Ross -Degan et al, 1996)	Before-and-after	Pharmacists	Health system	Educational needs of pharmacists were assessed. Subsequently underlying motivational factors and constraints were identified which helped in designing and implementing a face-to-face educational intervention	Sale of Oral Rehydration Salt (ORS), antibiotics and anti-diarrhoeals were measured in children under 5 to estimate change	Sales of ORS in intervention pharmacies increased by an average of 32% (95% CI 15-44%) in Kenya (almost a two-fold increase) compared to controls and anti-diarrhoeal sales declined by an average of 15% (p<0.05)		

Indonesia(Ross-Degnan et al, 1996)	Randomised controlled trial	Pharmacists	Health system	Educational needs of pharmacists were assessed. Subsequently motivational factors and constraints were identified which helped in designing and implementing a face-to-face educational intervention	Sales of ORS, antibiotics and anti-diarrhoeals were measured in children under 5 to estimate change	Sales of ORS increased by 21% (95%CI 3-39%) in Indonesia compared to controls ($p < 0.05$) and anti-diarrhoeal sales declined by an average of 20% ($p < 0.05$)	Cost estimation of this intervention is desirable to inform policy	
------------------------------------	-----------------------------	-------------	---------------	--	---	---	--	--

Educational materials

Country	Study design (level in the hierarchy)	Participants	Settings	Intervention	Outcomes/ Professional behaviour assessment	Results	Methodological issues	Research and practice implications
Sri Lanka(Ang unawela, Diwan & Tomson, 1991)	Randomised controlled trial (1)	Doctors with same prescribing status	Primary and secondary health care	Group A received a fortnightly bulletin on the use of appropriate drugs along with two related seminars. Group B received seminars only while group C did not receive any intervention	Proportion of patients prescribed antibiotics in the two intervention groups was measured	A non-significant decrease in the proportion of patients prescribed antibiotics in the two intervention groups was seen (38.8 to 31.5% in A; 31.5 to 24.1% in B; 32.2 to 31.8% in C; p=ns)	The small sample size did not allow these results to be statistically significant	Drug information bulletins can be of value in developing countries, where brochures from drug companies are often the only sources of information

<i>Multiple strategies</i>									
Country	Study design (level in the hierarchy)	Participants	Settings	Intervention	Outcomes/ Professional behaviour assessment	Results	Methodological issues	Research and practice implications	
Mali(Kelley, Geslin, Djibrina & Boucar, 2001)	Controlled trial	Nurses	Community paediatric services	Performance peer-assessed by direct observation and fed back into workshops. Subsequent meetings to suggest improvement. Two districts afterwards also received formal training in integrated management of childhood illnesses (IMCI)	Task-indicators (17) were developed according to the IMCI algorithm. Compliance with these indicators was observed by direct observation at six monthly intervals over a year	Performance feedback improved health care workers' compliance (34 to 85% $p < 0.05$) in short term. In addition, performance feedback was significantly cheaper than formal training (\$108 per health worker vs. \$430 per worker for training)		Performance feedback had the greatest impact in areas in which health care workers performed poorly initially	

<p>Indonesia(S antoso, Suryawati & Prawaitasar i, 1996)</p>	<p>Randomised controlled trial (1)</p>	<p>Doctors</p>	<p>Primary care</p>	<p>Group A received a face-to-face educational outreach intervention along with educational materials. Group B received educational seminars with the relevant materials. Group C did not receive any intervention. All interventions were informed by prescriber-consumer focus group results</p>	<p>Usage of anti-diarrhoeals and Oral Rehydration Salt therapy</p>	<p>A significant reduction of antimicrobial usage after small-group face-to-face intervention (77.4 +/- 2.7% to 60.4 +/- 2.9%; $p < 0.001$) or formal seminar (82.3 +/- 3.0% to 72.3 +/- 3.6%; $p < 0.001$), and the former caused significantly ($p < 0.001$) greater reduction than the latter. There was also a significant ($p < 0.01$) reduction in the use of anti-diarrhoeals after both interventions, i.e. from 20.3 +/- 3.7% to 12.5 +/- 3.3% ($p < 0.01$) after face-to-face intervention and from 48.5 +/- 4.1% to 27.0 +/- 4.3% ($p < 0.01$) after seminar. However, the formal seminar had a ($p < 0.01$) greater impact than the small group face-to-face intervention.</p>		<p>Disparity in the above results show that both methods work differently and it may be appropriate to use either one of these depending on the type of educational message</p>
---	--	----------------	---------------------	--	--	--	--	---

<p>Uganda(Ka fuko, Zirabamuza le & Bagenda, 1999)</p>	<p>Randomised controlled trial</p>	<p>Doctors, nurses, etc.</p>	<p>Primary health care (127) units from six districts</p>	<p>Group A1 received practice guidelines, feedback on their baseline professional performance, targeted training and direct supervisory sessions, Group A2 received all except supervisory sessions, Group B received guidelines only and Group C remained as control</p>	<p>Change in clinical behaviour was assessed by measuring compliance with malaria and general management guidelines and WHO indicators of drug use</p>	<p>A significant reduction in drug prescription rate in group A1, which was given feedback + formal training + supervisory sessions and A2, which received feedback + formal training (A1 2.39 to 2.14; A2 2.35 to 2.09; B 2.37 to 2.45 and C 2.45 to 2.45) compared to group B which only received printed guidelines and group C controls. Compliance to national prescription guidelines also increased (percentage of patients treated according to guidelines A1 21.4 to 55.2; A2 24.0 to 52.0; B 24.8 to 32.3 and C 24.8 to 29.9) in A1 and A2 with little improvement in B</p>	<p>This study again highlights the added value of audit and feedback to educational strategies and guidelines. However, personal supervision seems to add little benefit</p>
---	------------------------------------	------------------------------	---	---	--	---	--

2.4.1.1.1. Comments

Almost all studies included in this review claim that some form of clinical audit is likely to influence change in the professional behaviour. However, there are some methodological limitations to consider. These are as follows:

Given the difficulties that researchers in the developing world have in publishing their research in respected journals there may be significant publication bias. This is compounded by the fact that many journals, until recently were unwilling to publish research with negative findings(Alderson & Roberts, 2000).

The evidence is mostly based on non-controlled before-and-after studies together with a few controlled studies. It is difficult to justify a causal link between intervention and the outcomes, without controlling for confounding factors.

Many non-controlled studies in the above review used changes in the local mortality trends to justify their conclusions but failed to compare it with the general trend for those variables in that part of the world.

A significant number of studies measured only clinical outcomes and not indicators based on processes of care. This also raises question on the causal link between those outcomes and the intervention under review.

Several controlled studies failed to provide a comparative analysis of the characteristics of the participants in the controlled and the intervention arm.

In the absence of reliable routinely collected data, direct observation was used as a method to ascertain compliance in many cases. This method lacks reliability and also is likely to influence professional behaviour(Marquez, 2001).

A recent Cochrane review assessing the effectiveness of audit and feedback in improving professional practice in developed health systems concluded that audit and feedback can be effective in improving professional practice especially when baseline adherence to recommended practice is low(Jamtvedt et al, 2003). However, when it has been found to be effective, the effect size was often moderate(Jamtvedt et al, 2003). The quality of studies included in this review was mostly strong to moderate according to Cochrane review criteria. Due to the poor quality of the majority of the studies included in this review, evidence for audit and feedback in developing countries can only be classified as weak. It must be stated that the weakness of the evidence of the effectiveness of audit and feedback is mostly due to the poor research designs. This does not suggest that this intervention is unlikely to work in developing countries. Future researchers, policy makers and providers intending to implement audit in their health system can draw on the findings of this review as follows.

Audit and feedback has been shown to be more effective in the above studies when it has been adopted as part of a multifaceted approach. Interventions combining local consensus-based guideline development, audit combining peer review and feedback, along with targeted training are more likely to change health professionals' clinical behaviour.

Change is likely to take place when audit has been designed to suit the local culture, where those who need to implement change have been involved all along and where recommendations are feasible given available resources and existing practices(Stocking, 1992).

Similarly, analysing problems and finding solutions with the help of focus groups of local teams is more likely to make change strategies successful. Local teams need to identify the "avoidable factors" in order to inform recommendations for change. Avoidability depends on the local context and the availability of resources. For example, what is considered as an avoidable factor in the UK health service may not be avoidable in rural health care settings in West Africa(Mancey-Jones & Brugha, 1997).

One of the pre-requisites of conducting clinical audit is the existence of agreed clinical guidelines or standards of care. In developed countries, use of explicit guidelines to compare health care professionals' practice has been seen as threatening to the autonomy of physicians. This practice has also been accused of reducing innovation and providing ammunition to litigation lawyers(Barron, 1991). However, in developing countries where huge variations exist in the level of knowledge and skills of health professionals, use of explicit guidelines to inform and reinforce good practice are becoming generally more acceptable(Larsen, 1992). In the majority of inadequately resourced health systems, either such guidelines do not exist or are very poorly compiled with(Heiby, 1998).

Performance can be measured using process indicators, which have been shown (in previous research) to result in improved clinical outcomes. Structure-based indicators are likely to be influenced by organisational and resource constraints. Such indicators may not truly reflect professional performance. Similarly, measuring clinical outcomes, without process indicators makes it difficult to interpret clinical performance. Often factors other than quality of care influence clinical outcomes which makes it difficult to make any judgements on clinical care. Other indicators based on service utilisation and patient satisfaction are also less sensitive to the quality of clinical care provided in a health service.

Change is likely to occur where audit and feedback has been introduced as a quality assurance tool by the Ministry of Health with clear allocation of resources and prioritisation as a health service major task(Mahabir & Gulliford, 1999).

The audit cycle aims to implement and secure change by constantly reassessing practice. Almost all studies in the review were able to demonstrate improvement in short term, but often improvement shown in clinical performance was either not measured or not subsequently sustained in the longer term. Clinical audit is unlikely to have a beneficial impact if practiced as a time limited activity. In order to improve quality, all such activities need to be fully sustainable.

Many authors in this field have come to similar conclusions. Since this review, a criterion-based audit conducted in the maternity units of a hospital in Uganda has shown improvements in the management of pre-eclampsia(Weeks et al, 2005). The researchers discussed how the clinicians overcome some of the major constraints to a successful audit e.g. the strong hierarchical structure within the medical profession, the lack of resources to support audit activities, the poor access to published evidence, the poor quality of clinical records and resource constraints. Clinicians had ownership of the process and were able to implement cost-neutral solutions in many cases to achieve improvement within the hospital. A case study of this project concluded that criterion based audit can be implemented in resource poor countries where it helps in empowering local people to find cost-effective solutions to local problems(Weeks et al, 2003). Audit criteria need to be based on local expert consensus as well as research evidence in order to make them realistic to the local conditions(Graham et al, 2000). However, the focus should be on the problem analysis and implementation of change with provision of constant organisational support(Weeks et al, 2003). Due to a hierarchical culture in many health systems in developing countries, senior management should always be involved in the process, as often changes are required at the organisational level.

Despite the fact that clinical audit is widely practiced in developed nations, this practice has not attracted enough attention in many developing countries, often due to poor understanding of the audit process(Bankole, Lawal & Adejuyigbe, 2003). However, successful audit can be implemented through context specific and targeted training. In countries with limited resources and extra pressure to provide quality services at a minimal cost, quality assurance tools such as clinical audit can potentially be of immense value. The dual function of clinical audit, monitoring practice and education, can have a particular value in health services in developing countries given the pressure on human and financial resources(Wagaarachchi et al, 2001).

2.4.1.2. Education and training

This section covers all educational interventions excluding use of educational outreach and educational materials. Educational interventions combined with other interventions compared with no interventions have also been included. However, studies comparing educational interventions with other interventions will be discussed in the section on multiple strategies.

This section (19 studies) includes 13 studies testing educational courses, seminar series or training workshops. Four studies combine two or more forms of educational interventions. One study examines the effectiveness of a distant-learning course and another assesses the value of an interactive group discussion. These studies comprise four randomised controlled trials, six controlled trials and nine before-and-after non-controlled studies (Table 2.4). Eight studies examined change only in doctors' clinical behaviour (six in primary care, two in hospitals). Five studies restricted their assessment to either nurses or community health workers. Three studies included both doctors and nurses, whilst another three assessed all hospital staff in a particular department. 14 studies assessed change in compliance to agreed standards and three examined improvement in patients' outcomes. Two studies analysed changes in both outcomes and processes.

2.4.1.2.1. Comments

Almost all studies in this sub-category have investigated effects of various educational strategies by demonstrating improved compliance of health professionals to agreed quality standards and/or patients' outcomes. At least half of the studies were controlled, which makes the presented evidence a little stronger than that available for audit and feedback. However, there are a number of quality issues, which need to be considered in drawing conclusions from it.

The educational strategies varied from a seminar to intensive courses on the one hand and from distant learning courses to interactional sessions on the other. This makes it difficult to reach overall conclusions on the benefits of these educational strategies. No one educational design appeared to have an advantage over another and strategies using multiple educational methods appeared more successful. It was also shown that one type of educational strategy was successful in improving a specific clinical behaviour while other types were more successful in changing other behaviours. The evidence base does not allow a comparative analysis between the didactic educational sessions and the interactive tutorial sessions, due to lack of appropriate methodology in the included studies. However, one Cochrane review (evidence largely derived from developed countries) found that interactive

workshops can result in moderately large changes in professional practice compared to didactic sessions alone(Thomson O'Brien et al, 2001).

Interventions informed by the educational needs of the health professionals and provided in keeping with the organisational cultural context of the health system appeared to be more effective(Hesketh et al, 1994). Similarly, educational sessions addressing barriers and facilitators to putting knowledge into practice were also more successful(Hadiyono et al, 1996). Studies examining prescribing behaviour have been able to demonstrate improvement subsequent to educational interventions, but often only in the short term. Improvements have not been sustained over a prolonged period, implying the need for continuing educational strategies. Many studies tested educational strategies in combination with other interventions, without allowing for any comparative sub-group analysis. This makes it difficult to draw conclusions about the effectiveness of educational strategies alone. As commented on in previous sections, many studies only measured clinical outcomes without demonstrating a link between these and change in practice. Moreover, many studies used direct observation, interviews, simulated patients or recording of patient-clinician encounters for measuring processes of care, which are prone to many biases as discussed previously.

Since this review, another non-randomised controlled study has been published demonstrating the effectiveness of face-to-face educational intervention in influencing prescribing behaviour of clinicians(Obua et al, 2004). After attending a one day interactive educational sessions, there was a 23-28% improvement in various prescribing behaviours. However, this study used simulated patients that may have influenced outcomes. Authors did not comment on the longer term sustainability of improved behaviour. A similar educational intervention was given to a group of pharmacists and store-keepers on the assessment and treatment of acute respiratory infections in children in a controlled study(Tumwikirize et al, 2004). No improvements were noted after the intervention in the assessments and prescriptions by pharmacists. This study highlights that lack of knowledge may not be the key factor in influencing pharmacists' practices and other influences need to be explored in order to develop effective interventions.

Despite lack of strong evidence in developing countries, it appears from the above review that educational strategies can bring improvements in professional behaviour in clinical areas with well-defined quality standards. However, these improvements rely on the baseline performance. Educational interventions must be designed according to local needs and context and often should be combined with other interventions of proven effectiveness.

2.4.1.3. Local consensus development

I found three studies that examined the impact of local consensus development on the professional behaviour of clinicians. All studies were non-controlled before-and-after studies, capable of demonstrating only an association between the intervention and behaviour change.

In summary, it appears that developing algorithms and guidelines through local consensus may not be sufficient to change professional behaviour. The implementation of guidelines needs to be complemented by other organisational changes and interventions (e.g. audit and feedback) to facilitate change. Other systematic reviews have also been inconclusive with regards to the effectiveness of local consensus development alone in improving compliance to quality standards(NHS CRD, 1994).

2.4.1.4. Educational outreach

I found two trials using educational outreach to modify professional behaviour (Table 2.4). Both trials were similar in terms of intervention, target behaviour and outcomes assessment. However, they were conducted in different countries using a different research design. Since this review a cluster randomised trial has been published to assess the effectiveness of educational outreach in influencing nurse practitioners in South Africa(Fairall et al, 2005). 40 primary care clinics in the intervention group received educational outreach visits related to the integrated management of common respiratory disorders. There was a significant improvement of the case detection rates for TB and steroid therapy of asthma in patients attending these clinics compared to controls.

A Cochrane review based on trials mostly from developed countries concludes that the educational outreach visits appear to be a promising approach to modifying health professional behaviour, especially prescribing(Thomson O'Brien et al, 2000a). The evidence of the effectiveness of educational outreach in developing countries is scanty but promising. More research is needed in evaluating this approach in various settings.

2.4.1.5. Local opinion leaders

Research from developed countries shows that the use of local opinion leaders results in mixed effects on professional practice(Thomson O'Brien et al, 2000b). I found only one study conducted in a developing country. Further research is required to determine the circumstances in which they are most likely to influence the practice of their colleagues.

2.4.1.6. Educational materials

Current evidence on the effectiveness of printed educational materials in influencing professional practice is dubious. I found only one study of educational materials that met the inclusion criteria of this review. In combination with other interventions it has shown mixed results according to a Cochrane review (Freemantle et al, 2000).

2.4.1.7. Mass media, Marketing, Reminders and Patient mediated interventions

I was unable to find any studies of the above interventions that fulfilled the inclusion criteria of this review.

2.4.1.8. Multiple strategies

I found three relevant studies. Audit and feedback appear to be a cost effective way of implementing clinical guidelines. However, additional educational strategies may have an added advantage in sustaining this improvement.

2.5. Discussion

Studies in this review have been summarised and discussed already in their respective section. However many common themes have emerged which can be summarised in the following sections.

2.5.1. Limitations of the review

The majority of the studies in the above review have concluded that the interventions have been effective in improving professional behaviour but there are a number of quality issues, which should be considered before reaching final conclusions.

The majority of the trials reviewed here have shown improved performance subsequent to interventions. A significant number of studies included in various Cochrane reviews on the effectiveness of quality assurance interventions have shown mixed or negative results (Freemantle et al, 2000; Thomson O'Brien et al, 2000a; Thomson O'Brien et al, 2000b; Thomson O'Brien et al, 2001; Jamtvedt et al, 2003). A very small proportion of studies included in these reviews were from developing countries. There is a strong possibility of publication bias towards trials in developing countries indicating success only. Researchers in general are less likely to report trials with negative results. However, evidence of the existence of publication bias against authors from developing countries already exists from surveys of high impact-factor medical journals and their editorial boards (Horton, 2003).

Only eight studies in the above review were randomised controlled trials. Of the rest, ten studies had a control group, which was not comparable to intervention group. Most other non-controlled studies had poor designs and did not report the socio-cultural context in which inappropriate clinical behaviour takes place (Le Grand et al, 1999).

In many low-income countries, health services in the public sector are usually provided at primary care level by non-medical health professionals. Services are often delivered by a very strong unregulated private sector. Some studies in this review focussed on primary care, but the majority of trials examined change in clinical behaviour in public hospital settings.

Some studies examined clinical outcomes without measuring processes of care. Such studies failed to describe other possible factors influencing outcomes. It was not possible to justify a causal link between outcomes and the intervention establishing change in clinical practice.

Studies often used direct observation, interviews with patients and service providers, audio or video recording and simulated patients to determine change in practice. Such methods are liable to biases and/or altered behaviour as discussed in previous sections.

Change was usually observed over a short time scale. In the few studies in which the post-intervention period consisted of two different time frames, the improvement observed earlier either disappeared or reduced.

Interventions varied in structure and process within the same category and were often used in combination with interventions from other categories. Such trials rarely had a comparative design to tease out the effectiveness of different components of the interventions.

Many studies lacked power to detect statistically significant differences and often did not state p values and confidence intervals.

Cost implications of interventions were not discussed in the great majority of studies in this review.

2.5.2. Facilitators and barriers to change

Despite the limitations mentioned above, important lessons can be learnt from the studies in this review. The following is a list of facilitators and barriers that played an important role in effective implementation of the interventions in changing professional practice. Some of these have been identified by other reviewers (Table 2.5).

The studies discussed above strongly suggest the added benefit of combining multiple interventions to initiate change in professional practice. Educational strategies combined with audit and feedback appears to be most effective. Interventions introduced in isolation are less likely to succeed in changing practice.

Table 2.5: Reasons for poor prescribing habits among physicians in developing countries

Shortcomings in medical education
Lack of trustworthy clinical and pharmacological judgement
Unreliable sources of information-usually drug companies
Pressure exerted by patients
Desire of physicians to do something
Lack of research and continuing medical education
Lack of institutional support to change for primary care physicians

(Perez-Cuevas et al, 1996; Le Grand et al, 1999; Schwartz, Soumerai & Avorn, 1999)

Interventions informed by local needs and sensitive to local cultural context are more likely to succeed. Educational strategies must focus on identifying local educational needs of the health providers. Educational materials while addressing knowledge gaps must also take account of the local factors that promote or inhibit good practice in individual health care workers. Similarly, audit and feedback interventions should focus on identifying 'local solutions' to 'local problems'. What appears to work in developed countries may not achieve the same results in low and middle-income countries.

Involvement of local service providers and health professionals from the design to the delivery stage of the intervention helps in establishing local ownership and is more likely to influence clinical behaviour. Prescriptive interventions from external sources may not take account of local factors, therefore threaten, and alienate local health care professionals.

Organisational support from leaders of the health systems on a continuous basis is an essential pre-requisite for successful implementation of all of the above quality assurance interventions. None of these activities is cost-neutral and requires resources allocated on a regular basis. Political will and commitment to quality assurance is likely to pave the way to success. Interventions employed in isolation

without securing political commitment may have short-term benefit, but are unlikely to bring long-term sustained improvement.

Prior to the introduction of any intervention, consensus on the quality of care standards must be reached. The success of the intervention should be evaluated on the basis of improved performance against these standards e.g. WHO's quality indicators to define appropriate use of medicines are used to measure any improvement in prescription behaviour (Hogerzeil, 1995). In the absence of agreed standards and mechanisms to measure improved performance, any intervention is likely to lose its focus.

2.5.3. Policy implications

Introduction of quality assurance interventions that work through improving professional practice are desirable in developing countries for many reasons, as stated previously. Despite insufficient evidence of the effectiveness of these interventions in the developing world, policy makers should consider adapting these interventions to the local context and introducing them in their health systems followed by careful evaluation. Such efforts should be multifaceted and informed by the local facilitators and barriers to their implementation. International donor agencies and non-governmental organisations must provide financial and technical support to developing countries in implementing and evaluating these interventions. Such support will be in line with WHO's commitment to provide system support to health care around the globe.

2.5.4. Research gaps

This review has helped in identifying many research gaps in this field. International donors, Non-Governmental Organisation (NGOs), WHO and civil societies should provide support for controlled trials of better design to test the effectiveness of these interventions in isolation and in combination. Studies must be conducted over a prolonged period to assess the implications, influence and feasibility of sustained intervention in a health system. Such studies should identify local barriers and facilitators in implementing quality assurance and influencing change in professional behaviour. Local cultural factors should be identified and theories of change must be tested in these contexts.

Studies exploring and comparing the cost effectiveness of various interventions should be conducted to inform health policy makers of their full implications. Use of local opinion leaders, educational bulletins, patient mediated reminders, social marketing and educational outreach should be examined in the context of developing country health systems. More research is needed in ways of influencing private practitioners and non-medical community/primary health care

workers. Given the existing potential, the role of educational outreach in influencing both public and private practitioners would also be worth exploring. However, cost effectiveness of such interventions must also be evaluated in order to justify their use.

Most of the current evidence of effectiveness is based on influencing prescribing behaviour. However, surveys have shown poor quality in other areas such as diagnosis, monitoring of child development, referrals, instituting preventative and control measures etc.(Nicholas et al, 1991). More work is needed to examine the role of these interventions influencing these specific behaviours. Priority should also be given to conditions, which affect vulnerable populations of societies with poor access to health care.

2.6. Conclusion

Strong evidence exists of the effectiveness of audit and feedback, educational strategies, opinion leaders, educational outreach and local consensus development in combination with other interventions(Freemantle et al, 2000;Thomson O'Brien et al, 2000a;Thomson O'Brien et al, 2000b;Thomson O'Brien et al, 2001;Jamtvedt et al, 2003;NHS CRD, 2003). However, most of this is based on studies conducted in developed countries. Since such quality assurance tools are dependent on local factors, it is desirable to have strong evidence of their effectiveness in the developing world. Such evidence does not yet exist except from one or two case studies, as is apparent in this review. Evaluation of quality assurance tools, such as audit and feedback, should be a top research priority in developing countries. International institutions with greater experience of health systems where quality assurance is routine practice should provide technical support to developing countries in conducting such research. This review provides a useful insight into some of the methodological issues of conducting similar research in developing countries.

Chapter 3 Clinical diagnosis of smear negative pulmonary tuberculosis in developing countries: A review of the evidence

This chapter provides a brief introduction to smear negative tuberculosis and highlights related diagnostic challenges. It also presents a summary of the evidence for various interventions such as diagnostic algorithms, guidelines and scoring systems used to improve its diagnosis.

3.1. Introduction

Tuberculosis continues to be a major cause of human mortality and morbidity, infecting almost a third of the world's population (Lauzardo & Ashkin, 2000). Inadequate case detection and cure rates have been identified as reasons for a mounting global TB burden (Maher, Chalet, Spinaci & Harries AD, 1997). Sputum microscopy and sputum culture have been advocated as two useful tools for diagnosing pulmonary tuberculosis (PTB). However, most tuberculosis control programmes in low-income countries do not have access to culture facilities in their primary care diagnostic centres. Moreover, it takes six to eight weeks before Acid Fast Bacilli (AFB) culture results can be interpreted, reducing its usefulness as a first line diagnostic test. Under these circumstances, sputum smear examination for AFB is the most useful test for diagnosing PTB. However, the AFB smear examination has a sensitivity of only 50-60% according to a number of studies (Aber et al, 1980). This is partly because a positive smear requires 5000-10,000 AFB per mm sputum sample. Sputum culture requires only 10-100 AFB per mm (Kim et al, 1984; Parry, 1993), detecting PTB in around 80% of cases (Levy et al, 1989). The quality of microscopic performance is also responsible for differences in the AFB smear sensitivity (30% to 80%) compared to AFB cultures (Alausa, Osoba, Montefiore & Sogbetun, 1977; Petersen & Urbanczik, 1982; Levy et al, 1989). In a recent study, a significant proportion of "smear negative TB" patients diagnosed in a TB facility in Pakistan turned out to be smear positive on re-examining their sputum in a reference laboratory (Siddiqi et al, 2006). In the absence of readily available sputum culture in low-income countries, the majority of smear negative TB is diagnosed on the basis of clinical presentation, radiological findings and other laboratory based indicators.

Smear negative tuberculosis is currently defined as a group of symptomatic patients with at least two sputum smear examinations negative for AFB on different occasions in whom PTB is later confirmed by culture, biopsies or other investigations (Maher et al, 1997). Studies prior to the HIV epidemic estimated that there were 1.22 cases of pulmonary smear negative and extra-pulmonary

tuberculosis for each smear positive case(Colebunders & Bastian, 2000). Researchers in countries with a relatively low PTB prevalence have advocated that smear negative tuberculosis poses less of a threat to public health than smear positive TB(Long, 2001). This is based on its low infectivity potential, minimal extent of disease and relatively good prognosis even without treatment. The transmission rate of smear negative tuberculosis patients relative to smear positive TB is around 22%(Behr et al, 1999). However, nearly half of all PTB cases are smear negative resulting in a considerable overall disease burden.

In countries with a high HIV prevalence, smear negative tuberculosis has been shown to have a poorer prognosis(Hargreaves et al, 2001). One study in sub-Saharan Africa, found one-third of patients with smear negative tuberculosis died within a year of their initial diagnosis(Banda et al, 2000). Approximately one third of the rest developed recurrent PTB.

The literature on the clinical features of PTB, traditionally does not distinguish between smear negative and smear positive tuberculosis. However, attempts have been made to identify the distinctive clinical features of smear negative tuberculosis. This distinction, a reflection of the diverse behaviour of AFB and the human immune system, is made to assist diagnosis rather than an attempt to classify smear negative tuberculosis as a separate clinical entity.

3.2. Aims and objectives

A number of criteria, clinical scoring systems, tools and algorithms have been developed to facilitate the diagnosis of PTB in TB suspects with repeated negative sputum smears. The purpose of this review is to evaluate the evidence base for these tools to aid clinicians and policy makers in tuberculosis control programmes in developing countries. The review only considers the use of those diagnostic tools, which are available to doctors working in primary healthcare based tuberculosis diagnostic centres in developing countries with a high TB prevalence. Therefore, this review does not examine the use of serology, bronchoscopy and PCR.

3.3. Methods

I retrieved the relevant published literature by using the search strategy described in Table 3.1. I also searched for relevant articles in the contents tables of the International Journal of Tuberculosis and Lung Diseases for the last ten years. I also examined the reference lists of papers identified using the above strategy for further relevant studies.

Authors around the world with extensive publications on the subject and members of TB net were contacted to locate any unpublished material.

All retrieved titles and abstracts were scrutinised for relevance to the topic. Analytical studies, which identified demographic, clinical, radiological and simple laboratory based indicators facilitating the diagnosis of smear negative tuberculosis, were included. An assessment of methodological quality was undertaken for each paper.

Table 3.1: Search strategy

Databases	Key words and phrases
Medline	Tuberculosis
Pub-Med	Mycobacterium tuberculosis
Embase	TB
HealthSTAR	Sputum negative
Web of Science	Smear negative
	AFB negative
	Negative for AFB
	Abacillary
	Diagnosis
Period of search	Language
1966 onwards	English

3.4. Results

Fifteen studies fulfilling the above criteria were selected. Table 3.4 provides an outline of these and Table 3.5 summarises the validity and clinical usefulness of each study. Most studies validated diagnostic tools/criteria against sputum culture. However, a number of studies included in this review also used other less recognised methods of confirming the diagnosis of PTB.

3.4.1. Diagnostic indicators for smear negative tuberculosis

3.4.1.1. Demographic indicators

Smear negative tuberculosis has been shown to be more common in older patients than younger patients in a low HIV prevalent country in one study (Samb et al, 1999). However, countries with a high HIV prevalence have an even age distribution. This is believed to be due to HIV affecting relatively younger age groups (Parry, 1993).

3.4.1.2. Clinical indicators

Three studies aimed to identify frequently occurring clinical features in smear negative tuberculosis in high HIV/TB prevalent areas.

In an Ethiopian hospital based study authors found that loss of appetite, weight loss, fever, night sweats, chest pain, haemoptysis and breathlessness were more frequent in patients with PTB (both smear positive and smear negative tuberculosis) than in patients without PTB (Tessema, Bjune, Assefa & Bjorvat, 2001). However, patients with smear negative tuberculosis had night sweats for a longer duration than smear positive patients. Smear positive patients had more frequent fever and weight loss compared to the smear negative group (Odds ratio [OR] 4.1 [95% CI 1.2-15.0] and 6.4 [95% CI 2.3-17.8] respectively). The “gold standard” against which sensitivity of these indicators was measured was diagnosis by a group of TB physicians, which may have been due to lack of resources, although the authors do not clarify this in the paper. This may have introduced misclassification bias distorting the study outcomes. Another study conducted in Tanzania and Burundi, identified four clinical criteria for diagnosing smear negative tuberculosis (Samb et al, 1997).

- Presence of cough longer than 21 days (OR 5.43 [95% CI 1.95-15.1])
- Presence of chest pain longer than 15 days (OR 1.98 [95% CI 0.77-5.12])
- Absence of expectoration (OR for expectoration 0.42 [95% CI 0.15-1.18])
- Absence of shortness of breath (OR for breathlessness 0.26 [95% CI 0.01-0.66])

Diagnosis of smear negative tuberculosis using any two of the above criteria had a high sensitivity but low specificity (85% sensitivity, 67% specificity, 43% positive predictive value and 94% negative predictive value). Use of three of the criteria improved the specificity but reduced the sensitivity (49% sensitivity, 86% specificity, 50% positive predictive value and 86% negative predictive value). With the addition of lymphadenopathy (OR 3.84 [1.38-10.7]) to two of the above symptoms, the sensitivity and specificity improved further. Sputum culture, tissue

histology and positive clinical and radiological response to the anti-tuberculosis therapy were used as the 'gold standard' for PTB diagnosis. However, patients with chronic lung conditions were excluded from the study, limiting its generalisability. The prevalence of HIV was high (71%) in both case and control groups. Community-acquired pneumonia was the most frequent lung pathology in the non-tuberculosis control group. These criteria may be used to differentiate smear negative tuberculosis cases from community-acquired pneumonia in areas with a high HIV prevalence. Another study in Tanzania found cervical lymphadenopathy to be a significant predictor of smear negative tuberculosis patients (Aris et al, 1999). However, this study used extra-pulmonary histological samples as the "gold standard" for PTB diagnosis, which compromises the validity of the findings.

In low HIV/high TB prevalent areas, a Senegal based study failed to demonstrate any clinical features differentiating smear negative tuberculosis patients from smear positive cases other than the absence of cough (OR 10 [1.96-50.0]) (Samb et al, 1999). Limitations of this study were that it used a small sample size and the diagnosis was confirmed using sputum culture in only 20% of cases. The overall prevalence of HIV in both case and control groups was 8.9%.

Only one study identified in this review looked at a population with a low HIV/TB prevalence (Kanaya, Glidden & Chambers, 2001). Cough with expectoration was identified as a negative predictor of smear negative tuberculosis (OR 0.3 [0.01-0.06]). This study was unable to identify any other differentiating clinical features possibly due to a small sample size.

Cough for more than 3 weeks warrants AFB microscopy according to the current WHO guidance. However, one study, conducted in a high HIV and TB prevalent area, confirmed smear negative tuberculosis in 35% of patients with a cough unresponsive to antibiotics of only 1-3 weeks duration (Banda et al, 1998). The majority of these patients had atypical chest x-ray changes. This study suggests that PTB needs to be considered in patients with short duration of cough associated with weight loss and lack of response to antibiotics particularly living in overcrowded places in high HIV/TB prevalent areas. Another study conducted in south India showed that the diagnostic sensitivity is likely to increase if patients are screened at an earlier stage of cough more than 2 weeks (Thomas, 2006). A cost-benefit analysis of screening people with two weeks of cough would be required before possible implementation by tuberculosis control programmes.

3.4.1.3. Radiological indicators

In settings with limited microbiological services, the diagnosis of PTB is heavily dependent on chest X-ray findings. However, in such settings, access to

specialist radiology support is also usually limited. A survey conducted in Malawi demonstrated that medical officers misdiagnosed one third of clinical vignettes, which described typical tuberculosis radiological signs (Nyirenda, Harries, Banerjee & Salaniponi, 1999).

A Dutch study showed that ninety-two percent of PTB cases (both smear negative and positive) in low HIV/TB prevalent countries had typical chest X-ray appearances (Wilcke, Askgaard, Nybo & Dossing, 1998). However, in 8% of these patients, the chest X-ray findings were atypical (lower lobe infiltrates, miliary pattern, hilar lymphadenopathy and occasional normal chest X-rays). Of these, half were smear negative. 89% of patients with cavities on chest X-ray were smear positive compared to 53% without cavities ($p < 0.05$). This study identified criteria differentiating pulmonary smear negative tuberculosis from smear positive tuberculosis. These criteria did not differentiate between smear negative tuberculosis and non-TB cases. Exclusion of those with a history of HIV or previous tuberculosis from this study limits its generalisability in these patient groups.

A study in California conducted in a low HIV setting showed lobar consolidation or diffuse changes on chest X-ray were negatively associated with smear negative tuberculosis (OR 0.3) (Kanaya et al, 2001). The same study identified a strong association between smear negative tuberculosis and mediastinal lymphadenopathy in HIV positive patients (OR 7.2).

Two other studies showed that TB patients with HIV are more likely to have atypical chest X-ray appearances (pulmonary infiltrates with no cavities, lower lobe involvement, intrathoracic lymphadenopathy and sometimes a normal X-ray) than tuberculosis patients without HIV (Harries, Maher & Nunn, 1998b; Banda et al, 2000). In high HIV/TB prevalent areas 75% patients with smear negative tuberculosis are likely to have atypical chest X-ray findings (Tessema et al, 2001). Patients with smear negative tuberculosis are less likely to have cavities on the chest X-ray (Odds ratio 2.56) (Samb et al, 1999). One study found 25% of all PTB patients to be smear negative with few cavities on chest X-ray (Kim et al, 1984). The limitations of these studies have been discussed in the previous section.

Another study in low HIV settings showed that primary care physicians were able to diagnose the majority of smear negative pulmonary TB cases (sensitivity 0.79; CI 0.69–0.89) using the TB guidelines and training package based on three key findings: presence of cavities, upper lobe infiltrates and pleural effusion (Siddiqi et al, 2006). This suggests that use of agreed radiological criteria for TB and appropriate training can help to improve the diagnostic skills of primary care clinicians working with limited facilities in low-HIV prevalent countries. However,

this may not be applicable to sub-Saharan African countries with a high-HIV prevalence, and few clinicians and X-ray facilities.

Smear negative patients may also present with either normal or minimally abnormal chest X-ray(Harries et al, 1998a). One study confirmed PTB by sputum culture in 21% of tuberculosis suspects with negative smears and normal or minimally abnormal chest X-ray. Forty-seven percent of such patients developed typical chest X-ray findings after three months. A third of the culture negative suspects also developed typical tuberculosis radiological signs during follow up. Despite its limitations, including a significant loss to follow up, the study does suggest that close monitoring of smear negative TB suspects with normal or minimally abnormal chest X-ray may be useful in areas with high HIV/TB prevalence.

3.4.1.4. Sputum concentration

Many authors have recommended sputum liquefaction and concentration through centrifugation to improve detection of positive AFB in negative smears through direct microscopy. Two studies have demonstrated an almost two fold increase in the sensitivity of AFB detection compared to direct microscopy(Gebre et al, 1995;Habeenzu, Lubasi & Fleming, 1998). However, neither study looked at clinical outcomes. Studies assessing clinical outcomes have demonstrated a more modest benefit in using these techniques. In one study the overall sensitivity increased from 54.2% to 63.1% after concentration ($p<0.0015$). In HIV-positive patients, sensitivity increased from 38.5% before to 50.0% ($p<0.0037$) after concentration(Bruchfeld et al, 2000). This improvement was less remarkable when compared with the sensitivity of direct microscopy supported by clinicians' judgement in diagnosing PTB. Another study did not show any overall benefit of sputum concentration over direct microscopy in diagnosing PTB(Wilkinson & Sturm, 1997). Researchers used two separate sputum samples for the two different techniques, which may have resulted in under or over estimation of the actual benefit of sputum concentration.

The evidence supporting the use of sputum concentration is conflicting. Moreover, such techniques require centrifugation, increased time and expertise and the resource implications of this need to be considered before recommendation to low-income countries.

3.4.1.5. Tuberculin test

The tuberculin test is of limited value in diagnosing PTB in populations with either a high prevalence of TB or a policy of BCG immunisation at an early age(Cowie & Escreet, 1980). It may be useful in a low TB/HIV population where it

is more likely to be positive in smear negative tuberculosis patients compared to other pulmonary pathologies (OR 4.8)(Kanaya et al, 2001). However, information bias due to fewer controls having tuberculin tests administered may have contaminated the above results. Similar studies in HIV prevalent areas have shown fewer positive tuberculin tests among smear negative patients due to impaired immunity(Aris et al, 1999). Overall smear negative cases are less likely to be tuberculin positive compared to smear positive patients. Extensive literature is available on the use of the tuberculin test in the diagnosis of PTB but this is beyond the scope of this review.

3.4.1.6. Other laboratory markers

Apart from direct microscopy, TB diagnostic centres in low-income countries have limited access to other laboratory-based investigations. Authors have argued that haematological and biochemical markers can be used in the diagnosis of PTB and in determining response to its treatment(Morris, Bird & Nell, 1989). However, use of haemoglobin levels, haematocrit, C-reactive protein and ESR have poor sensitivity and specificity when used in isolation(Cowie & Escreet, 1980;Yanagisawa et al, 1996;Al Marri & Kirkpatrick, 2000). When used along with other clinical criteria only haematocrit of less than 30% has been shown to improve the sensitivity and specificity of the clinical diagnosis of smear negative tuberculosis(Samb et al, 1997)

3.4.2. Diagnostic drug trials

An antibiotic trial is a useful tool in excluding chest infections in the diagnostic protocol for PTB(Harries et al, 1998b). The WHO advocates a single course of antibiotics for all tuberculosis suspects with two or more negative smears to exclude chest infections(Maher et al, 1997). According to a South African study the sensitivity of sputum smear test for diagnosis of PTB is increased by adding one course of antibiotics from 61% to 80% but the specificity decreases from 94% to 78%(Wilkinson, De Cock & Sturm, 1997). The low sensitivity may have been a result of confounding by the presence of superadded-infection and fluctuation of the symptoms of PTB. The lowered specificity could be due to antibiotic resistance. Addition of a chest X-ray at this stage, as suggested by the WHO, is likely to improve the specificity of the algorithm. Use of two successive courses of antibiotics has also been demonstrated to improve the sensitivity (89%) and specificity (84%) of smear negative tuberculosis diagnosis as follows(Wilkinson et al, 2000). Patients in a study with negative smears were first treated with amoxicillin for 5 days followed by a course of erythromycin for non-responders. This study was conducted in in-patients and the strategy may be less effective in outpatient settings. Additionally the antibiotic resistance patterns of community-acquired pneumonias in

a particular region would need to be considered prior to implementation of any such strategy.

Anti-tuberculosis drug trial is generally not recommended for diagnosis of smear negative tuberculosis, as many organisms causing chest infections are also sensitive to some of these drugs. However, an algorithm based on anti-tuberculosis drug trial including ethambutol, pyrazinamide and isoniazid has been proposed to diagnose disseminated tuberculosis in high HIV prevalent areas (Harries et al, 2000). The benefit of such an approach has been questioned due to the possibility of misuse in TB control programme settings. There is also the risk of failing to detect tuberculosis in areas where isoniazid resistance is high. Moreover, little evidence exists that such a trial leads to improved diagnosis (Fourie & Weyer, 2000). However in a recent study use of expanded case definitions and objective criteria to assess improvement after ATT has shown to improve diagnosis (Wilson et al, 2006).

3.4.3. Diagnostic algorithms

Researchers have attempted to develop guidelines, diagnostic prediction scoring models and algorithms for smear negative tuberculosis based on various indicators. Many countries have adopted the WHO guidelines (Figure 3.1); but these guidelines fail to incorporate any radiological or clinical signs in the diagnostic decision tree.

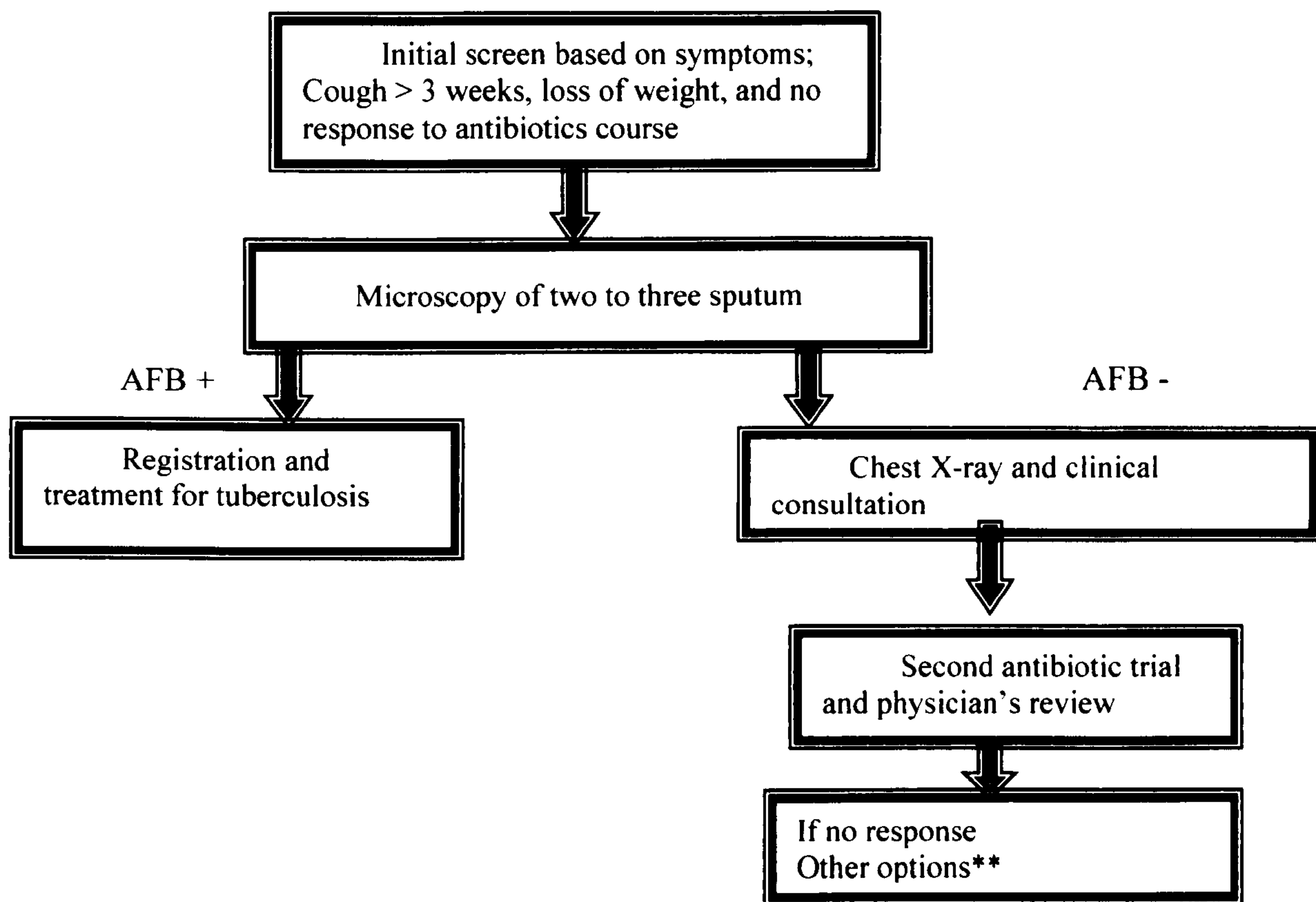
In Malawi, these guidelines were modified to include three further criteria (Harries, Hargreaves, Kwanjana & Salaniponi, 2001).

- Chest X-ray with unilateral lymphadenopathy or cavitations
- Weight loss, no response to antibiotics and bilateral radiographic infiltrations involving three or more zones
- Cough for more than 3 weeks, weight loss, no response to antibiotics and negative sputum smear regardless of chest X-ray findings

The usefulness of these criteria in the diagnosis of smear negative tuberculosis needs to be ascertained, but they do suggest situations in which PTB may be misdiagnosed using the current WHO guidance. An audit of the Malawi guidelines found that non-adherence to diagnostic criteria and errors in registering and making a clinical diagnosis resulted in over-diagnosis of smear negative tuberculosis.

One research group validated and estimated the cost of tuberculosis case detection using two different algorithms (Harries et al, 1997). Screening of PTB suspects with chest X-ray followed by sputum smear examination was compared with screening by sputum smear followed by chest X-ray. Initial screening using chest X-ray was less specific (0.31 compared to 0.25) and more costly.

Kanaya et al created a Tuberculosis prediction score (TPS) by using four clinical predictors identified by a retrospective case-controlled study (Kanaya et al, 2001). Based on the β coefficient derived from logistic regression analysis, each predictor was given a certain TPS along with a likelihood ratio (Table 3.2). Using the TPS in this model, one can predict the probability of smear negative tuberculosis in patients in areas with three different levels of TB prevalence (Table 3.3). Information bias may have prevented the detection of other possible unmeasured and unreported diagnostic indicators. This was further compounded by a small sample size leading to reduced power to detect all differentiating variables. Despite its limitations, the model may be a useful guide in low HIV areas.



*Additional investigations e.g. sputum induction, lymph node aspiration etc.

**In smear negative patients with failure to response to two courses of antibiotics, one can lead to the following actions:

- To treat as smear negative tuberculosis with appropriate treatment
- To consider other diagnosis
- To observe and reinvestigate for TB over three months

Figure 3.1: WHO algorithm for diagnosing TB in poorly-resourced countries

Table 3.2: TPS using multivariate predictors

Score of Points	Study Patients	Control Patients	Likelihood Ratio
-2	3	52	0.2
-1	9	55	0.5
0	16	26	1.8
1	14	8	7.1
2	1	0	
3	4	0	
Total	47	141	

+ 1 point = positive TST result; - 1 point = expectoration or infiltrate observed on chest radiograph not typical of TB; + 2 points = both HIV-positive status and mediastinal lymphadenopathy observed on chest radiograph.

Aris et al carried out a prospective study and proposed a diagnostic scoring system to discriminate smear negative tuberculosis patients from patients with other pathologies(Aris et al, 1999). The diagnostic score (D) can be estimated from the following formula;

$$D = 1.29(\text{matted lymph node}) + 0.55(\text{mantoux reaction}) + 0.76(\text{cervical lymphadenopathy}) + 2.21(\text{pleural effusion}) - 2.19(\text{kaposi's lesion}) - 0.51(\text{upper/mid zone opacities on x-ray}) - 1.55$$

Where the presence of each indicator = 1 and absence of each indicator = 0

Equation 3.1: Formula for calculating diagnostic score (D)

A particular limitation of this study was the use of extra-pulmonary histological samples as the “gold standard”. This scoring system may be useful if validated using sputum cultures.

A research group in Zimbabwe developed another scoring system for the diagnosis of primary and secondary PTB(Bergman, 1995) This was based on the subjective assignment of scores to a number of clinical, radiological and laboratory indicators observed in one year of follow up among smear negative tuberculosis patients. However, no details were given of how these indicators were selected and how the scoring system was validated.

Another study in Addis Ababa Tuberculosis Centre developed a scoring system based on weights given to each clinical and radiological indicator in PTB patients(Tessema et al, 2001). However, the system was only verified against the final clinical diagnosis made by expert TB physicians and, therefore, cannot be recommended.

Table 3.3: Post-test probability of TB given the prevalence of smear negative TB in three different settings

Geographic area	Prevalence of smear negative TB, %	Hypothetical score	LR	Post-test probability of TB, %
High prevalence	5	-2	0.2	1
		0	1.8	8
		2	7.1	26
Moderate-to-low prevalence	3	-2	0.2	0.6
		0	1.8	5
		2	7.1	18
Very low prevalence	< 0.1	-2	0.2	0.02
		0	1.8	0.2
		2	7.1	0.7

The risk of TB with a given score (posterior probability) was derived by multiplying the patient's risk of TB based on the estimated prevalence of TB (prior probability) with the LR, and converting the result (posterior odds) to posterior probability.

3.5. Discussion

Attempts have been made to develop tools to assist clinicians in the diagnosis of smear negative tuberculosis. The present review describes such studies, highlighting a number of methodological issues, which limit their validity and usefulness. All studies were hospital based causing possible selection bias. A number of methods were used for validating diagnosis ranging from culture, histology, clinical judgement and response to TB therapy. Small sample size, variable exclusion criteria and heterogeneity between studies also makes these diagnostic tools of doubtful validity and usefulness.

The escalating number of patients with paucibacillary PTB in countries with an HIV epidemic makes it imperative that the problem of diagnosis of smear negative tuberculosis is addressed (Foulds & O'Brien, 1998). However, this presents a considerable challenge given the atypical nature of the presentation of PTB in HIV patients (dry cough, absence of haemoptysis etc.) (Harries et al, 1998b).

The current evidence suggests that in high HIV/TB prevalent areas, the presence of cough for more than three weeks with repeated negative AFB smears, chest pain, cervical lymphadenopathy, absence of expectoration and shortness of breath is more suggestive of PTB than community acquired pneumonia (Samb et al, 1997). Clinicians are less likely to find typical radiological signs of PTB in high

HIV areas. The index of suspicion should still be high if there are pulmonary infiltrates with no cavities, lower lobe involvement, intrathoracic lymphadenopathy and sometimes a normal appearance on chest X-ray. Tuberculin test, ESR, CRP and other basic laboratory test are likely to be non-specific. Sputum concentration techniques, if found to be cost-effective, may be useful in low-income countries in assisting clinicians in the diagnosis. Whilst a single course of an appropriate antibiotic can be recommended in excluding chest infection, strategies based on two courses of antibiotics require further investigation in outpatient settings. Some objections have recently been raised to the strategy of an antibiotic trial. In a hospital-based study in Pakistan, two-thirds of patients suspected of TB did not return for a visit after the antibiotic trial (Siddiqi et al, 2006). Moreover, 6.8% of those who did return, and showed improvement, were later diagnosed with TB. Studies in high-HIV prevalence settings in sub-Saharan Africa reported high improvement rates (8-9%) of pulmonary TB patients after antibiotic treatment. A trial of anti-tuberculosis drugs is a theoretically attractive option but is unsupported by evidence of effectiveness. The danger is of increased multi-drug resistance and under-diagnosis of PTB. The clinical scoring systems developed for high HIV prevalence countries are based on relatively weak evidence and cannot be recommended to clinicians before further validation.

In countries with low HIV/TB prevalence, clinicians should expect typical radiological signs on chest X-ray in cases of smear negative tuberculosis. The specificity of the tuberculin test can be increased when combined with other clinical criteria in these settings. The scoring system suggested by Kanaya et al can also be useful in such situations.

Although there is little current evidence of effectiveness of any of the diagnostic tools described above, they can provide a starting point for the development of diagnostic protocols by tuberculosis control programmes. Policy makers intending to use such tools need to assess the suitability of these in their given situation. They would need to consider the local epidemiology, such as the prevalence of HIV, TB, other pulmonary pathologies and antibiotic resistance patterns, before implementation. The existing literature may be useful in stimulating discussion amongst health professionals and other stakeholders. These groups can then incorporate local experience and data to develop or modify their own tuberculosis management guidelines. Modified algorithms may include certain radiological or clinical features (varying in each setting) to develop a diagnostic decision tree model. Once validated, these context specific guidelines may be adopted more widely.

Misdiagnosis of smear negative tuberculosis can be reduced by developing diagnostic tools, which incorporate the diagnosis of other non-tuberculosis pulmonary pathologies. Where current WHO guidelines have been implemented, it is also worth exploring the role of clinical audits in improving the diagnosis of smear negative tuberculosis.

This review has also identified several research needs. New diagnostic techniques are required in addition to AFB microscopy for the identification of smear negative tuberculosis. These need to be appropriate for use in low-income countries (Foulds & O'Brien, 1998). There is ongoing research into developing more cost effective microbiological and serological diagnostic solutions. However, before such tests are widely available, diagnostic scoring systems and algorithms need to be developed and validated to assist clinicians working in resource poor settings. Research collaboration is required between countries with similar HIV prevalence in order to address these research needs and to develop joint management guidelines, which can be applied and evaluated in different situations.

Table 3.4: Summary of studies reviewed

Study	Objective	Design	Findings
Low HIV, low TB incidence			
California(Kanaya et al, 2001)	To identify clinical, demographic, and radiological predictors of smear negative pulmonary TB.	Hospital based (out-patients) retrospective case-control.	Positive tuberculin test OR 4.8(2.0-11.9), dry cough and typical chest X-ray are associated with positive TB cultures
	To develop a "prediction rule" to assist in the diagnosis of smears negative pulmonary TB	Cases: Patients with two negative sputum smears and positive cultures Controls: Patients with negative sputum smears and cultures	In patients with HIV, mediastinal lymphadenopathy is related to positive TB cultures OR 7.2(1.4-36.0)
Denmark(Wilcke et al, 1998)	To correlate chest radiographic changes with bacteriological results in patients with TB	Retrospective case control hospital based study (outpatients). Cases: Patients with typical chest X-ray changes of TB Controls: Patients with atypical chest X-ray changes of TB	Majority of TB cases showed typical radiological signs of TB. However, in 8% of cases the chest X-rays findings were atypical. Of these, half were also smear negative. 89% of patients with cavities on chest X-ray were smear positive compared to 53% without cavities (p<0.05)
Low HIV, high TB incidence			
Senegal(Samb et al, 1999)	To correlate the clinical, radiological and demographic findings in TB patients with their sputum smear results and HIV status	Hospital based (out-patients) prospective cohort study	Absence of cough, absence of cavities on chest X-ray, age more than 40, CD4 count >200/mm and HIV positivity is more common in smear negative TB cases.
High HIV, high TB incidence			

South Africa(Wilkinson & Sturm, 1997)	Usefulness of sputum concentration for the diagnosis of smear negative TB	Hospital based (outpatients) prospective cohort study.	Overall diagnostic sensitivity of smear microscopy was not increased by sputum liquefaction and concentration
Ethiopia(Bruchfeld et al, 2000)	Usefulness of sputum concentration for the diagnosis of smear negative TB	Hospital based (outpatients) prospective cohort study.	The overall sensitivity increased from 54.2% using conventional direct microscopy to 63.1% after concentration ($p<0.0015$). In HIV -positive patients, sensitivity increased from 38.5% before to 50.0% after concentration ($p<0.0034$).
Ethiopia(Habeenzu et al, 1998)	Usefulness of sputum concentration for the diagnosis of smear negative TB	Hospital based (outpatients) prospective cohort study.	The sensitivity increased from 30% to 70%
Zambia(Gebre et al, 1995)	Usefulness of sputum concentration for the diagnosis of smear negative TB	Hospital based (outpatients) prospective cohort study.	The sensitivity increased from 43% to 76%
South Africa(Wilkinson et al, 1997)	To determine the value of a trial of antibiotics in the diagnosis of smear negative TB	Hospital based (outpatients) prospective cohort study.	Diagnostic sensitivity increased from 61% to 80%, but specificity fell from 94% to 78%.
South Africa(Wilkinson et al, 2000)	To evaluate a diagnostic algorithm for PTB based on smear microscopy and response to a trial of two courses of antibiotics	In-patient hospital based study	Diagnostic sensitivity increased to 89% and specificity to 84%
Zimbabwe(Bergman, 1995)	To develop a diagnostic scoring system for smear negative TB based on clinical and radiological indicators	Hospital based (outpatients) retrospective case control study.	Proposed diagnostic scoring system based on various indicators without validation
Ethiopia(Tessema et al, 2001)	To develop a diagnostic scoring system for smear negative TB based on clinical and radiological indicators	Hospital based (outpatients) retrospective cohort study.	Diagnostic scoring system with high sensitivity (93%) and a high specificity (94%)

Tanzania and Burundi(Samb et al, 1997)	To identify clinical and radiological features which characterise smear negative TB	Retrospective case control study based in two hospitals (out-patients) Cases: smear negative pulmonary TB Controls: non TB patients	Cough >21 days, chest pain, absence of sputum and dyspnoea is common in smear negative TB cases
Tanzania(Aris et al, 1999)	To develop criteria for diagnosis of smear negative tuberculosis	Hospital based in-patient prospective case-control study Cases: Smear negative TB patients Controls: Non-TB patients	Developed clinical scoring system based on Mantoux test, lymphadenopathy and chest X-ray findings
Malawi(Harries et al, 1998a)	To determine prevalence of TB cases with normal or minimally abnormal chest X-rays among smear negative TB suspects	Hospital based (out-patients) prospective cohort study	21% of smear negative TB suspects with normal chest X-ray were diagnosed with TB by culture
Malawi(Banda et al, 1998)	To determine the prevalence of TB (smear negative and smear positive) in patients with short duration of cough (between 1-3 weeks) unresponsive to antibiotics	Hospital based (out-patients) prospective cohort study	35% patients had TB. Of these 2/3rd were smear negative

Table 3.5: Appraisal of included studies

Studies	Indicators	Validity	Clinical usefulness
1. Studies using TB culture to validate final diagnosis			
California(Kanaya et al, 2001)	Clinical, radiological and demographic features and "prediction rule" based on these	Low power due to small sample size Possibility of confounding variables Information bias due to fewer controls having tuberculin tests	Limited application of the "prediction rule" in high HIV/TB situations However indicators identified may be useful for clinicians to differentiate smear negative TB patients from other non-TB pathologies
Malawi(Banda et al, 1998)	Clinical-short duration of cough	Small sample size	Short duration of cough may be more relevant in High HIV/TB areas. Need to demonstrate added benefit of diagnosing these patients early. Cost-benefit ratio of such strategy needs to be assessed before implementation
Ethiopia(Habeenzu et al, 1998)	Sputum concentration techniques	Outcomes were related to specimens and not patients	Efficacy demonstrated but not effectiveness
Zambia(Gebre et al, 1995)	Sputum concentration techniques	Outcomes were related to specimens and not patients. Auramine-phenol stain followed by florescent microscopy was used to confirm the diagnosis	Efficacy demonstrated but not effectiveness
Ethiopia(Bruchfeld et al, 2000)	Sputum concentration techniques	Little benefit demonstrated compared to direct smear microscopy supported by physicians' clinical diagnoses	
South Africa(Wilkinson & Sturm, 1997)	Sputum concentration techniques	Separate samples were taken for the two sputum examination techniques and this may have off set the added advantage of concentration techniques	

South Africa(Wilkinson et al, 1997)	Antibiotic diagnostic trial	Low sensitivity may have been due to confounding by superadded-infection and fluctuation of TB symptoms Low specificity due to possible confounding due to antibiotic resistance	Specificity may be improved if the full algorithm including subsequent chest X-ray is also applied
South Africa(Wilkinson et al, 2000)	Two antibiotics diagnostic trial		Trial was conducted among in-patients. This strategy may be less effective in outdoor clinics
Denmark(Wilcke et al, 1998)	Radiological signs	These criteria differentiate between pulmonary smear negative TB from smear positive TB cases. However, they do not differentiate between smear negative TB cases and non-TB cases	Limited due to strict exclusion criteria-patients with history of HIV or previous TB were not included
Malawi(Harries et al, 1998a)	Radiological signs-normal or minimally abnormal chest X-ray in smear negative cases	Significant loss to follow up in the study may have influenced the results	No applicable to low HIV/TB prevalent areas
2. Studies using TB culture, histology and response to anti-tuberculosis treatment to validate final diagnosis			
Tanzania and Burundi(Samb et al, 1997)	Clinical and radiological signs	Differentiates between smear negative TB and patients with other pulmonary pathologies	Study restricted to hospital patients with a narrow inclusion criteria
Senegal(Samb et al, 1999)	Clinical, radiological and demographic indicators	Only 20% of cases were culture confirmed among smear negative TB Study has a small sample and wide confidence intervals	Less useful as clinicians need to differentiate smear negative TB from non-TB and not from smear positive cases
3. Studies using extra-pulmonary cytology and histology samples to validate final diagnosis			
Tanzania(Aris et al, 1999)	Scoring system based on clinical and radiological indicators	Small sample size Diagnosis based on extra-pulmonary samples without sputum cultures limits its validity in pulmonary TB	Case definition included pleural effusions (extra pulmonary TB)
4. Studies using only specialist clinical judgement to validate final diagnosis			

Zimbabwe(Bergman, 1995)	Scoring system based on clinical and radiological indicators	No details given of how the scoring system was developed or validated	Also included children with tuberculosis
Ethiopia(Tessema et al, 2001)	Scoring system based on clinical and radiological indicators	Poor criteria for validation of final diagnosis	

Methods

In this part of the thesis, I present the aims and the objectives of this study followed by a description of methods.

In chapter four, the aims and objectives of the study are presented.

In chapter five, I describe the methods adopted for this study and present anticipated limitations and constraints in the application of this approach.

Chapter 4 Aims and Objectives

Clinical audit is one of the most widely used tools to influence professional practice and, therefore, improve quality of health care. Previous sections have summarized the evidence of its effectiveness in both developed and developing countries and highlighted the scarcity of evidence in resource-poor health systems. Clinical audit is a complex intervention and influenced by the context in which it is implemented. It is likely that the model developed for well-resourced health systems may not be effective in middle and low-income countries. Most studies conducted in these countries have had methodological limitations and therefore failed to provide strong direct evidence. Research has also neglected the contextual factors that may facilitate or hinder the implementation of clinical audit. Chapter 2 concluded that further evaluative research is required in resource-poor settings. Any such evaluation needs to incorporate an understanding of the barriers and facilitators to change in professional practice.

I aimed to contribute to the evidence-base on the effectiveness of clinical audit in poorly resourced health systems using the management of tuberculosis as an example. I, therefore, investigated the effectiveness of clinical audit in changing the practice of health care professionals providing care to patients with suspected tuberculosis and negative sputum smears. The patient pathway under consideration was the provision of care to patients with suspected tuberculosis from the point of first contact with the health service to their final diagnosis (referred to as diagnostic care). Management of TB after diagnosis was beyond the scope of this study.

My initial focus was on the care provided to patients with suspected TB with negative sputum smear results. The specific objectives of this work are as follows:

4.1. Objectives

To determine the effectiveness of clinical audit in changing the practice of primary care health workers providing care to patients with suspected tuberculosis (and negative sputum smears) in resource-poor settings

To establish the contextual factors which impede or facilitate change in health care professionals' clinical behaviour following the introduction of clinical audit

To develop an evidence-based audit intervention, which addresses issues of implementation, for a TB control programme setting

To develop suitable research methods for evaluation of clinical audit in resource-poor settings

Chapter 5 Methods

I used two strategies to meet the objectives described in the previous section. The research was conducted in two parallel phases. In Phase 1, I evaluated the effectiveness of clinical audit, and in Phase 2, I carried out a qualitative exploration of the facilitators and barriers to implementing clinical audit. I describe these in two sections below, structured as follows:

- Potential approaches to address the research objectives
- Justification for the approach used
- Detailed description of research methods used
- Anticipated problems and constraints

5.1. Phase 1

In this phase, I carried out an evaluation of the effectiveness of clinical audit in poorly resourced settings.

5.1.1. Critique of study designs to assess effectiveness

The classical model of evaluation of policies and programme consists of five basic steps (Illsley, 1980):

Identifying the goals of the programme under evaluation

Translating the goals into measurable indicators

Measuring indicators for the study group who have been exposed to the programme

Measuring indicators for an equivalent group that has not been exposed to the programme

Comparing results for the experimental and control groups

Clinical audit, as previously described, is a complex intervention. It is often difficult to define its precise components and goals, and to determine how to measure its impact. Research methods to evaluate its effectiveness are still under development and fraught with complexities (see chapters 1 and 2). In the short history of research related to clinical audit, researchers have used various study designs, each with specific advantages and pitfalls.

The following is a list of study designs that could be used to assess effectiveness:

- Observational studies
- Quasi-experimental studies
- Randomised controlled trials

5.1.1.1. Observational studies

Observational studies contribute to epidemiological research by finding associations and generating hypotheses for causal links between exposure and effect(Vandenbroucke, 2004). These are usually conducted by collecting data on a range of population variables. They may be helpful in trying to understand the determinants of behavioural change and generating hypotheses to be tested by other evaluative designs(Grimshaw, Campbell & Eccles, 2000). These studies are usually cheaper to conduct compared to other epidemiological studies and often exploit natural phenomena. Such studies are not as robust as quasi-experimental and randomised trials in establishing causal links and dealing with biases and confounding factors.

Observational studies can also be useful in understanding the characteristics of interventions that are likely to result in improved compliance to agreed standards(Grilli & Lomas, 1994). However, in evaluating the effectiveness of clinical audit, observational studies are of limited usefulness and have rarely been used. By virtue of their design, it is not possible to account for factors other than the intervention in question that may have influenced the clinical behaviour.

5.1.1.2. Quasi-experimental designs

Quasi-experiments are studies that use interventions, outcome measures, and experimental units, but do not use random assignment to create the comparisons from which treatment-caused change is inferred(Cook & Campbell, 1979). Comparisons are usually made between non-equivalent groups. Various quasi-experimental designs have been used in health care research(Cook & Campbell, 1979). The following three methods will be discussed in more detail.

- Uncontrolled before-and-after studies
- Time series designs
- Controlled before-and-after studies

5.1.1.2.1. Uncontrolled before-and-after studies

Uncontrolled before-and-after studies measure process and/or outcome indicators before and after the introduction of the intervention and any statistically significant difference is attributed to the intervention. This design is the most commonly adopted method to evaluate the effectiveness of clinical audit, especially

in resource poor countries. Data collection for this design does not demand additional resources as data is routinely collected as part of the audit process. However, this method is limited by several potential biases.

In the absence of a contemporaneous control arm, any secular trends can be wrongly attributed to the intervention. Often, considerable time elapses before providers' performance is measured subsequent to the introduction of clinical audit. Other changes in the health service and wider society can influence clinical behaviour, which may be totally unrelated to the audit process. Statistical adjustments can be made to account for some of these influences. However, unknown or immeasurable confounding factors limit the robustness of findings(Cook & Campbell, 1979).

An effect can also be observed because of continual improvement or decline in providers' performance over time, irrespective of the intervention. This threat to internal validity, in which changes are due to the passage of time *per se* in the course of the study, is called *maturation*.

Similarly, if for any reason, measurement of provider performance is below average just before the intervention, a post-intervention measurement is likely to show an improvement due to a phenomenon called "regression to the mean". This is less likely to occur in pooled results.

Improved performance may also be observed in uncontrolled studies due to the "*Hawthorne* effect"; an awareness of being observed or the special attention received leads to behavioural change among participants or active compliance with the supposed expectations of researchers(Wickstrom & Bendix, 2000). This phenomenon can be accounted for in controlled studies, if the two participating groups are treated equally in all respects other than the intervention under investigation. However, in uncontrolled studies it may be responsible for overestimation of the effectiveness of interventions. An overview of 45 meta-analyses that reported pooled results separately for controlled and uncontrolled studies, found that the observed effect size was greater in the uncontrolled studies than in controlled studies(Lipsey & Wilson, 1993).

Despite their limitations, uncontrolled before-and-after designs are commonly used in developing countries to measure the effectiveness of health care interventions including those aimed at clinical behaviour. Increasingly more researchers are using mixed methods for evaluating health services often combining before-and-after studies with some qualitative methods. This approach can be more useful in understanding the relationship between variables compared with using an uncontrolled before-and-after design in isolation.

5.1.1.2.2. Time series designs

Interrupted time series is a research design that allows the same group to be compared over time by considering the trend of the data before and after introduction of the intervention (McBurney, 1994). The intervention interrupts sequential measurement of the dependent variable and the trends in the data series before and after the intervention are examined to determine its influence on the dependent variable. The results are analysed by comparing pre- and post-treatment trends in a change in intercept (or level) and a change in slope (or trend) (Cook & Campbell, 1979). This design has advantages over the uncontrolled before and after design in several respects. It can overcome the two problems of *maturation* and regression to the mean identified in the previous section by observing changes over numerous data points, both before and after the intervention.

Interrupted time series studies have their own inherent limitations. A change in the trend may be due to some other relevant event introduced at the same time as the intervention under investigation. This limitation, in which outside events influence participants in the course of the experiment, is called *history*. The influence of *history* can be accounted for by either:

Interrupted Time Series With A Non-equivalent Control Group Series (Cook & Campbell, 1979): In this design, same variables are also measured at similar intervals in a control group; or

Interrupted Time Series With Non-equivalent Dependent Variables (Cook & Campbell, 1979): In this design another variable independent of the intervention but also likely to be influenced by outside factor is measured over same time period.

Other limitations of interrupted time series include:

- The intervention may have a delayed effect due to its slow diffusion among the participating population, therefore, showing a delayed increase in the variable time-trend. This can be overcome by delaying the start of observations. However, this is a particular problem for interventions when the delay period cannot be predicted or changes according to setting.
- Time series modelling usually requires a minimum of 50 data points (more than 20 before and after the intervention (Cook & Campbell, 1979; Crabtree et al, 1990). Such data are not always available especially at the required time intervals. This creates problems for evaluations of clinical audit that rely on routine data collection systems. If a new data collection tool is introduced, then it will be necessary to wait for a prolonged period to attain sufficient data points before the introduction of audit.

- Time series modelling results may be difficult to interpret.
- Another difficulty with using archival and/or routinely collected data is that the data collection system may improve over time during the study period giving spurious results. This is called instrumentation(Cook & Campbell, 1979).
- In circumstances where controlled studies are not possible due to resource or other constraints, interrupted time series can be a useful tool to evaluate clinical audit as long as its limitations are recognised and other possible confounding factors are acknowledged.

5.1.1.2.3. Controlled before-and-after studies

In these studies, the experimental group is exposed to the intervention under study and the dependent variable(s) or relevant outcomes are measured before and after exposure. These results are compared with an appropriate control group. However, allocation to intervention or control groups is not based on random assignment(Bowling, 2002). This is one of the most frequently used research designs in social and health care research, and it can address all but the following four threats to internal validity(Cook & Campbell, 1979).

- Subjects in any group tend to grow more experienced, more tired, or more bored with the passage of time. Often pre and post-test analyses fail to identify such trends in the control or the experimental group. The investigator often faces the dilemma of judging the plausibility of causally irrelevant growth patterns that may be only affecting the experimental group. This phenomenon is called *selection-maturation*. It is a particular issue when respondents self-select themselves to receive a treatment. Such people are usually more motivated and have an intrinsic desire to improve which may influence recovery, and produce over inflated estimates of effectiveness of the intervention.
- Many scales measuring outcomes have intervals which are not equal, and changes are often easier to detect at some points in the scale. This is particularly problematic when the two groups are far apart from each other on the scale.
- Non-random selection can also lead to differential statistical regression. An example of this occurs when the researcher intends to match an experimental group to another group with a different mean score. Such matching can result in one group mean regressing to its population, whilst the other group may be different and not show such regression.

- Interaction of selection with the *history*, often termed the *local history*, can cause events that interfere with the experimental group but not the control group.

The above points highlight some of the dilemmas faced by the investigator using the controlled pre-and-post design to infer causality. Despite its frequent use, researchers find it difficult to attribute causality based on non-randomised selection of the two groups.

It is often argued that a randomised design is just as easy or difficult to use under circumstances where a non-randomised controlled study is proposed, but is likely to give results that are more valid(Grimshaw et al, 2000).

5.1.1.3. Randomised trials

RCTs are considered to be one of the most robust and efficient way of assessing the effectiveness of interventions in health care(Duley & Farrell, 2002). These can be further subdivided into two groups:

- Patient randomised trials
- Cluster randomised trials

5.1.1.3.1. Patient randomised trials

Patient randomised controlled trials involve the random allocation of participants between experimental groups receiving a treatment or intervention, and control groups receiving standard or placebo treatment(Bowling, 2002). Randomisation is used to reduce the possibility of potential confounders being distributed unequally between experimental and intervention groups. Despite this, RCTs are also subject to certain biases and limitations, especially when interventions other than drug treatments are evaluated. Some of these are listed below:

- Blinding is generally desirable in RCTs but is not always possible to conceal the allocation group for some interventions.
- If the same provider is required to give treatment to patients in both control and treatment groups, contamination is possible resulting in an undesired treatment effect in the control group. This is a particular problem for interventions designed to change clinical behaviour, as it would be extremely difficult and unrealistic for clinicians to change their practice from patient to patient based on group allocation(Grimshaw et al, 2000).
- Randomisation does not eliminate the risks to external validity. Patients are often included in the study based on ease of accessibility, and do not always

represent the general patient population pool. The treatment effect observed may not, therefore be widely generalisable.

- RCTs are often difficult to set up in health care due to ethical, legal, and political reasons. This is a particular problem when interventions are complex and require either a policy shift or major reorganisation.
- RCTs may be inappropriate for assessing rare adverse effects of medical treatments and evaluating interventions designed to prevent rare events, mainly due to the problem of recruiting an adequate sample size.
- RCTs would not be appropriate for evaluation of the long-term effects of interventions on human beings, which would require observation over a very long time frame.
- Effectiveness of interventions influenced by patients and doctors' preferences is also underestimated by random allocation to trial groups.

5.1.1.3.2. Cluster randomised trial

Cluster randomised trials are comparative studies that are designed to evaluate interventions that operate at a group level, manipulate the physical and social environment, or cannot be delivered to individual patients e.g. complex interventions (David, Sherri, V & Jonathan, 2004). In this, the unit of randomisation is at one level (health centres, clinicians etc.) and the process and outcomes are often measured at a different level (individual patients, etc), thereby avoiding contamination (see section 5.1.1.3.1) that may occur in individual randomisation. The unit of assignment is an identifiable group not created randomly, but through some physical, social, geographic, or other connexion.

Cluster randomised trials are not free from difficulties. Since the unit of assignment is a group not individuals, the numbers are rarely sufficient for random distribution to account for all confounding factors. Such studies, therefore, need to incorporate design strategies to take account of these constraints.

- An intra-class correlation is likely to exist among members of the same group, resulting in variance beyond the expected variance occurring in randomisation on an individual basis.
- Cluster randomised studies present difficulties of obtaining informed consent and ethical approval as groups are randomised before approaching individual patients.
- It is often difficult to determine the unit of inference as the intervention can work at different levels. These decisions need to be made in advance and

carefully thought through in the light of the research question(Donner & Klar, 2004).

- Cluster randomised trials are extensively used in public health research due to their administrative efficiency, high patient compliance rates and lower risk of contamination compared to RCTs. Extra vigilance needs to be observed in following the correct methods for analyses of results from cluster RCTs, and making statistical adjustments for variance influenced by intra-class correlations(Sherri, V, David, Jessica & Jonathan, 2004).

In general, despite being the gold standard for health care research, randomised controlled trials present a number of challenges to investigators and policy makers evaluating interventions designed to alter professionals' clinical behaviour. These are summarised as follows(Grimshaw et al, 2000):

- Health care professionals are only likely to change if motivated, and randomisation does not take account for this major behavioural determinant. This may lead to negative results on occasions when a particular intervention was only effective in a motivational environment. For interventions in which a clinician's motivation is a pre-requisite, randomisation may not be the most appropriate methodology(Black, 1996).
- Randomised trials are often lengthy and do not produce results in time to inform policy. Often decisions have to be made before results from such trials are available. In the event of subsequent negative results, managers face the dilemma of withdrawing or continuing the policy.
- Randomised trials often do not have adequate power due to an insufficient sample size. Recruiting large numbers of health professionals and facilities is challenging despite the existence of several research networks.

5.1.2. Methods used in Phase 1

This study was part of a collaborative project between the university departments of three Latin American countries (Peru, Bolivia and Cuba), the UK and Belgium, funded by an European Union grant. Each Latin American country had a research team, which worked in collaboration with the two teams in the UK and Belgium. The aim of the project was to assess the effectiveness of the following strategies in improving the diagnosis of smear negative TB:

- Clinical audit
- External quality assurance
- Organisational changes - decentralisation

Overall, the programme of study was designed to avoid interference between the three strategies by choosing different sites and times for the intervention. The team in Belgium provided the overall coordination of the research programme and led on the external quality assurance strategy. The Cuban team led the organisational strategy. The UK team provided the lead and coordination to the clinical audit strategy, and it is this last strategy that forms the basis of my study.

I chose to use an uncontrolled before-and-after quasi-experimental design for evaluating the effectiveness of clinical audit in influencing professional practice in all three-study countries (Peru, Bolivia and Cuba). I decided to collect time-series data to understand trends during the study period, but did not attempt a time-series analysis for reasons given before and elaborated in the discussion chapter.

5.1.2.1. Justification of study design

I used this approach as the most practical and useful design available, given the constraints of the project. These were as follows:

- A group of 5-10 health centres is generally required for the introduction of clinical audit in primary care in a collaborative model. Resources allocated to this component of the research allowed me to recruit only 5-10 health centres in the single study sites in Peru and Bolivia and in the two study sites in Cuba. This meant that I could only select four study sites in different settings leaving no allowance for any control sites.
- Clinical audit was a relatively new concept in these three countries and there was no experience of conducting clinical audit in the management of TB. There was no information on the feasibility of implementing audit in these settings. No pre-existing intervention models were therefore available to us for implantation in a controlled trial.
- There is a lack of information (e.g. outcome measures or appropriate sample size) in the published literature to inform the design of a trial of clinical audit in poorly resourced settings.
- A mathematical model for a time-series analysis requires certain assumptions, usually based on data collected in previous research in such settings. Due to the limited evidence-base, I was not able to make these assumptions with any significant level of confidence.

I considered an uncontrolled before-and-after study design an appropriate method in these settings despite its limitations. This design although not as robust as a controlled study, can still be used to infer causality between an intervention and outcomes. However, attention is required to address potential biases through careful

design and confounders by using other research methods. Combination with a study of trends of outcomes measured throughout the study period was used to avoid potential observational bias associated with measuring outcomes only at the beginning and the end of the study.

I chose to use a mix of methods to determine whether the audit intervention (or its components) could be effectively implemented in primary care in poorly resourced settings and to obtain information useful to developing appropriate methods for a subsequent trial of the intervention.

I did not select an observational study design; these offer logistical advantages, but fail adequately to address many inherent biases and confounding factors.

An interrupted time series design may have advantages over an uncontrolled before-and-after design. It addresses issues of *maturation*, secular trends, and regression to the mean by analyzing more than just pre- and post- data points. However, it requires a minimum of 50 data points out of which at least 20 must be collected before the intervention. This was not feasible given the circumstances in this project. The analysis relies on complex mathematical modelling that interprets sequential changes between each monthly data point. Interpretation may be problematic if data show large variation from month to month (often due to small sample size). I decided to collect monthly data and present time series charts to describe trends. I decided not to carry out mathematical modelling and a time series analysis, as I observed large variations in data from month to month for individual health centres in the initial stages of data collection.

A controlled before-and-after study would be preferable to an uncontrolled before-and-after design to evaluate effectiveness. A controlled design was not feasible given the funding constraint (limiting the number of sites and healthcare professionals it was possible to recruit). However, before conducting resource intensive controlled trials of complex interventions, it is desirable in any case to carry out a limited exploratory study (Campbell et al, 2000). The purpose of this is to refine the intervention based on contextual factors identified during the study, to assess effective implementation, and to develop appropriate research methods for a larger controlled trial.

A patient randomised controlled design is usually considered unsuitable for evaluating complex interventions due to possible contamination effects between intervention and control groups. As previously discussed, it would be unrealistic to expect health professionals to change clinical behaviour from patient to patient.

A cluster randomised controlled trial offers several advantages over other designs and would be the method of choice to evaluate the effect of clinical audit on

health professionals' clinical behaviour. However, cluster randomisation does not allow for practitioners' preferences and thereby removes the potential effects of personal motivation, which is a key determinant of change in professional behaviour. The success of interventions to change practice has been related to a sense of ownership of the process; this conflicts with the situation in experimentation, in which the investigator attempts to impose as much control on the subjects in the study as possible (Black, 1996).

Clinical audit is designed to generate collaborative working between health centres within districts and municipalities. It was, therefore, not appropriate to select individual health centres as units of inference, due to the potential for contamination. The appropriate unit of inference for each country would be the district or municipality. For an adequately powered cluster randomised controlled trial numerous districts would need to be recruited raising financial and administrative problems. The randomised controlled trial was originally designed to test individual clinical interventions and processes of care, and its extension to health systems programmes and policies, such as clinical audit, may be problematic (Lord & Littlejohns, 1997). As already mentioned above, a smaller exploratory study is often necessary to address some of these problems.

5.1.2.2. Settings and Participants

This study was conducted in primary care settings in three Latin American countries, Cuba, Peru, and Bolivia between January 2002 and December 2005. This selection was based on:

- Strong existing reciprocal research links with university departments in these countries
- Personal interest of the local research teams in the research question
- Poorly resourced health systems in developing countries
- High incidence of pulmonary tuberculosis (PTB)
- A recognition of problems with quality of diagnostic care of suspected TB cases with negative smears by the local TB control programmes
- To provide a variety of settings for the research

Cuba was selected as an interesting setting to study the research question as it was considered to have a relatively well run primary health care given the socio-economic conditions.

Initially I planned to conduct the study in both urban and rural settings in each country. However, resource limitations limited the study in Peru to urban settings.

One district (Canto Grande) was selected based on a high incidence of tuberculosis and proximity to the research team base in Lima. In Bolivia, two districts were selected, one rural and the other urban based again on high incidence of tuberculosis. The districts were geographically near to each other and to the base for the research team in Cochabamba. For the purposes of the study, both districts were treated as a single study site. In Cuba, the same selection criteria were used to select two municipalities, one in Havana City (urban setting), and one in Las Tunas (semi-urban setting). These were treated as two separate study sites. All health centres in selected municipalities and districts in the three countries were recruited to participate in the study.

In each health centre, all staff involved in the care of patients with suspected tuberculosis (mainly primary care physicians, TB nurses, managers) participated in the study. The effect of repeated audit cycles on the clinical behaviour of these professionals was assessed by determining change in processes of care at repeated intervals.

5.1.2.3. Intervention

The intervention consisted of two complete audit cycles carried out in all selected districts in Peru and Bolivia, and Cuba.

No existing guidelines or models for implementation of clinical audit in poorly resourced settings were available. Guidelines used in developed countries were consulted (Baker, Hearnshaw & Robertson, 1999; Morrell & Harvey, 2002) and a generic plan was prepared based on the principles outlined in these. This was circulated and discussed with all research partners invited to a workshop. A final plan was agreed which is presented in Table 5.1.

Table 5.1: Steps in an audit cycle

Selection of a topic
Specification of desired performance
First data collection
Implementation of change
Second data collection
Comparison with the baseline performance

(Baker et al, 1999; Morrell & Harvey, 2002)

A list of all key stakeholders was generated in each district or municipality. This included health professionals delivering health care in the selected facilities, patient groups' representatives, voluntary workers, and TB control programme

managers. A stakeholders' conference was held in each district to give information about the clinical audit project and to develop a 5-10 member audit committee. These committees consisted of:

- Primary care physicians
- Nurses including TB nurses
- TB laboratory technicians
- TB specialist
- TB programme coordinator

The audit committee's first task was to agree a set of audit criteria and standards(Hearnshaw et al, 2002).

- Audit criteria are explicit statements that define what is being measured and represent elements of care that can be measured objectively. Each criterion consists of a numerator and a denominator.
- A standard is the threshold of the expected compliance for each criterion (these are usually expressed as a percentage).

Members of the committee were asked to draw up a list of problems faced in delivering high quality diagnostic-related care to patients with suspected PTB. They were asked to use clinical guidelines, patient care pathways, and analysis of critical points in health care delivery to generate this list. The audit committee then identified the common problems, and converted these into measurable criteria and standards rating each problem in relation to its evidence-base, health impact, measurability, and potential to achieve a realistic solution. A scoring system was developed based on the above four factors and members of the audit committee were asked to score each proposed criterion against these factors (Table 5.2). All factors were equally weighted in the scoring system. The committee was then asked to select three to six criteria with the highest scores for the first audit cycle.

Table 5.2: Table used for scoring each criterion against four factors

	Evidence base	Measurability	Health Impact	Feasibility for change
Criterion 1				
Criterion 2				
Criterion 3				
Criterion 4				
Criterion 5				
Criterion 6				

After agreeing the standards and criteria, the audit committee developed an inquiry tool for each standard. If any criteria could not be measured using routinely collected data, then a new inquiry tool was developed and introduced in each

participating health facility. The inquiry tool was designed in consultation and agreement with local health professionals and managers. The inquiry tool was piloted in two health centres before introducing it in all health centres.

For each criterion, the numerator and denominator were defined explicitly. The sample size required to detect a minimum change of 10% was estimated for each criterion. For some standards, the committee judged it necessary to collect data on all patients while for others a sample was selected. A data extraction tool to record data from the inquiry tool was developed for each standard. Proportions and confidence intervals were estimated using Excel worksheets.

Data collected over a six-month period were analysed as proportions for each standard for each health centre per month. An analysis of the extracted data was fed back to the audit committee at the end of each data collection cycle.

The audit committee judged the results against agreed standards and discussed possible reasons for any disparity using situation analysis tools such as the fishbone diagram (Figure 5.1)(Baker et al, 1999). The output from this process was a list of possible reasons for poor performance for each standard according to five categories (Table 5.3).

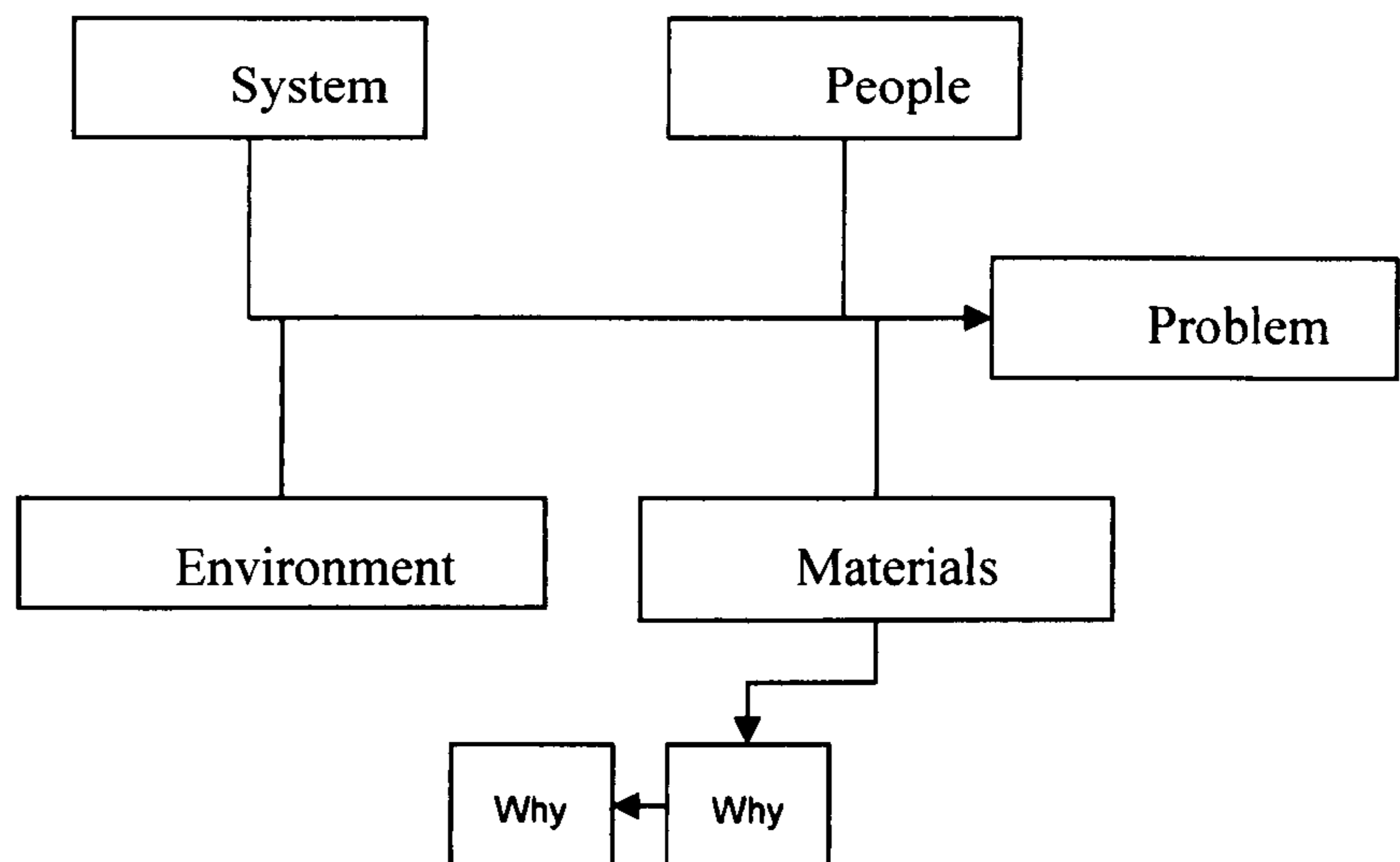


Figure 5.1: Fish bone diagram for problem analysis

The audit committee used the problem list to generate realistic strategies for change and to make relevant recommendations. Guidance was provided to the audit committee on effective strategies for implementing change at an organizational and individual level (Table 5.4)(Baker et al, 1999). These recommendations were incorporated into an action plan describing clear roles, responsibilities, resource requirements, periods, and anticipated difficulties.

It was acknowledged that 3-6 months would be required for the implementation of improvement strategies and for these to produce an impact. Therefore, it was agreed to measure data monthly throughout the audit cycle but only provide feedback at six monthly intervals.

I planned to complete at least two audit cycles with three data collection cycles.

Table 5.3: Template table for problem analysis

List of Problems identified at the Audit committee meeting					
Date / City / country					
Duration of the meeting					
Numbers attended					
	Staff	Health system	Environment outside health sector (patients etc.)	Resources	Miscellaneous
Standard 1					
Standard 2					
Standard 3					
Standard 4					
Standard 5					

Table 5.4: Strategies for implementing change after feedback

Strategies	Target
Feedback	Health professional
Reminders	Health professional
Opinion leaders	Health professional working as a team
Facilitation	Groups of health professionals
Patient mediated interventions	Health professional
Conferences	Groups of health professionals
Educational materials	Health professional
Small group education	Groups of health professionals
Educational outreach	Health professional
Total quality management	Organisations
Financial incentives	Health professionals
Reorganisation of services	Organisations
Advertising	Health professional and organisations

Adapted from (Baker et al, 1999)

5.1.2.4. Outcomes

To determine the influence of clinical audit on diagnostic care for patients with suspected TB, the clinical audit criteria set by clinicians were also used as outcome

measures. These were assessed continuously, providing aggregated monthly data points throughout the project (24 in total). The proportion of patient contacts in which diagnostic care was based on agreed guidelines was determined for each criterion. An aggregated mean proportion for each study site was estimated by calendar month. Results were presented to audit committees by health centre, but for the purposes of the analysis to determine effectiveness of the intervention, they were aggregated at the district or municipality level.

5.1.2.5. Analysis

Data were analysed and presented in two ways:

Trends of the proportions of patients meeting each criterion by health centre and study site each month over the study period

The *relative* and *absolute* differences between the mean proportion of patients meeting each criterion by health centre and study site for the first and last six months.

For each criterion, the proportion of patients receiving appropriate care was estimated monthly by health centre as follows:

$$P_{it} = n_{it}/d_{it}$$

Where:

P_{it} = Proportion of patients meeting the criterion at health centre i for month t

n_{it} = Number of patients meeting the criterion at health centre i for month t

d_{it} = Number of patients who could have met the criterion for health centre i for month t

I used a trend line to display all results for P_{it} for each criterion by individual health centre and by district or municipality.

P_{bi} and P_{ai} represent the mean proportion meeting each criterion for the first and the last six months respectively at each health centre. I calculated the *absolute* difference (Pd_i) between the two proportions as follows:

$$Pd_i = P_{ai} - P_{bi}$$

The *relative* difference (Pe_i) was calculated using Shep's modification (Fleiss, Levin & Paik, 2003):

$$Pe_i = \frac{P_{ai} - P_{bi}}{1 - P_{bi}}$$

This can account for any potential opportunity for change. For example, if the proportion meeting a given criterion before the intervention is high, then the

potential for improvement will be relatively small. Shep's modification allows comparison of changes in proportion irrespective of the differences at baseline.

Standard errors (SE) and 95% confidence interval(CI) for P_{e_i} and P_{d_i} were calculated as follows(Fleiss et al, 2003):

$$SE [\text{Inverse log}(1 - P_{e_i})] = \text{Square root } [P_{ai}/d_{ai}(1 - P_{ai}) + P_{bi}/d_{bi}(1 - P_{bi})]$$

An approximately 95% confidence interval for $\ln(1 - P_{e_i})$ is

$$\text{Inverse log}(1 - P_e) - 1.96 \times SE \leq \text{Inverse log}(1 - P_e) \leq \ln(1 - P_e) + 1.96 \times SE$$

$$CI^{\text{lower}} \leq P_e \leq CI^{\text{upper}}$$

5.1.2.6. Anticipated difficulties with the design

This section summarises some of the anticipated limitations and difficulties in using the methods described in the preceding section.

The uncontrolled before-and-after trial design and trend charts pose doubts about internal validity, as they do not account for external factors that may influence the trend in a given direction. This may lead to a false acceptance that a particular trend is caused by the intervention. This phenomenon, as previously discussed, is called history. The qualitative methods used in phase 2, would help to counteract this, by determining potential confounding factors in the various study settings.

Measured outcomes rely heavily on routine or archival data collection systems, which may be problematic. Often outcomes are selected based on what is available, as opposed to what is ideally required. I used an inquiry tool where collecting routine data would have given a biased result.

Two of the criteria for selecting audit standards (used as outcomes in the time series analysis) are availability and measurability. However, there may be a mismatch in what is perceived to be available, and what is actually available from routine data collection systems. This will only become apparent with hindsight. A pilot may be used to address this problem, giving audit committees an opportunity to revise standards set if necessary. Such alterations need to be recorded to help in the interpretation of results.

More importantly, there are often inherent biases in the routine data collection system, often referred to as instrumentation, which can cause difficulties with data collection. This is understandable as routinely collected data in a health service is collected for different purposes in developing countries, and is not always useful for clinical audit. Often construct labels for the numerator and denominator do not reflect the operational definitions used for data collection. These definitions may also not match exactly with the definitions agreed by audit committees. Definitions

often also change over time without changing the actual data collected (e.g., case definitions may change). Definitions should be scrutinised by the person collecting the data, and any discrepancies addressed and recorded. Data can often be missing or vary widely, due to inaccurate data collection procedures. Research investigators using such data can be made aware of these issues through training, and asked to record any difficulties encountered.

Routinely collected data can also be inflexible. It may not be possible to aggregate at monthly data points as planned. Similarly, it may also be difficult to separate data for analysis by various independent variables (age, sex etc.)

As all outcomes were based on the criteria decided by audit committees, there is a possible danger of losing control over what is measured. There is also the possibility that audit committees may have only measured something during one cycle, and replaced it with another standard in the subsequent cycle. In this study, I determined to continue to measure data on outcomes even if they were later discontinued as a standard.

Data collection procedures may vary from health centre to health centre. It may not be possible to collect data on the criteria agreed by audit committees in all health centres. The systematic biases (as mentioned above) may also vary from centre to centre for each criterion. It may be necessary to change the data extraction tool because of these differences between centres.

A new inquiry tool was introduced, where a routine data collection system is unavailable (as was likely to be the case in health centres in Peru and Bolivia), to measure certain standards. This raised a number of difficulties and biases. There are administrative challenges in introducing a new data collection system. Any new system should not be perceived to require extra work and cost by health professionals and managers respectively. A new inquiry tool needs to be developed in consultation with health professionals and the administration working in the setting. Teething problems need to be identified in pilots and addressed appropriately. Another problem is that a new data collection system is likely to introduce a confounding factor. It will be difficult to differentiate whether the observed trend is due to the intervention or the new inquiry tool. This would not be an issue if the inquiry tool were part of the intervention. Moreover, since the trends in the outcomes were measured over a period beyond the first audit cycle at many time points, sustained changes could be compared against other sharp changes in the data.

I selected districts based on the incidence of PTB introducing possible selection bias. Most of this was attributable to self-selection within health facilities;

not all health centres within each district were to participate in the audit, and it was expected that health professionals who are more motivated to change their practice would be more likely to participate in the project. There may be other unknown factors affecting participation such as the relationship between researchers and health professionals, other professional commitments and their perception, understanding and knowledge of the audit process. Some of these issues were addressed in the case study.

Clinical audit is an intervention that is likely to diffuse only gradually. This is likely to affect the data analysis. Processes during the audit cycle were recorded and plotted, along with the outcomes, to understand the timing of the effect and of various events during the audit process.

It is possible that clinical audit results in a delayed effect on professional behaviour. Since we do not know the causal lag, it is difficult to predict statistical inference. However, a detailed log of the recommendations, action plan, and their implementation would help in understanding such an effect.

The unit of inference was the district as the intervention was applied collectively in all the participating health centres within districts. However, aggregated data for the district cannot show variations in the effect size between health centres, and individual data sets from each centre would not have sufficient power to make statistical sense. This could nullify significant improvements in one health centre due to little or no improvement in others.

Audit is a complex intervention and there could be a number of potential issues in evaluating its implementation in three different countries. There may have been time delay before the start of the audit cycle due to varying educational needs of key stakeholders. Its importance may have been perceived differently in each country, leading to varying difficulty in acquiring approval from local administration. Local politics could also play a significant part in how soon and how effectively audit could be commenced. The dynamics of each audit committee would also affect the project. Audit by its nature is a voluntary activity, but health professionals in countries with an established audit culture are engaged in the process as part of their professional responsibility. This obviously was not the case for health professionals working in the various study sites. There may have been expectations of incentives for participants.

The audit process clearly depends on a multitude of factors that would not be addressed or detected by an uncontrolled before and after study. I used a qualitative approach in Phase 2 of the study, to inform some of these issues.

5.2. Phase 2

The aim of this phase is to gain an understanding of the barriers and facilitators to change in clinical practice of health professionals. This will be helpful in designing and implementing a complex intervention to influence clinical practice i.e. clinical audit, and also help in illuminating, interpreting, and qualifying the results from phase 1.

Here I discuss the theoretical assumptions made to frame my research question. I will describe the theories explaining the role of knowledge, its acquisition and its validity. This is followed by an account of the research methods used in this phase, and their anticipated limitations and problems.

5.2.1. Theoretical framework

Theoretical assumptions that form the basis of my research question can be studied at four different levels(Green & Thorogood, 2004):

Macro theories: these relate to the social world and how it works

Middle-range theories: these provide a link between macro theories and observed behaviour in society in order to generate research questions and hypotheses

Epistemological theories: these relate to the origin and validity of knowledge

Broad orientations: these are the broad theoretical principles providing the basis for the qualitative research methods of this phase

5.2.1.1. Macro theories

These theories aim to define the working of the social world. There are two main views on 'how the world works':

5.2.1.1.1. Functionalism

This is an approach to political science that sees society as a balanced system in which roles, norms, and individual psychology function to create social and political order(Opello & Rosso, 1999)

5.2.1.1.2. Critical theory

The critical theorists see society as a collection of many factions, each fighting against each other for power and resources. This theory highlights contradictions imposed upon modern human beings by varieties of social organisation that abuse formal rationality in order to deny power to classes of citizens(O'Connell, 1975)

Since health professionals are members of a society just like other human beings, their clinical behaviour is not isolated from the interactions between the

forces working in a social organisation. The two perspectives on the interaction between society and change in health professionals' clinical behaviour based on these two theories are as follows:

- A consensus theorist (Functionalism) would see change as a harmonious process between health professionals and the society driven by non-contentious aims(O'Connell, 1975).
- A conflict perspective (Critical theory) would see change as a conflict between health professionals and the social organisation, often driven by many influences working in different directions(O'Connell, 1975).

The research question in this phase is based on the latter approach. The research theorises that change in health professionals' clinical behaviour is likely to bring conflict between various forces and factions working in contradictory directions, and my aim is to understand these dynamic interactions. A critical perspective is required to understand conflicts among professionals as well as between professionals and organisation.

5.2.1.2. Middle-range theories

These help in generating research questions by linking theories about how the world works to human behaviour in everyday settings. Different research questions may be generated by researchers, based on the underlying theoretical frameworks on which their respective disciplines are rooted. The underlying middle range theory behind the stated objective of this phase is that health professionals' ability to change their clinical behaviour is usually dependent on various psychological, organisational, physical, and societal factors. Some of these factors inhibit change, while others are likely to facilitate change and help in expediting this process.

5.2.1.3. Epistemological theories

Epistemological theories differ in terms of what kind of knowledge research should produce and what is considered to be valid and believable(Alderson, 1998). These theories, often not explicitly stated by researchers, underpin practice and planning of health care research. It is useful to summarise the differences between the more commonly held theories and to state the theoretical framework adopted in this phase of the research.

5.2.1.3.1. Positivism

According to positivism, a stable reality exists in this world at all times(Green & Thorogood, 2004). There is a perfect scientific explanation for various phenomena observed in this world, including health and illness. The aim of the current research according to the positivist's belief should be to uncover the cause

and effect relationship between different elements and establish the laws governing the natural world. However, its focus on empiricism and emphasis on value-free inquiry lends itself to criticism by social scientists. Positivist dichotomies do take some account of the context of observable phenomena, but always attempt to define these in terms of measurable variables(Alderson, 1998). Clinical behaviour of health care professionals is a complex phenomenon, and is a likely to be the result of a complex interaction between different organisational, psychological, and social forces. It is difficult to explain clinical behaviour in terms of some measurable variables such as age, sex, workload etc. Positivist assumptions can only explore simple relationships and would be unable to cope where multiple factors interplay to produce the dynamic nature of human behaviour.

5.2.1.3.2. Feminist theory

This implies that all knowledge produced predominately by men is based on their perceptions and experiences(Alderson, 1998). It is therefore imperative to base scientific inquiry from a feminist perspective.

5.2.1.3.3. Postmodernism theory

In postmodernist theory, truth is not "out there" waiting to be discovered, but is something constructed by people(Hodgkin, 1996). These "truths" are always provisional and dependent on context and power. A postmodernist will question evidence-based medicine and ask whose "evidence" is this anyway, and whose interests does it promote?

5.2.1.3.4. Participatory theory

This implies that because of the positivist notion of striving for a 'neutral' position most researchers have isolated themselves from wider society and this has led to knowledge being consolidated within a small elite. The participatory approach sees research as a co-operative enterprise between scientists and the community, and in many cases aims to empower the most weak and marginalised sections of the community.

5.2.1.3.5. Phenomenology

Phenomenology is based on the paradigm that 'reality' is multiple and is socially constructed by individuals because of their interactions in the society based on their perception and experiences(Bowling, 2002). It emphasises that social 'facts' are characterised and recognised by their 'meaningfulness' to members of society and research should aim to discover these social meanings. There are two approaches to phenomenology.

Humanists base their conclusions on accounts of human experiences of their social world, often uncritically accepting their account as valid. On the other hand, interpretative sociologists use these accounts as data recognising that the social meaning emerging from them is unlikely to be standardised across individuals and societies.

Any innovation aimed at changing professional behaviour is likely to produce different responses in the individuals involved. These are likely to give rise to social meanings, which will vary across individuals and societies. Similarly, other social, organisational, and psychological forces will be perceived differently as a deterrent or a catalyst. The research question posed in phase 2 lends itself naturally to this theory. An account of these perceptions and experiences will help in constructing a 'social reality' that is meaningful to professionals in their context.

5.2.1.4. Broad research orientation

In the previous section, I discussed some theoretical assumptions that underpin the qualitative research related to this research project. In this section, I will give an outline of the orientations used to provide a framework to the methods adopted in this phase (Green & Britten, 1998; Green & Thorogood, 2004).

5.2.1.4.1. Naturalism

This refers to a preference for studying phenomena in their 'natural' environment. This allows researchers to explore human behaviour in the world they live in. Ethnography is perhaps the most realistic way of being naturalistic. My study design will be based on the notion of naturalism and attempt to study health professionals' clinical behaviour in their own settings. However, there will be some impact of any observation on the field, and it will be the responsibility of the researcher to minimize and account for that effect.

5.2.1.4.2. Focus on understanding and meaning

This study will attempt to understand and interpret social meanings from the health professionals' perspective. As discussed previously, this will help in understanding the 'reality' of clinical behaviour change in the eyes of health professionals. It will help determine the deterrents or facilitators for change as perceived by health professionals.

5.2.1.4.3. Inductive research and grounded theory

This describes research that is carried out without predetermined theories and hypotheses, and theories emerge as data is analysed. Contrary to this is the deductive approach that uses data to refute or confirm pre-determined hypotheses. The wide

range of influences that need to be taken into account in this research project led me to adopt an inductive approach. Data collected during this phase will be used to generate theories that grow out of the data, and are related directly to the activities taking place in the settings. This approach is also often termed 'grounded theory'.

5.2.1.4.4. Emphasis on the description of the settings

There is a strong emphasis on the description of the settings in this research design as a good description in itself may be an explanation, and can often help researchers to understand causes and consequences.

5.2.1.4.5. Emphasis on the context and holism

Contextualism implies studying events and behaviour in their context. Holism indicates studying social groups and other social entities together. Both Contextualism and holism are important as they help in studying events and behaviours not in isolation but in the context of a complete social entity in the settings where these occur.

5.2.1.4.6. Emphasis on the process

Phase 2 is designed to capture the processes of change, realising the dynamic nature and the constant flux of social events. This approach helps in understanding this aspect of the phenomena under study.

5.2.1.4.7. Flexibility of the research design

Despite the theoretical assumptions described above, there was sufficient flexibility within the research design to incorporate and capture emerging themes and theories from the initial research.

5.2.2. Methods used in phase 2

Traditionally, researchers have classified qualitative methods on a hierarchical basis, the three categories being exploratory, descriptive, and explanatory (Yin, 1994). However, such categorisation has been criticised by many contemporary researchers as many research designs can be used for varied purposes depending on the conditions and research question (Yin, 1994). In this section, I intend to give a brief description of the available designs for qualitative research followed by reasons for choosing the selected methods. This will be followed by a detailed description of methods and the anticipated problems.

5.2.2.1. Critique of study designs

These are as follows (Green & Britten, 1998).

- Experiments

- Surveys
- Observational studies
- Case studies
- Action research

5.2.2.1.1. Experiments

Experimental designs are used to demonstrate a cause and effect relationship between variables and usually involve an intervention with observations before and after to determine its effect. However, these are rarely used in qualitative research, as in most cases, the interest is in understanding and interpreting phenomena rather than demonstrating a simple causal relationship.

5.2.2.1.2. Surveys

Surveys aim to collect the same information from each case in the study. This is usually done through questionnaires and structured interviews of a representative sample of cases from the population under study. This design is rooted to a certain extent in the positivist approach that there is a 'reality' out there, which is same for everyone, which can be discovered. This is not the case in many research paradigms, where the emphasis is on uncovering the social meaning of events to individuals in their social world.

5.2.2.1.3. Observational studies

These provide a description and understanding of events and behaviours in particular social settings. They are suited to situations where documentation is required of what happens in everyday contexts.

5.2.2.1.4. Case studies

A case study is a method to study a phenomenon in some detail. It is defined as an empirical inquiry, which investigates a contemporary phenomenon within its real life context, especially when the boundaries between phenomenon and context are not well defined. A major advantage of this study design is that it can study many more variables of interest, using multiple sources of information. This helps to develop a better understanding of the context and allows a triangulated approach.

5.2.2.1.5. Action research

This has its roots in the participatory approach discussed previously. Action research combines the production of knowledge, with the aim of bringing change in society. Research participants take an active role in setting the agenda, development, planning, and execution of the study. It aims to empower marginalised social groups by their participation in the generation of knowledge.

5.2.2.2. Choosing an appropriate design

There is a considerable overlap between the above study designs in terms of their research purposes. However, certain conditions determine the suitability of these designs to answer a research question(Yin, 1994). These conditions, described in detail by Yin et al are as follows:

- Purpose of research question
- Requirement for control over events or behaviours
- Focus on contemporary events
- Theoretical assumptions

The case study design lends itself to the research question posed in this phase of the study to for the following reasons (Table 5.5):

This study aims to understand the phenomenon of change in the clinical behaviour of health professionals. It attempts to explore how this change is brought about, and why it is easier for some professionals to change than others. Critical theory that underpins this study, points towards various negative forces and constraints, which the social world places on the health professional, interfering with the change process. This study aims to uncover these forces and constraints.

The research question in this phase focuses on understanding change phenomena and professional behaviour without attempting to manipulate or change these. This would rule out using an experimental or action research design.

A case study design is suited to answer questions that are rooted in social construction theory. This study proposes to use an interpretative approach as opposed to a humanistic approach. This is the preferred approach to seek explanations and interpretations of observed behavioural events(Yin, 1994).

As the study aims to understand contemporary events and behaviours, using a past description would be unsuitable.

Table 5.5: Selecting the appropriate study design for the research question

Strategy	Research question	Requirement for control over behavioural events	Focus on contemporary issues	Theoretical framework
----------	-------------------	---	------------------------------	-----------------------

Experiment	Determine cause-effect (how, why)	Yes By attempting to change events and behaviours through interventions	Yes	Positivist
Surveys	Measures variables (how much, how many or what)	No Not the aim of the study	Yes	Positivist
Observational studies	Describes phenomena/events (what, how much, who, where, how many)	No Aim is to study the behaviour in its settings not to manipulate it	Yes/No	Phenomenology with humanistic approach
Case studies	Understand phenomena in its context (how, why, what)	No manipulation of behaviour required	Yes	Phenomenology with interpretative approach Post-modernism
Action research	Studies phenomena to bring social change (how, why, what)	Yes By empowering marginalised groups	Yes	Participatory theory

Adapted from (Yin, 1994)

5.2.2.3. Selected research design

I proposed to conduct one case study in each Latin American country participating in the research.

For a case study, five components of the study design should be defined at the beginning(Yin, 1994):

The study question

Its propositions

Its unit of analysis

The logic linking the data to the propositions

The criteria for interpreting findings

This study aims to understand the change process in the clinical behavior of health professionals. The propositions under study are the various factors that act either as barriers or facilitators to change. The unit of analysis was a group of health professionals working in the health centre of a district or municipality between 2004 and 2005 (the years under study). The group was part of a team signed up to bring

improvement in their clinical performance, as defined and measured by the audit committee; they took part in the audit process and some were also members of the audit committee or had representation on it. Some barriers and facilitators may have differed between individuals in each group. However, for the purpose of this study I assumed that the group would be likely to share most of the organizational, physical and socio-cultural factors influencing change in clinical behaviour. Therefore, each group was studied as one case. Data were collected from the sub-units (individual health professionals) and analysed together as one case, and linked to the propositions using pattern-matching (see below)(Campbell, 1975).

A multiple case design was selected. The purpose of using multiple sites was replication as opposed to sampling. The project consisted of three case studies, one in Peru, one in Bolivia, and one in Cuba. Each used an embedded design, where data were collected from individual health professionals (sub-units), producing a single case report for each country. Each case study was used to draw cross case conclusions and develop theories. I have presented findings as a cross-case report in the results and discussion chapter (Figure 5.2).

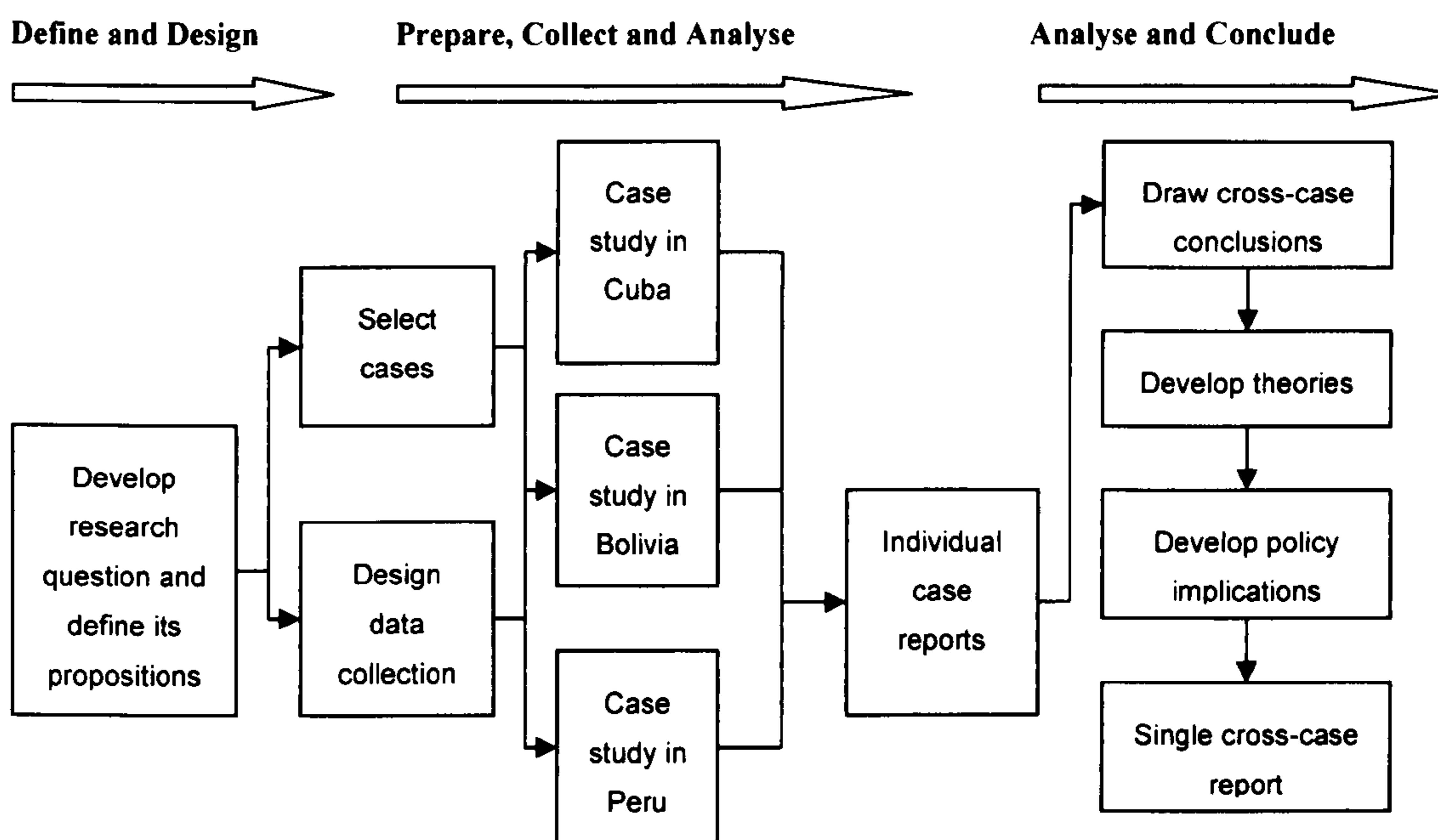


Figure 5.2: A multiple case study design

5.2.2.3.1. Grounded Theory

It must be emphasised that the case study design does not have a pre-determined theory but rather relies on a grounded theory to emerge during analysis. The theoretical framework adopted lends itself to an inductive design. The study site selection was based on literal and not on theoretical replication. The settings in each case study were slightly different from country to country. However, the purpose

was not to present contrasting circumstances, but to explore whether the theory generated from these case studies could be sustained in different settings.

5.2.2.3.2. Collection of evidence for each case study

It is important to define the ‘case’ under study and the ‘unit’ and ‘sub-unit’ of analysis.

A ‘case’ is defined as a group of primary care health professionals working in various health centres which are all part of the same district or municipality, and therefore constitute a single unit or case for analysis.

A ‘sub-unit’ is an individual health professional working in a health centre that is the source of information and data collection. Data collected from individual sub units were used in the analysis of each case study. To illustrate this further, Table 5.6 shows how data sources at the two levels are obtained to generate evidence for each case study.

Table 5.6: Methods of investigation in a case study

	From individual professionals	From a group of professionals in the same district
Data about individual professionals	Interviews	Participant observations
Data about group of professionals in the same district	Interviews	Documents Participant observations

A range of methods can be used to conduct data collection for a case study (Table 5.7). As apparent from the table, no one method provides clear advantages over the others. Triangulation is another reason for using multiple sources of evidence in a case study(Yin, 1994). Therefore, the following three sources of data collection were used in each case study.

- Interviews
- Participant observation
- Documentation

5.2.2.3.3. Documentation

The following were used to extract information for the case study:

Table 5.7: Methods used for collecting evidence for case studies

Sources of evidence	Strengths	Weaknesses	Comments related to phase 2
---------------------	-----------	------------	-----------------------------

Documentation	<p>Stable-can be reviewed repeatedly</p> <p>Broad coverage-covers long periods, many events, many settings</p> <p>Exact-contains factual knowledge</p> <p>Unobtrusive-not collected for the purpose of the case study</p>	<p>Irretrievability-can be difficult to access</p> <p>Reporting bias-unknown bias of the person collecting information</p> <p>Selection bias-if the data is incomplete, one only selects information that is available</p>	Useful-activities of audit committee are reported in the minutes of the meeting
Interviews	<p>Targeted and focused on the study topic</p> <p>Data can be collected at an individual level</p> <p>Insightful and rich in information</p>	<p>Response bias</p> <p>Selection bias</p> <p>Recall bias</p> <p>Bias due to poorly constructed questions</p> <p>Bias due to reflexivity-interviewee gives what interviewer wants to hear</p>	Useful-interviews if conducted properly at an individual level can be very insightful.
Direct Observation	<p>Reality-covers events in real time</p> <p>Contextual-covers context of the event</p>	<p>Selection bias-unless broad coverage</p> <p>High resource requirement (time and human)</p> <p>Reflexivity-by influencing the event through observation</p>	Not feasible-requires human resources beyond the scope of the project to make it unbiased
Participant-Observation	<p>Reality and Contextual</p> <p>Insightful into interpersonal behaviour and motives</p>	Bias due to investigator's manipulation of events	<p>Feasible and practical</p> <p>Can bring useful insight into group dynamics and interpersonal dynamics of a team</p>

Adopted from(Yin, 1994)

- Written communications (letters, e-mails) between members of the audit committee and the research team
- Agenda and the minutes of the audit committee
- Visit and the progress reports prepared by research teams in each country

- The routine data collection registers and 'clinical history' files from health centres

The information collected from these sources was used to:

- Validate factual information (names of audit committee members, number and timings of meetings)
- Corroborate and augment evidence collected through interviews and other sources
- Infer clues for further investigations

5.2.2.3.4. Participant-Observation

A research assistant, trained in clinical audit, was assigned to facilitate the audit process and chair all audit committee meetings in each country. This provided the opportunity for the research assistant to give an insightful account of the dynamics of the audit committee and increased accessibility to health professionals for subsequent interviews. Similarly, access to some of the documentation required for this study would not have been possible without this arrangement. An external observer, not part of the audit committee would not have been able to have the same closeness to the process or to the members of the audit committee. Each research assistant was asked to keep a personal diary to record his or her account of 'what went on' in the committee meetings.

This approach does have a number of difficulties. It is often argued that the participant may bring in personal bias, which can manipulate the whole process and raise questions about the validity of its findings. However, in relation to this study, the research assistant acted only as a facilitator, which is an essential requirement of any audit process. Another potential problem is that the researcher gives his or her impression of 'what went on' which may differ from what actually occurred. Research assistants were sufficiently trained and were given a framework to record their observations. This framework prompted them to make contemporaneous records of, for example, who attended the meeting, how the issues were presented, what were the dynamics of the meeting, how the decisions were made and with what level of agreement.

5.2.2.3.5. Interviews

I proposed to conduct focused, open-ended, and semi-structured interviews with key informants in each case study to take place in the middle of the project. Purposive sampling, which entails explicitly selecting interviewees who are likely to generate appropriate data, was used to select key informants (Green & Britten, 1998). All audit committee members, and at least one other health professional (non-

member of the audit committee) from each health centre that participated in the study were to be interviewed. Theoretical sampling, in which informants are continuously recruited until emerging theories reach a saturation point, was not possible due to resource constraints. It was judged that 12 to 16 interviews of health professionals from each district or municipality would be needed. Some of these were members of the audit committee, whilst others were health professionals working in health centres involved in the audit process. Interviews were planned to take place after completion of at least one audit cycle. This was expected to provide an in depth account of the audit process soon after completion of the first cycle. However, there was some flexibility in the timing of the interviews, given the potential delay in establishing the audit process.

Interviews were conducted by a researcher, who was not part of the audit process, and not previously known to the interviewees. These researchers were expected to have experience of carrying out qualitative research and interviewing in health care. A training session was held to refresh general techniques and skills. Pilot interviews were conducted to revise interviewing techniques and questions in the guide. Interviews were conducted over a period of two months. During this period, supervisory meetings were organised between the research assistant and the researcher conducting interviews to discuss any problems with the process.

Key informants were approached by the interviewing researcher in each district. Appointments were made to conduct interviews and a timetable proposed. It was proposed to conduct interviews at the informant's workplace but in a separate room to avoid disturbance and interruption. During interviews, information about the role and position of the informant was recorded. A 'topic guide' was used to conduct interviews (Appendix 3). This approach required an inviting statement from the interviewer on the topics covering the research question. This avoids asking predetermined leading question that can narrow down the discussion to a specific issue. A framework for these topics was generated after discussions with all audit facilitators. The purpose of this was to define the context in which changes in professional practice occur. This framework consisted of the following:

- Political influence both at macro and micro level
- Influence of colleagues and other team members
- Leadership at different levels
- Specific issue around each audit criterion

This framework was used to design the 'topic guide' approach in the form of three to four opening statements. These statements helped to explore the contextual factors that the study aimed to uncover. The statements were also framed in

different forms to prompt discussion. Prompt and probing questions were built in to the interviews to encourage an open discussion of the issues. Each interview was expected to last for one to two hours.

Interviews are generally considered more reliable if audio-taped and transcribed. However, transcription is time-consuming and eight to ten hours are usually required to transcribe one hour of interview. Given the limited resources for phase 2 of the study, a hand written record of the interview was considered more practical. The hand written textual information was translated and analysed and was then sent back to the interviewer to check validity.

5.2.2.3.6. Data collation and analysis

Data from the above three sources was collated in a database(Yin, 1994). An annotated bibliography was created of all documentary evidence collected during the case study. Information collected in personal diaries was classified and categorised for easy storage and retrieval.

Since each case study used an embedded design, in which data were collected from individual health professionals acting as a 'sub-unit' of analysis, a different approach was used for the analysis. Within each 'case', data were analysed first at the 'sub-unit' level. Patterns across different 'sub-units' were compared and conclusions were drawn on that basis. These conclusions formed the basis of each case study. Conclusions from the three case studies were then compared, and inferences were drawn using explanation building techniques (see below).

Data collected during interviews were analysed using an open coding method. This is defined as a process of breaking down, examining, comparing, conceptualising and categorising data(Strauss & Corbin, 1990). Raw data were broken down and compared to see similarities and differences between recorded incidents, phenomena and thoughts. All similar incidents were labelled and subsequently grouped together in categories according to their properties and dimensions. Each category was given a conceptual name, using phrases either from the interviewers themselves (in vivo coding) or from existing literature.

Explanation building aims to analyse case study data by building an explanation about the case. The final explanation is usually a result of a series of iterations. It generally starts from the findings of the first 'sub-unit'. This helps to develop theoretical propositions which are then subsequently compared with the findings of the rest of the 'sub-units'. Explanation building is a refined technique that also entertains rival explanations. This results in a set of final explanations for each case study based on repeated reiterations. Information collected from the interviews provides the main source of evidence for the above technique.

Explanations developed from these interviews were compared against each other for each case. This was expected to strengthen the validity of the final explanations.

The above analysis was complemented by analysis of chronological events during the audit cycle, using mainly the documentary evidence and participant-observations. The theoretical explanations generated from the above analysis were compared with the chronology of events. This usually helps to strengthen internal validity of the study especially if the sequence of events follows a pattern predicted by the explanations, and not by the rival theories.

5.2.2.4. Anticipated methodological problems in phase 2

The following are some of the methodological limitations anticipated in phase 2 of this study:

The case study design used in this phase captured information about the barriers and facilitators to change as perceived by the informants. However, evidence was collected from more than one source to triangulate inferences. Moreover, a chain of evidence was established by using chronological analysis along with explanation building.

The conclusions in the case study report relied on inferences about the phenomena of change. These were drawn from the interviews, documentation, and participatory-observations. All inferences are liable to a threat to internal validity. However, a well-conducted analysis based on explanation building combined with chronological analysis can overcome this issue.

The external validity of a case study is judged on the generalisability of its findings. This is a major issue for research conducted in specific context. Barriers and facilitators to change identified in this study may not be generalisable to other settings. However, this is a multiple case design based on replication logic. Each 'case' offers a different set of circumstances, and develops explanations from the combined analysis of all three case studies. This can generate theories that may be relevant to many similar settings.

Reliability of the findings often depends on clear documentation of the procedures in the study. It also relies on using standard techniques and tools that can be replicated in other settings. Use of audio-taped interviews helps to improve reliability. However, as stated previously, this was not possible due to resource limitations.

Direct observation offers another valid source of evidence for case studies. In this study, this would have required numerous researchers spending hours observing in the many health facilities included in the study. This was not feasible given the resource constraints.

5.3. Conclusion

In this chapter, I have outlined the objectives of the proposed study. I have summarised research methods, which can potentially answer the research questions of interest. I have presented the study designs selected for the two phases of the study, along with the arguments supporting their selection. I have also highlighted some of the anticipated difficulties and methodological limitations of the selected designs. In the following chapters, I present the results of this study.

Results

The results section is subdivided into the following chapters:

- Chapter 6 Description of the three Latin American countries: this chapter provides brief background to the three Latin American countries focussing on their health status and organisation of health services. It also gives a brief introduction to the status of TB control in each country
- Chapter 7 Study sites: this part of the thesis introduces the study sites selected in the three countries. It describes the TB indicators in comparison to other parts of the country and explains organisation of TB services in the respective districts and municipalities
- Chapter 8 Implementation of clinical audit: this chapter discusses the process of introducing and implementing audit cycle in the three countries.
- Chapter 9 Results of the clinical audit: this chapter presents the results of both phase 1 and phase 2 for each country.

Chapter 6 Description of the three Latin American countries

This chapter provides a brief description of the three Latin American countries (Peru, Bolivia and Cuba) which participated in this project. It provides a summary of the current health status and health care organisation in each country. It ends with a description of the existing TB control programmes.

6.1. Peru

6.1.1. Geography, politics and population

Peru has been the seat of many ancient Andean civilisations, most prominently the Incas. The 16th century saw the Spanish invasion, which was followed by three hundred years of colonisation. Peru finally gained its independence in 1821. After being denied democracy for many years by various regimes, Peru has been politically volatile even in recent years(CIA, 2005).

Peru is situated in the western part of South America, bordering the South Pacific Ocean, between Chile and Ecuador (Figure 6.1). Climate varies from dry desert in the west and warm tropical forests in the east. Terrain in general is coastal plain in the west, high and rugged Andes in the middle and jungle of the Amazon Basin in the east. Peru is divided into 25 administrative divisions often referred to as regions, with their own regional governments. Lima is the capital city where nearly a third of the total population resides. An estimated 27,544,000 people currently live in Peru (15% whites, 45% indigenous, 37% mixed and 3% others) and 72% of this population is urban. The average annual population growth rate has declined from 2.8% in 1961-1972 to 1.7% in 2000. The official language is Spanish and Quechua and 90% of the population are Roman Catholics. Literacy rate is as high as 91% with slightly better rate for men than women.

After being in political turmoil in recent years, Peru is still deeply divided politically and economically. Minority elite of Spanish descent control political power and most of its wealth, whereas the indigenous populations are largely excluded from both; they make up the many millions of Peruvians who live below the poverty line.

Economic and infrastructure development has largely been neglected and despite a high (4-5%) growth rate and low inflation, unemployment (9.7%) is still rife in the country. The real GDP per capita was US\$ 2,180 in 2000. That year, 10.2% of the economically active population (11.9 million) were unemployed and 50.8% were underemployed(WHO, 2003a). From 1993 to 2000, the per capita social

spending increased from US\$ 91.30 (3.9% of the GDP) to US\$ 180.20 (7.9%). In addition, extreme poverty decreased from 26.8% of the population in 1991 to 14.8% in 2000. However, between 1997 and 2000, the income distributive inequality, expressed by the ratio of the richest quintile to that of the poorest quintile, increased from 4.9 to 7.8.



Figure 6.1: Map of Peru

There has been a gradual increase in the life expectancy at birth from 43.9 to 68.3 years in the last 50 years (WHO, 2005b). Nevertheless, the persistence of inequalities is reflected by the three times higher risk of dying in Huancavelica (13.0 per 1,000) than in El Callao (3.6 per 1,000). Similarly, there is a 21-year difference in life expectancy at birth, which is 56.8 years in Huancavelica and 78.0 years in El Callao. The adjusted estimated communicable disease mortality declined from 247.5 to 146.4 per 100,000 population between 1987 and 1997. However, mortality from cardiovascular diseases and from peri-natal conditions decreased to a lesser extent; in contrast, mortality from external causes and cancers has increased.

6.1.2. Major health problems

Despite a decline in infant mortality rate from 88.2 per 1,000 live births in 1987 to 45.0 per 1,000 during the period 1995-2000, the diseases preventable by immunization, acute respiratory infections, intestinal diseases, meningitis, septicaemia, malaria, and nutritional deficiencies caused 42% of all deaths in children under than 5 years old (2.9 million) (Table 6.2). The risk of dying from

acute diarrhoeal disease, septicaemia and malnutrition is 8-10 times higher among children living in the poorest communities(WHO, 2003a). In 2000, the country had a cumulative total of 11,310 reported cases of AIDS and an estimated 76,000 carriers of HIV. It is estimated that nearly 2.5 and 3.5 million population live in areas of high risk of malaria and dengue fever.

Cardiovascular disease mortality has reduced from 132.7 to 104.9 per 100,000 population in the last 15 years. During the same period, mortality from malignant neoplasm did not change significantly, but the proportion of deaths from cancer increased from 9.0% to 14.2%. Deaths due to violence have declined but the number of road traffic accidents has increased from 52,633 in 1990 to 79,695 in 1999.

6.1.3. Health reforms and organisation

In 1995, the Peruvian government agreed to five health policy guidelines, committing to: universal access to public health services and individual care; modernization of the health sector; re-structuring functions of financing, provision and regulation; prevention and control of priority health problems; and, promotion of healthy living conditions and life styles. During this period, there was a marked and significant increase in public and private expenditures in health. New public funds were mainly targeted towards programmes focussing on primary care and the expansion and rehabilitation of public health infrastructure. However, questions have been asked as to whether the expansion of health infrastructure has helped to enhance equity of access to health services in Peru(Valdivia, 2002).

The Basic Health Programme for All included provision of basic health care packages for children, adolescents, women of childbearing age, and the adult population. The emphasis was on decentralization of basic health care and enhancing capacity of primary care, in particular in areas of higher poverty. The public subsector comprises 51% of the country's hospitals, 69% of the health centres, and 99% of the health posts. The country is carrying out the following priority strategies: 'Stop Tuberculosis' using DOTS (directly observed treatment, short course) and DOTS-Plus; eradication of polio and measles; elimination of neonatal tetanus; Integrated Management of Childhood Illness (IMCI); "Roll Back Malaria"; elimination of leprosy; elimination of *Triatoma infestans* from household environments and interruption of transmission of Chagas' disease through transfusion; elimination of urban canine rabies; surveillance of antimicrobial resistance; safe blood supply; and surveillance, prevention, and control of other emerging and re-emerging diseases.

The national epidemiological surveillance system includes 3,500 notification units. Information on morbidity from hospital care is collated in each facility and

disseminated periodically. The Ministry of Health is responsible for processing mortality information. The public sector institutions organise their services according to the levels of complexity. However, adequate referral mechanisms between the different levels are deficient, health facilities do not share resources, nor are they organised into networks, and the allocation of resources at different levels of complexity is unbalanced. In 2000, the country had 1.2 hospital beds per 1,000 population. Between 1992 and 1996, the number of health professionals increased in all categories: the number of doctors rose from 7.6 to 10.3 per 10,000 population; nurses, from 5.2 to 6.7; dentists, from 0.7 to 1.1; and obstetricians, from 1.1 to 2.1, still maintaining a centralist and inequitable distribution.

6.1.4. TB and its control

Peru is among the 23 countries with the highest diagnosed TB incidence in the world. According to 1999 data, it accounted for 15% of the TB population, but only 3% of the of the general population of the Americas (Suarez et al, 2001). However, the incidence of tuberculosis has been declining in Peru since 1992 (Figure 6.2). The annual risk for acquiring tuberculosis among young children (5-6 years) fell from 2.0-2.5% at the beginning of the 1990s to 0.9% in 1997-1998. Currently, around 155 TB cases per 100,000 population are diagnosed per year (133 pulmonary; 88 with positive smears) (Table 6.1 and Figure 6.3). The incidence of TB does vary depending on the socio-economic status. One study estimated the incidence of TB among the residents of a shantytown in Lima as 364 cases per 100,000 per year (Sanghavi et al, 1998). HIV is far less common (0.56%) than in sub-Saharan Africa but nearly 1.3% of tuberculosis cases are coinfecting with HIV infection. In 17.8% of TB cases, primary resistance to at least one of the anti-tuberculosis drugs exist, while multidrug resistance exists in 3.0 % of cases.

The National TB control programme (NTP) was revised in 1990 and the WHO DOTS strategy was adopted. The programme focused mainly in improving case detection by providing diagnostic facilities at primary care health centres and improving cure rates by providing patient incentives and using local community leaders as health promoting agents (Shin et al, 2004). This contributed to the decline in the incidence of TB and related mortality in the last decade, and put Peru among the three countries that WHO recognised for making most progress in TB control (Wise, 1998). Despite this progress, the incidence of TB remains among the highest in Americas. In the recent 5-6 years, Peru's NTP has suffered due to serious administrative and funding problems in the Ministry of Health. This led to a rapid deterioration in the situation. In 2004, following reorganisation in the Ministry of Health (MoH), a National Sanitary Strategy for the Prevention and Control of Tuberculosis has been created to replace the NTP.

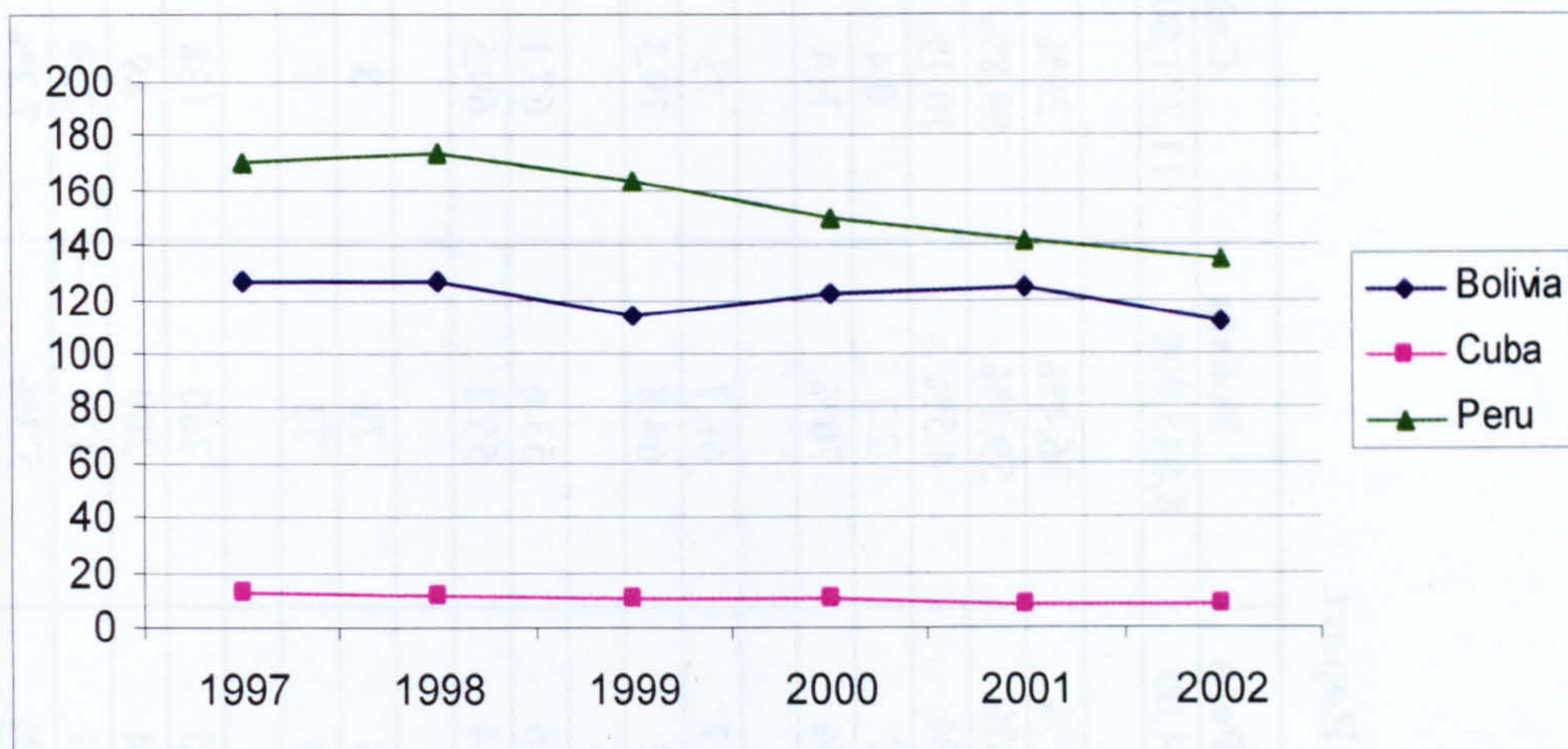


Figure 6.2: A comparison of the annual incidence of TB (per 100,000) of the three Latin American (LAM) countries

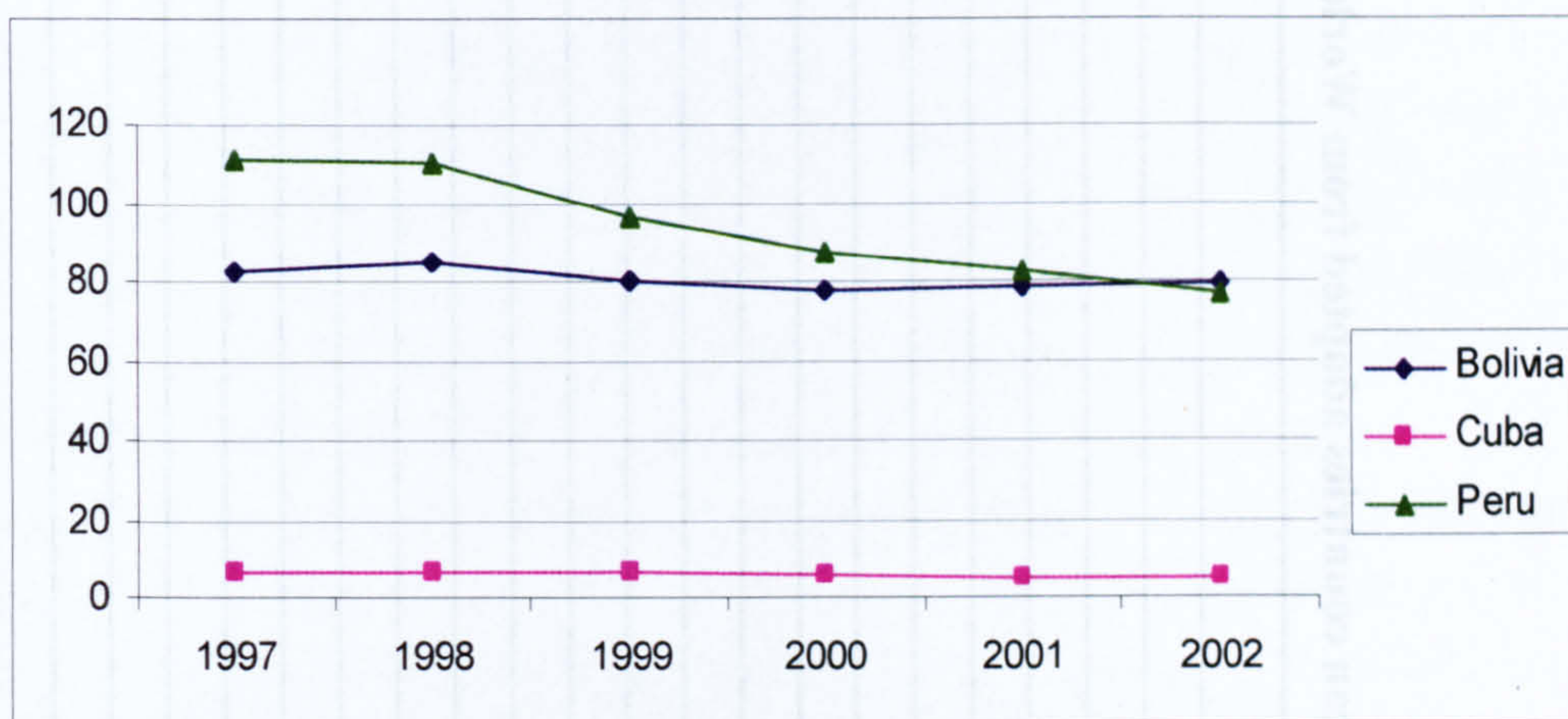


Figure 6.3: A comparison of the annual incidence of smear positive TB (per 100,000) in the three LAM countries

Table 6.1: TB indicators for the three LAM countries

	Number of new TB cases in thousands 2002	Number of new cases of smear positive (Sm+) cases in thousands 2002	DOTS population coverage (%) 2002	DOTS Sm+ detection rate (%) 2002	success rate under DOTS (%) 2001-02 cohort	Primary MDR TB %	TB/HIV %
Bolivia	10,201	6,829	86	75	82	1.2	2.3
Cuba	896	538	100	91	93	0.3	7.0
Peru	36,092	20,533	100	84	90	3	1.3

Table 6.2: Population indices of the three Latin American countries adopted from World Health Report

	Population Indices		
	Peru	Bolivia	Cuba
Total population	27,544,00	8,645,000	11,271,000
Age structure			
0-14 years:	32.1%	36.4%	20%
15-64 years:	62.8%	59.1%	69.8%
65 years and over:	5.1%	4.5%	10.1%
Annual population growth rate	1.7	2.2	0.4
Percentage of population living below poverty line	54%	70%	NA
Life expectancy at birth			
Male	67.7	61.7	75
Female	72	64.8	79.3
Healthy life expectancy at birth			
Male	59.6	53.6	67.1
Female	62.4	55.2	69.5
Child mortality (per 1,000)			
Male	38	78	8
Female	34	73	7
Adult mortality (per 1,000)			
Male	205	260	138
Female	144	209	89
Total health expenditure per capita (Int. \$)	231	125	229
Total health expenditure as percentage of GDP	4.7%	5.3%	7.2%
General government expenditure on health as % of total expenditure on health	55%	66.3%	86.2%
General government expenditure on health as % of total general government expenditure	12.1%	10.3%	11.4%
Private expenditure on health as % of total expenditure on health	45%	33.6%	13.8%
Prepaid plans as % of private expenditure on health	16.1%	7.7%	NA
Out-of-pocket expenditure on health as % of private expenditure on health	81.7%	85.7%	76.8%
HIV/AIDS adult prevalence	0.6%	0.1%	<0.1%

(WHO, 2004)

6.2. Bolivia

6.2.1. Geography, politics and population

Bolivia is considered one of the highest and most isolated countries in South America, was named after independence leader Simon Bolivar. Bolivia got its independence in 1825 from Spanish rule but remained politically unstable for many years subsequent to a series of nearly 200 coups and counter-coups. A democratic civilian government was established in 1982, but the country faces many challenges including, extreme poverty, corruption and disputes with farmers growing coca-the raw material for cocaine.

Bolivia is situated in the central part of South America, west of Brazil (Figure 6.4). The climate varies from cold and dry to tropical and humid depending on the altitude. The Bolivian terrain is also varied with rugged Andean peaks and highland plateau (Alta Plano) on the one hand, to lowlands in the Amazon Basin on the other. Bolivia has the highest point in South America, Nevada Sajama 6,542 m, and shares control of the highest and largest lake in the world, Lake Titicaca at 3,805 m. Bolivia is divided into nine administrative departments. Its government capital is La Paz and its legal capital is Sucre.



Figure 6.4: Map of Bolivia

Nearly 8,645,000 people live in Bolivia (Quechua 30%, mestizo [mixed white and Amerindian ancestry] 30%, Aymara 25%, white 15%), with nearly two thirds of the population comprising of the indigenous people. Around 95% of the population belong to the Roman Catholic faith. Bolivia has three official languages; Spanish, Quechua and Aymara. The national literacy rate is 87% (males slightly higher than females).

Bolivia is one of the poorest countries in South America. The political and economic life is mostly dominated by rich city elites, who are mostly of Spanish ancestry, whereas the majority of Bolivians, mainly indigenous, are low-income farmers, miners, small traders or artisans.

In the 1980s, Bolivia suffered a deep economic recession due to the collapse of the tin market resulting in unemployment and inflation. Successive policy measures resulting in an open market economy and privatisation have helped to curb inflation and restore foreign confidence. However, these policies have also widened the already huge wealth gap and generated great social unrest. In 2000, major civil unrest kept growth down to 2.5%, and Bolivia's GDP failed to grow in subsequent years. Current unemployment rate is around 11.7%.

Bolivia is one of the world's largest producers of coca, the raw material for cocaine. A crop-eradication programme has fuelled tension amongst many of Bolivia's poorest farmers for whom coca is often the only source of income. The country also has the second-largest reserves of natural gas in South America, but a great deal of dissatisfaction exists over the exploitation and the export of the resource.

Bolivia is yet to develop a comprehensive system to record vital statistics. Estimated national under-registration of mortality was estimated at approximately 63%. In a study on mortality in Bolivia conducted in 2000, it was highlighted that leading broad causes of mortality were: diseases of the circulatory system (30.3% of deaths), communicable diseases (12.0%), and external causes (10.7%). Almost 11% of all deaths were classified as non-specific.

6.2.2. Major health problems

Infant mortality has declined steadily over the last decades but less so in rural areas. Among children dying under the age of 5 years, nearly 37% die of diarrhoeal diseases, 20% of pneumonias and 16% due to peri-natal disorders (Table 6.2). Vaccine preventable diseases are gradually declining due to increasing immunisation coverage and inclusion of new regimens. The average annual incidence rate of HIV/AIDS remained around three cases per million population (1990-1997). Sentinel surveillance

detected a prevalence of HIV lower than 1% in pregnant women and 5% in populations with high-risk behaviour. Bolivia had 40,212 cases of cholera between 1991 and 1995, resulting in 814 deaths. Since then, there has been a constant decline in incidence. Malaria and Chagas disease are endemic in the majority of Bolivian territory. However, cases of yellow fever have gradually declined over the last few years. Chronic malnutrition among children under three years exists to a significant proportion, 26% in general, but 36% in rural areas, and in 44% of children with illiterate mothers. The prevalence of anaemia is 67% in the same age group. In the country's main cities, the prevalence of diabetes mellitus is 7.2%. The prevalence of hypertension is 18.6% in the urban adult population.

6.2.3. Health reforms and organisation

National health policies in Bolivia are aimed to develop the health system to ensure universal access to primary health care. The main lever behind the health reforms is the Basic Health Insurance, a tool designed to guarantee all citizens access to preventive and curative health services at a sustainable cost. This system provides health care and nutrition for children under 5 years; immunization and promotion of nutrition; and attention to priority problems, including tuberculosis, malaria, cholera and sexually transmitted infections.

Bolivia's health system comprises public, private and the social security system. The Ministry of Health and Social Welfare is responsible for sectoral regulation, and for issuing and applying policies and national standards. Public health care services are accessed by 43% to 48% of the population and social security funds account for 22% of coverage. Between 20% and 25% of the population, do not have access to health services. The prevention and control of acute respiratory infection, acute diarrhoeal disease, sexually transmitted infections, cervical cancer, other chronic and degenerative disorders, nutritional disorders, and domestic violence is part of the national health care programme. The National Epidemiological Surveillance, set up in 2000, includes mortality, morbidity, nosocomial infections, risk factors, environmental surveillance and basic indicator data. Bolivia has 3,165 health care organisations and 12,554 hospital beds. An imbalance exists between human resources available and the tasks required to solve problems, due to an unusual ratio between administrative and medical staff.

In 1999, 72% of the population had access to potable water services (93% urban; 37% rural) and 61% had access to sanitation and excreta disposal services (79% urban; 33% rural). Bolivia is currently receiving foreign aid through the World Bank and other agencies and investing in improving access to preventative and curative services.

6.2.4. TB and its control

Bolivia ranks amongst the top three countries in Americas for highest incidence of tuberculosis. The incidence has declined at a slower pace than in Peru (Figure 6.2). In 1999, 9,272 tuberculosis cases were reported, 12.6% less than in 1996 (Table 6.1 and Figure 6.3). The number of cases with respiratory symptoms fell by 13% between 1996 (71,959 cases) and 1999 (62,371 cases), and in the same period, the number of diagnostic sputum smears fell by 14.1% (from 133,316 to 114,564).

DOTS strategy was partly adopted in 1994 in some parts but later on fully embraced in most parts of the country. DOTS coverage is around 84% and the case detection and cure rates are still behind many other countries (Table 6.1). Among those who begin treatment, incompleteness rates range from 10% to 12%. The high drop out rate from many parts of the country poses a big challenge for the Bolivian National TB programme (Pelly, Moore, Gilman & Evans, 2004). A study among Aymara speaking communities proposed that hidden costs of treatments, poor access to care, ethnic discrimination, and prior maltreatment by the health system are often the reasons for abandoning treatment (Greene, 2004).

The Bolivian National TB programme aims to detect 80% of new smear positive TB cases and achieve a 90 percent treatment success rate by 2005. However, to meet these objectives, the NTP needs to increase the number of trained health care personnel in the programme, increase awareness through mass-media campaigns to address poor compliance and engage with the private and voluntary sector to deliver DOTS strategy.

6.3. Cuba

6.3.1. Geography, politics and population

Cuba portrays an image of defiance and integrity despite decades of US embargo and the fall of the Soviet communist block. Spanish rule over Cuba began in 1492, and lasted for four centuries. In the early half of the 20th century, Cuba was ruled by various US backed dictators until the last one, Batista, was thrown out by a revolution led by Fidel Castro. Since then Castro has led the country towards an exemplary health and social care aided by subsidies received from the USSR. The real impact of the US embargo was felt after the fall of the Soviet block, and led to rationing of basic commodities. Some recovery has since been made through expansion of tourism, mixed economic reforms and assistance received from Canada and some European countries.

Cuba is a Caribbean island, situated just 100 miles south of Florida Keys (Figure 6.5). Cuba generally enjoys a tropical climate nearly all year round with a rainy season lasting between March and October. However, the eastern coast is vulnerable to strong hurricanes between August and November. Cuban terrain is mostly plain with rolling hills. More rugged mountains are in the southeast region. Among 11 million Cubans, there are 51% mulatto, 37% white, 11% black and 1% Chinese. Cuba's official language is Spanish. Literacy rate is 97% with little gender difference. Before the revolution, 85% of Cubans were Roman Catholic. Cuba has 14 provinces and one special municipality. Sugar, tobacco and coffee remain Cuba's main produce and exports.



Figure 6.5: Map of Cuba

Cuba was in recession after the collapse of the Soviet block. However, the economy has recovered since 1995 and the GDP has grown steadily at an annual average rate of 4.8% from 1994 to 2000. Tourism revenues have become a major contributor towards the national economy. The unemployment rate was 7.5% in 1990, when more than 155,000 workers lost their jobs; however, in 1998 only 3,044 workers were unemployed. The agriculture sector consists of a cooperative sub-sector, a private sub-sector, and a state sub-sector. The state has handed over 100,000 hectares of government-owned land to farmers in the last 6 years to encourage production of crops.

6.3.2. Major health problems

The leading causes of death in 2000 were chronic non-communicable diseases. Coronary heart diseases, malignant neoplasm and cerebrovascular diseases accounted for nearly 60% of all deaths. From 1996 to 2000, there was a 10% reduction in mortality

from heart diseases, while malignant neoplasm increased by 6.6%. Mortality in urban areas was 1.4 times greater than in rural areas. Cuba is now amongst the few places in the world those have introduced a complete ban on smoking in public places.

Heart disease remains the leading cause of death, with 180.3 deaths per 100,000 population in 2000 (Table 6.2). The majority of deaths occur after the age of 65 years. Mortality from cerebrovascular diseases has also risen to 72.9 per 100,000 population. Arterial hypertension constitutes the principal risk factor. Mortality from malignant cancers has increased from 108 to 112 per 100,000 population between 1990 and 2000, affecting more men than women. Among the most frequent cancer sites were trachea, bronchia, and lung (22%) as well as colon and rectum (9%). The prevalence of diabetes mellitus has increased to 23.6 per 1,000 population in recent years. The National Diabetes Mellitus Programme is involved in a variety of activities, including training, and activities to increase the detection of the disease and improve the availability of effective treatment. Suicide deaths were 16.4 per 100,000 population. For older people, Cuba provides community services through a comprehensive programme, oriented towards health promotion. There are also grandparents' homes, which serve more than 60,100 older people. Cuba has a very effective malaria control programme in place. The National Immunization Programme protects against 13 diseases. Vaccination coverage is higher than 95%. Cuba produces vaccines against meningitis B and C and exports these to other Latin American countries. However, mortality from influenza and pneumonia remain among the five leading causes of death in children and in the general population. Since 1997, the flu vaccine has been administered to all older persons as well as to immuno-compromised patients. In Cuba the AIDS/HIV epidemic remains a problem in certain high risk groups. Nevertheless, all receive treatment free of charge. The annual incidence of AIDS ranged between 8.9 in 1996 to 15.1 per 100,000 of population in 2000. Iron deficiency anaemia is the most frequent nutritional problem in Cuba, affecting 23% of pregnant women in their third trimester of pregnancy and 46% of children between 6 months to 2 years of age in 2000.

6.3.3. Health reforms and organisation

Since the revolution, the government has provided generous resources to the health system, partly protecting it from the recession in the 1990's and resulting in low child mortality and high life expectancy (Garfield, 2004). The US embargo raised the cost of medical supplies and food. However, rationing, universal access to primary health care, a highly educated population, and preferential access to scarce goods for the

vulnerable population helped protect most Cubans from what otherwise could have been a health disaster (Garfield & Santana, 1997).

The Cuban Ministry of Public Health's policy is based on increasing the efficiency and quality of health services, ensuring the sustainability, and reducing health inequalities between regions and population groups. The policy gives high importance to health promotion and disease prevention activities, decentralization, inter-sectoral collaboration, and community development. Current government health strategy aims to strengthen primary care and improve services provided in secondary care. The strategy for strengthening primary health care (PHC) aims to improve the capacity of family medicine clinics and polyclinics. Health of mothers, children and older people is a high priority in the health sector. The health system is structured in three levels that correspond to the administrative subdivisions of the country: national, provincial, and municipal. The Ministry of Public Health is responsible for enforcing state policies on health protection, ensuring compliance with regulatory policies on research, introduction of health technologies, and regulation and quality control of pharmaceutical products, cosmetics, foods, chemical products, and medical equipment and devices.

The primary health care system consist of 31,000 physicians and nurses, working in a network of 442 polyclinics, 64 rural hospitals and some 22,000 family medicine clinics. Aproximately 99% of Cubans are covered by the health care system, which addresses needs of individuals and families throughout the life cycle. Cuba has 58.2 physicians per 10,000 population in 1999. As a reflection of decentralisation and the strengthening of primary health care the central government's share in the distribution of expenditure on public health has declined.

6.3.4. TB and its control

Cuba remains among one of the countries with the lowest TB incidence countries in the world and represents a good example of how it is possible to control tuberculosis effectively, despite few resources, by applying internationally accepted control strategies and by giving adequate support to the programme through political commitment (Marrero, Caminero, Rodriguez & Billo, 2000). Cuba's national TB control programme was first established in 1964 and was instrumental in the rapid decline of the incidence of tuberculosis at an average rate of 4% per year (Gonzalez et al, 2000) (Figure 6.2). The incidence rates of all tuberculosis types declined from 16.4 in 1995 to 12.0 per 100,000 persons in 1999 with an annual reduction of 5% (Table 6.1 and Figure

6.3). PTB incidence rate was reduced from 15.1 in 1995 to 10.4 in 1999, whereas extra PTB increased from 1.3 to 1.6 in the same period(Sevy Court et al, 2003).

Of all new cases, 40-50 % patients were diagnosed at polyclinics. Amongst these, 67.6% were diagnosed on the basis of positive smears, 15.2 % on positive cultures and 13.8 % on clinical and X-rays evidence only(Sevy Court et al, 2003). The average delay between onset of symptoms and final diagnosis improved from 42 days in 1995 to 28.6 days in 1999(Sevy Court et al, 2003). While mortality remains below 1 per 100,000, the incidence varies within different municipalities, depending upon the socio-economic status and overcrowding level(Molina, I, Lopez & Alonso, 2003). The cure rate is 92% and BCG vaccination coverage of newborns is 99%. In 7% of cases during 1986-1999, there was an association of HIV infection and tuberculosis.

The National TB programme is fully integrated in the National Health system and adhere to the same policy. However, it does have some complementary actions: the search and diagnosis of tuberculosis through microscopy and cultures in persons suffering from respiratory symptoms for more than 14 days who present to health services; follow up of high risk groups; chemotherapy delivered as directly observed therapy (DOTS) for new cases, and DOTS Plus in case of multi-drug resistant tuberculosis; and BCG vaccination of all new-borns and delivering of chemoprophylaxis to contacts of smear or culture positive cases.

Chapter 7 Study sites

This study is conducted in three countries at four different sites. Two of these sites were in Cuba (one urban, one semi-urban) and one each in Bolivia (partly rural and partly urban) and Peru (urban). The selection criteria have been discussed previously in the methods section. This section provides details of the study sites. It provides some key TB indicators collected by the respective National TB programmes in recent years (2002-03) for these districts. It discusses the organisation of the health service to deliver care to these patients with suspected tuberculosis in these districts. It also describes the typical pathway of patients with suspected TB going through the health system.

7.1. Peru

7.1.1. Study sites and TB indicators

This investigation was conducted in the district of San Juan de Lurigancho in northern Lima. Canto Grande is one of several health networks within this district and consists of 15 primary level health centres, and one secondary level centre. It is a densely populated, underprivileged urban area with a population of approximately 470,000 inhabitants. According to the Peruvian National TB Programme, in 2002, 179/100,000 people developed tuberculosis in Canto Grande, which is much higher than the national average (121.2/100,000). Eight health centres from Canto Grande agreed to take part in the study. TB indicators from these centres are presented in Table 7.1.

7.1.2. Current service provision in selected sites

7.1.2.1. Structure

The health centres included in the study have a variable workload and capacity. All but one of the centres have laboratory facilities to conduct TB smear examination and only the secondary level health centre (Canto Grande health centre) has culture facilities. Two centres have facilities to conduct chest X-rays. Canto Grande health centres also have a chest specialist on site, who is also responsible for seeing referrals from neighbouring health centres (Table 7.2).

7.1.2.2. Process

The NTP defines all patients with cough and expectoration for more than 2 weeks as 'Sintomáticos Respiratorios' (SR). This section describes the usual SR patient

journey through the health system in Canto Grande. SR patients usually report to the primary health care centre, where they are attended by either a NTP technician or nurse (the person responsible for initiating screening of SR and for requesting a sputum smear) or by a physician (Figure 7.1). In both situations, the first set sputum smears are requested and the patient is asked to report to the physician. If the patient has a positive smear result, he will be seen by the clinicians and registered by the NTP to commence TB treatment promptly. If the first set of smear results is negative, the patient may or may not report to the physician for an evaluation. If the patient does report to the physician, depending on the clinical condition of the patient, the physician may request a second set of sputum tests after a course of antibiotics of 5 to 10 days. The physician may also request a chest X-ray or can just wait and monitor. If the chest X-ray and the clinical presentation suggest smear negative pulmonary TB, the physician makes a diagnostic decision and consults with the chest specialist in order to get the authorisation to commence TB treatment for the patient. The chest specialist can refute the diagnosis of the first physician, but this occurs on very rare occasions. The patient can be referred to a hospital by the chest specialist in order to have access to more sophisticated diagnostic tools (e.g. bronchoscopy). A sputum culture is requested before a smear negative patient starts TB treatment. For SR patients, sputum smears and cultures are free; nevertheless, they have to pay for the first medical consultations, the chest X ray and any antibiotics prescribed. The majority of patients with smear negative TB are actually diagnosed by the general physician at the first level, except for patients who seek medical care directly at a hospital and have their first consultation with a chest specialist (Figure 7.1).

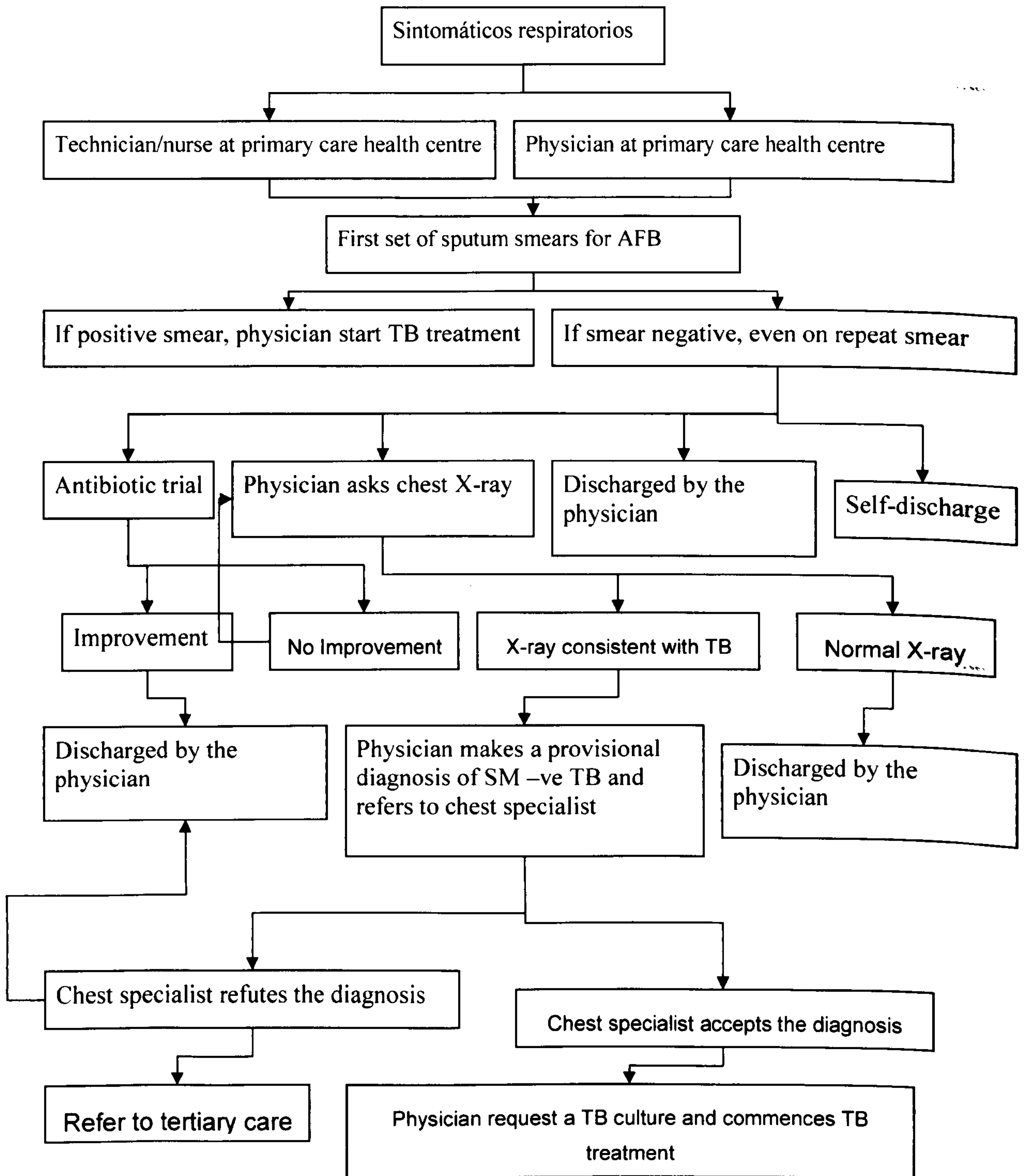


Figure 7.1: A Patient's journey through the health system in Canto Grande, Lima

Table 7.1: TB indicators from participating health centres from Canto Grande district in Lima, Peru (2002)

Health Centre	PTB suspects (SR)	Smear +ve PTB	Smear +ve PTB/SR	Smear -ve PTB	Smear -ve culture +ve PTB	Sm-ve Cu+ve/Sm-ve PTB	Extra pulmonary TB	All TB	Sm-ve PTB/PTB	Sm-ve PTB/All TB	Extra PTB/All TB
Canto Grande	2696	110	4.1%	11	2	18.2%	30	151	9%	7%	20%
Huascar II	1111	59	5.3%	10	2	20.0%	12	81	14%	12%	15%
Proyectos Espaciales	633	25	3.9%	6	3	50.0%	2	33	19%	18%	6%
Santa Maria	314	28	8.9%	3	1	33.3%	3	34	10%	9%	9%
Jaime Zubieta	1111	52	4.7%	10	0	0.0%	13	75	16%	13%	17%
Cruz de Motupe	921	45	4.9%	5	0	0.0%	17	67	10%	7%	25%
J.C. Mariategui	967	67	6.9%	7	2	28.6%	20	94	9%	7%	21%
Ganimedes	1254	54	4.3%	22	6	27.3%	8	84	29%	26%	10%
Total	9007	440	4.9%	74	16	21.6%	105	619	14%	12%	17%
Canto Grande District	13032	726	5.6%	109	27	24.8%	169	1004	13%	11%	17%

Table 7.2: A general overview of the service provision at the participating study sites in the three countries (2002)

	Lima, Peru	Cochabamba, Bolivia (urban)	Cochabamba, Bolivia (rural)	Havana, Cuba (urban)	Las Tunas, Cuba
Study area	Canto Grande	District Metropolitano Sur	District Quillacollo	Municipalities : Havana Vieja, Marianao, 10 de Octubre	Municipalities: Puerto Padre, Majibacoa, Las Tunas
Population covered	469,072	336,286	260,312	699,927	318,124
Health facilities reporting to NTP	15 primary care health centres. One also provides secondary level care	9 primary care health centre. One also provides secondary level care	8 primary care health centres. One also provides secondary level care	17 'Policlínicos': primary care health centres with some specialist support	10 'Policlínicos': primary care health centres with some specialist support
with AFB lab	12	4	6	17	10
X-ray facility	2	2	1	17	8
General practitioners	75	14	24	1591	862
Chest specialists	1	1	1	1 (dedicated to TB control programme)	2
Radiologists	0	0	0	17	2
Culture lab in (or from) study area	1 in study area	1 (reference lab outside study area)	0	3 (reference lab in Havana)	1
Other/comment		60% of all patients with possible TB in the area attended by one health centre	52% of all patients with possible TB attended by one health centre	<i>Commission of Diagnosis</i> of smear negative TB (one in each province) to help in the diagnosis of SN PTB	<i>Consultation of Classification</i> for the diagnosis of TB and with persistent symptoms referred to the <i>Commission of Diagnosis</i>

Table 7.3: Critical points in the SR patient's journey through the health systems in the selected sites

	Peru	Bolivia, urban	Bolivia, rural	Cuba, urban	Cuba, rural
Decision to do AFB screening	Any health worker; Patient himself	Admission nurse, physician	Admission nurse, physician	physician	physician
Number of slides to find 1 positive* (AFB tot/AFB+)	16	13	14	200 (patients, not slides)	
Direct costs to the patient	- Consultations with physician - Any examination, but AFB - Any treatment but TB			None	
Type of clinician to first see 'SR'	Majority: general physicians	60% of SR in the area attended in one health centre by chest specialist ; other centres by general physicians	52% of SR in the area attended by chest specialist in one health centre. Others by general physicians	general physicians	general physicians
Diagnosis SN TB	Majority : GP	All : Chest specialist	All: Chest specialist	In theory, all by Commission of Diagnosis of smear negative TB	Commission for Diagnosis of smear negative TB
Decision to treat	Chest specialist	Chest specialist	Chest specialist	In practice some by chest specialist	But first to Consultation of Classification

7.2. Bolivia

7.2.1. Study sites and TB indicators

In Bolivia, this study was conducted in the two districts of Cochabamba, district Metropolitano Sur (urban) and district Valle Bajo (rural) with a population of 329,787 and 283,406 respectively. The smear positive TB case notification rate in the urban and rural district was 70.7/100,000 and 60.3/100,000 respectively, in 2002. Amongst 17 health facilities in both districts, eight health centres took part in the study, four from each district. The basic TB indicators are described in Table 7.4 for these centres.

7.2.2. Current service provision in selected sites

7.2.2.1. Structure

Metropolitano Sur has nine primary care health centres, one of which also provides secondary level care (Cochabamba health centre). The only chest specialist in the area is based in this centre (Table 7.5). There are no facilities for TB sputum culture within the district, but the reference laboratory is only 2 kilometres away from Cochabamba health centre. This reference laboratory also performs sputum AFB screening for out-patients for this centre. Cochabamba health centre covers 35% of the district population, but handles 60% of registered 'SR' patients, 77% of AFB slides, and 49% of new TB patients enrolled in the district. It generally carries a good reputation and is located near the biggest city market.

Valle Bajo district has eight health facilities, of which Quillacollo health centre, with the only X-ray equipment in the area, provides both primary and secondary care. Quillacollo health centre covers 40% of the district population, but handles 52% of registered 'SR', 51% of AFB slides, and 44% of new TB patients enrolled in the district. The closest culture lab is in Cochabamba (15 km from Quillacollo health centre).

Table 7.4: TB indicators from participating health centres in Cochabamba, Bolivia (2002)

Health Centre	PTB suspects (SR)	Smear +ve PTB	Smear +ve PTB/SR	Smear -ve PTB	Smear -ve culture +ve PTB	Sm-ve Cu+ve/Sm-ve PTB	Extra pulmonary TB	All TB	Sm-ve PTB/PTB	Sm-ve PTB/All TB	Extra PTB/All TB
Cochabamba	1541	109	7.1%	4	3	75.0%	44	157	3.5%	2.5%	28.0%
Alalay	232	30	12.9%	1		0.0%	4	35	3.2%	2.9%	11.4%
S Pagador	271	30	11.1%	3	1	33.3%	1	34	9.1%	8.8%	2.9%
Cerro Verde	155	12	7.7%	0	missing	missing	4	16	0.0%	0.0%	25.0%
Total	2199	181	8.2%	8	4	50.0%	53	242	4.2%	3.3%	21.9%
Metropolitano Sur District Total	2199*	233	10.6%	13	6	46.2%	77	323	5.3%	4.0%	23.8%
Quillacollo	1191	64	5.4%	2	2	100.0%	21	87	3.0%	2.3%	24.1%
Vinto	298	37	12.4%	0			2	39	0.0%	0.0%	5.1%
Colcapirua	206	17	8.3%	1	1	100.0%	15	33	5.6%	3.0%	45.5%
Mallco Rancho	211	10	4.7%	0	missing	missing	1	11	0.0%	0.0%	9.1%
Total	1906	128	6.7%	3	3	100.0%	39	170	2.3%	1.8%	22.9%
Valle Bajo District Total	2308	171	7.4%	6	4	66.7%	43	220	3.4%	2.7%	19.5%

*data only available from the four centres included in the study.

Table 7.5: Health facilities at the participating health centres in Cochabamba, Bolivia (2002)

Centre	Population	Resources					Laboratory workload (AFB screening)		
		General physicians	Specialists	Nurses	Personnel within NTP	Consultation rooms	Slides	Slides +	Slides /Slides
Cochabamba	115,589	1	11	21	4	9	4262	347	8%
Alalay	23,337	2	1	4	1	3	635	58	9%
S. pagador	31,648	3	2	7	3	3	416	35	8%
Cerro verde	46,531	2	2	5	1	3	221	17	8%
Quillacollo	114,175	3	20	25	5	6	3018	223	7%
Vinto	34,620	2	7	11	4	3	783	94	12%
Colcapirua	44,464	5	3	8	0	3	538	26	5%
Mallco Rancho	12,760	4	8	11	3	6	560	45	8%

7.2.2.2. Process

In Bolivia, patients coughing for two, or more than two weeks are considered to be TB suspects or 'Sintomáticos Respiratorios' (SR). In the health centres participating in the project, SR patient are generally referred by the admission secretaries to the clinician (Table 7.3 & Figure 7.2). However, in secondary care health centres majority of SR patients are seen by a chest specialist, as opposed to general practitioners. According to the NTP guidelines, health professionals are expected to request three sputum samples for all SR patients. In practice, sputum examination is requested either by the NTP nurse (who works closely with the clinician), or by the clinician himself. Patients are expected to pay a consultation fee, the cost of medicines prescribed and radiological investigations. However, the AFB sputum test is free of charge. There are no clear national guidelines on how to manage these 'SR', once the AFB results are negative. Patients are often given a trial of antibiotics, offered an X-ray or both. In case of suspicion of SN-PTB based on an abnormal chest X-tray, cultures are expected to be requested. However, treatment should start without waiting for the culture result if the

suspicion is strong. The NTP advises referral of such patients to a chest specialist and discourages general practitioners from diagnosing smear negative PTB on their own.

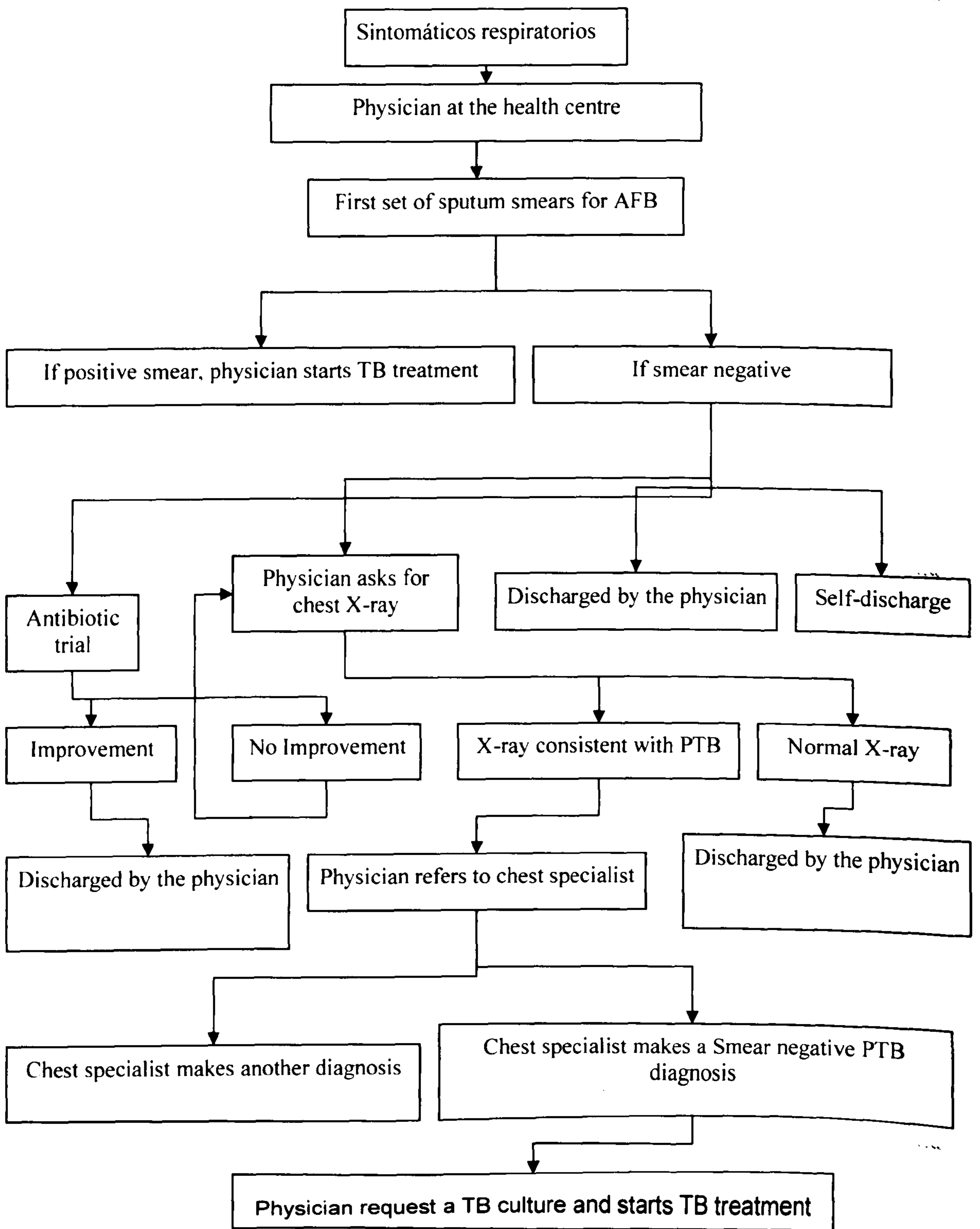


Figure 7.2: A typical SR patient's journey through the health system in the participating centres in Bolivia

7.3. Cuba

7.3.1. Study sites and TB indicators

This study was conducted in the selected municipalities of two Cuban provinces, Havana (urban) and Las Tunas (rural). The city of Havana is the capital of Cuba. It covers an area of 739 km², has a population of 2.2 million (2,977 per km²) and is divided into 15 municipalities. The province of Las Tunas is situated in the east of the country, at 718 km of Havana. Las Tunas was included in the current investigation because it is less developed and has rural areas that are representative of the agriculture areas in the mountains of Cuba. It covers an area of 6,375 km² and the population is estimated at 530,538 inhabitants (80.5 inhabitants per km²). The province is divided into 8 municipalities.

The two municipalities that participated in this project Havana Vieja and Las Tunas, cover a population of 93,575 and 184,703 respectively. The smear positive TB case notification rates in the Havana and Las Tunas were 5.5/100,000 and 5.7/100,000 respectively, in 2002. Five health zones took part in the study from each municipality. The basic TB indicators are described in Table 7.6 for these centres.

7.3.2. Current service provision in selected sites

7.3.2.1. Structure

Each province has a reference laboratory for tuberculosis located in the provincial centre of hygiene and epidemiology. Both provinces have general hospitals, and paediatric and surgery clinics at university centres. Each municipality has a municipality hospital. Each municipality is further divided into health zones; each zone has a polyclinic that is responsible for the management and the organisation of health services in these health zones (1 polyclinic per 25,000 inhabitants). Each health zone is further divided into "territorios-poblaciones" of 600 to 700 inhabitants that are covered by general practitioners and nurses.

Each municipality included in this study has its own network of general practitioners. The polyclinic has specialist consultations and most of them have a clinical laboratory and radiology facilities. The polyclinic sends sputum samples for culture and quality control to the municipality laboratory at the municipality centre of hygiene and epidemiology or to the provincial reference laboratory for tuberculosis.

The Havana Vieja municipality comprises of 172 general practitioner clinics, also known as 'clínico medico familia' (CMF) and five polyclinics. The Las Tunas

municipality comprises of 260 CMFs and five polyclinics. Laboratory facilities exist in all polyclinics. However, X-ray facilities are only available in three polyclinics in Havana Vieja and four in Las Tunas (Table 7.7). In Havana Vieja, a commission for the decision on the diagnosis and management of smear negative SR patients exists at the provincial level. Similar referral systems exist in Las Tunas, where patients with negative smears are expected to be referred to the secondary level, the provincial hospital in Las Tunas for expert opinion.

Table 7.6: TB indicators from the participating health zones in Cuba (2002)

Health Centre	PTB suspects (SR)	Smear +ve PTB	Smear +ve PTB/SR	Smear -ve PTB	Smear -ve culture +ve PTB	Sm-ve Cu+ve/Sm-ve PTB	Extra pulmonary TB	All TB	Sm-ve PTB/PTB	Sm-ve PTB/All TB	Extra PTB/All TB
Diego Tamayo	490	2	0.4%	1	0	0.0%	3	6	33.3%	16.7%	50.0%
Tomás Romay	452	2	0.4%	2	1	50.0%	0	4	50.0%	50.0%	0.0%
Antonio Guiteras	146	0	0.0%	0	0		0	0			
Angel A. Ceballo	735	5	0.7%	0	0		0	5	0.0%	0.0%	0.0%
Robert M. Zulueta	213	3	1.4%	1	0	0.0%	0	4	25.0%	25.0%	0.0%
Habana veija	2036	12	0.6%	4	1	25.0%	3	19	25.0%	21.1%	15.8%
Province Habana*		142		45	18	40.0%	25	212	24.1%	21.2%	11.8%
Pity Fajardo	538	3	0.6%	1	0	0.0%	1	5	25.0%	20.0%	20.0%
Aquiles Espinosa	512	4	0.8%	0	0		1	5	0.0%	0.0%	20.0%
Gustavo Aldereguía	478	2	0.4%	0	0		1	3	0.0%	0.0%	33.3%
Guillermo Tejas	248	3	1.2%	1	1	100.0%	1	5	25.0%	20.0%	20.0%
Bartle	67	0	0.0%	0	0		0	0			
Las Tunas	1843	12	0.7%	2	1	50.0%	4	18	14.3%	11.1%	22.2%
Province Las Tunas*		28		11	7	63.6%	7	46	28.2%	23.9%	15.2%

*The figures for numbers of SR patients in the two provinces are not available

Table 7.7: Health facilities at the participating health zones in Cuba (2002)

Health zones	Population	General Practitioners clinics	Total number of doctors	Laboratory for AFB microscopy	X-ray facilities	Maximum distance between population and health facilities	
						CMF	Polyclinic
Havana Vieja							
Diego Tamayo*	14148	28	66	Yes	No	200 m	800 m
Tomás Romay*	28349	42	119	Yes	Yes	200 m	700 m
Antonio Guiteras*	7662	15	87	Yes	Yes	300 m	400 m
Angel A. Aballí*	26994	45	91	Yes	No	100 m	800 m
Robert M. Zulueta*	19422	32	72	Yes	Yes	500 m	2 km
Las Tunas							
Piti Fajardo	53590	75	149	Yes	yes	260 m	15 km (Zone Rural)
Aquiles Espinosa	44350	61	133	Yes	Yes	500 m	6 km (Zone Rural)
Gustavo Aldereguia	42502	60	117	Yes	Yes	100 m	5 km (Zone Urban)
Guillermo Tejas	33262	47	136	Yes	No	1 km	3 km (Zone Sub-Urban)
Bartle	11087	17	25	Yes	Yes	200 m	5 km (Zone Rural)

7.3.2.2. Process

Most SR patients are seen by general practitioners at CMFs, where such patients are screened for PTB by smear testing and cultures. Up to one-third of SR patients are also seen by the doctors in polyclinics directly, but this is rare. Once the smear is negative, and the symptoms persist for more than three weeks despite antibiotics, patients are expected to have an X-ray. The case notes of such patients along with X-rays are expected to be brought in front of a *Commission of Diagnosis* at the provincial level, where a decision is taken about the diagnosis or further course of action. Such patients are expected to be followed up still at the CMF level. In Las Tunas, patients with negative smears and persisting symptoms are referred to the chest specialist at the secondary hospital for "*Consultation of Classification*" (Figure 7.3). The diagnosis of smear negative tuberculosis is made by a provincial "*Commission of Diagnosis*".

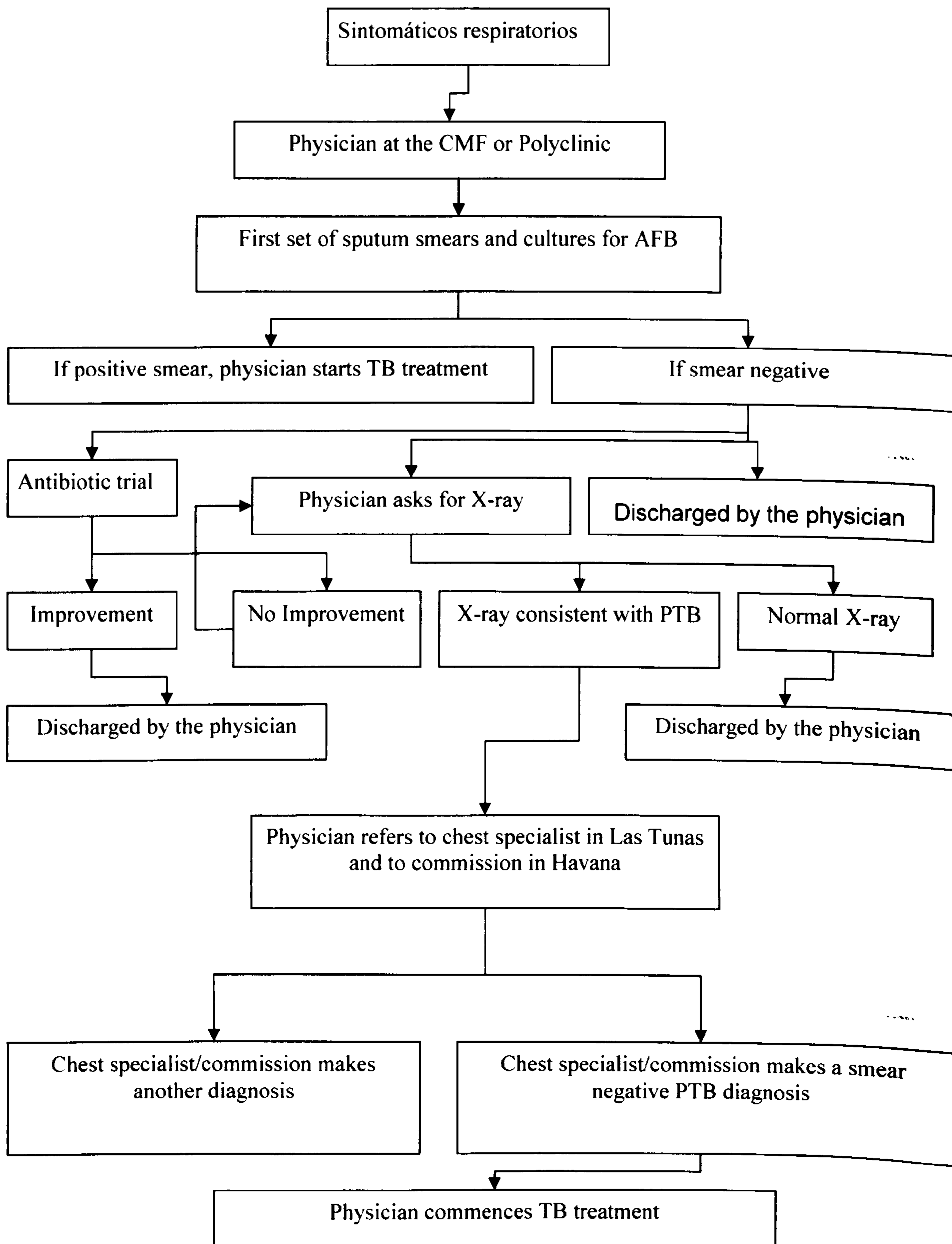


Figure 7.3: A typical SR patient's journey through the health system in the participating centres in Cuba

Chapter 8 Implementation of clinical audit

This section describes the process of implementing clinical audit in the four study sites. It explains the development of audit committees and their functioning in agreeing quality standards, analysing problems and generating solutions to match their performance against quality standards. The actual results obtained during the audit cycles will be discussed in the following chapter. A discussion and a critique of the audit process will also be presented in subsequent sections.

8.1. Peru

8.1.1. Development of the audit committee

In April 2003, a workshop was held in Lima on clinical audit, which was attended by health professionals from all participating health centres in the project. During this workshop, a multi-professional audit committee evolved, comprising of volunteer representatives from all participating health centres. The committee agreed on the following terms of reference:

- To agree on standards and criteria for clinical audit
- To guide the process of data collection
- To receive audit results, conduct a problem analysis and propose solutions for improvement
- To develop and implement an action plan in order to stimulate change

The audit committee consisted of nine members (Table 8.1). Eight (six physicians and two nurses) were representing their respective health centres and one member from the research team acted as a chairperson/facilitator. The committee agreed to meet on a monthly basis in the first instance for approximately three hours on each occasion. Special permission was granted by the district authorities to attend these meetings during normal working hours. In one of the first few meetings, the name 'audit committee' was changed to 'the quality improvement committee'. However, for the purpose of consistency, this thesis will still refer to it as the audit committee.

8.1.2. Selection of the criteria and standards

In the first meeting in May 2003, the audit committee examined the current NTP guidelines for the diagnostic management of SR and discussed the possibility of developing a diagnostic algorithm (from which the standards and criteria could be derived) for the purpose of audit. In a subsequent meeting in August 2003, the audit

committee attempted to identify local problems in the diagnosis of SR patients and proposed quality criteria and standards for auditing. In a follow up meeting in October 2003, the audit committee assessed all proposed criteria against the evidence base, measurability, health impact and feasibility of change (see methodology chapter). By using a scoring system based on the above assessment, the audit committee short-listed and refined these standards (Table 8.2 and Table 8.4). Standard 4 was dropped after the first set of data collection due to very small numbers. However, two new standards 4a and 4b were introduced by the audit committee at this stage.

Table 8.1: Audit committee in Lima, Peru

Number of health centres involved	8
Number of members in the committee	8+1 (facilitator)
Number of members in a position to implement changes (working in health centres)	8
Timing of meeting	3 hours (working hours) every month
1st cycle	October 03 - March 04 April 04 - September 04
2nd cycle	April 04 - September 04 October 04 - March 05
3rd cycle	October 04 - March 05 April 05 - September 05
Attendance of those in a position to implement change (average, %)	67%

8.1.3. Data collection

The next task for the committee was to guide the data collection process. In principle, routine data collection systems were used where available. These included case notes, SR registers, laboratory registers and TB registers. However, in order to measure certain criteria, it was necessary to produce a separate inquiry tool, which was then incorporated within the routine system in order to reduce bias. A stamp was developed to facilitate doctors in recording patient clinical information in a systematic way, and to allow measurement of their performance against the agreed standards. The inquiry tool (stamp) was first piloted and then used in routine practice. At initial analysis, it was shown to be in use in the majority (87%) of cases. Data collection started in December 2003, after agreement on the quality standards. Data were collated in pre-designed Excel worksheets. The first set of data were analysed and presented to the audit committee in April 04.

Table 8.2: Agreed criteria (standards) in Lima, Peru

	Criteria	Standard	Numerator	Denominator
1	Proportion of patients having smear examination for AFB (registered as SR) who comply with the definition of SR	85%	Number of patients coughing for two or more than two weeks (14 or more days) who are requested to have a smear examination	Number of patients who are requested to have smear examination
2	Proportion of patients with SN PTB, whose cultures are reported back in the treatment register	70%	Number of SN PTB patients who had culture results entered into treatment register	Number of patients with SN PTB
2a	Proportion of patients with SN PTB, whose cultures are requested by doctors	70%	Number of SN PTB patients who had cultures requested by doctors	Number of patients with SN PTB
2b	Proportion of patients with SN PTB, whose culture results are entered in the laboratory register after being requested by doctors	70%	Number of SN PTB patients who had culture results entered in the laboratory register	Number of SN PTB patients who had cultures requested by doctors
2c	Proportion of patients with SN PTB, whose culture results are entered in the treatment register after being entered in the laboratory register	70%	Number of SN PTB patients who had culture results entered into the treatment register	Number of SN PTB patients who had cultures results in the laboratory register
3	Proportion of SR who were not asked to have X-rays at the first appointment	70%	Number of SR patients (without previous X-ray) not being requested to have X-ray at their first visit	Number of SR patients at their first appointment (without previous X-ray)
4*	Proportion of SR diagnosed to have other pathologies other than TB based on chest X-ray findings who have chest X-rays consistent with TB	<10%	Number of SR having chest X-ray consistent with TB but diagnosed to have pathologies other than TB	Number of SR patients with chest X-ray consistent with TB
4a**	Proportion of SR patients being followed up at their second appointment who had a smear request at their first visit	70%	Number of SR patients returning for their second appointment	Number of SR patients with smear for AFB requested at their first appointment
4b**	Proportion of SR patients returning for their follow up appointment with a smear result	90%	Number of SR patients with smear result at the second appointment	Number of SR patients returning for their second appointment

*Standard 4 was abandoned after the first data collection due to very small numbers

**Standard 4a and 4b were introduced at the second data collection stage.

8.1.4. Issues related to data collection, collation, analysis and validation

The issues relating to data collection, collation, analysis and validation were discussed by the committee and possible solutions were provided (Table 8.5).

8.1.5. Problem analysis, recommendations and action planning

Subsequent to data presentation, the audit committee were able to use a systematic method of problem analysis (Table 8.6 and Table 8.7). Solutions were arrived at and a detailed action plan was prepared (Table 8.3). Sub analysis of standard two was useful in understanding the level of problems and developing effective solutions. The audit committee discussed standards where little improvement was made in the last six months. Members discussed various barrier and limitations in improving performance against those standards. The committee also discussed standards where significant improvement was made, and decided to continue measuring it in subsequent cycles. Data were subsequently collected, analysed and presented to the audit committee again in November 2003, thereby completing the first full audit cycle. The audit committee met eight times during the full audit cycle.

Table 8.3: Recommendations after the first audit cycle

Standard 1: To have educational sessions for staff in different health centres. To use posters, reminders and leaflets for local staff and patients in different places. These educational sessions and materials explained the appropriate use of the smear test

To have posters in other community centres outside the health sector to raise awareness about who requires a smear examination

Standard 2: To introduce a new register for the culture of smear negative TB patients recording the quality of the sample. To use diagrams and charts to help remind laboratory technicians about good practice in culture examination

Standard 3: Education and feedback to the doctors. Educational posters for patients to explain the use of X-rays

Standard 4: Education and feedback to doctors and laboratory staff. Poster and leaflets for patients to emphasise the importance of follow up and smear results

Table 8.4: The process of standard setting in Lima, Peru

Criteria (Standards)	Evidence base	Health impact	Feasibility of change	Measurability
1. Proportion of patients having smear examination for AFB (registered as SR) who comply with the definition of SR (85%)*	According to the perceptions of health professionals on the committee, a significant proportion of patients registered as SR, and having AFB microscopy, do not comply with the definition of SR. There is evidence that there is little health gain in screening people with cough less than 2 weeks	Current practice results in an inefficient system resulting in loss of already limited resources	A number of patients coming to health centres have smear examination, either through self or health professional referral. There is an extra pressure from the NTP to do more smear tests to meet their targets, which may resist change; however, a demonstration of inefficiency in the system may itself be the driver for change	Currently these measurements can be made from another study conducted in five centres in Canto Grande. However, later, an alteration in the laboratory form and the SR register has been proposed to record the duration of cough. Since many of the patients do not come to see the doctor, this standard cannot be measured from the clinical case notes
2 (a, b, c). Proportion of patients with SN PTB, whose cultures are requested (by the doctor), taken (in the laboratory of health centre), analysed (in the hospital laboratory) and reported back in the treatment chart (70%)	The culture results provide feedback to help doctors to improve their diagnostic skills, provide an opportunity for requesting sensitivities if poor clinical response in culture positive patients, and make contact tracing more vigilant in culture positive patients	The health impact is limited to a small proportion of patients rather than the majority of SR patients	Once the level of missing information is identified, it will be easier to identify possible reasons for failure to comply with this standard	The measurement will be done by comparing the treatment record with the registers of the secondary laboratory, and the health centre laboratory. The sample size for this small group of patients may be an issue in demonstrating change
3 Proportion of SR who are not asked to have X-rays at the first appointment (70%)**	There are WHO guidelines, which suggest that X-ray should only be considered, once the two smears are negative, and patient has failed to respond to a course of antibiotics. There is some evidence that X-ray at first appointment deters microscopy at the first level reducing the specificity of the diagnosis	This avoids unnecessary X-rays at the first appointment and allows health professionals to focus on smear examinations and antibiotic trials	There is a possibility of changing the behaviour of health professionals. However if there is lack of consensus among professionals on this issue, it may create difficulties	This standard cannot be measured from the routine data collection. A new stamp is used at every new appointment, which will help in recording this information

<p>4. Proportion of SR diagnosed to have other pathologies by doctors in health centres based on chest X-ray findings who have chest X-rays consistent with TB (validated by chest specialist) <10%***</p>	<p>The evidence suggests that the validity of X-ray findings and feedback from a specialist can improve the diagnostic yield of X-ray, with an impact on improvement of patient outcomes</p>	<p>Diagnostic accuracy for SR patients with abnormal radiological signs on chest X-ray</p>	<p>Patients who are diagnosed to have SN TB on the basis of X-ray findings are reviewed by the chest specialist before or soon after the commencement of the treatment. However, feedback and training on diagnosis of other pathologies is not available, which can result subsequent to measuring this standard</p>	<p>The stamp will help in recording the radiological findings and other diagnoses. X-rays of such patients will be collected and validated by the chest specialist</p>
<p>4a and 4b. Proportion of SR patients being followed up at their second appointment with a smear request at their first visit</p>	<p>According to WHO guidelines, all patients with smear tests should report back for follow up as nearly half of patients with PTB may have negative smears</p>	<p>Potential huge impact in improving diagnosis of SN PTB</p>	<p>The laboratory reporting system can be improved. However, there are difficulties in persuading patients to return if there are physical and social barriers</p>	<p>Data can be measured using the inquiry tool</p>

* *The 15% may possibly include a small percentage of patients who do not have cough for more than 2 weeks and still have PTB*

** *This will cover patients who have no clinical signs and symptoms of TB*

*** *This criteria was taken out after the first data collection due to a very small sample size*

Table 8.5: Data handling issues in Lima, Peru

Criteria (Standards)	Data collection	Data collation	Data analysis	Data validation
1. Proportion of patients having smear examination for AFB (registered as SR) who comply with the definition of SR	Data were collected for another study within the same project. Sufficient sample size due to broad definition of denominator	Excel work sheets prepared	Data to be further sub analysed before presenting	A proportion of the data for this standard was validated against the information collected in case notes
2 (a, b, c). Proportion of patients with SN PTB, whose cultures are requested (by the doctor), taken (in the laboratory of the health centre), analysed (in the hospital laboratory) and reported back in the treatment chart	These data have been collected by using the health centres and laboratory registers. The database indicates the centre where the TB patient receives treatment and where the diagnosis of smear negative TB was originally made	A new database has been created for entering the culture data	Sample size is an issue for this standard due to narrow definition of denominators	Data cannot be validated from other sources. However, multiple sources of information were used, and any inconsistencies highlighted to detect any biases in the system
3 Proportion of SR who are not asked to have X-rays at the first appointment	Data collected using the new inquiry tool	A new excel data base	Sufficient sample size available	Validated from the clinical case notes
4. Proportion of SR diagnosed to have other pathologies by doctors in health centres based on chest X-ray findings who have chest X-rays consistent with TB (validated by chest specialist)	To measure this standard, all X-rays needed to be validated. However, the majority of patients having a chest X-ray take their films home	A new excel data base	Small sample size due to narrowly defined denominators	No other source of validation
4a and 4b. Proportion of SR patients being followed up at their second appointment with a smear request at their first visit	Data collected using the new inquiry tool	A new excel data base	Sufficient sample size. Analysed at two levels	Validated from case notes and laboratory registers

Table 8.6: Problem analysis after the first data collection

List of problems identified at the Audit committee meeting Date / City / Country					
	Staff	Health system	Environment outside health sector (patients etc.)	Resources	Miscellaneous
Standard 1	Health staff does not follow guidelines No active NTP team in some Health centres	Targets set by NTP No training of NTP staff; high turn-over	High-risk area and high TB suspect Patients leave their samples spontaneously because they fear to be infected and develop the disease. Patients with abnormal x-rays	Free sputum examination Some centres do not have funds to hire a nurse for the NTP	
Standard 2	Some labs do not follow the guidelines. Lab technicians from other centres do not pick up results from Canto Grande	No register available in Canto Grande for cultures sent or results collected. Results of contaminated cultures delivered too late. Poor organization in NTP for cultures results feedback	Control patients before treated When culture requested, some patients do not provide sample		
Standard 3	Physicians want to save time. Diagnosis is easier, and try to avoid losing patients	Production exigency of the centre	Patients demand to have x-rays High incidence and prevalence for TB	Conflict of interest: X-rays represent extra income for the health centre	Poor quality of X-rays from other centres

Standard 4a and 4b are not included in the first data collection period

Table 8.7: Recommendations and action planning

standard	Solutions and recommendations	Action
1	<p>Training NTP staff (internal)</p> <p>Participation and reactivation of the NTP team</p> <p>Lectures in health centres</p> <p>Lectures in the community (external)</p>	<p>Regular meeting with NTP staff</p> <p>Bimonthly meetings used to train health promoters from certain centres</p> <p>Provide posters for the different HC sections (obstetrics, dental care, paediatrics, laboratory, waiting room, etc) to remind staff of the SR definition</p> <p>Weekly lectures for health staff and for patients in the waiting room</p>
2	<p>Have a register with all culture requests; train person in charge</p> <p>Train one NTP staff for SN PTB monitoring and follow up</p>	<p>Provide posters on SR in schools, community centres and mothers' clubs with the help of health promoters</p> <p>Creation of a culture register in Canto Grande (recording cultures received, processed, results transmitted, quality of sample)</p> <p>Create flux diagrams for NTP and labs to remind staff of good practices for cultures (sample collection, systematic culturing of 3rd and 4th samples)</p>
3	<p>Train physicians, technicians, etc.</p> <p>Educate patients to avoid X-ray before AFB</p>	<p>Lectures for health staff. Difficulties to implement the change due to 1) some HC have a financial incentive to prescribe X-ray; 2) physicians ask for x-rays because it is a high risk area, 3) pressure from the patient 4) several patients arrive to the health centre with X-rays done elsewhere (there is sub registration of patients who arrive with x-rays) ; 5) main problem is existence of private radiological centres in the surrounding areas</p>

8.2. Bolivia

8.2.1. Development of the audit committee

In December 2002, stakeholders were invited to a clinical audit workshop in Cochabamba. These included chest specialists, general practitioners, TB nurses, managers, and epidemiologists. The purpose of this workshop was to introduce people to clinical audit and invite them to participate in the project. However, it was not until April 2003, that an audit committee evolved and held its first meeting (Table 8.8). The committee agreed to the following terms of reference:

- To agree on standards and criteria for clinical audit
- To guide the process of data collection
- To receive audit results, conduct a problem analysis and propose solutions for improvement
- To develop and implement an action plan in order to stimulate change

The initial stages of the audit committee consisted of three chest specialists, two epidemiologists and one microbiologist. It was realised early on that the committee membership was not fit for purpose. A committee supervising audit in primary care requires multi-professional representation from primary health care staff. Without the involvement of staff working at the front line in primary care, it was unlikely to have much influence in bringing improvement. Committee membership was revised to include key health professionals (doctors and nurses) from all health centres participating in the clinical audit. The committee met on a monthly basis after normal working hours. Later in the project (2004 onwards), the district authorities granted permission for the committee to meet during office hours.

Table 8.8: Audit committee in Cochabamba, Bolivia

Number of health centres involved	8
Number of members in the committee	14
Of which, numbers of members in a position to implement changes (working in the health centres)	8
Timing of meeting	Evenings initially (2003) but now working hours (2004-05)
Number of meetings between October 2003-October 2004	3
Attendance of those in a position to implement change (%)	5/8 (63%)

8.2.2. Selection of the criteria and standards

In its April 2003 meeting, the audit committee examined the WHO and NTP guidelines for the diagnostic management of SR and developed a diagnostic

algorithm (from which the standards and criteria could be derived) for the clinical audit. In the subsequent three to four meetings, a number of problems were identified in the diagnostic management of SR patients. These problems were discussed and quality criteria were proposed along with achievable standards (Table 8.9). In October 2003, these criteria were scored against the evidence-base, measurability, health impact and feasibility of change (Table 8.10). The six criteria with the highest total were selected for the first audit cycle.

Table 8.9: Agreed criteria and standards in Cochabamba, Bolivia

	Criteria	Standard	Numerator	Denominator
1	Proportion of SR (TB?*) patients whose case notes could be retrieved	90%	All patients registered as SR (TB?) whose case notes could be retrieved	All patients registered as SR (TB?)
2	Proportion of SR (TB?*) patients who meet the agreed definition of SR (cough for two or more than two weeks)	95%	All patients registered as SR (TB?) who meet the SR definition	All patients registered as SR (TB?)
3	Proportion of SR (TB?*) patients who were requested to have a smear for AFB	90%	All patients registered as SR (TB?) who were requested to have smear examination	All patients registered as SR (TB?)
4	Proportion of SR (TB?*) patients requested to have a smear test who provided a sample to the laboratory	90%	All patients registered as SR (TB?) who were requested to have smear test provided sample to the laboratory	All patients registered as SR (TB?) who were requested to have smear test
5	Proportion of SR (TB?*) patients that reported to the laboratory for AFB smear test, who provided at least two samples that were not salivary	90%	All patients registered as SR (TB?) that reported to the laboratory for AFB smear test, provided at least two samples that were not salivary	All patients registered as SR (TB?) who were requested to have smear examination and provided a sample to the laboratory
6	Proportion of SR (TB?*) patients who were not asked to have an X-ray at their first appointment	90%	All patients registered as SR (TB?) who were not requested to have an X-ray at the first appointment	All patients registered as SR (TB?)

**In Bolivia, patients registered as TB? (possible TB) were also included in the denominator*

Table 8.10: A systematic assessment of the selected audit criteria in Cochabamba, Bolivia

Criteria	Evidence base	Feasibility of change	Measurability	Health Impact
Proportion of SR (TB?) patients whose case notes can be retrieved	Better data collection systems can improve monitoring and evaluation of health service provision	Health centres without a system to record case notes agreed to start keeping such records	In some cases clinical files exist but data cannot be retrieved because of illegibility of the registration number in the register	Dependent on other factors as well
Proportion of SR (TB?) patients who meet the agreed definition of SR (cough for two or more than two weeks)	Loss of resources in conducting excessive smear examinations inappropriately. Also there is no evidence that smear examination before 2 weeks increases PTB diagnostic yield	Possible pressure from the NTP to do more smears which may act as a disincentive	Currently can be measured with data from another study but later a TB nurse can check the duration of cough when making an entry into the SR register	It will improve efficiency in the system and reduce the work load on laboratory technicians which is likely to improve quality
Proportion of SR (TB?*) patients who were requested to have a smear for AFB	The smear test is the gold standard for diagnosing TB and is recommended by WHO guidelines	Possible through education and improving systems	Easy to measure by examining the SR register	Maximum impact is in improving the diagnostic quality of care given to the SR

<p>Proportion of SR (TB?*) patients requested to have a smear test who provided a sample to the laboratory</p>	<p>The smear test is the gold standard for diagnosing TB and is recommended by WHO guidelines</p>	<p>This depends on patient compliance, but improvements can be made through education and improving systems</p>	<p>Easy to measure by comparing the laboratory and SR registers</p>	<p>Maximum impact is in improving the diagnostic quality of care given to the SR</p>
<p>Proportion of SR (TB?*) patients that reported to the laboratory for AFB smear test, who provided at least two samples that were not salivary</p>	<p>All suspected TB patients must have at least two smear examinations according to WHO guidelines</p>	<p>The second sample is a problem as it depends on patient compliance with follow up visits. However, there are variations in the samples per patient from 1-3 in different centres, thereby meaning that some role is played by the health service, so there is scope for change</p>	<p>Easy to measure through the laboratory register</p>	<p>Maximum impact is in improving the diagnostic quality of care given to the SR</p>
<p>Proportion of SR (TB?*) patients who were not asked to have an X-ray at their first appointment</p>	<p>WHO guidelines recommend no X-ray at the first appointment</p>	<p>Possible to change. However, many clinicians perceive this as causing delay in diagnosis and often loss to follow up</p>	<p>Possible to measure from case notes</p>	<p>X-ray at the first appointment is likely to shift the focus away from smear testing</p>

8.2.3. Data collection

The audit committee discussed three options for data collection:

- A stamp for collecting clinical information at each appointment (similar to Lima)
- An inquiry tool (data collection form) developed by a sub-committee
- Using patient clinical file and other routine sources to collect data and using the inquiry tool as a prompt for clinicians to record important clinical information

The absence of a triage system in health centres, which could put the stamp in patients' clinical files prior to their appointment, deterred the audit committee from recommending this option. The committee agreed to pilot the inquiry tool in selected centres. However, after the introduction of the inquiry tool in the pilot phase, it was found to be too time consuming to complete it in addition to making clinical case notes. The audit committee, therefore, agreed to use the inquiry tool as a prompt to write important clinical information in the patient case notes. It was also agreed that all data required for the agreed criteria, would be collected either directly from the case notes or from laboratory and SR registers. It was discovered that in many health centres, case notes were not being used to record patients' clinical details. Instead, all information was being recorded on the outpatient slip, which was not kept in the hospital. It took considerable time (almost six months) and effort to introduce case notes in these health centres as a routine measure to record clinical details. Although standards were agreed in October 2003, the data collection could not start until April 2004 due to these initial problems with data collection sources. A pilot study was also done during this period, which helped to refine and improve the data collection system. Data were collected from April to September, collated in a pre-designed excel based data collection form, analysed and presented to the audit committee in September 2004. The second cycle of data collection started in October 2004 and went on until March 2005. The final cycle of data collection took place between June 2005 and December 2005.

8.2.4. Issues related to data collection, collation, analysis and validation

Issues relating to data collection, collation, analysis and validation were discussed by the committee and possible solutions were provided (Table 8.11).

Table 8.11: Issues with data collection for each standard in Cochabamba, Bolivia

Standards	Data collection	Collation	Analysis	Validation
<p>Proportion of SR (TB?*) patients whose case notes could be retrieved</p>	<p>The denominator of this indicator is all patients registered as SR in the clinical registers by the doctor. However, many SR patients are registered as TB? TB suspect etc. In order to avoid bias, it was recommended to collect the denominator (SR +TB? TB suspects) but to keep this distinction when collating these data to detect any biases. All data were to be collected from all health centres. However, in two large health centres, only a sample was collected (cases presented in the last week of each month to avoid bias)</p>	<p>These data were entered into Epi-data, keeping the distinction between SR, TB suspects, TB, TB? etc in both the denominator and the numerator to detect any biases</p>	<p>These data were analysed as proportions and results presented to the committee by the individual centres (as well as overall performance). Problem analysis needed to examine both the staff behaviour and system of record keeping in each health centre. Solutions included ways in which this retrieval could be improved</p>	<p>It was not possible to validate these data. However, biases were detected by broadening the denominator, and analysing data both with and without using the broad definition of the denominator</p>
<p>Proportion of SR (TB?*) patients who meet the agreed definition of SR (cough for two or more than two weeks)</p>	<p>The denominator was all patients listed as SR in the clinical register and whose case notes were available to check the definition. The numerator was all patients with cough for more than two weeks. If information was missing, then the proportion needed to be mentioned with the results and the results were presented after excluding the missing information from the denominator</p>	<p>A form for data entry was created in Epi-data. All data entry was done directly to this database rather than into a separate register as done previously</p>	<p>Data were analysed in Epi-info or Excel and presented to the committee for individual health centres. Missing information was also presented. Discussion on problem identification included all levels and all possible reasons for non-compliance</p>	<p>It was not possible to validate these data, as laboratory data did not include this information. However, a small scale survey of a group of consecutive SR patients on a certain day of month was used to validate the results</p>

<p>Proportion of SR (TB?*) patients who were requested to have a smear for AFB</p>	<p>The denominator included all SR patients whose case notes available. The numerator included were all patients who were requested to have a smear examination according to their case notes</p>	<p>Data were entered in the above form. However, SR with case notes with missing information were presented separately and excluded from the denominator</p>	<p>Information was analysed and presented along with the proportion of missing information and validation of the results (see adjacent cell). Discussions explored all possible reasons for not ordering the test as well as missing entries in the lab registers for those where the test was ordered</p>	<p>Validation was done for a selected sample (25) every six months for each centre</p>
<p>Proportion of SR (TB?*) patients requested to have a smear test who provided a sample to the laboratory</p>	<p>The denominator was all patients where a smear test was ordered and the numerator was all patients where such a sample was received by the lab. This information was collected from the laboratory register and the clinical case notes</p>	<p>Data were entered in the above form</p>	<p>Information was analysed and presented along with the proportion of missing information</p>	<p>Validation was done for a selected sample</p>
<p>Proportion of SR (TB?*) patients that reported to the laboratory for AFB smear test, and who provided at least two samples that were not salivary</p>	<p>Here the denominator was all patients who reported and delivered their smears for AFB microscopy. This information was collected from the lab register; therefore, the definition of SR was not strictly applied. However, this is unlikely to create any bias as the samples were collected in a similar way, whether SR or not</p>	<p>Data were entered in Epi-data</p>	<p>Data were presented for each health centre to the audit committee. Validation data were also presented and definition of saliva was agreed and disseminated to all the labs in the health centres</p>	<p>This was done in two ways. Lab technicians have differing perceptions of what saliva is. There is no agreed definition, therefore, these data lack reliability. This was overcome by collecting all samples (sputum) one afternoon (once every six months) from all centres and conducting an external review for the proportion with saliva. Similarly, AFB positive smears were also examined for smears prepared from “saliva” samples and compared across all health centres</p>

///

///

///

<p>Proportion of SR (TB?*) patients who were not asked to have an X-ray at their first appointment</p>	<p>The denominator is all patients with SR and case notes.</p>	<p>Missing information was excluded and presented separately. Similarly all patients arriving with an X-ray already done elsewhere were also excluded and presented separately</p>	<p>Data analysis and presentation excluded patients presenting with an X-ray already done elsewhere. Discussions on problem identification included all possible reasons (patients' expectations, doctors' attitude)</p>	<p>It was not possible to validate this information. However, in some health centres, radiology departments kept their registers and limited validation was done in those centres</p>
--	--	--	--	---

8.2.5. Problem analysis, recommendations and action planning

The audit committee met after each data collection to discuss the results, review the audit criteria, analyse problems, identify solutions and make recommendations (Table 8.12). Subsequently, the audit committee facilitator made individual visits to all health centres, held meetings with local clinicians, TB nurses and laboratory technicians and provided individual feedback. Subsequently, action plans were negotiated and approved by all health centres in order to bring improvement in order to meet standards set by the committee.

Table 8.12: Recommendations after the first feedback in Cochabamba, Bolivia

- There were issues with data collection due to variable case definitions used for SR. A single case definition was agreed, to be used in future. A number of strategies were proposed which are discussed in the following chapter
- A series of feedback meetings were organised for members of the staff of each participating health centres
- It was agreed that a staff representative from each health centre would work locally in their respective health centres, with other members of staff, to develop local solutions to improve standards

8.3. Cuba

8.3.1. Development of the audit committee

Subsequent to a seminar on clinical audit, in April 2003, and several workshops in Havana, an audit committee was formed in Havana Vieja. Similar workshops also took place in Las Tunas resulting in the emergence of two audit committees in Las Tunas (Table 8.13).

In Havana Vieja, the audit committee consisted of five doctors from different general practices or CMF, one TB nurse based at the municipality level, and two laboratory technicians based in two of the polyclinics. The members were selected on the basis of their expression of interest in the project. The committee was led and facilitated by the municipality TB programme director. In the initial phase of the project, three out of five clinicians left the committee as they were seconded by the government on overseas duties. This resulted in considerable delay before more doctors were recruited and inducted in the audit process.

Two committees were formed in Las Tunas in April 2003, one at secondary care (SHC) and the other at primary care level (PHC). In the primary care committee, seven members (five general practitioners and two nurses) were

recruited in the beginning. In the hospital committee (secondary care), five members, all doctors including a microbiologist, a pathologist, a chest specialist and a radiologist were included. The director of the TB control programme for the municipality led and facilitated both committees.

Both committees agreed to the following terms of reference and subsequently met every week. However, both committees worked independently in developing audit criteria, data collection and other activities. The terms of reference of these committees were as follows:

- To agree on standards and criteria for clinical audit
- To guide the process of data collection
- To receive audit results, conduct a problem analysis and propose solutions for improvement
- To develop and implement an action plan in order to stimulate change

Table 8.13: Audit committees in Havana and Las Tunas, Cuba

	Havana (Urban)	Las Tunas (Semi-Rural)
Number of health centres involved	5	5
Number of members in the committee	8 + 1 facilitator	8 PHC; 6 SHC
Number of members in a position to implement changes (working in health centres)	2	3
Timing of meeting (evening vs. working hours?)	3h/working hours	
Number of meeting between October 2003-October 2004	26	39 PHC; 25 SHC
Attendance of those in a position to implement change (average, %)	100%	100%

8.3.2. Selection of the criteria and standards

The national TB guidelines in Cuba do not include a TB diagnostic algorithm. These guidelines were discussed in audit committees in both municipalities. Local committees developed a diagnostic algorithm, based on the NTP guidelines and the WHO literature, to help in the derivation of criteria and standards. Subsequently, committees in both Havana Vieja and Las Tunas met regularly and after numerous discussions produced a list of possible standards and criteria.

All standards and criteria were examined and revised by the committees. These were judged against their relevance to the quality of diagnostic care provided to the SR patients, measurability, feasibility of change and health impact. The initial list included 20 criteria. Many of these were modified and reduced to a short-list of 14. A further short-list was generated using a scoring system based on the above-mentioned criteria (Table 8.14 and Table 8.15).

Table 8.14: Selected criteria and standards in Havana and Las Tunas, Cuba

	Criteria	Standard	Numerator	Denominator
<i>Havana Vieja</i>				
1	Proportion of patients with cough for >21 days who had a chest X-ray	90%	Patients coughing for more than 21 days and had a chest X-ray	Patients coughing for more than 21 days
2	Proportion of patients with cough for >21 days, 2 negative smears and a chest X-ray compatible with PTB who were referred to the <i>Commission for Smear negative TB Diagnosis</i>	80%	Patients with cough for >21 days, 2 negative smears and a compatible chest X-ray who were referred to the commission	Patients with cough for >21 days with two negative smears and a compatible chest X-ray
3	Proportion of patients with cough >14 days who had a valid (not salivary) second sputum sample examined in the laboratory within 72 hours of sputum collection	80%	Patients with cough >14 days who have a valid (not salivary) second sputum sample examined in the laboratory within 72 hours of sputum collection	Patients with cough >14 days
4	Proportion of patients with cough for >14 days who had sputum results recorded in the general practice register	80%	Patients with cough for >14 days who have sputum results recorded in the general practice register	Patients with cough for >14 days
5	Proportion of patients with cough for >14 days who had second sputum sample delivered to the laboratory within 72 hours of consultation	90%	Patients with cough for >14 days who have a second sputum sample delivered to the laboratory within 72 hours of consultation	Patients with cough >14 days
6	Proportion of patients with cough for >14 days who had a second sputum sample of suitable quality for processing in the laboratory	90%	Patients with cough for >14 days who have a second sputum sample of suitable quality for being processed in the laboratory	Patients with cough >14 days
7	Proportion of patients with cough for >14 days for whom cultures were requested to the central laboratory and the samples were found adequate	95%	Patients with cough for >14 days on whom cultures were requested to the central laboratory and the samples were found adequate	Proportion of patients with cough for >14 days on whom cultures were requested to the central laboratory
8	Proportion of medical requests for sputum smear microscopy with complete clinical information	95%	Number of medical request for sputum smear microscopy with complete clinical information	Number of medical requests for sputum smear microscopy
<i>Las Tunas</i>				

1	Proportion of SR patients for whom AFB is requested, who have their first sample submitted and processed within 48 hours of medical consultation	90%	SR patients for whom AFB is requested, who have their first sample submitted and processed within 48 hours of medical consultation	All SR patients
2	Proportion of SR patients for whom AFB is requested, who have their second sample submitted and processed within 72 hours of medical consultation	85%	SR patients for whom AFB is requested, who have their second sample submitted and processed within 72 hours of medical consultation	All SR patients
3	Proportion of samples for AFB culture that are not contaminated	90%	All samples for AFB cultures that are not contaminated	All samples for AFB cultures
4	Proportion of patients with cough > 14 days that have the <i>Consultation of Classification</i> who have a chest X-ray and two sputum smear examinations	95%	Number of patients with cough > 14 days that have the consultation with a chest X-ray and two sputum smear examinations	Number of patients with cough > 14 days
5	Proportion of patients with cough > 21 days that access the <i>Commission of Diagnosis</i> with proof of tuberculin testing and prior antibiotic trial	95%	Number of patients with cough > 21 days that access the commission with proof of tuberculin testing and prior antibiotic trial	Number of patients with cough > 21 days

Table 8.15: A systematic process of selecting audit criteria in Havana and Las Tunas, Cuba

Criteria (Standard)	Evidence base	Ease of measurement	Possibility of change	Health Impact
Havana				
1. Proportion of patients with cough for >21 days who had a chest X-ray (90%)	X-ray is essential in the diagnosis of smear negative TB in case of persisting symptoms	Possible from case notes	It is part of NTP guidelines and X-ray facilities exist at the majority of polyclinics in Havana Vieja	Can improve the diagnosis of smear negative TB
2. Proportion of patients with cough for >21 days, 2 negative smears and a chest X-ray compatible with PTB who were referred to the <i>Commission for Smear negative TB Diagnosis</i> (80%)	The commission is an expert panel making diagnostic and management decisions on smear negative SR cases with persistent symptoms	From routine data collection system This may be problematic for the analysis due to the sample size	Possible as it is part of the NTP guidelines	Improve diagnosis of smear negative TB. However, impact may be on a small number of cases only
3. Proportion of patients with cough >14 days who had a valid (not salivary) second sputum sample examined in the laboratory within 72 hours of sputum collection (80%)	Many smears reaching the lab are of not good quality or sufficient quantity, hence influencing the diagnosis of SR patients.	SR and laboratory registers	Often poor transport from the general practice to the polyclinics is a hindrance	Improve diagnosis of SR patients
4. Proportion of patients with cough for >14 days who had sputum results recorded in the general practice register (80%)	The availability of sputum examination results to the family doctor is crucial to provide a diagnosis to patients with suspected TB	The family doctor's register	Retrieval of the results from polyclinics and their entry into the family doctor's registers	Availability of the results will have a huge impact on the diagnosis of patients with suspected TB

5. Proportion of patients with cough for >14 days who had second sputum sample delivered to the laboratory within 72 hours of consultation (90%)	The delivery of a sputum sample to the laboratories in polyclinics is crucial for further analysis	Laboratory registers and family doctor registers	Often poor transport from the general practice to the polyclinics is a problem	Impact on the diagnosis of all patients with suspected TB
6. Proportion of patients with cough for >14 days who had a second sputum sample of suitable quality for processing in the laboratory (90%)	Sputum quality is important for examination	Laboratory registers	Poor patient education and poor instructions	High impact on TB diagnosis
7. Proportion of patients with cough for >14 days for whom cultures were requested to the central laboratory and the samples were found adequate (95%)	Cultures are conducted frequently in patients with suspected TB and the quality of sputum is crucial to have an adequate culture examination	Laboratory registers	Poor patient education and poor instructions	Relatively less impact on the TB diagnosis but can improve efficiency
8. Proportion of medical requests for sputum smear microscopy with complete clinical information (95%)	Without clinical information, samples were often not processed jeopardising the diagnosis of such patients	Laboratory and family practice registers and medical request forms	Persuading family doctors to complete request forms	Potentially big impact especially if samples are discarded due to poor clinical information on the request forms
Las Tunas				
1. Proportion of SR patients for whom AFB is requested, who have their first sample submitted and processed within 48 hours of medical consultation (90%)	Many smears reaching the lab are of not good quality or sufficient quantity hence influencing the diagnosis of SR patients	SR and laboratory registers	In Las Tunas poor transport from the general practice to the polyclinics is a problem	Improved diagnosis of SR patients
2. Proportion of SR patients for whom AFB is requested, who have their second sample submitted and processed within 72 hours of medical consultation (85%)	Many smears reaching the lab are of not good quality or sufficient quantity, hence influencing the diagnosis of SR patients	SR and laboratory registers	In Las Tunas poor transport from the general practice to the polyclinics is a problem	Improved diagnosis of SR patients

<p>3. Proportion of samples for AFB cultures that are not contaminated (90%)</p>	<p>Culture examination is part of NTP guidelines for diagnosing smear negative PTB. Contamination can influence the results and thereby clinical outcomes</p>	<p>Possible from laboratory registers</p>	<p>Improving quality in laboratory procedures can bring improvement</p>	<p>Improved diagnosis of smear negative TB patients</p>
<p>4. Proportion of patients with cough > 14 days that have the <i>Consultation of Classification</i>, who have a chest X-ray and two sputum smear examinations (95%)</p>	<p>NTP guidelines suggest that every TB suspect should have two smears and a chest X-ray</p>	<p>From clinical records and registers</p>	<p>Through influencing clinical behaviour</p>	<p>Impact on the diagnosis of patients with suspected TB</p>
<p>5. Proportion of patients with cough > 21 days that access the <i>Commission of Diagnosis</i> with proof of tuberculin testing and prior antibiotic trial (95%)</p>	<p>NTP guidelines in Las Tunas promote referral of patients who have been coughing for more than 3 weeks to the Commission with having the tuberculin test and antibiotic trial</p>	<p>Clinical notes</p>	<p>Influencing clinical behaviour</p>	<p>Can influence cost effectiveness</p>

8.3.3. Data collection

Criteria were generally agreed in October 2003 but data collection did not start until April 2004. Considerable delays were due to factors external to the project:

- Many committee members left on overseas secondments, and replacement members were recruited, trained and inducted into the committees
- Renovation of several health centres during that period
- Intense emergency preparedness to cope with an imminent hurricane threat

Data were mainly collected from routine data in health centres (clinical files, consultations and SR registers and daily returns from general practices). In Havana Vieja, a specific form for the follow up of SR was introduced. In Las Tunas, a register for SR was introduced, to record any SR actively identified during routine home visits.

8.3.4. Problem analysis, recommendations and action planning

Data were collated in the pre-designed databases. Data analysis was done on a quarterly basis and presented to the audit committees in October 2004. Subsequently, recommendations were made to improve certain standards through a process of problem analysis (Table 8.16).

Table 8.16: Recommendations of the audit committee after the feedback in Cuba

Havana
Training to be provided to doctors on the definition of SR and the requirements for X-rays
On-site training will also be provided to other staff about appropriateness of X-rays
Renovation in the health centres is currently taking place. This situation will be exploited to provide more facilities to the laboratories performing better quality and timely sputum smear examinations
It is proposed to improve the data collection system in the SR registers and daily returns from family medical centres
Las Tunas
Training of doctors in definition of SR and X-ray requests
Improvement in the system of requesting X-rays and also X-ray facilities at the health centres
To develop a chest specialist referral system and maintain on-going training of clinicians
A new system to be introduced to detect SR among high risk groups through an active process

Chapter 9 Results of the clinical audit

In previous chapters, I have provided the background to this study, describing the three study sites and the process of implementation of clinical audit. This chapter presents the following quantitative and qualitative results obtained in each Latin American country:

- Quantitative results obtained for each standard
- Key points discussed during the problem analysis for each standard in the audit committee
- Key recommendations made by the audit committee and progress made against each standard
- Thematic analysis of the qualitative interviews conducted at each study site

The first three of these are presented together for each standard, and the fourth, the thematic analysis is presented separately for each of the study sites. In the following chapter, I will discuss these results in more detail.

9.1. Peru

9.1.1. Clinical audit

This sub-section first presents a summary of the results and then gives more detailed results for each standard under respective subheadings.

Figure 9.1 illustrates a comparison between the trend lines for all standards measured in Lima, Peru over the two-year data collection period. During this period, three audit cycles were completed, each including a period of six-month data collection and analysis, presentation and feedback of the results to the audit committee and action planning for improvement. This meant that the results were fed back every six months in March and September each year stimulating a new wave of development and revision of the action plans for improvement. Figure 9.1 shows that apart from standard 4a, no standard demonstrates a clearly visible improvement. The trend lines also show considerable variation from month to month, particularly for standard 2.

For all criteria measured in Lima, the *absolute* and *relative* difference (as defined in the methodology chapter) between the mean proportions of the first and the last quarter of the total data collection period are presented in Table 9.1 and Figure 9.2 respectively. The improvement in the *absolute* difference between the two quarters reaches statistical significance for standard 4a and 1. There is a

significant deterioration in standard 4b. No significant change is observed for standards 2 or 3. Despite the observed changes in at least two standards, none of the criteria reached the standards agreed by the audit committee. Similar observations can be made in Figure 9.2, illustrating the *relative* difference between the mean proportions of the first and the last quarter of the data collection period for all standards.

Table 9.1: Absolute difference between the mean proportions of the first and the last quarter for all standards in Lima, Peru

Standards	Mean proportion in the first quarter	Mean proportion in the last quarter	Difference (95% CI)	z	p value
1	0.46	0.53	0.07 (0.02-0.11)	3.00	less than 0.001
2	0.53	0.60	0.07 (-0.25-0.38)	0.41	ns
3	0.42	0.42	0.01 (-0.05-0.07)	0.25	ns
4a	0.37	0.55	0.18 (0.12-0.23)	5.94	less than 0.001
4b	0.83	0.69	-0.14 (-0.22-0.07)	-3.81	less than 0.001

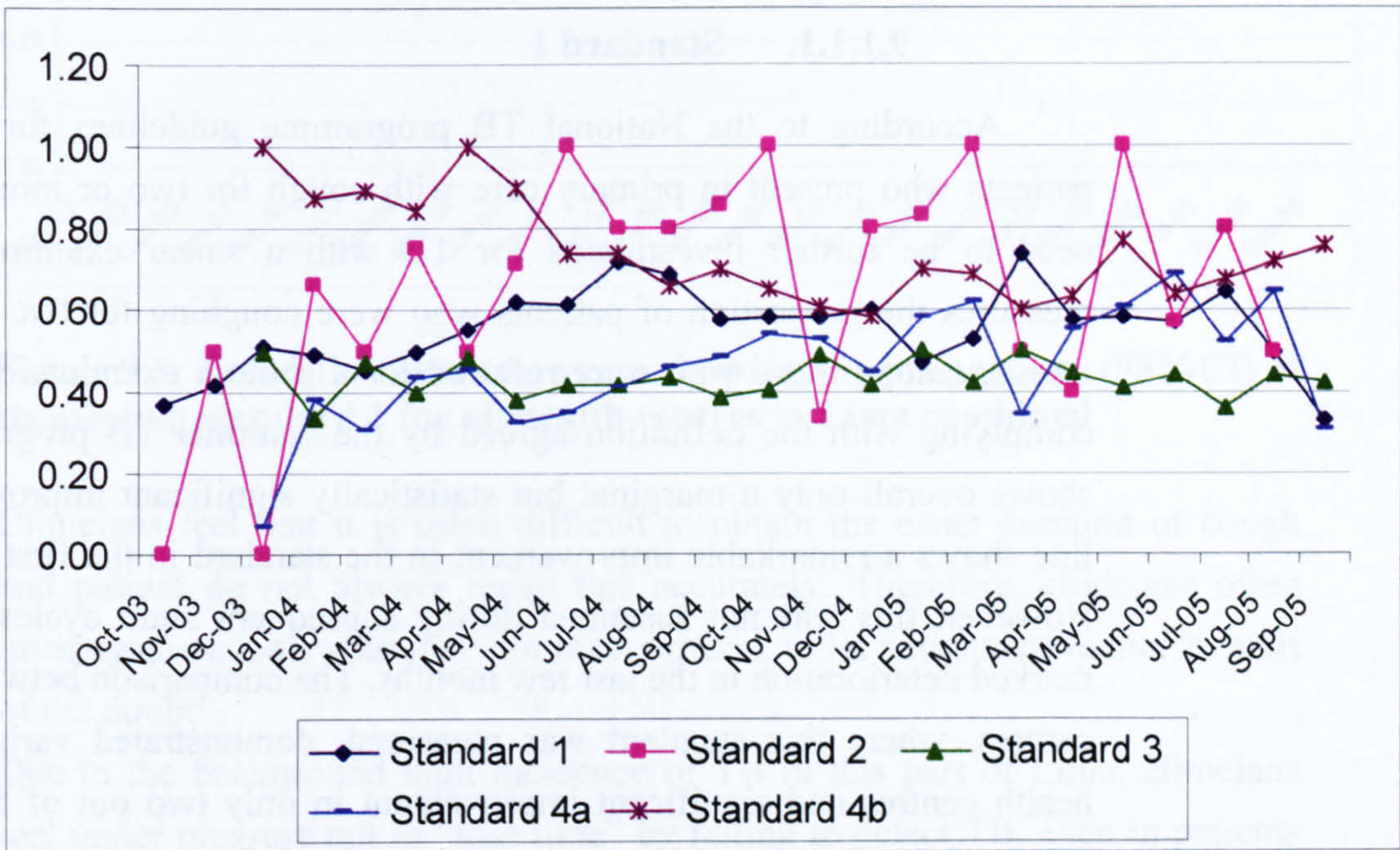


Figure 9.1: A comparison of trends for all standards in Lima, Peru

Further, in this sub-section, results for each standard are presented in more detail within the context of the discussions that took place in the audit meetings about these results.

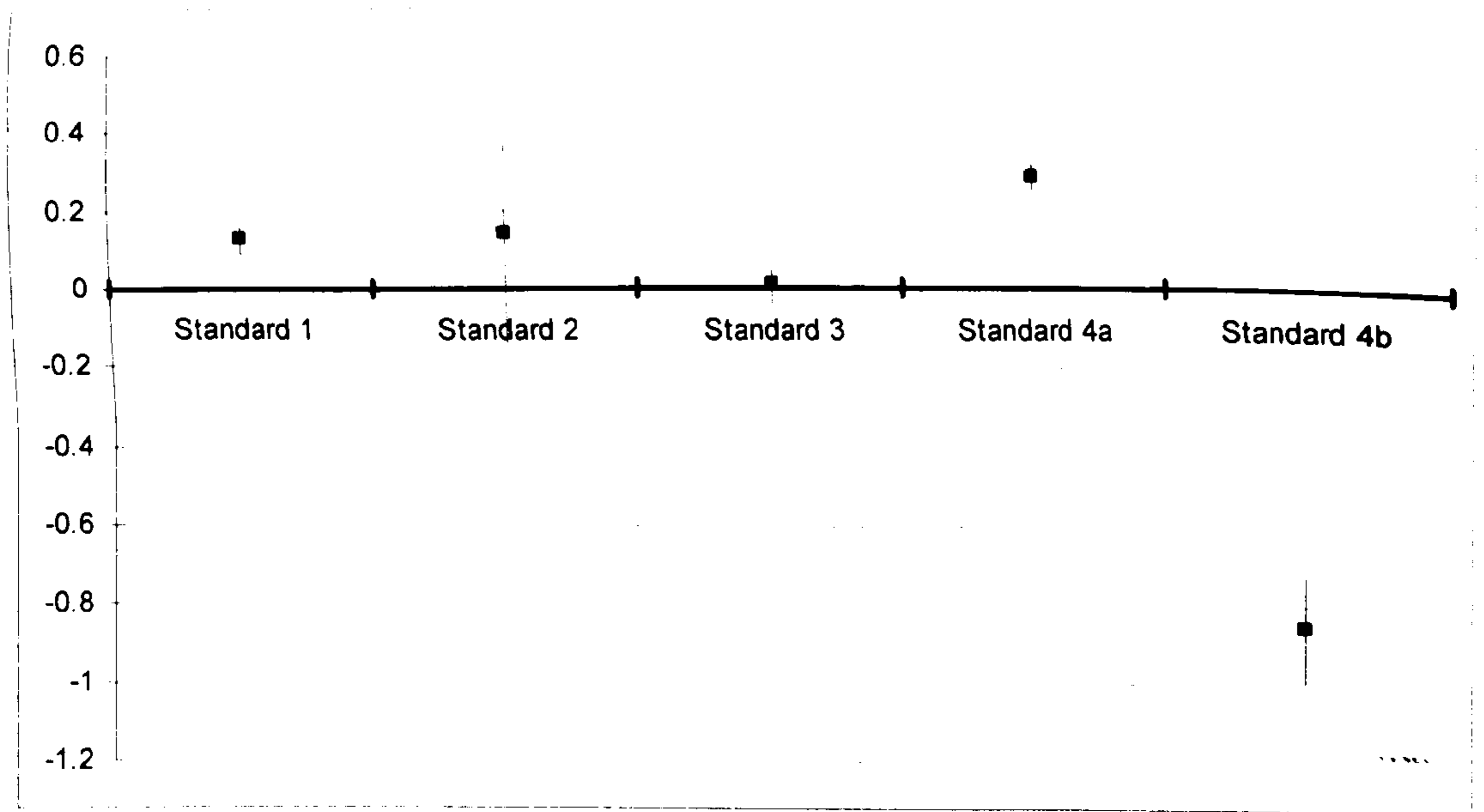


Figure 9.2: Relative difference between the mean proportions (95%CI) of the first and the last quarter for each standard in Lima, Peru

9.1.1.1. Standard 1

According to the National TB programme guidelines for Peru, only those patients who present in primary care with cough for two or more than two weeks need to be further investigated for TB with a smear examination. Standard 1 measures the proportion of patients who were coughing for two or more than two weeks, among those who were referred for a sputum examination for TB, thereby complying with the definition agreed by the National TB programme. Figure 9.4 shows overall only a marginal but statistically significant improvement. The trend line shows a remarkable improvement in the standard in the first year (Figure 9.3). However, this was not sustained during subsequent audit cycles, and there was a marked deterioration in the last few months. The comparison between the five health centres, where this standard was measured, demonstrated variation between the health centres and significant improvement in only two out of five health centres (Figure 9.4).

The problem analysis conducted to understand poor performance of the health centres against this standard illustrated the following points during the audit committee meetings.

- One of the indicators set with in the National TB programme in Peru is to perform TB screening in at least six percent of all adults presenting in primary care. The underlying assumption is that there would be active case finding by the primary health care staff in their community. In the absence of active case detection, patients attending the health centres with respiratory symptoms are inappropriately asked for sputum examination, especially at the end of each

month, when there is more pressure on the staff to meet the TB programme targets.

- Patients often consult with clinicians to exclude TB, even if they do not meet the clinical criteria. This is often due to high sensitization of people due to high TB incidence in the area, and lack of familiarity with the clinical signs and symptoms of TB. Clinicians are under a lot of pressure to screen such patients in order to maintain trust.

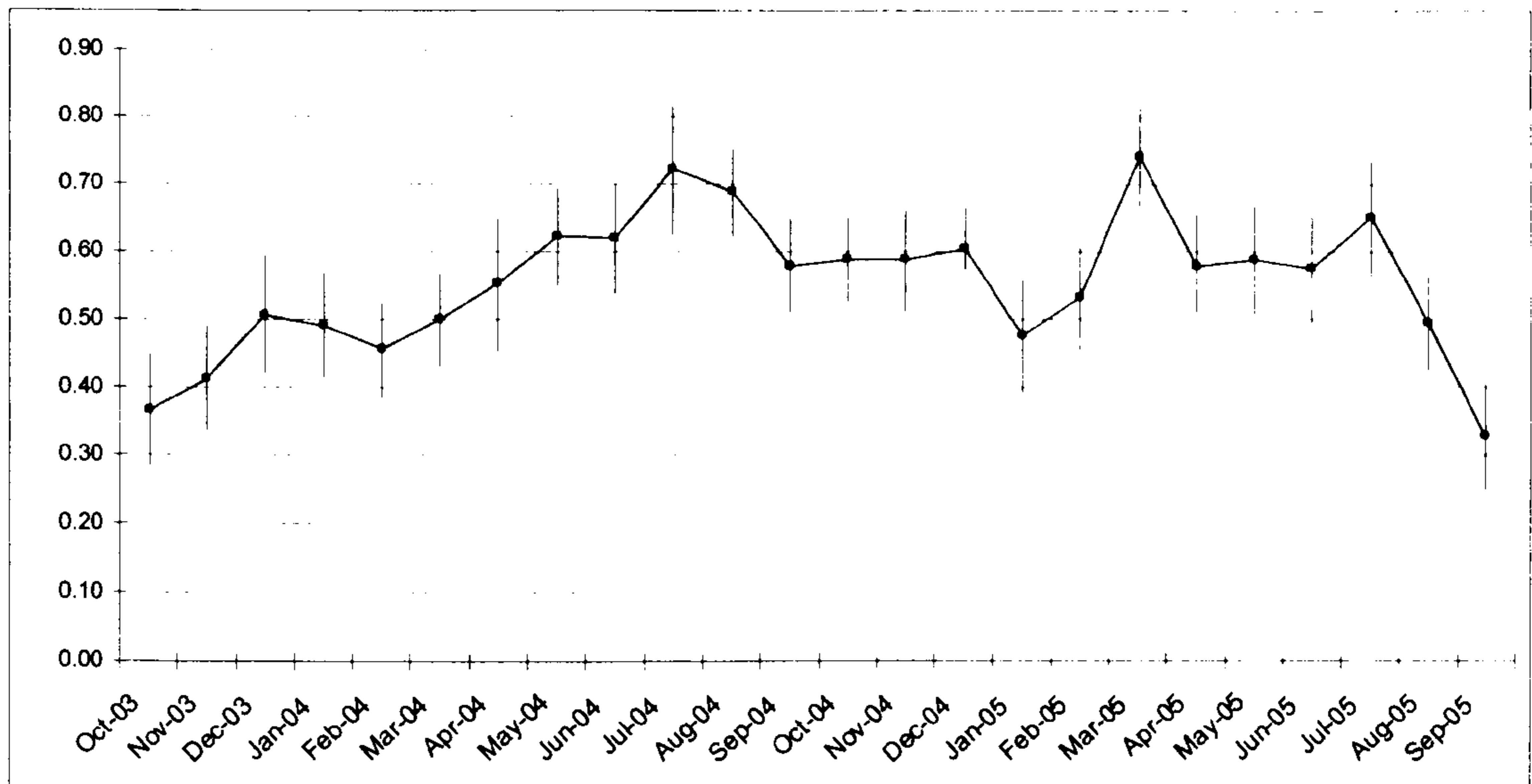


Figure 9.3: Trend line over two years showing the proportions (95%CI) of patients meeting standard 1 for all health centres in Lima combined

- Clinicians feel that it is often difficult to obtain the exact duration of cough and patient do not always recall this accurately. Therefore, clinicians often investigate patients who may not meet criteria, to let patients have the “benefit of the doubt”.
- Due to the background high incidence of TB in this part of Lima, clinicians feel under pressure not to “lose time” by failing to detect TB, even in patients who do not meet the criteria for sputum testing. This issue applied especially to the asymptomatic contacts of patients with tuberculosis. The national programme guidelines for the management of TB contacts also lack clarity.
- The committee also reflected on the lack of motivation among staff to follow standards due to high workload, frequent changes in staff, and unsafe environment. Some of these generic issues are discussed further in the thematic analysis.

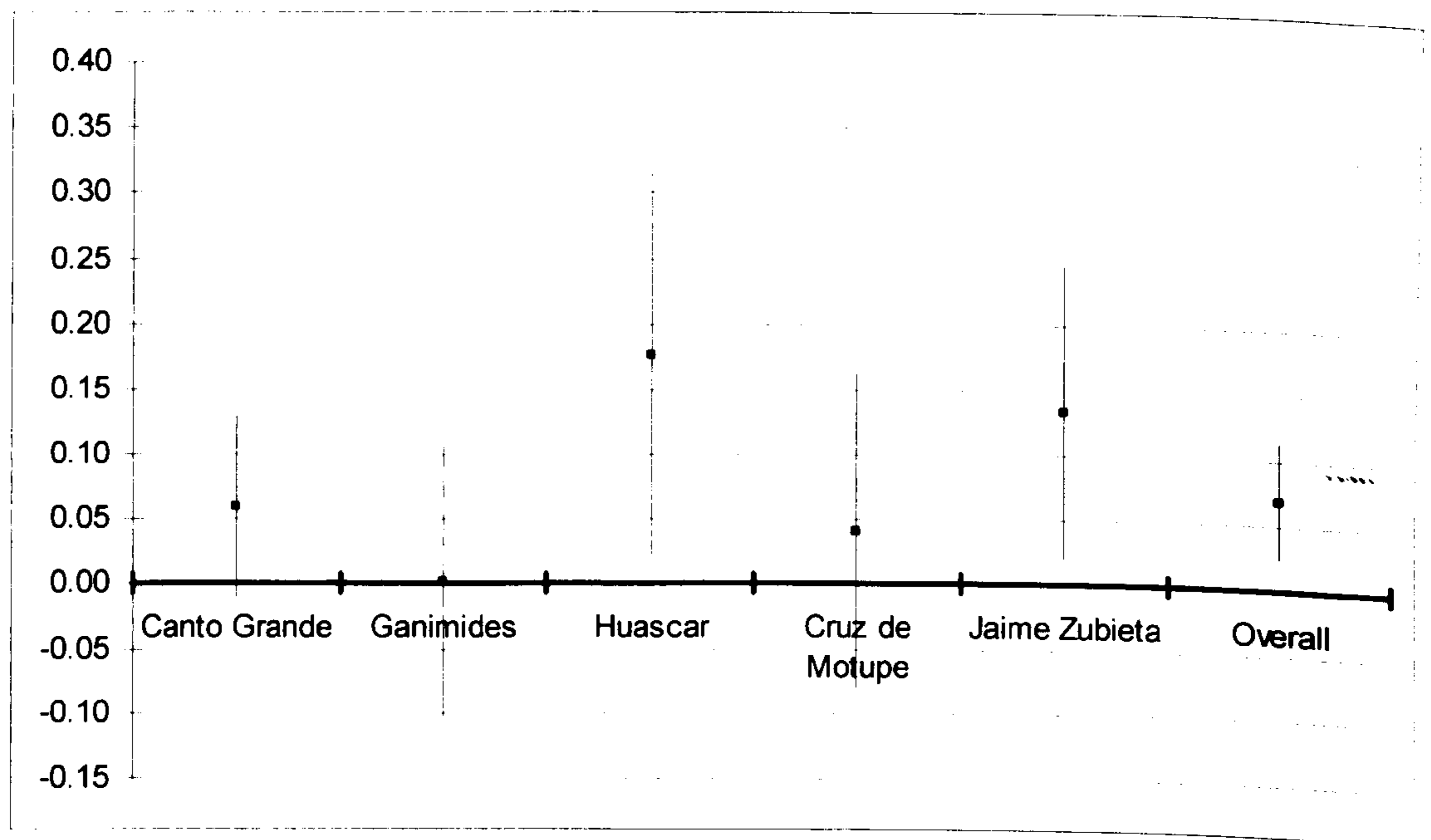


Figure 9.4: Absolute difference between the mean proportions (95%CI) of the first and the last quarter for standard 1 in each health centre in Lima, Peru

Despite the above difficulties, the committee kept measuring this standard and striving for improvement. Members felt that the inability to meet standard 1 resulted in inappropriate investigations, inefficiency and increased workload on the laboratory staff that ultimately could result in poor quality of the sputum examination. They suggested a number of solutions:

- Training sessions and materials for primary health care staff to educate them about the agreed criteria for investigating patients with TB
- Educational materials and campaigns to help patients and the general public understand the symptoms and signs of TB
- Meetings with the local TB programme coordinator to discuss the negative influence of the programme indicators on primary health care staff trying to comply with the guidelines set by the programme itself

9.1.1.2. Standard 2

According to the National TB programme guidelines for Peru, all patients diagnosed and thereby registered as smear negative TB patients, ought to have a sputum culture requested, with results reported back to be entered in the clinical notes and TB register. Standard 2 measures the proportion of smear negative TB patients in whom the sputum culture was requested, processed and reported back into the clinical file as per guidelines. Three more standards were measured within standard 2 to sub-analyse the different steps involved in achieving standard 2 (see chapter 8). However, the number of patients constituting the denominators for these indicators was relatively small. A sub-analysis was presented to the audit committee

in order to facilitate the problem analysis with respect to each health centre. However, this sub-analysis did not demonstrate any statistical significance perhaps due to small numbers (Table 9.2). Figure 9.6 show the results for standard 2, which is an amalgamation of the three standards (2a, 2b and 2c). Figure 9.5 shows a trend of improvement after the first audit cycle, but this improvement is not sustained in the later cycles and shows a rapid deterioration in the last few months. This is similar to the observations made for the trends for standard 1. However, variations between months and between health centres are even more marked. This is partly due to the small numbers in the denominators.

Table 9.2: Absolute difference between the mean proportions in the first and the last quarter: a sub-analysis of standard 2

Standards	Mean proportion in the first quarter	Mean proportion in the last quarter	Difference (95% CI)	z	p value
2	0.53(8/15)	0.60(15/25)	0.07 (-0.25 to 0.38)	0.41	ns
2a (No. of SN TB patients that had a culture requested/ all SN TB patients)	0.57(8/14)	0.79(19/24)	0.22 (-0.09 to 0.53)	1.41	ns
2b (No. of patients SN TB with culture processed in the lab/ all SN TB patients with a culture requested)	0.83(5/6)	0.75(15/20)	-0.08 (-0.44 to 0.27)	-0.46	ns
2c (No. SN TB patients with culture result in files/ all SN TB patients with culture processed in the lab)	0.80(4/5)	1.00(15/15)	0.20 (-0.15 to 0.55)	1.12	ns

The following issues were highlighted in the audit committee meetings to explain the poor performance in this standard.

- Patients were diagnosed to have smear negative TB in all health centres. However, the facility to perform culture was present only in a laboratory situated in another part of the city. Poor communication and lack of coordination between the laboratory and TB programme staff was highlighted as one of the main reasons for non-compliance with standard 2.
- According to the laboratory staff, TB programme staff and the physicians did not fill the request forms adequately. This resulted in wastage and inability of the laboratory to process such samples.

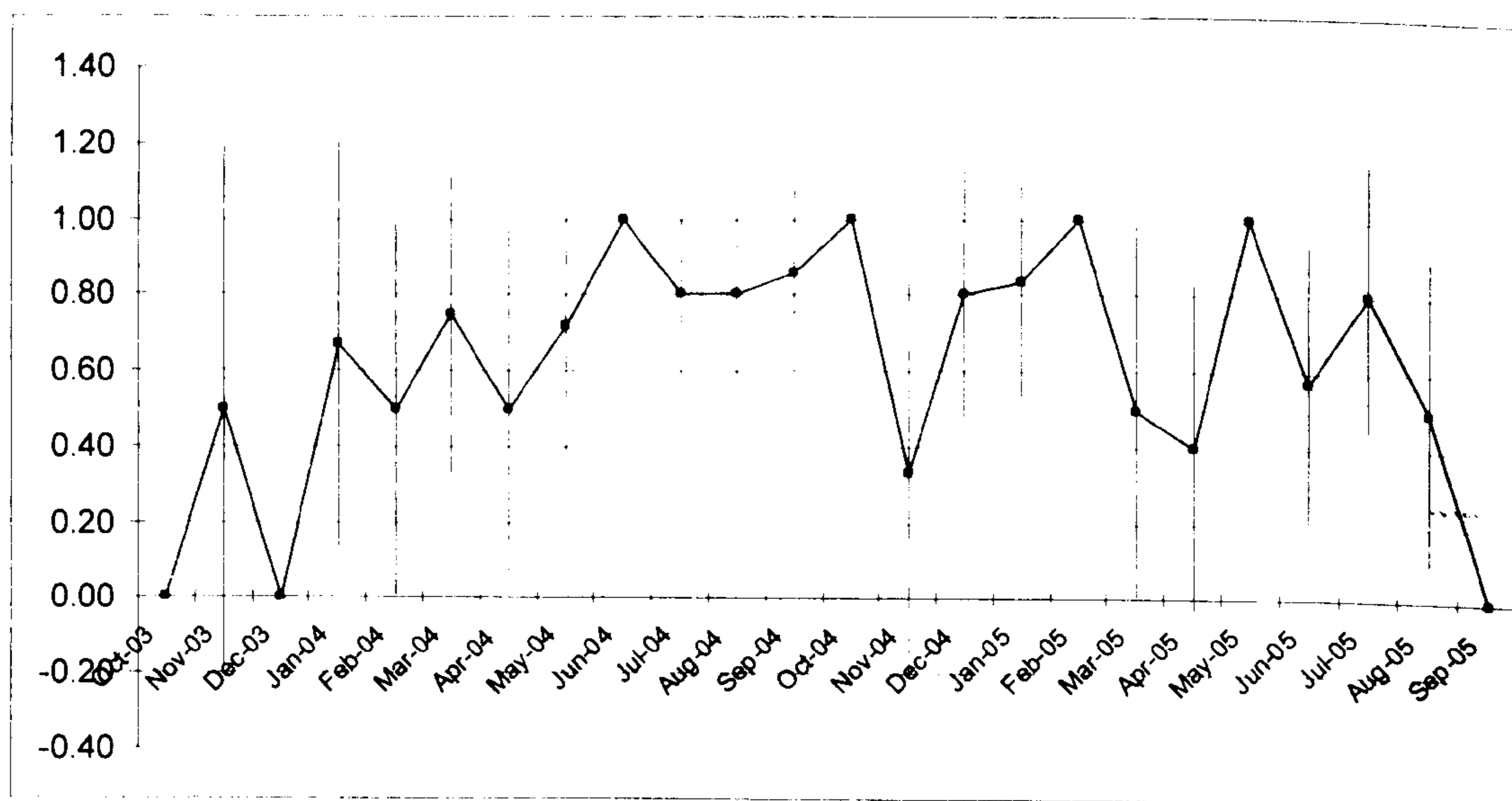


Figure 9.5: Trend line over two years showing the proportions (95%CI) of patients meeting standard 2 for all health centres in Lima combined

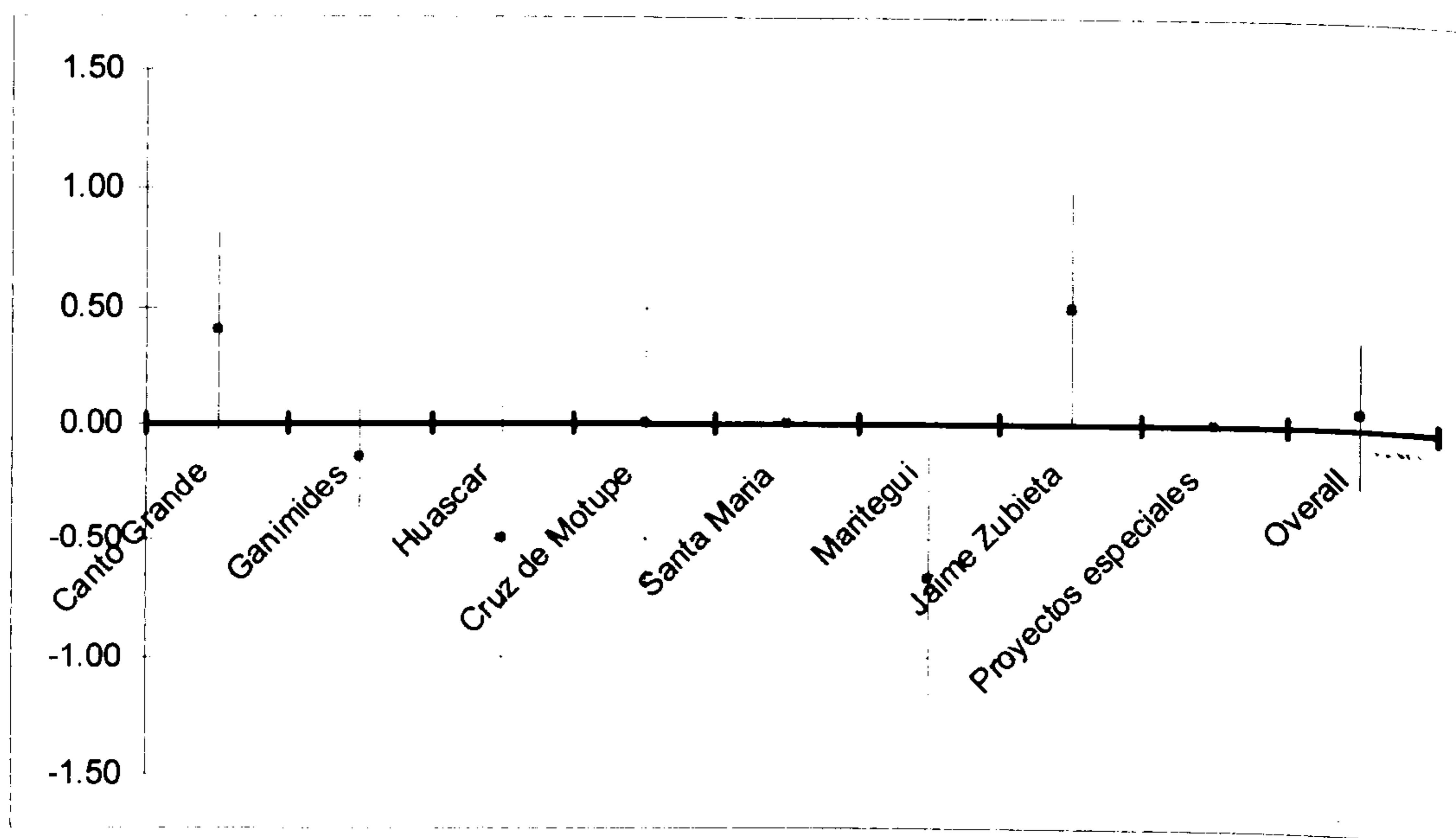


Figure 9.6: Absolute difference between the mean proportions (95%CI) of the first and the last quarter for standard 2 in each health centre in Lima, Peru

- If the sample was not adequate for the culture, clinicians were only told weeks after the request, by which time patients would have received treatment rendering another culture request worthless.
- Even if a culture was processed, results were not sent to the relevant health centre.
- There were no assigned personnel for the transport of samples and transmission of results between the culture laboratory and the health centres.

- Work overload on the laboratory, which was the only facility to process TB cultures in the city, was highlighted as another reason for not meeting standard 2. Due to this increased workload, systems to liaise between the health centres and the laboratory were further weakened.
- Poor dissemination of the TB guidelines among all health care staff including laboratory personnel was thought to be another reason for poor compliance with standard 2.

Despite its relevance to only a small number of patients within the TB diagnostic process, standard 2 was felt important for clinicians to provide them with feedback on their diagnosis of smear negative TB. The following actions were taken as proposed by the audit committee after the feedback.

- A new culture registration book was introduced that could help in tracking samples and results between the health centres and the laboratory.
- Staff training took place to complete culture request forms adequately
- Meetings were held between laboratory staff, TB programme staff and the local authorities in order to resolve issues related to communication and coordination.
- Authorities were approached to assign responsibility to the appropriate personnel for weekly reporting of culture results.
- Subsequent to a meeting held in August 05 between TB programme staff and laboratory staff, an agreement was reached on the policy and procedures for culture requests, sputum sample quality, and sample transport from health centres to the laboratory, and processing within the laboratory.

9.1.1.3. Standard 3

According to the TB programme and current WHO guidelines, chest X-ray should only be requested once clinicians have reviewed the sputum examination results and a course of antibiotics has been demonstrated to produce no clinical improvements among patients with suspected TB. Standard 3 measures the proportion of patients with suspected TB that were not requested to have a chest X-ray at their first visit to the health centre. Patients were excluded if they had already had a recent X-ray from another provider for the same illness episode. Figure 9.7 shows no improvement in this standard and minimal variation between months. There was also little variation between different health centres for this standard (Figure 9.8).

During the audit committee meetings the following issues emerged which were deemed to be responsible for the minimal change in standard 3 over two years.

- Despite TB programme guidelines, clinicians still rely on an early chest X-ray to diagnose TB in an area that is perceived to have a high incidence of TB.
- The audit committee believed that there could be some incentives for clinicians, prompting them to make inappropriate X-ray requests (often from private providers).
- Clinicians perceive constant pressure from their patients for “better and faster” diagnosis. Another step in the diagnostic process may result in losing patients to other providers.
- Many clinicians working in the health centres (not audit committee members) do not agree with this part of the guidelines. Some clinicians also think that “time cannot be lost” in obtaining an X-ray due to the high prevalence of multi-drug resistance and late presentations.

The following actions were proposed by the committee to improve on this standard:

- To organise training sessions on the radiological signs of PTB
- Training to medical staff on the application of evidence-based medicine
- To improve access and reduce the cost of chest X-ray in the public sector and to explore how to remove some of the perverse incentives for inappropriate chest X-ray requests
- To develop a public-private partnership to influence X-ray provision in the private sector

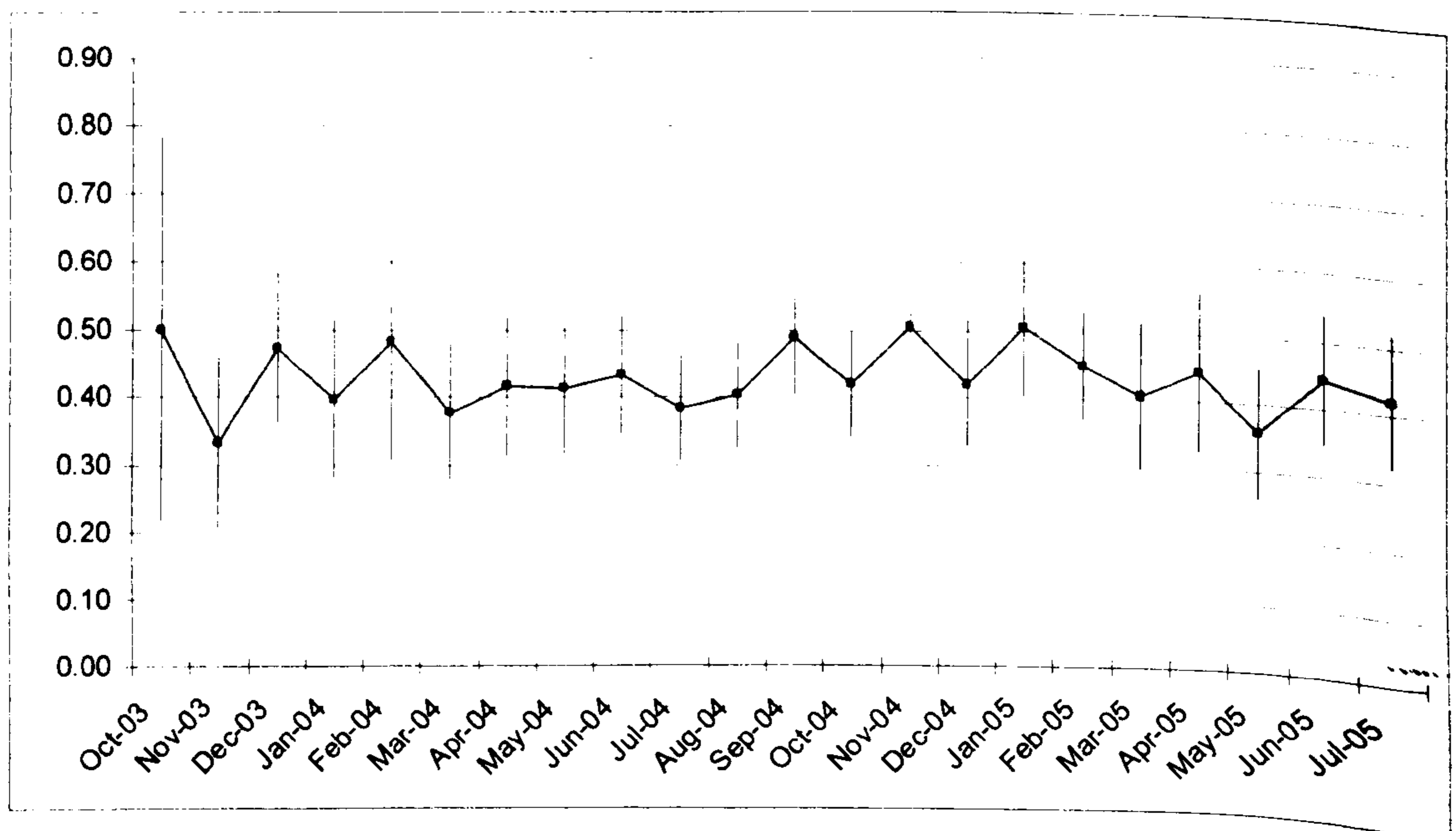


Figure 9.7: Trend line over two years showing the proportions (95%CI) of patients meeting standard 3 for all health centres in Lima combined

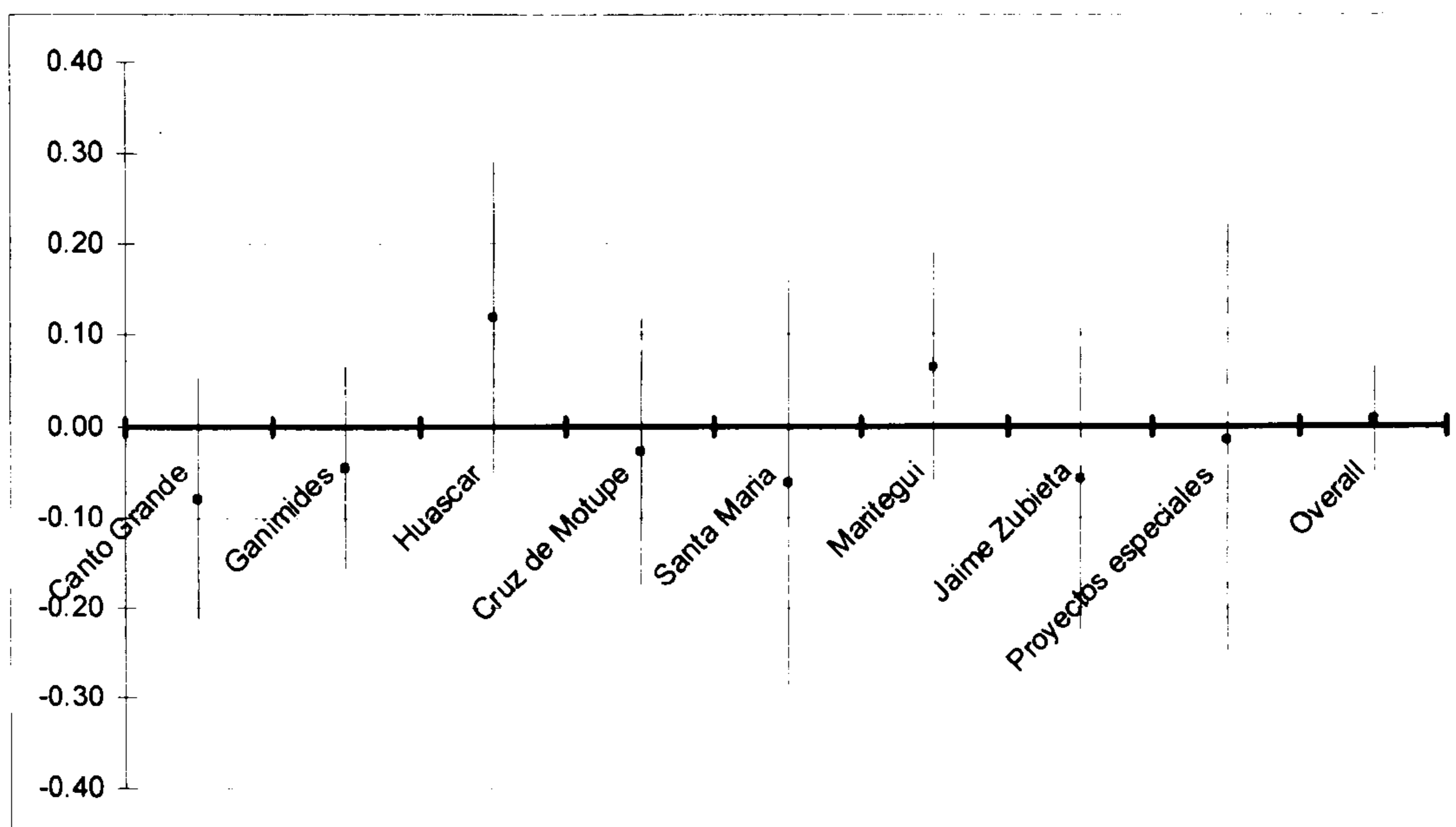


Figure 9.8: Absolute difference between the mean proportions (95%CI) of the first and the last quarter for standard 3 in each health centre in Lima, Peru

Following the action planning, a number of workshops were held on identifying radiological signs of PTB. Workshops were also conducted on the importance and application of evidence-based medicine and research.

9.1.1.4. Standard 4a and 4b

According to WHO guidelines, all patients with suspected TB (as defined by the National TB programme) should have at least two sputum smear examinations. Clinicians should review the results in order to make further diagnostic decisions using the diagnostic algorithm. Standard 4a measures the proportion of patients with suspected TB who return for a review to the health centre once sputum smear examination has been requested in the first visit. Standard 4b measures the proportion of these patients returning for a review to the health centre with their smear examination result. Figure 9.9 and Figure 9.10 show the trends for these standards over the two-year period (except for the first two months due to delay in the start of data collection). There is a gradual improvement in standard 4a showing that health professionals managed to persuade more patients to return for a review; however, there was a relative reduction in the number of these patients returning with their sputum results (4b). Similarly, a comparison between the proportions in the first and the last quarter show the same discrepancy between the two standards (Figure 9.11 and Figure 9.12). Nevertheless, on combining the two standards, there is an overall increase in the proportion of patients who returned with sputum examination results (Table 9.3).

Table 9.3: Absolute difference between the mean proportions in the first and the last quarter of standards 4a, 4b and their combination

Standards	Mean proportion in the last quarter	Mean proportion in the first quarter	Difference (95% CI)	z	p value
4a No. of patients returning to the second visit / all patients that had a sputum requested at the first visit	0.55	0.37	0.18 (0.12 to 0.23)	5.94	Less than 0.001
4b No. of patients returning with smear result / all patients returning to the second visit	0.69	0.83	-0.14 (-0.22 to 0.07)	-3.81	Less than 0.001
4a+4b No. of patients returning with smear result / all patients that had a sputum requested at the first visit	0.38	0.31	0.07 (0.01 to 0.12)	2.42	Less than 0.05

The audit committee considered standard 4a and 4b as two key standards due to the potential impact on and relevance to case detection rates. During the committee meetings, the following factors were discussed as the major impediments in achieving these standards.

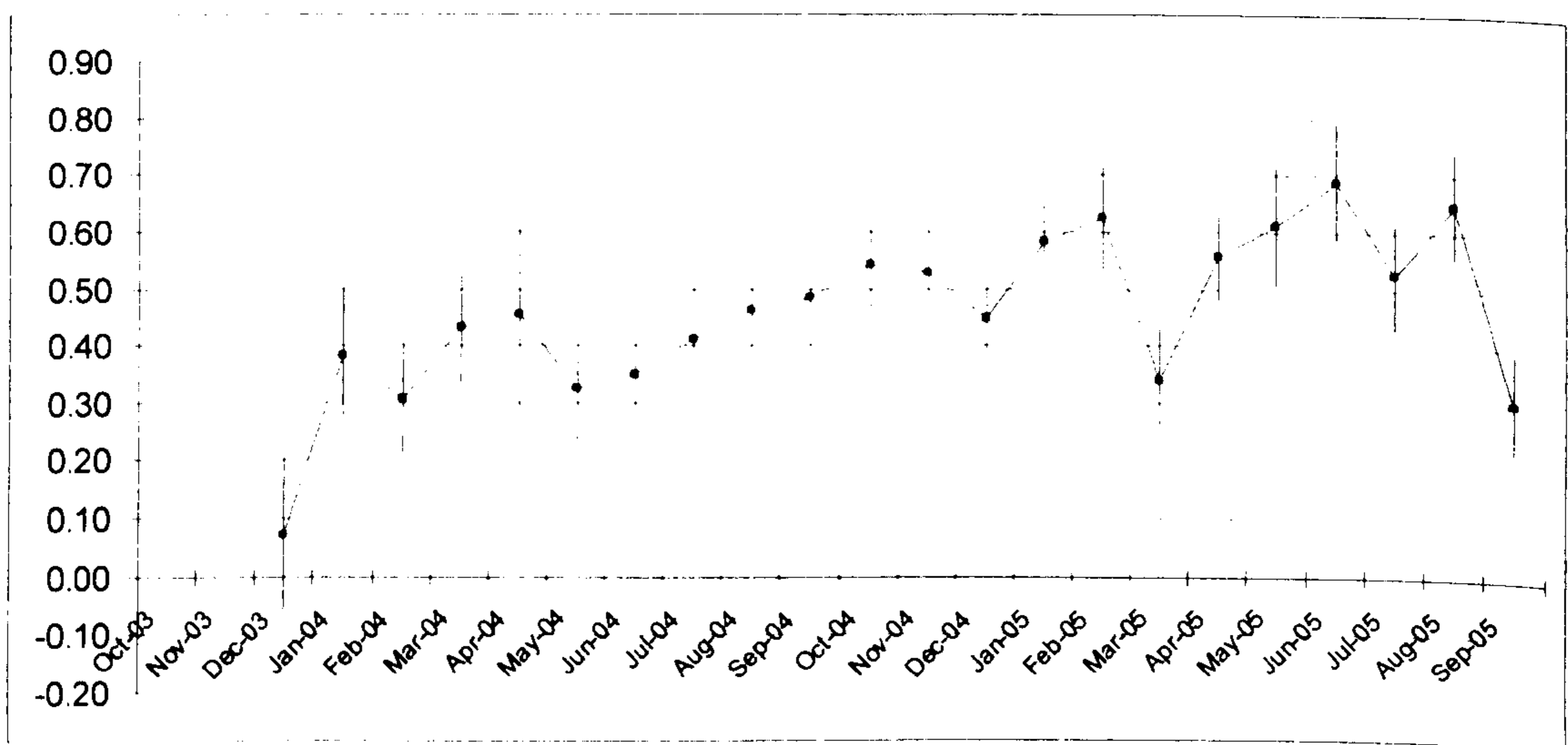


Figure 9.9: Trend line over two years showing the proportions (95%CI) of patients meeting standard 4a for all health centres in Lima combined

- When patients collect their sputum results from the laboratory and find that they are negative for AFB, they often do not bother going back to clinicians for follow up. There is little awareness about smear negative TB, and patients consider themselves to have possible TB only if the sputum examination is positive for AFB. In addition, there is a consultation cost to be paid by the

patient for each visit to the clinician and own costs in terms of time of waiting or coming back for another appointment.

- Patients sometimes show and discuss their laboratory results with the clinician at the clinic door; both patients and clinicians consider this to be cheaper, and less time consuming. However, this may lead to missing of the next steps in the diagnostic pathways.
- Clinicians in the committee also pointed towards the lack of clarity in the TB programme guidelines for patients with negative TB smear results.

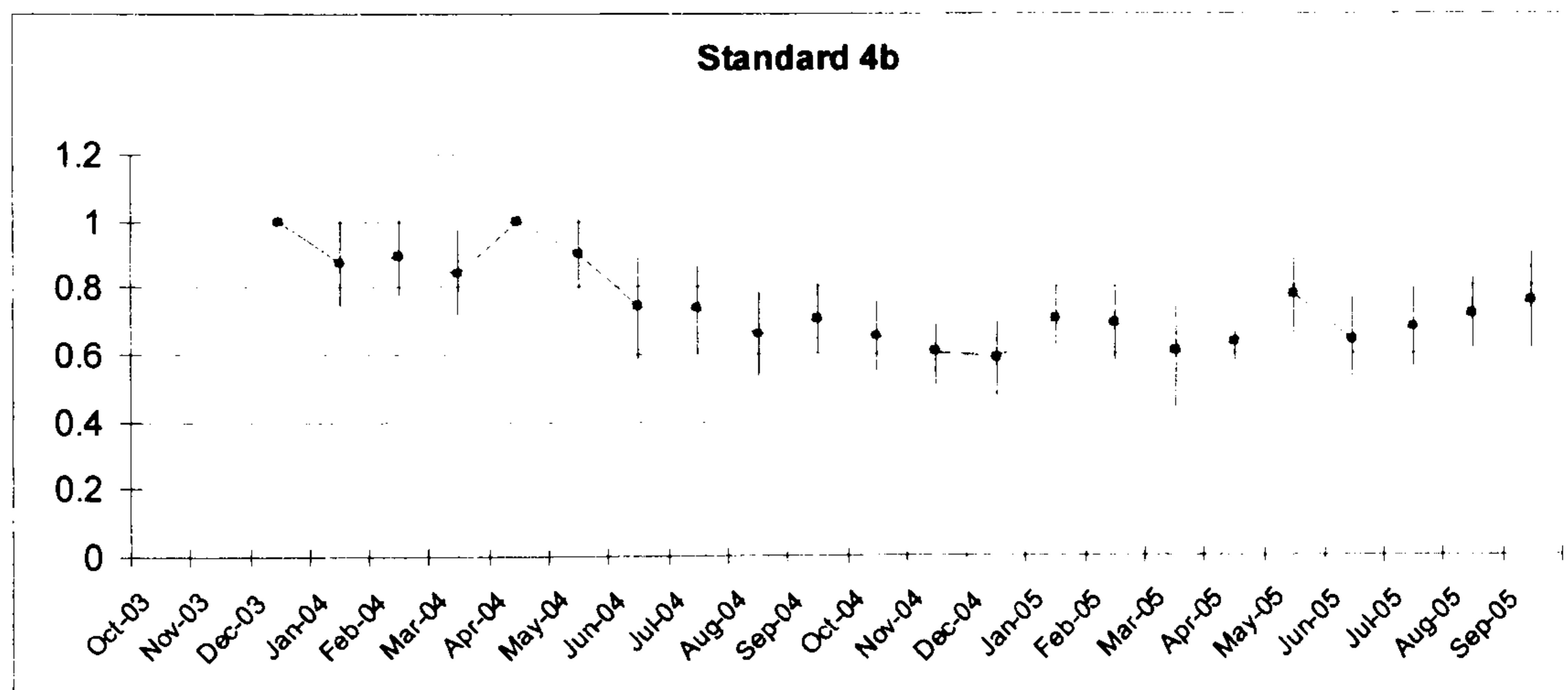


Figure 9.10: Trend line over two years showing the proportions (95%CI) of patients meeting standard 4b for all health centres in Lima combined

The audit committee proposed the following actions to improve these two standards.

- Partial or total acquittal of the cost for a second medical visit.
- Smear result to be directly filed in the patients' case notes and not to be handed out to patients directly.
- Laboratory would only hand out the results to patients if they were able to show a health centre slip confirming their second visit appointment.
- To hand out a leaflet with the sputum request clearly stating that "You might have TB even though your sputum smear turns out negative; do come back for a second visit".
- Community education campaigns highlighting that a negative TB sputum result does not rule out TB.
- The committee also learned that patients were being told that their results are "suspicious" despite being negative by the laboratory staff in order to persuade them to visit their doctor. However, this was not a strategy endorsed by the audit committee.

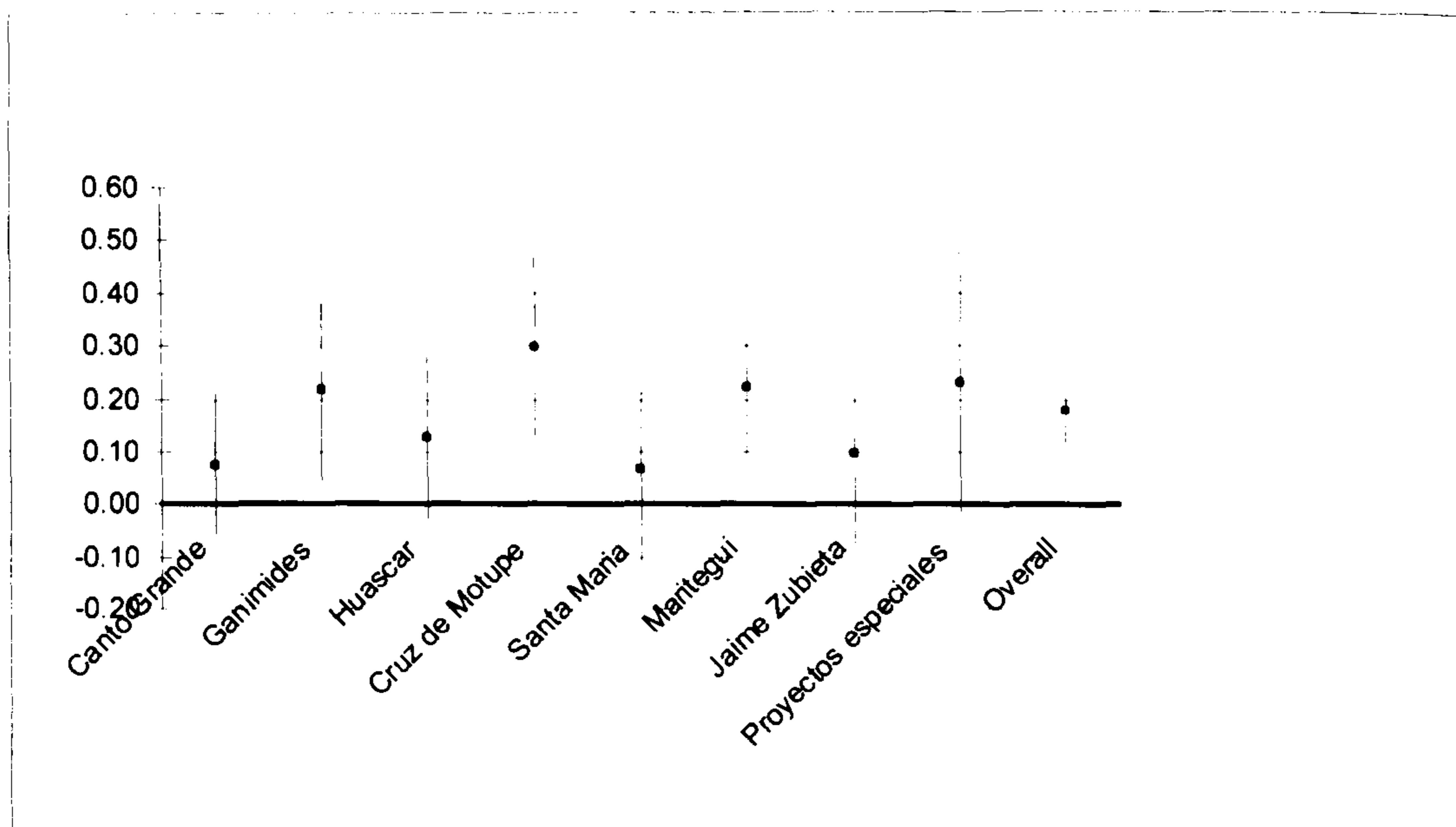


Figure 9.11: Absolute difference between the mean proportions (95%CI) of the first and the last quarter for standard 4a in each health centre in Lima, Peru

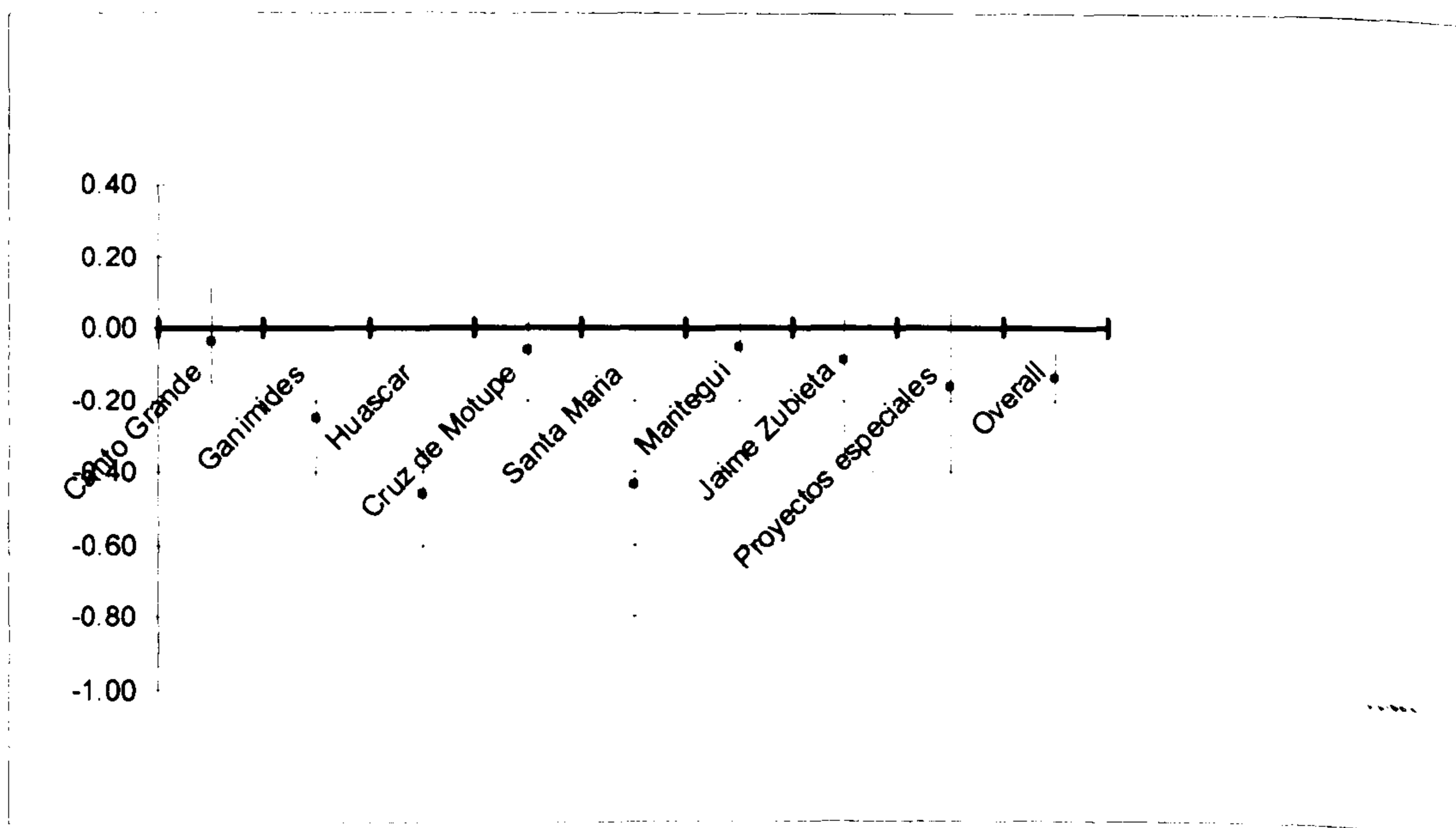


Figure 9.12: Absolute difference between the mean proportions (95%CI) of the first and the last quarter for standard 4b in each health centre in Lima, Peru

9.1.1.5. Summary

In summary, three audit cycles were completed in Lima. The audit committee met regularly on a monthly basis and received feedback on a six monthly basis. Problem identification and action planning to implement solutions were done subsequently. In between six monthly feedbacks, audit committees met to review on

the progress against their action plans. Despite this intervention, none of the standards reached their desired and agreed levels. Statistically significant improvement was detected in two out of five standards; however, only one of these observations carried clinical significance. The following sub-section presents the findings of the qualitative interviews conducted in June and July 05, which will help to elucidate the above results.

9.1.2. Themes from qualitative interviews conducted in Peru

Sixteen interviews were conducted with key health professionals working in the health centres that took part in the project. These included eight doctors (general practitioners), seven nurses and one laboratory technician. Mean age of the interviewees was 41 years (range 25-60 years). Mean duration in the current post was 2.5 years (range 0.25-8 years).

The following main themes emerged from these interviews

9.1.2.1. Shared goals (lack of support from the TB programme)

Teams are perceived to be effective if they have a shared vision, objectives and targets. Consensus between clinicians and managers on what needs to be done in order to bring improvement appears to be one of the biggest determinants of improving quality of care. People generally agreed that a successful team needs common goals. However, tensions due to lack of such agreement were reflected in almost all interviews (Box 1.1). These tensions were felt at many levels:

- NTP at the Ministry level (central) asked health centres to recruit a certain number of 'sintomaticus respiratorious' to reach their targets, and clinicians tried to restrict this recruitment to only those patients fulfilling the agreed definition.
- Clinicians had differing opinions on the appropriateness of X-ray at the first or second appointment. This was also in conflict with the NTP guidelines that require X-rays to be performed at the second visit.
- Clinicians held differing views as to who should qualify to have a smear examination and be registered as 'sintomáticos respiratorios'.
- Local NTP teams and other staff in the health centres differed on how much priority TB patients should receive over other patients.
- Public and private practitioners working in the same area did not have a consistent approach to managing TB patients.

Box 1.1: Shared goals

“The important thing in a team is that everyone have the same goal, that they work for the same thing” (TB Programme head [doctor])

“The team has a single and common mission and vision” (TB Programme head [doctor])

“The MINSA (NTP at the Ministry level) goal for recruiting ‘sintomáticas respiratorias’ has a negative influence, since it forces us to recruit non-‘sintomáticas respiratorias’ patients to reach the goal” (TB Programme laboratory technician)

“What prevents an improvement are the goals stated by MINSA” (TB Programme head [doctor])

“The MINSA goal hinders our goal as it forces us to meet the (MINSA) goal just to meet it, even though they are not all true ‘sintomáticos respiratorios’” (TB Programme nurse)

“When the report (MINSA) deadline is close, the detection intensifies and increases..” (TB Programme head [doctor])

“reaching this goal is not possible because we cannot ignore the high number of patients who come with cavitations or with almost no lung and that are smear negative. I need the X-ray to include them in the programme” (TB Programme head [doctor])

“every doctor has his own clinical point of view and they don’t easily accept changes. They justify by saying that according to the patient’s clinical history, the negative smear result is not reliable” (TB Programme head [doctor])

“it is difficult to unify criteria- some doctors agree on the assigned goal, others don’t” (TB Programme head [doctor])

“not all members of the health centre get involved with the PCT” (TB Programme nurse)

9.1.2.2. Health professionals’ views on patients’ perspective

Clinical decisions and actions are often influenced by patients’ perceptions about them. A number of clinicians felt that by following the NTP in a variety of situations, they would lose their “credibility”, and eventually patients. The following clinical situations were mentioned repeatedly, (Box 1.2) where clinicians felt their

actions (as per guidelines) may not be trusted as the right course of action by patients.

- Requesting smear examination only when someone is coughing for more than two weeks
- Not performing an X-ray at the first encounter between doctor and patient
- Asking patients with suspected tuberculosis to return to the health centre after a course of antibiotics

Box 1.2: Health professionals' views on patients' perspective

“they lose trust in one, they think the doctor doesn't know what they have, and they decide to go somewhere else - to another doctor”(TB Programme head [doctor])

“Regarding those who don't come back is generally due to disbelief: ‘I'm not a patient, I don't feel sick’”(TB Programme nurse)

“There's pressure on behalf of some of the patients to get into the PCT since despite not being ‘sintomáticus respiratorious’, they think they're being treated wrongly if not included in the programme”(TB Programme head [doctor])

“Another problem that explains why some don't return is that some receive their results and it is negative and they think they are healthy”(TB Programme head [doctor])

“What also happens is that if the patient is smear negative he thinks he is healthy. This is more often because the assistant doctors give them antibiotics or symptomatic medication that diminish the symptoms entering an apparent ‘recovery’ phase”(TB Programme head [doctor])

“one has to request it for them. If one does not do that, one loses credibility, and finally loses the patient. I'd rather request the X-ray than to lose my credibility”(TB Programme head [doctor])

“they lose trust in one, they think the doctor doesn't know what they have, and they decide to go somewhere else - to another doctor”(TB Programme head [doctor])

Clinicians admitted that they deviated from the guidelines in many cases in order to do what they thought their patients would perceive as a “credible” decision. They also proposed to run an education campaign aimed at influencing patients' perceptions about TB diagnosis.

9.1.2.3. Lack of resources

Lack of human and financial resources appears to be one of the main limiting factors in service improvement (Box 1.3). Poor infrastructure and years of disinvestment featured as one of the main reasons for lack of capacity to provide a better service. However, at least two interviews recognised possible waste of resources in the system leading to inefficiency in an already under resourced system.

Box 1.3: Lack of resources

“For example, in the mornings I help the PCT, but I have other programmes besides it, which means there is not much time for the patients in the PCT” (TB Programme nurse)

“there are no funds for simple things, sputum jars for example” (TB Programme nurse)

“Lack of resources, inadequate infrastructure, staff with too much workload, which prevents quality care. The patient care is by quantity not quality, when it should be the other way around” (TB Programme nurse)

“The lack of resources is a negative influence - there weren't small cups at the beginning of the year” (TB Programme head [doctor])

“Staff is not permanent, they have other duties, the work load is excessive. Not all the staff is “involved” in the work” (TB Programme laboratory technician)

“There's the fact that the environment and the infrastructure are not the proper ones - we do not have chest X-rays. The technical staff have low incomes and are demanded a lot of work” (TB Programme head [doctor])

“What doesn't allow for improvement: the PCT service doesn't have the proper and necessary infrastructure” (TB Programme head [doctor])

“It is not enough to have good intentions and good ideas. Without resources there can't be any progress” (TB Programme head [doctor])

“the State doesn't spend on health and education - if there's no investment in health and education, there won't be any development, despite all the goodwill” (TB Programme head [doctor])

9.1.2.4. Communication

Lack of communication emerged as one of the barriers in improving quality of clinical care (Box 1.4). Lack of communication at many levels can act as a deterrent to improvement. The following were highlighted in the interviews:

- Need for clear communication between a leader and her subordinates. This related to feedback and information
- Need for good communication between district management and health centres in terms of clear policies and feedback
- Poor links and communication channels between laboratories and clinical staff which led to procedures and policies which did not make sense to clinicians and resulted in poor quality of care
- Need for good interpersonal relationship and communication between members of a multidisciplinary team

Box 1.4: Communication

“There should be more meetings with the lab personnel-without their support improvement is difficult” (TB Programme [doctor])

“What is important in a boss is constant and direct communication with the team, to see the mistakes in the programme and correct them in time” (TB Programme [doctor])

“The problem we face with the reference laboratory is that sometimes they refuse to take our samples. In fact, they accuse us of not reading the guidelines, but we do read it....All the problems could be solved if we discussed it with them in our routine meetings with the laboratories This way we could homogenize criteria towards the lab samples and their handling” (TB Programme nurse)

“the DISA (district management) does not always give an adequate and complete feedback to the Microrredes (health centres), increasing the distance between them” (TB Programme co-ordinator (nurse) for all health centres)

“when information and feedback is not adequate and timely personal relations in the team deteriorate: others are not informed on decisions taken” (TB Programme co-ordinator (nurse) for all health centres)

“I think that when work is done in groups, they have to be connected, that is, there has to be coordination. Communication has to be direct. In our case its direct” (TB Programme nurse)

9.1.2.5. Poverty

Many interviewees perceived patients' socio-economic and employment status as one of the major inhibiting element in improving services (Box 1.5). Each visit to the health centre results in a direct cost for patients. Besides, this visit is often made at the cost of that day's wages. Interviewers perceived this as a major deterrent for patients to follow diagnostic algorithms that involve more than one clinic visit for diagnosis. Some interviews proposed ways to subsidise follow up visits.

Box 1.5: Poverty

"They also don't come back because they consider that they don't have enough money for secondary exams....when they have a job, they can't afford to miss one day" (TB Programme head [doctor])

"It also implies a big cost for them to return and they can't stop working" (TB Programme nurse)

"Those who don't return are because they don't have time. They work and cannot easily ask for permission. The PCT (National TB Programme) team should try to accommodate to those patients" (TB Programme head [doctor])

"'sintomaticus respiratorious', when they do not have money, it's difficult to exonerate them from payment, because they're not yet part of the programme" (TB Programme head [doctor])

"When patients don't return it is generally due to their strict work schedules which don't allow them any time off"(TB Programme nurse)

9.1.2.6. Frequent changes in policies and personnel

Interviewees expressed that frequent changes in personnel at the central level (often politically motivated) and subsequent changes in policies and procedures, result in lack of consistent improvement in the service (Box 1.6). This results in job insecurity, favouritism, delays in improvement, lack of long term planning and continuity.

Box 1.6: Frequent changes in policies and personnel

“There is no long term plan- each new government changes everything, including these programmes” (TB Programme nurse)

“Since there have been consecutive changes, there is no continuity”

“Another problem is the excessive rotation of those in charge” (TB Programme laboratory technician)

“Frequent administrative changes don't allow for the stability necessary for the development of the goals” (TB Programme [doctor])

“there are delays, probably due to constant changes in authorities” (TB Programme [doctor])

“so frequent changes in the directives and authorities cause many delays and stimulates favouritism” (TB Programme nurse)

“there are frequent authority changes, new guidelines, directives, suggestions, every time someone new comes we have to begin from zero. That represents a big delay for any improvement” (TB Programme [doctor])

9.1.2.7. Differential treatment towards healthcare professionals

There was a general sense of unfairness amongst health care professionals, leading to lack of motivation and willingness to improve services (Box 1.7). A number of interviewees stated that they are treated differentially by senior management in many ways. Some of these are as follows:

- Urban health facilities (being closer to the management) get more resources than rural health facilities
- Permanent staff are treated differently from temporary staff. They are given better pay and extra allowances
- People with political connections are treated with more respect
- People with personal relationships with senior management in the district or ministry level can get more for their health centres
- Doctors are given more opportunities for training over nurses and laboratory technicians

Box 1.7: Differential treatment towards health care professionals

“there is preference for those in the city over the ones in the peripheries” (TB Programme nurse)

“they should be fair. They should give everyone equal opportunities and should be measured with the same rod whether they are permanent or temporary. (TB Programme nurse)

“preference in access to resources is given to friends or people who know the bosses” (TB Programme [doctor])

“there is total indifference. You can tell the difference when you have acquaintances” (TB Programme laboratory technician)

“there is a difference. Permanent staff gets more help but the temporary ones don't. they are given leave, they don't work on Saturdays” (TB Programme laboratory technician)

“years ago I applied for a job and they asked me if I am a member of a certain party. If I was I would have got the job. This is not fair but this is very common here” (TB Programme nurse)

“It all works through who you know inside and other influences” (TB Programme nurse)

“the training should be for all of the team. It shouldn't only be for doctors. Nurses and technicians should also be involved” (TB Programme nurse)

“There is help given and things made easier depending on who you know” (TB Programme nurse)

“The whole team needs better training. Not only doctors” (TB Programme nurse)

“I should not be left on one side because I am a technician” (TB Programme nurse)

“we are almost rural. Help does not reach us. We only receive obligations and no rights” (TB Programme [doctor])

“state does not compensate us adequately especially if we are not permanent staff” (TB Programme nurse)

9.1.2.8. Participatory leadership

A participatory leadership style was seen as a major facilitator for improving patient care (Box 1.8). Conversely, a distant relationship between management and front line staff leads to lack of interest and apathy. Such a distant relationship, which was a feature of the dealings between the district management and the health centres, was mentioned as a barrier to improvement. Health professionals felt motivated by working with leaders who lead by example by taking initiatives and seeing these through. Participatory leadership helps leaders to understand the strength and weaknesses of their team and helps in solving problems. Such leaders, by showing empathy towards staff, command mutual respect. Box 8 provides a number of statements, where interviewees expressed this.

Box 1.8: Participatory leadership

“they are far away. They come once every three months, they don’t participate as a team” (TB Programme nurse)

“there is a total indifference, such as you are far away. You don’t visit us or inform us....on this level there is lack of interest and abandonment...” (TB Programme head [doctor])

“there is a lack of interest that does not encourage one to work” (TB Programme head [doctor])

“the boss should actively participate in the staff work” (TB Programme head [doctor])

“the boss should always keep track of the team. He must be involved in the teams work...should be very respectful. Identify him with the team, show solidarity with the team, and try to achieve balance, be always horizontal....” (TB Programme head [doctor])

“they must know and identify problems- know how to make a strength weakness analysis – they must educate their team on the identified weaknesses” (TB Programme nurse)

“the boss should be an example – they should be seen working – they should take initiatives towards the work involved” (TB Programme head [doctor])

“boss should help solve the problems- be creative with the solution..” (TB Programme coordinator (nurse) for all health centers)

“he should comply with his promises, otherwise they lose credibility...they will follow if you are fair.....if you are an example..”(TB Programme head [doctor])

“if there is a storm he has to be able to calm it down” (TB Programme nurse)

9.1.2.9. Safe environment

Provision of an environment where health professionals feel safe and also able to conduct patient assessments in privacy was one of the important factors identified by interviewees (Box 1.9). Health professionals perceive their working environment as an occupational health risk, as most of the time it does not comply with health and safety rules and regulations. Similarly, patients do not have waiting and consultation rooms where they can feel safe and confident that their privacy will be maintained.

Box 1.9: Safe Environment

“the environment is inadequate, there isn't a good place to conduct the interview- we as the personnel are at risk of being infected – we should be looked after and given a proper workspace” (TB Programme nurse)

“proper nourishment, health control, they should feel safe in the workplace.....this incentive should be giving proper working conditions” (TB Programme nurse)

“another reason that they don't come back is because of inadequate conditions in the PCT – the place where it is located is on a corner without a waiting room” (TB Programme head [doctor])

“the room still doesn't comply with bio-safety norms” (TB Programme laboratory technician)

“location where we work is totally inadequate – it does not meet the minimum bio-safety measures. Patients are received at a table at the door. It is dangerous for the personnel working here” (TB Programme nurse)

9.1.2.10. Stigma about TB

Patients' behaviour is often determined by the stigma about tuberculosis in society. Many interviewees felt that the reason many patients do not comply with TB management is because of social stigma attached with TB (Box 1.10).

Box 1.10: Stigma about TB

“they don't say whether they are really “sintomáticos respiratorios” – they are embarrassed of what others might say. Society excludes patients with tuberculosis....the apprehension they refer to is what people might say” (TB Programme nurse)

“there has already been refusal of other services to have them waiting in a waiting room beside other patients” (TB Programme [doctor])

“they don't want to return – they are embarrassed and don't want to be seen in the PCT” (TB Programme nurse)

“people are afraid and ashamed of saying they have TB” (TB Programme head [doctor])

9.1.2.11. No blame culture

Quality improvement measures require an organizational culture that does not blame and point fingers at individuals but addresses the problems by improving systems. Such transparency and a culture of no blame were felt as a requirement for improving quality of care (Box 1.11).

Box 1.11: No blame culture

“we must advise when mistakes are made – not as reprimand but to learn and improve the quality of care”

“Boss should accept personal mistakes and help them to improve” (TB Programme coordinator (nurse) for all health centers)

“The document and information of guidelines are always late or uncoordinated and then we are reprimanded, when it is them who are not communicating properly. Supervisors should be made to teach and learn, and not to judge” (TB Programme nurse)

9.2. Bolivia

9.2.1. Clinical audit

This sub-section first presents a summary of the results and more detailed results for each standard under respective subheadings.

Figure 9.13 illustrates a comparison between the trend lines for all standards measured in Cochabamba, Bolivia over an eighteen month data collection period. During this period, two audit cycles were completed, each including a period of six-month data collection and analysis, presentation and feedback of the results to the audit committee and action planning for improvement. As discussed in the previous sections (see methods chapter), for each audit cycle, data were collected for a period of six months. In the following three months, data were analysed and presented to the committee for feedback and action planning. Figure 9.13 illustrates that except for Standards 4 and 5, all standards started from the higher end of the scale and showed little change over the successive data collection periods. Both standards 4 and 5 started from the midpoint and demonstrated a visible improvement over the successive two cycles.

Table 9.4 and Figure 9.14 present the *absolute* and *relative* differences between the mean proportions of the first and the last audit cycles for all standards measured in Cochabamba. Standards 4 and 5 show statistically significant improvements between the two data collection periods. No significant change is observed for

standards 2, 3 and 6. However, there is a statistically significant improvement in the *relative* difference between the two periods for standard 2. There is a significant deterioration in standard 1. Despite the observed changes in at least two standards, none of the criteria reached the standards (90%) agreed by the audit committee except for standard 3. Similar observations can be made in Figure 9.14.

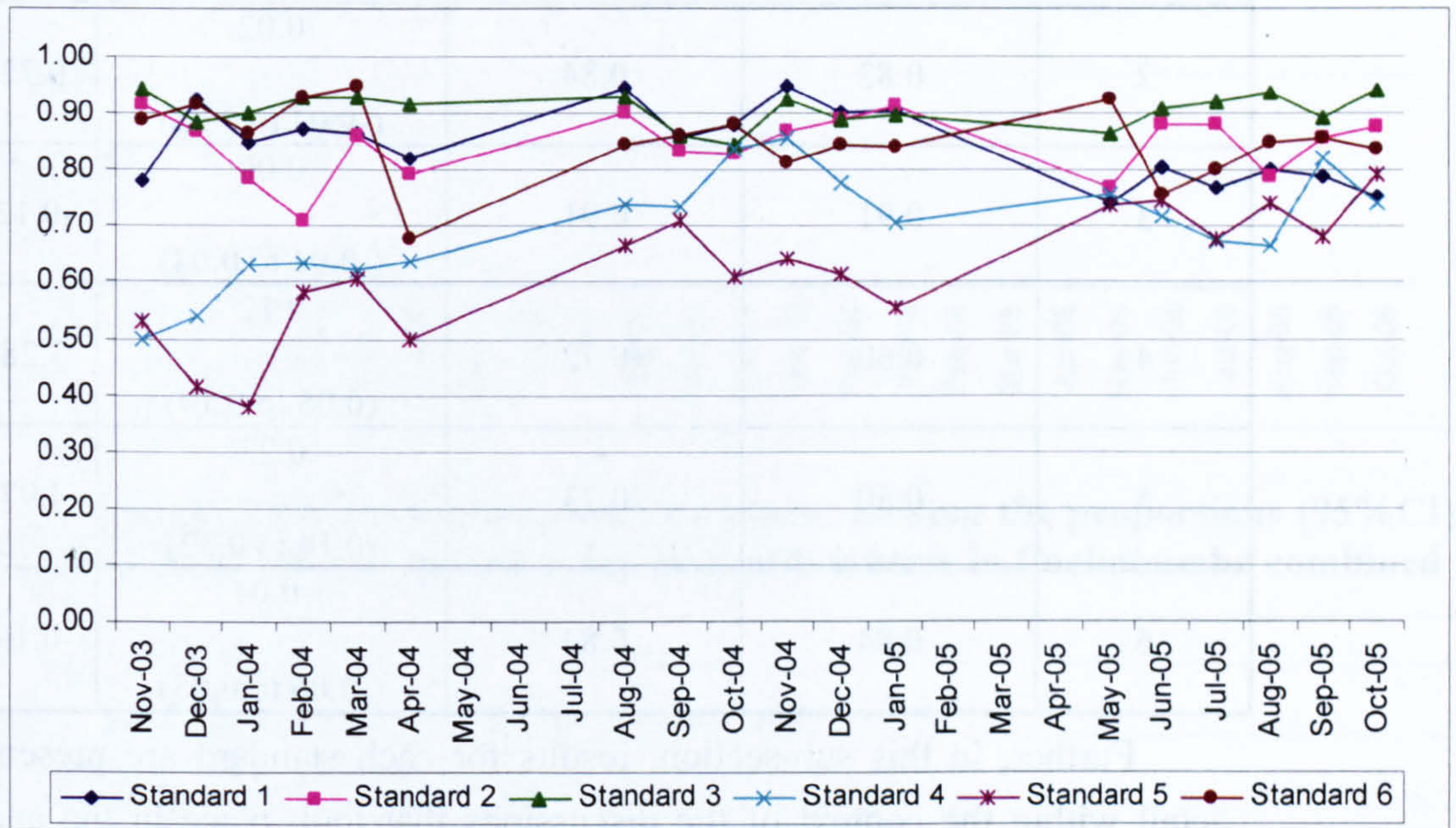


Figure 9.13: A comparison of trends for all standards in Cochabamba, Bolivia

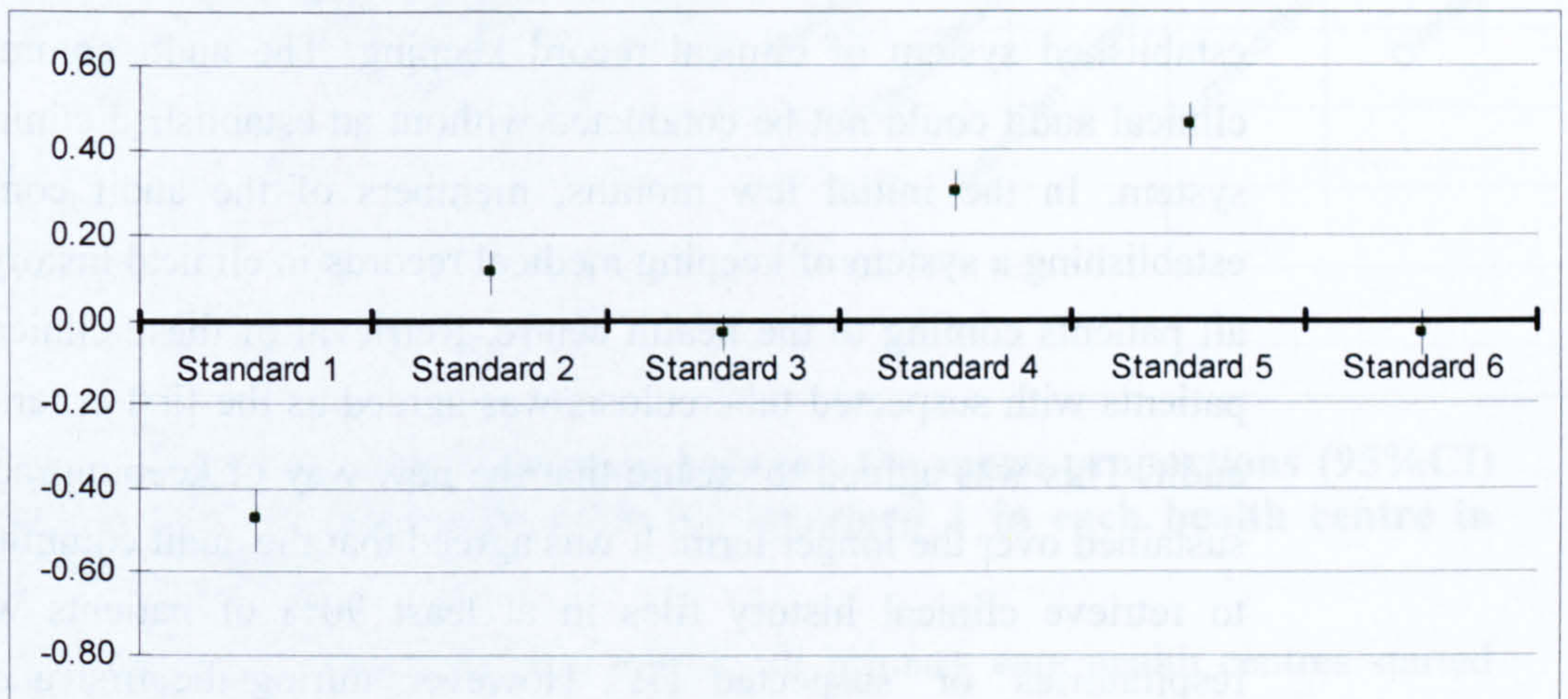


Figure 9.14: Relative difference between the mean proportions (95%CI) of the first and the last cycles for each standard in Cochabamba, Bolivia

Table 9.4: Absolute difference between the mean proportions of the first and the last audit cycle for all standards in Cochabamba, Bolivia

Standards	Mean proportion in the first cycle	Mean proportion in the last cycle	Difference (95% CI)	z	p value
1	0.85	0.78	-0.07 (-0.12 to 0.02)	-2.71	less than 0.002
2	0.82	0.84	0.02 (-0.04 to 0.08)	0.72	ns
3	0.91	0.91	0.00 (-0.04 to 0.04)	-0.12	ns
4	0.60	0.72	0.12 (0.05 to 0.19)	3.28	less than 0.001
5	0.50	0.73	0.23 (0.14 to 0.32)	4.97	less than 0.001
6	0.84	0.84	-0.01 (-0.06 to 0.05)	-0.19	ns

Further, in this sub-section, results for each standard are presented in more detail within the context of the discussions that took place in the audit meetings about these results.

9.2.1.1. Standard 1

In Cochabamba, some of the participating health centres did not have an established system of clinical record keeping. The audit committee realised that clinical audit could not be conducted without an established clinical record-keeping system. In the initial few months, members of the audit committee helped in establishing a system of keeping medical records in clinical history files allocated to all patients coming to the health centre. Retrieval of these clinical history files for patients with suspected tuberculosis was agreed as the first criterion for the clinical audit. This was agreed to ensure that the new way of keeping medical records was sustained over the longer term. It was agreed that the audit committee should be able to retrieve clinical history files in at least 90% of patients with “sintomáticos respiratorias” or “suspected TB”. However, during the first audit cycle this was achieved in 85% of cases, which was maintained in the second audit cycle but dropped to 78% in the last cycle (Figure 9.15). Except for one health centre that showed clear improvement, all the other health centres showed the same trend (Figure 9.16). However, these figures do not show the change in the clinical record system attributable to the introduction of clinical audit into these health centres.

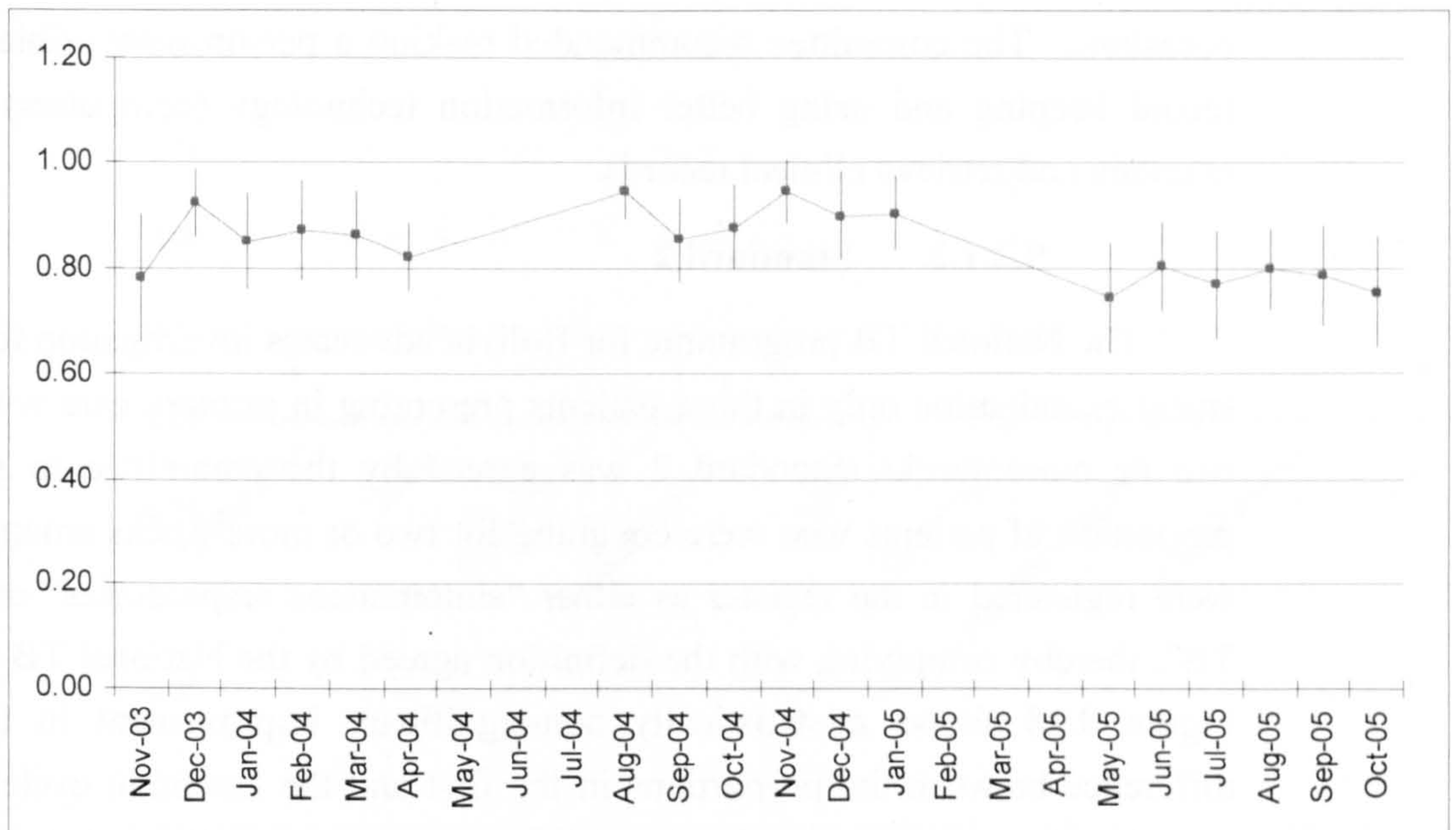


Figure 9.15: Trend line over two years showing the proportions (95%CI) of patients meeting standard 1, for all health centres in Cochabamba combined

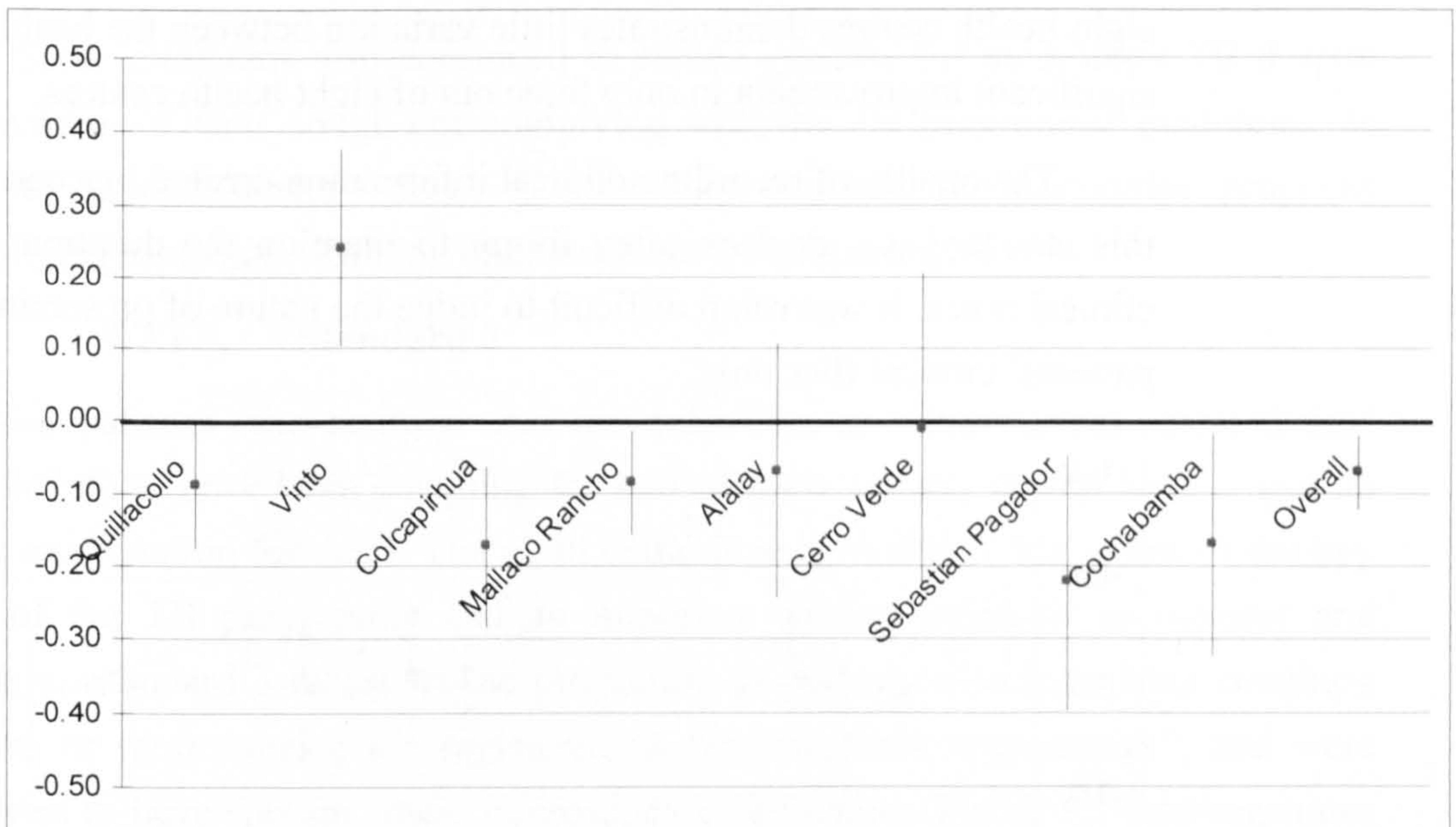


Figure 9.16: Absolute difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 1 in each health centre in Cochabamba, Bolivia

During the last data collection period, all primary care health centres started providing maternal and child health services resulting in increased number of consultations and lack of space in the health centres. Lack of sufficient room to store clinical records and their shifting from one room to another made the retrieval of clinical records quite difficult. The committee highlighted this as one of the main reasons for the drop in standard 1 during the second audit cycle. Clinicians' poor handwriting made the clinical file number or patient's name untraceable on many

occasions. The committee recommended making a person responsible for clinical record keeping and using better information technology (computers) to register, maintain and retrieve clinical records.

9.2.1.2. Standard 2

The National TB programme for Bolivia advocates investigation for TB with a smear examination only in those patients presenting in primary care with cough for two or more weeks. Standard 2 was agreed by the committee to measure the proportion of patients who were coughing for two or more weeks among those who were registered in the register as either “sintomáticos respiratorias” or “suspected TB”, thereby complying with the definition agreed by the National TB programme. Figure 9.18 shows a statistically non-significant improvement in the *absolute* difference between the proportions in the first and the last audit cycles. However, the *relative* difference shows only a marginal but statistically significant improvement. Figure 9.17 shows an unremarkable pattern maintained around the higher limit and shows little change in either direction. The comparison between the eight health centres demonstrates little variation between the health centres and non-significant improvement in only three out of eight health centres.

The quality of recording clinical information created inaccuracies in measuring this standard e.g. doctors often forgot to mention the duration of cough in their clinical notes. It was often difficult to judge the nature of presenting symptoms from patients' clinical files only.

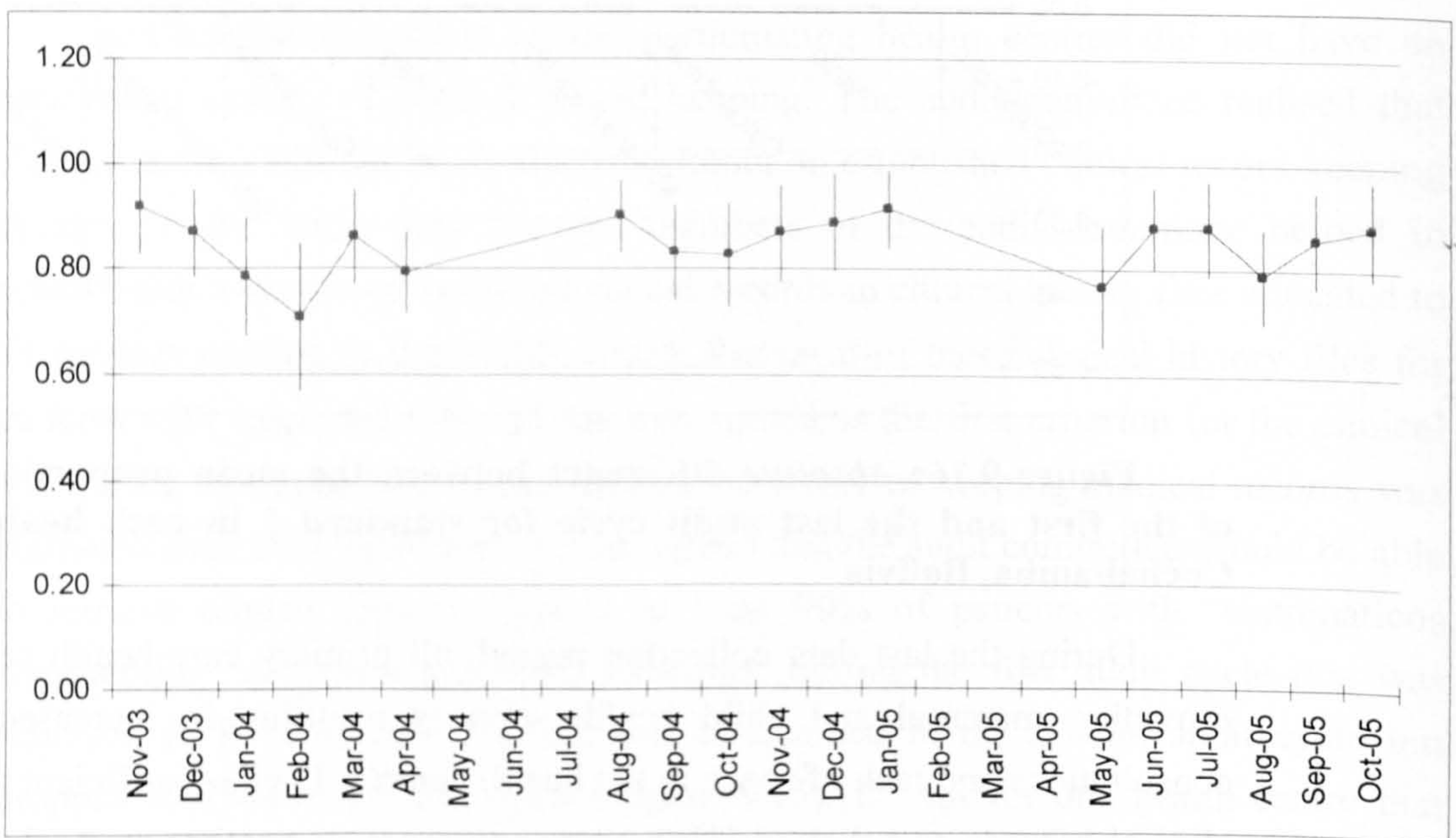


Figure 9.17: Trend line over two years showing the proportions (95%CI) of patients meeting standard 2 for all health centres in Cochabamba combined

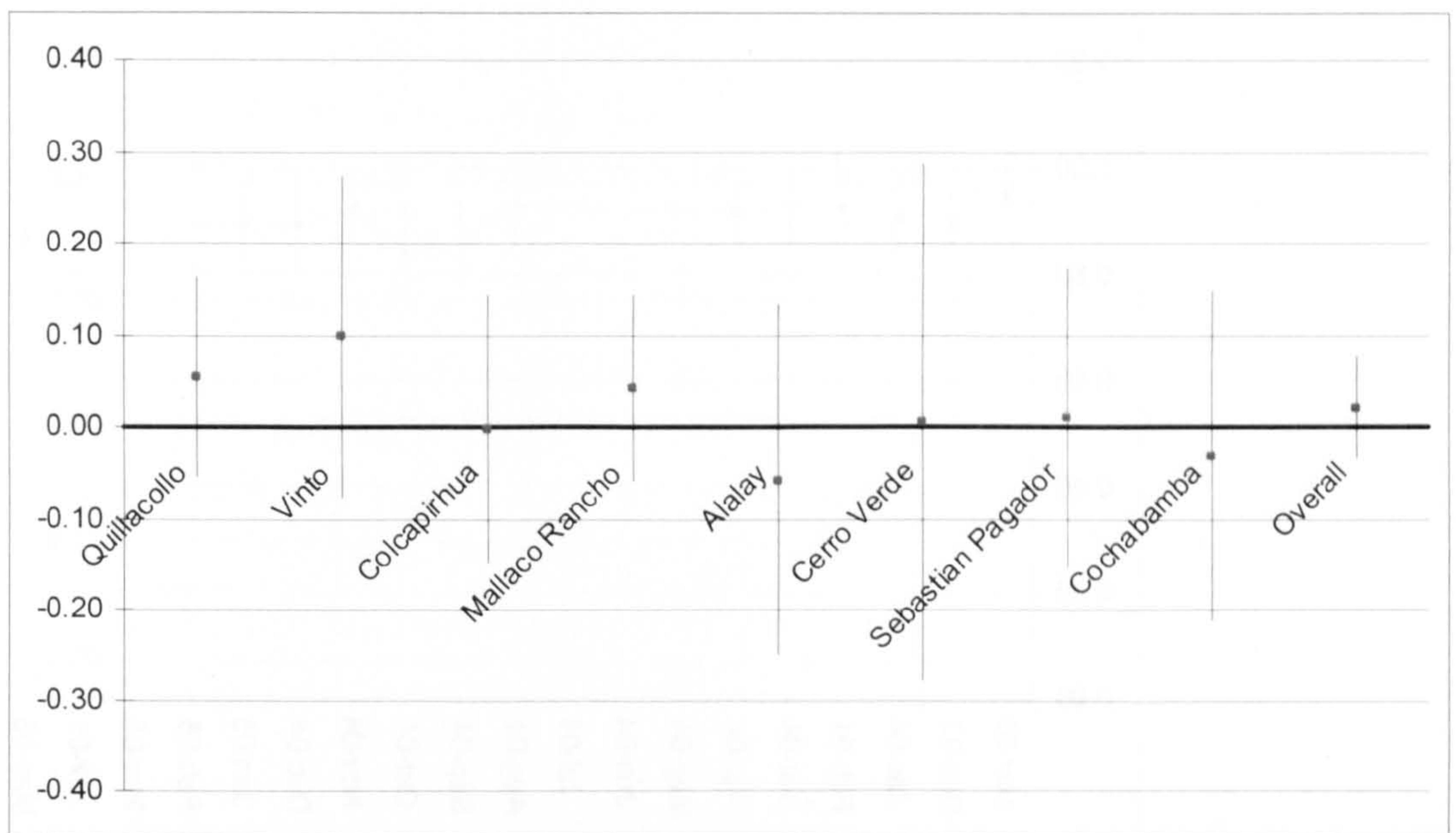


Figure 9.18: Absolute difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 2 in each health centre in Cochabamba, Bolivia

Some clinicians also continued to screen patients for pulmonary TB despite the duration of their cough not complying with the TB programme guidelines. In order to support health centres to meet this standard, the committee proposed intensifying clinicians' training on the criteria for screening PTB.

9.2.1.3. Standard 3

All patients who comply with the definition of “sintomáticos respiratorias” (and therefore, have been coughing for two or more weeks) should have a sputum smear examination for AFB. The audit committee agreed that this is one of the key aims of the TB programme and an important quality indicator to monitor and maintain. Standard 3 measures the proportion of patients who have been coughing for two or more weeks, are registered as “sintomáticos respiratorias”, and were requested to have sputum smear microscopy examination. Figure 9.19 demonstrates a steady trend for standard 3, which was maintained at the required level and was the only standard, which met the pre-determined levels. However, there was no *relative* or *absolute* difference between the proportion of patients meeting this standard in the first and the third audit cycles (Figure 9.20). There was also little variation between the health centres. Overall, health centres were meeting this standard almost from the start and were able to maintain it to the required level throughout with little variation in between different cycles.

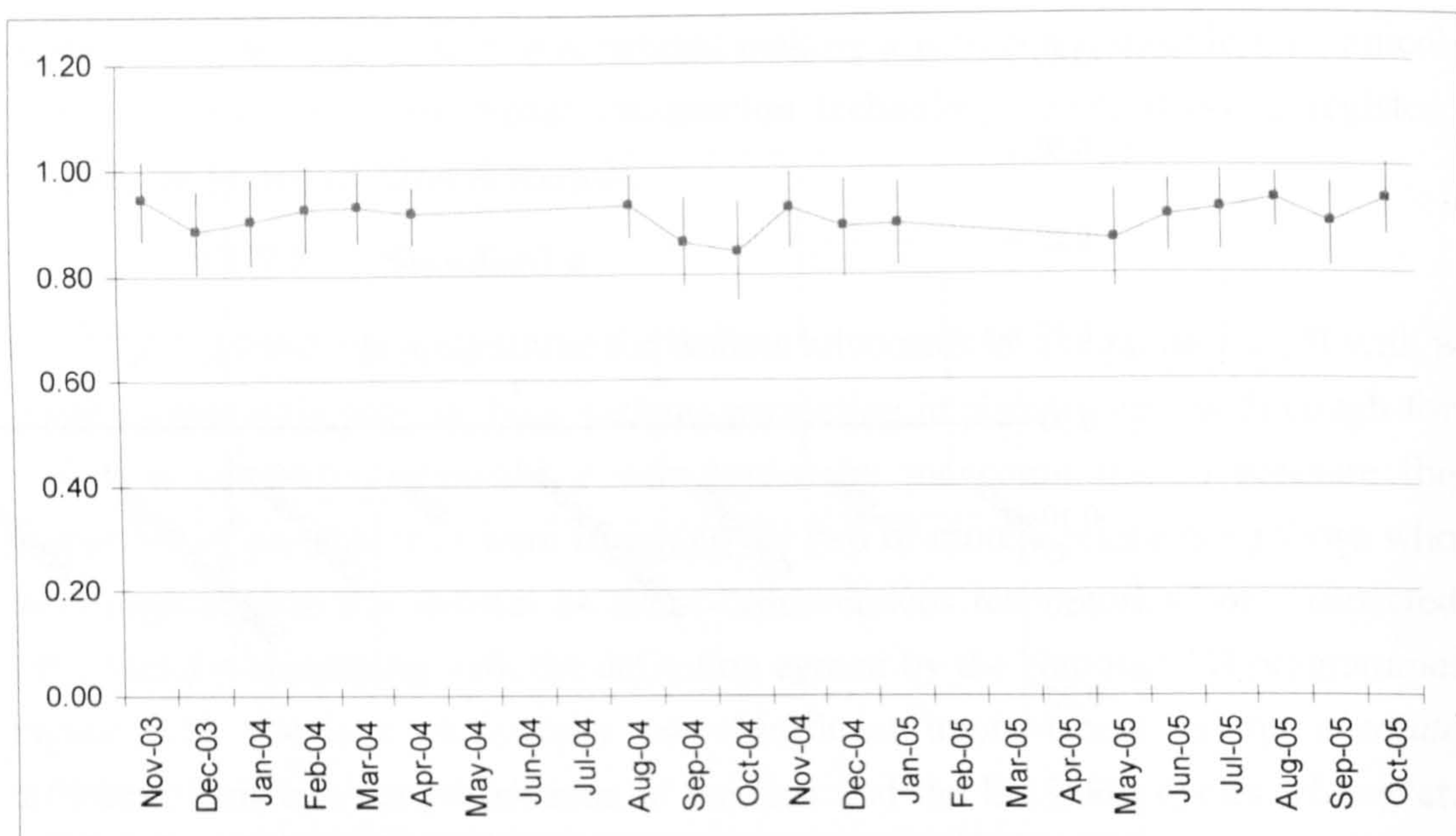


Figure 9.19: Trend line over two years showing the proportions (95%CI) of patients meeting standard 3 for all health centres in Cochabamba combined

The audit committee also acknowledged that even if doctors request a sputum examination, they might forget to record this on the patient's clinical file. Clinicians in the committee also argued that despite the TB programme's recommendation, every patient coughing for more than 15 days is not necessarily a potential TB patient and does not require a sputum examination e.g. patients with chronic obstructive pulmonary disease. Despite these exceptions, health centres maintained standard 3 at the required level. The committee continue to emphasise the importance of record keeping of all clinical decisions and investigation requests. It also recommended that even in patients coughing for more than two weeks where an alternative diagnosis is obvious, pulmonary TB must be ruled out due to its high prevalence.

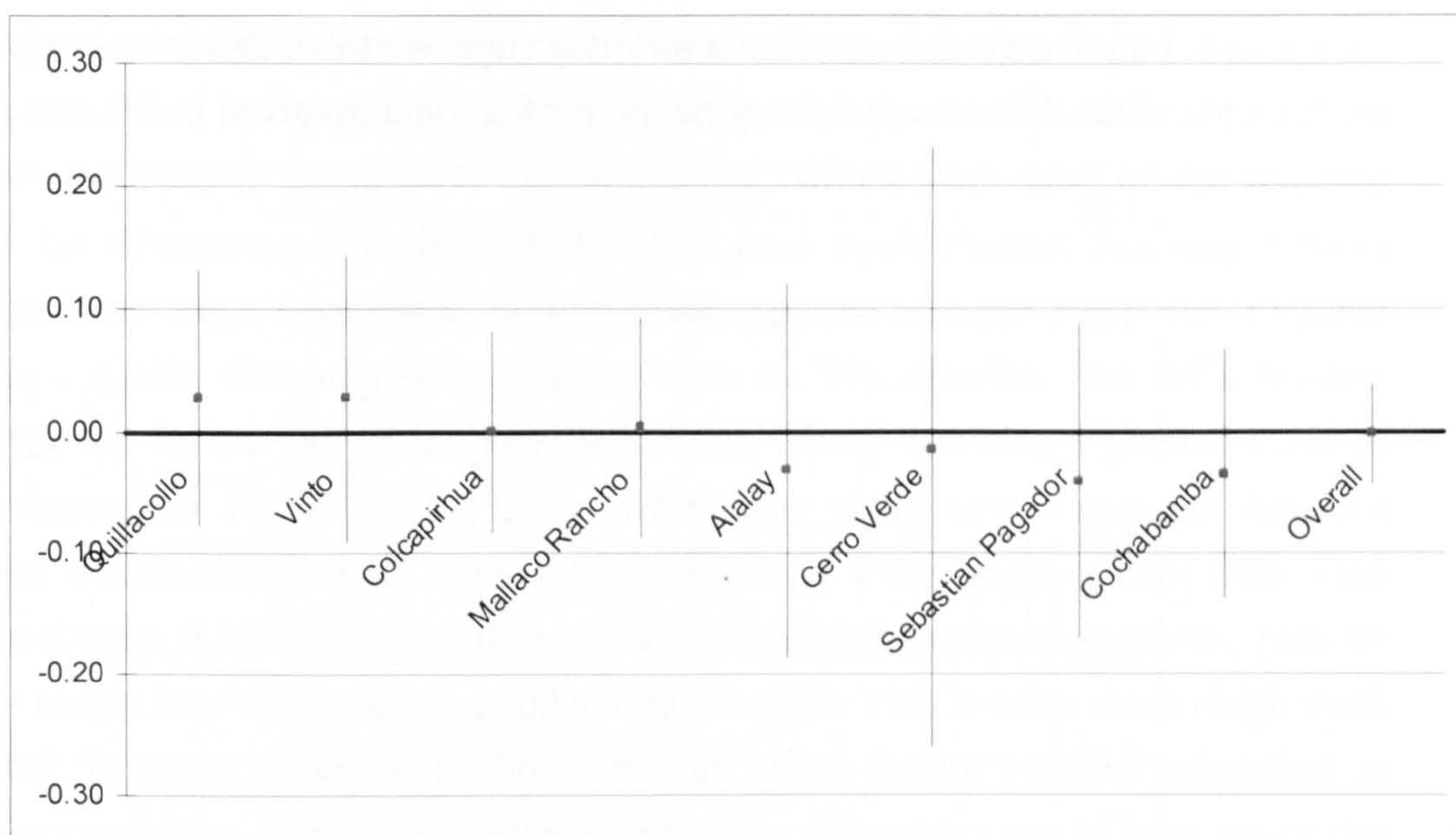


Figure 9.20: Absolute difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 3 in each health centre in Cochabamba, Bolivia

9.2.1.4. Standard 4

Despite clinicians' requests to have sputum smear examination, patients with "sintomáticos respiratorias" are often unable to deliver a sputum sample to the laboratory for microscopy. The audit committee believed that the existing system within the health centres does not ensure this key diagnostic step. Therefore, standard 4 was agreed as a measure of the proportion of patients who were requested to have a smear examination who actually managed to deliver a sputum sample to the laboratory. During the first audit cycle, only 60% of patients who were requested to have sputum smear examination managed to deliver a sample to the laboratory. There was a 12% *absolute* and a 30% *relative* improvement in this standard at the end of the third cycle. There was a sharp rise in the trend after the first cycle, which was maintained in the successive two cycles (Figure 9.21). There were also significant variations between different health centres with some centres showing more improvement than other centres (Figure 9.22).

The committee acknowledged that the national guidelines recommend collecting the first sputum sample on the same day as the first consultation. However, clinicians also recognise that the early morning samples produced on the second day following the initial consultation provide a higher yield. This is also one of the reasons for losing patients during the diagnostic process as numerous patients fail to return for the second visit. The audit committee recommended encouraging patients to provide the first sample on the day of their first consultation as per

national guidelines. The committee suggested that this is not only the responsibility of the TB nurse but every health professional involved in TB care.

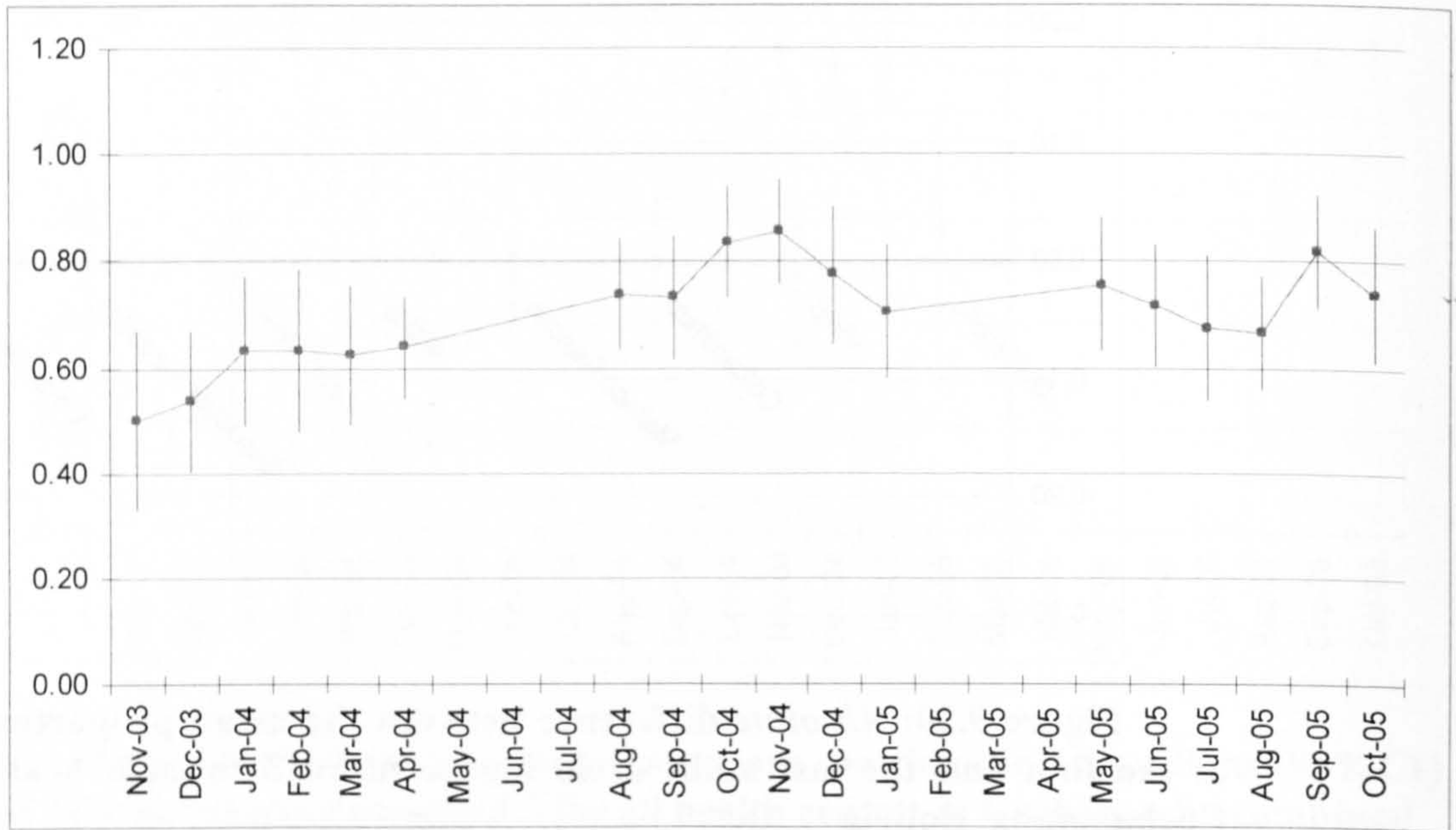


Figure 9.21: Trend line over two years showing the proportions (95%CI) of patients meeting standard 4 for all health centres in Cochabamba combined

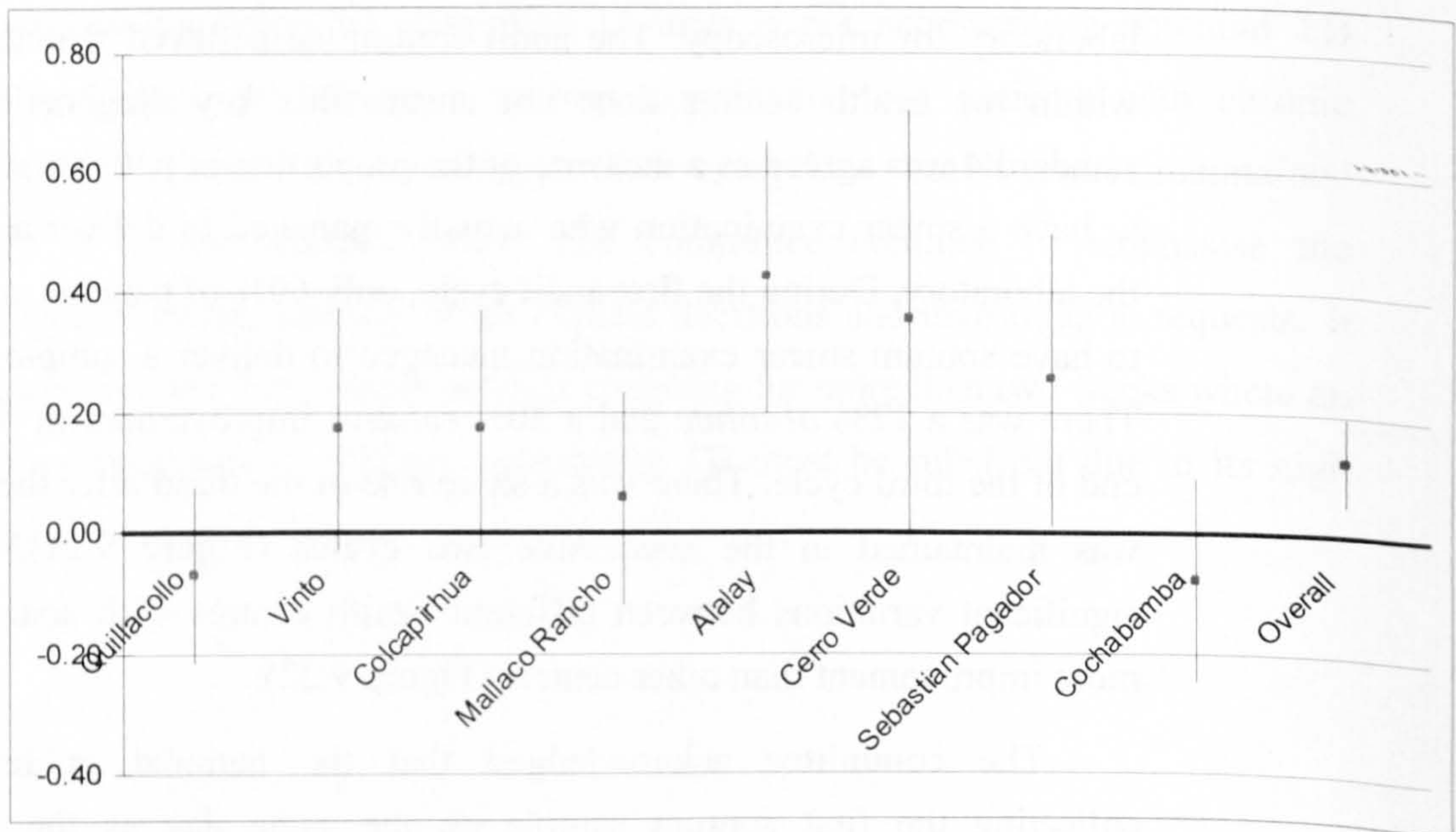


Figure 9.22: Absolute difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 4 in each health centre in Cochabamba, Bolivia

9.2.1.5. Standard 5

The audit committee suspected that the sputum samples that are delivered to the laboratory for examination are often of poor quality (e.g. saliva as opposed to

sputum) and therefore useless for microscopy examination. Standard 5 was agreed by the committee as a measure of the proportion of patients who managed to deliver at least two sputum samples to the laboratory, which were also of the required quality for microscopy examination. The first audit cycle showed that only 50% of patients who were successful in delivering sputum sample have the required specimen quality for microscopy. There was a 23% *absolute* and 46% *relative* improvement by the end of the last audit cycle. There was also a gradual trend of improvement in Figure 9.23. There were also significant variations between different health centres with some centres showing more improvement than other centres (Figure 9.24). The committee acknowledged that on most occasions, patients are not taught how to produce a good sputum sample. This is often due to high work overload. Doctors, nurses and laboratory staff often do not consider education as their responsibility. There is a tendency to assume that others would have given this information to patients. During the two audit cycles, the committee highlighted the importance of obtaining a good sputum sample. It encouraged all health personnel working in the health centres to feel responsible for communicating the importance and method of obtaining a good quality sputum sample. Committee members also urged all professionals to be committed to the quality of follow-up of all patients. Audit committee members did this through a number of local meetings with the health care staff of individual health centres. These meetings resulted in change in professional attitude reflected through improvement in their compliance with standard 5.

By combining standard 4 and 5 i.e. taking a proportion of patients who were able to deliver a high quality sputum sample to the laboratory, one can see that approximately one-third of patients who were requested to have a smear examination were able to deliver a suitable sample to the laboratory and this improved to a modest one-half after two audit cycles (Table 9.5).

Table 9.5: Absolute difference between the mean proportions in the first and the last audit cycles for standards 4 and 5, and their combination

Standards	Mean proportion in the first audit cycle	Mean proportion in the last audit cycle	Difference (95% CI)	z	p value
4. No. of patients delivering sputum sample in the laboratory / All patients that had a sputum requested by the clinicians	0.60	0.72	0.12 (0.05 to 0.19)	3.28	less than 0.001
5. No. of patients delivering a high quality sputum specimen suitable for microscopy / All patients delivering sputum sample in the laboratory	0.50	0.73	0.23 (0.14 to 0.32)	4.97	less than 0.001
4+5. No. of patients delivering a high quality sputum specimen suitable for microscopy / All patients that had a sputum requested by clinicians	0.30	0.53	0.23 (0.15-0.30)	6.00	less than 0.001

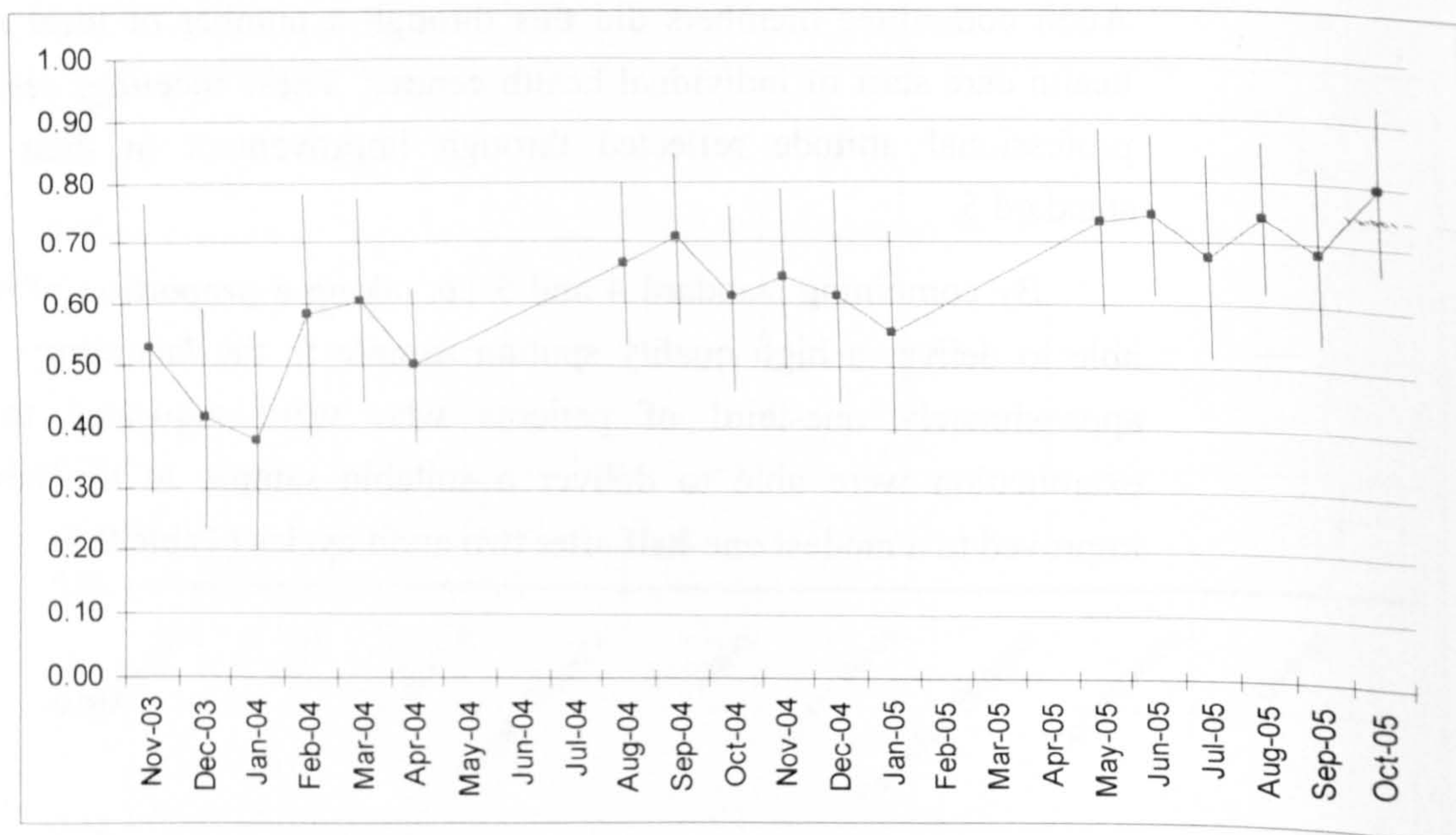


Figure 9.23: Trend line over two years showing the proportions (95%CI) of patients meeting standard 5 for all health centres in Cochabamba combined

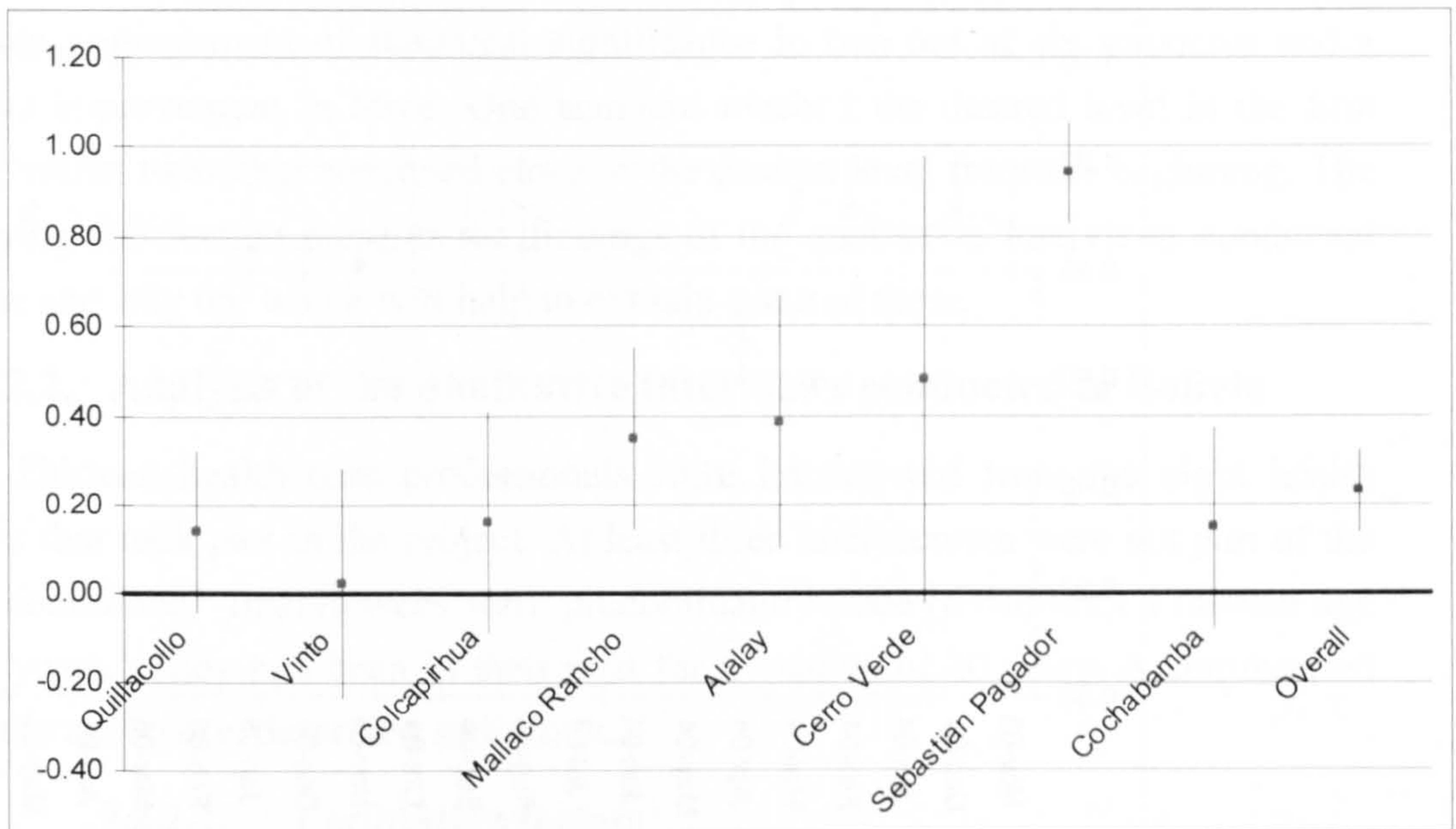


Figure 9.24: Absolute difference between the mean proportions (95% CI) of the first and the last audit cycle for standard 5 in each health centre in Cochabamba, Bolivia

9.2.1.6. Standard 6

According to the National TB programme guidelines in Bolivia, in the absence of sputum examination results and an antibiotic trial, patients should not have an X-ray at their first appointment. The committee agreed to measure this as a separate standard. Standard 6 measures the proportion of patients not having a chest X-ray at their first appointment in the health centres. Standard 6 show little variation over the two audit cycles and remained in the proximity of the desired range (Figure 9.25). There was no *relative* or *absolute* difference of any significance between the proportions measured in the first and the last audit cycles. Figure 9.26 shows little variation between different health centres.

During the problem analysis, the committee learned that the clinicians perceive immense pressure from their patients to request an X-ray at their first consultation and often feel compelled to do so despite clear recommendations from the TB programme. Some clinicians also believed that the majority of patients do not return for their second visit and the best chance to complete all investigations and reach a final diagnosis is during their first visit. Despite these pre-conceptions, the committee urged all participating health centres to follow the programme guidelines. It also encouraged communicating this as clearly as possible to patients.

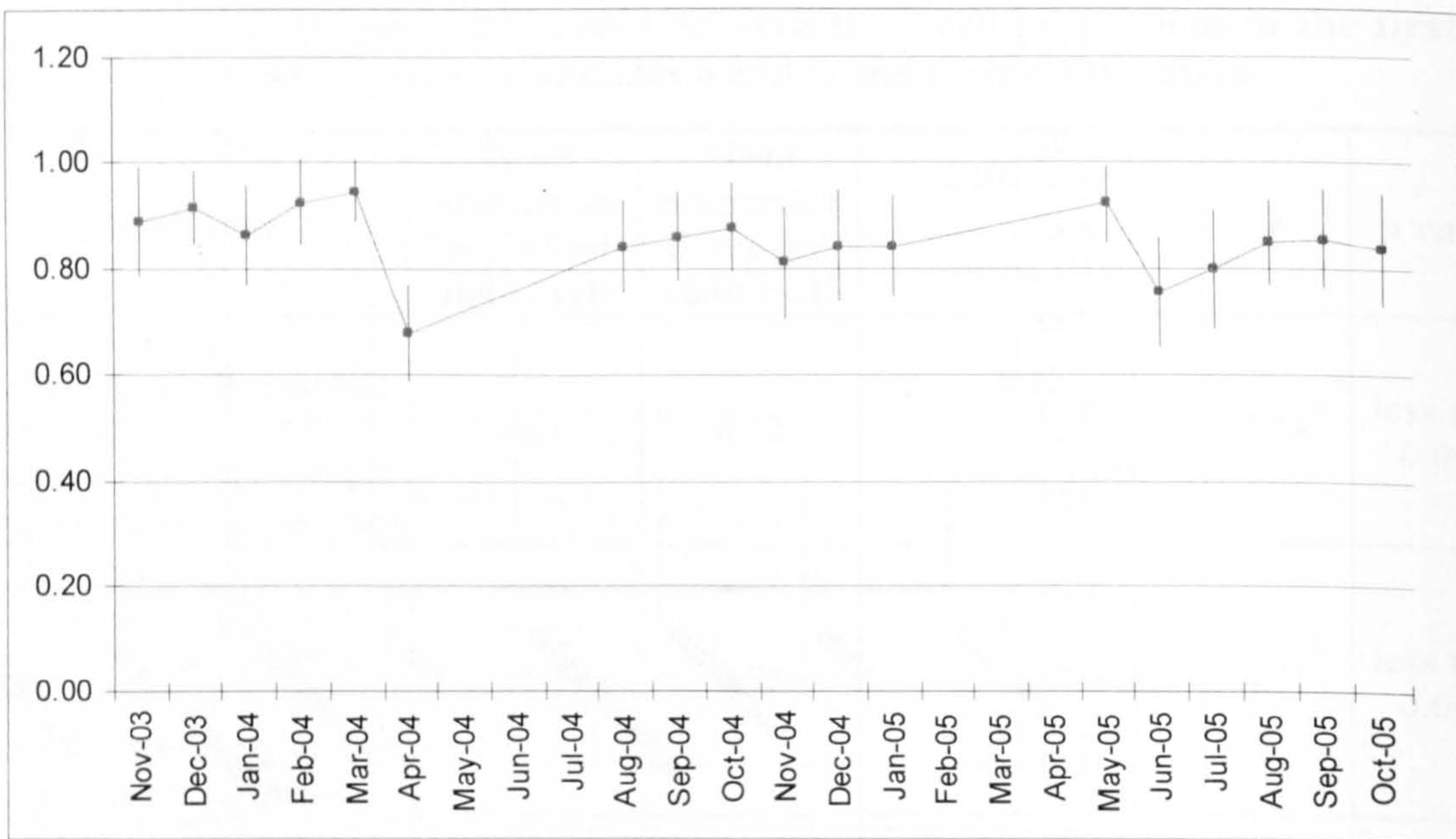


Figure 9.25: Trend line over two years showing the proportions (95%CI) of patients meeting standard 6 for all health centres in Cochabamba combined

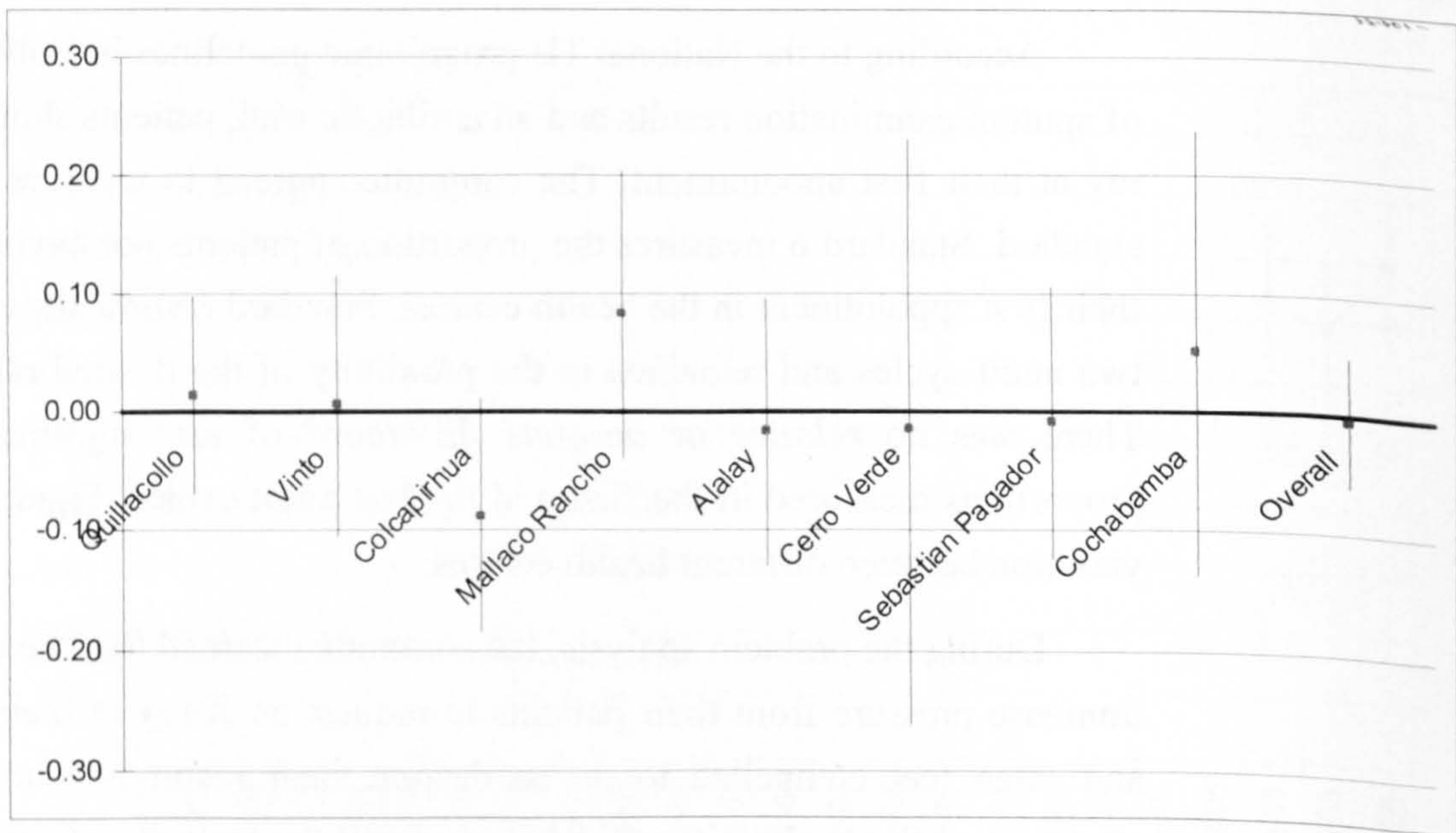


Figure 9.26: Absolute difference between the mean proportions (95%CI) of the first and the last audit cycle for standard 6 in each health centre in Cochabamba, Bolivia

9.2.1.7. Summary

In summary, two audit cycles took place in Bolivia. The audit committee met regularly and received feedback on a six monthly basis after each data collection period. Problem identification and action planning to implement solutions were done subsequently. The audit committee also met between the six monthly feedbacks, to review the progress against action plans. Following clinical audit, there was an

absolute improvement of statistical significance in two out of six standards and a relative improvement in three. One standard reached the desired level in the first cycle, whilst two other remained close to the desired level from the beginning. The following sub-section presents the findings of the qualitative interviews conducted in June and July 05, which will help to explain some of these.

9.2.2. Analysis of the qualitative interviews conducted in Bolivia

Thirteen health care professionals were interviewed from the eight health centres that took part in the project. At least three interviewees were not part of the audit committee. Interviewees were predominantly male (63%) with a median age of 52 years. They had been in their post for a median of 20 years. A summarised thematic analysis is described as follows:

9.2.2.1. Facilitating factors

9.2.2.1.1. Opportunity for training and professional development

Staff training in different aspects of TB care was seen as one of the biggest factors in improving clinical performance. Interviewees acknowledged that because of the quality improvement initiative (clinical audit) in the last couple of years, they have been able to identify and fulfil a significant proportion of their training needs (Box 2.1). Training and staff development activities were seen as essential components of any such initiative.

Box 2.1: Opportunity for training and professional development*

“...to improve things we would also have to train this staff ...” (doctor in a health centre)

“...workshops provided for the staff helped in improving quality...” (doctor from a health centre)

“...Training has to be provided in order for everything to function effectively...” (director of a health centre)

“...courses run in November on management of patients...”

“...Good information...training enables patients with respiratory symptoms to be identified...”

“...has an influence on training and helps to bring improvement...”

“...it’s encouraging that the doctors are trained through the audit process ...”

“...talks...have clarified the concept of a patient with respiratory symptoms...”

“...meetings and workshops on proper management that are provided by the programme are helpful...”

**during some interviews, designation of the interviewee was not recorded*

9.2.2.1.2. Appreciation of the relationship between quality improvement initiatives and improved performance

Several participants commented on the usefulness of clinical audit in highlighting areas of poor performance (Box 2.2). Once the gaps in quality were identified, it was then up to the clinicians and managers to bring their performance up to the standards. There were many comments where participants appreciated real improvements as a result of their performance feedback.

Box 2.2: Appreciation of the relationship between quality improvement initiatives and improved performance

“...audits helped us a lot because errors were detected in the medical treatment of patients...” (doctor of a health centre)

“...since the audits were implemented it’s definitely helped us to treat patients more effectively...” (doctor in a health centre)

“...teams ...cooperate and identify their mistakes in order to improve...”

“...the audit has helped us to introduce some changes...” (doctor from a health centre)

“...I can say that before the implementation of the clinical audits we didn’t have the help we now receive...Now we have order, rules...” (nurse in-charge of a health centre)

“... The audits helped...because after this was undertaken there was organised, systematised information...” (TB nurse in a health centre)

“...The audits really helped us to improve our quality of service. Because thanks to these, we’ve been able to correct mistakes, improve the quality of patient care and, above all, treat patients more humanely...” (director of a health centre)

“...Help with ... identifying errors, confronting the reality of the situation and looking for strategies to improve ...”

9.2.2.1.3. Investing time in educating patients

One of the key activities generated through this initiative was that a number of professionals spent time with the patients, ensuring that they understood the importance of producing a good sample, and of follow up to discuss the results. Clinicians also commented that just providing information is not enough, it is also important to demonstrate and monitor patients’ skills in carrying out the various activities such as producing good quality sputum (Box 2.3).

Box 2.3: Investing time in educating patients

“...we need to spend time with the patients and provide explanations... lack of understanding on part of patient, or inadequate explanation given by staff is a major constraint...” (doctor in a health centre)

“...Adequate and appropriate guidance of patients helped in monitoring patients...”
(director of a health centre)

“...what has been positive...motivating patients to bring the samples...monitoring of patients by support staff ...”

“...staff commitment...they manage to communicate effectively with the patients when they chat to them during the initial consultation... advice given to the patient

...patient provides good samples...”

“...patients were educated on how and when to take the sample...patients were monitored and contacted...”

“...doctor informs infirmary...infirmary takes sample...patient returns for microscopy analysis...doctor ensures that s/he receives the specimen bottle...laboratory ensures that a 2nd sample is requested ...”

“...Patient shown how to take good samples...”

“...patients are shown other patients’ samples so that they can see what they should look like...”

9.2.2.1.4. Participatory leadership

Clinical leaders were considered to be an important vehicle for change. A participatory style was seen as the key characteristic of such dynamic leadership. Interviewees recounted their experiences where empathetic leaders had been able to motivate staff to change towards improvement through good rapport and problem solving skills (Box 2.4).

Box 2.4: Participatory leadership

“...maintain harmonious relations with the staff under him/her, listening to the problems and difficulties voiced and helping to resolve them...” (director of a health centre)

“...leader should be able to demonstrate empathy in his or her relationships with the staff ...” (doctor in a health centre)

“...does not step out of the hierarchy but is involved with staff and authority...”

“...The leader should communicate, inform and update with explanations. She should be able to resolve problems...”

9.2.2.1.5. Supportive tools (guidelines, care pathways, algorithms)

During the audit cycle, a number of tools were prepared which were based on the TB programme guidelines. These were in the form of desktop guidance, care pathways and algorithms in the clinical notes. These tools were found to be very useful in prompting people to follow TB programme guidelines (Box 2.5). Interviewees felt that they were very useful in translating programme guidance into practice. In order to improve compliance with the current guidance, more information needs be made available in such user-friendly formats.

Box 2.5: Supportive tools (guidelines, care pathways, algorithms)

“...the implementation of standards and elaboration of flow charts helped significantly...information provided about the programme guidelines was very positive...” (doctor from a health centre)

“...what is useful is...a patient care pathway is drawn on paper, or on the medical records, to enable monitoring of the patient ...”

“...Using the diagram...has helped us to manage clinical practice and identify more patients ...”

9.2.2.1.6. Good communication and inter-personal skills

A number of interviewees mentioned that good communication within teams and superior interpersonal skills can help in improvement. During clinical audit, all results were fed back in the meetings as well as to the other health care staff in each centre respectively. This was appreciated by the staff. It was also noted that clinical leaders with communication and interpersonal skills managed to support their team through the improvement process far more effectively (Box 2.6).

Box 2.6: Good communication and inter-personal skills

“...good relations within the team and receiving help with work assists change... need support, solidarity, good team spirit and, above all, dialogue ...”(doctor from a health centre)

“...there are people who don't know how to deal with people...”

9.2.2.1.7. Rewarding competence

It was mentioned during the interviews that people will be more motivated to bring improvement to their work if they are rewarded for their efforts (Box 2.7). Incentives within the system can be strong motives to influence and change clinical behaviour. Likewise, some clinicians also mentioned that poor performers should be demoted from their positions.

Box 2.7: Rewarding competence

“...exclude all those who weren't committed because they don't carry out their duties properly...” (doctor in health centre)

“...Recognition and rewards to encourage improvement...”

9.2.2.2. Limiting factors

9.2.2.2.1. Poor system for clinical record keeping

Either health centres did not have a clinical record keeping system prior to the audit cycle or it was in a state that could not have been useful. In health centres where some record keeping existed, there were a number of problems with the way the records were produced, stored, maintained and retrieved. Interviewees felt that timely and accurate information is the key to the success of any quality improvement initiative. Therefore, if the health service does not have a robust patient registration and clinical record keeping system, such initiatives are likely to fail in producing improvements (Box 2.8).

Box 2.8: Poor system for clinical record keeping

“...identifying patients, monitoring and managing medical records is concerning as we don't have a computerised system...” (doctor from a health centre)

“...Having someone responsible for statistics...Having good records and files Implementation of technology (computerised system)...” (director of a health centre)

“...Lack of time and medical records are not compiled...admissions lost medical records...”

“...Patients are seen in clinics that don't send medical records...”

“...Doctor insists that patients have medical records ...”

“...There were no medical records...records are created but lost when filed...files are not managed...”

9.2.2.2.2. Partial support from the TB programme

Clinicians also felt that the TB programme failed to provide support to clinicians in delivering care to TB patients on many occasions. They identified that the programme does not provide adequate information on current evidence in user-friendly formats (Box 2.9). Similarly, clinicians' training needs are generally not addressed. Interviewees acknowledged that the programme is under resource constraints, and therefore, has difficulties in supporting health care workers in delivering care.

Box 2.9: Partial support from the TB programme

“...there is irregular management of the programmes...” (TB nurse from a health centre)

“Staff are not supported and the authorities don't assume their responsibilities”

“...team should be involved in the programme and should meet established standards...”

“...staff not participating in the Programme...constraint...”

“...An information manual about the TBC programme does not exist ...”

“...management have too many responsibilities, this hinders good work because they have other commitments, which mean aims can't be achieved...”

9.2.2.2.3. Frequent changes in policies and personnel

A number of appointments at the senior manager level are political, as mentioned above. This also results in rapid staff turnover due to the rapidly changing political atmosphere in the country. Each new senior manager changes policies and procedures that take a long time to implement and waste a lot of time and resources. This lack of continuity and rapid changes in policies de-motivates the health care staff and hinders improvement (Box 2.10).

Box 2.10: Frequent changes in policies and personnel

“...there’s a lack of continuity as far as the leaders of the programme are concerned.

Staff changes also hinder things; there’s no stability...” (doctor from a health centre)

“...there are constant changes in standards and regulations...” (director of one of the centres)

“...political intervention at a national level on the healthcare system obstructs management of the programme because of the constant changes of staff...” (nurse in charge from a health centre)

“...politics of change carried out by authorities ...obstruct the system and affect development...”

“...when there are changes of government because you don’t know if your job is secure, you don’t have the opportunity to grow in your job...”

“...The change of authorities has an effect on people’s work...”

“...There are always changes and trained staff are lost...”

9.2.2.2.4. Differential treatment towards healthcare professionals

Clinicians highlighted that the appointments within the health service are often based on political decisions rather than judgement of competence. Therefore, incompetent people may get appointed to higher positions. This results in frustration among the competent staff, sometimes losing motivation to strive for improvement (Box 2.11).

Box 2.11: Differential treatment towards healthcare professionals

“...Political intervention has definitely hindered ...the random allocation of responsibilities has caused a lot of damage...” (doctor in a health centre)

“...People who are trained and ready to do the job are not appointed...”

9.2.2.2.5. Poor coordination

A number of examples were quoted by the interviewees where a lack of coordination between laboratories and clinicians had resulted in poor performance and loss of patients to follow up. Clinicians stressed that in order to bring

improvements, coordination needs to be stronger between different parts of the health service (Box 2.12).

Box 2.12: Poor coordination

“...what was an inhibiting factor was staff has little or no suitable information about microscopy analysis...” (director of a health centre)

“...what is desirable... cooperation and coordination with the laboratory...”

“...Working on your own without any coordination means there is no work...”

“...Poor coordination with doctors and the laboratory ...a major limiting factor...”

9.2.2.2.6. Lack of resources

Lack of sputum bottles, staff and time was mentioned a number of times during the interviews as an important limiting factor in bringing improvement. Poor infrastructure and lack of initiatives in workforce development were seen as two of the main reasons for lack of capacity to provide a better service (Box 2.13).

Box 2.13: Lack of resources

“...they don't provide specimen bottles for microscopy analysis...” (TB nurse)

“...poor or limited supply of materials was a big hindrance...” (doctor from a health centre)

“...Lack of resources hinders some programmes and dedication of human resources to monitoring this situation...”

9.2.2.2.7. Patient access to services

Access to health centres and laboratories was not easy for all patients. Patients living away from the centres were thought to have difficulty in getting to the health centre for the second visit. Despite clinicians' efforts to prompt patients to come back for the second visit, many patients failed to report back after their first visit (Box 2.14).

Box 2.14: Patient access to services

“...Problem with taking a second sample because patients are not from the area...”

9.3. Cuba

The audit was conducted in two different sites in Cuba. The results of the audit component are discussed separately under respective subheadings as two audit committees used different criteria to measure different aspects of the diagnostic care. However, the qualitative interviews are analysed and presented together for both sites due to the similarity of the issues at both sites.

9.3.1. Havana-Audit

A summary of the overall results is presented below, followed by detailed results for each standard under respective subheadings.

Figure 9.27 and Figure 9.28 show the trends in the proportions measured for each standard over the total eighteen months during the study period. Data were collected for three six-month periods completing two audit cycles over eighteen months for the first four standards. The audit committee selected and introduced four new standards after receiving their first feedback. Two audit cycles, including three six-month data collection periods, were also completed for these new standards. At the end of each six-month data collection period, data were presented to the audit committee for feedback and action planning for improvement.

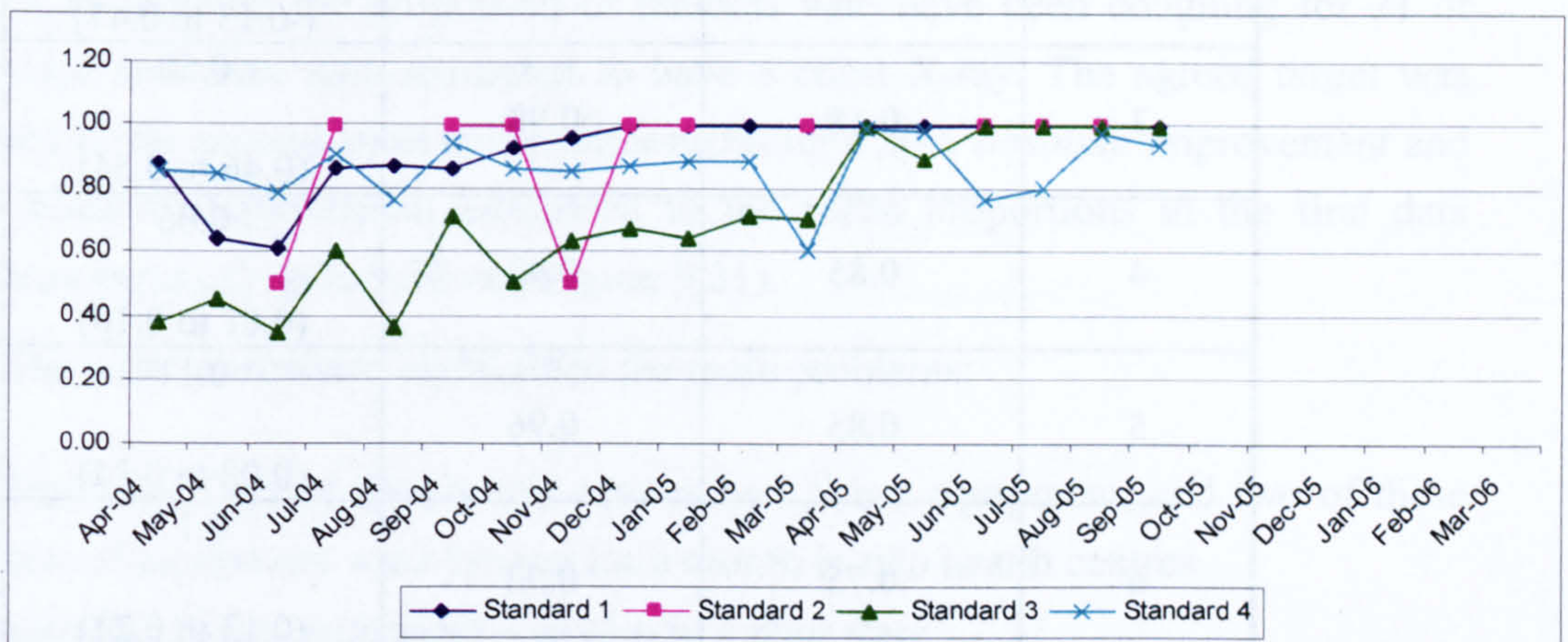


Figure 9.27: A comparison of trends for standards 1 to 4 in Havana, Cuba

Almost all standards demonstrate an improving trend over time. Less month-to-month variation is observed in the last six-monthly data collection period. Figure 9.29 and Table 9.6 shows the *relative* and *absolute* differences between the mean proportions of the first and last six-month data collection period respectively. The *absolute* difference demonstrates a statistically significant improvement in seven out of eight standards. Similarly, the *relative* difference also shows a significant improvement for all standards. The first four standards selected reached the agreed level set by the committee at the end of the second cycle. Out of the four standards added after the first six months, two reached the desired level.

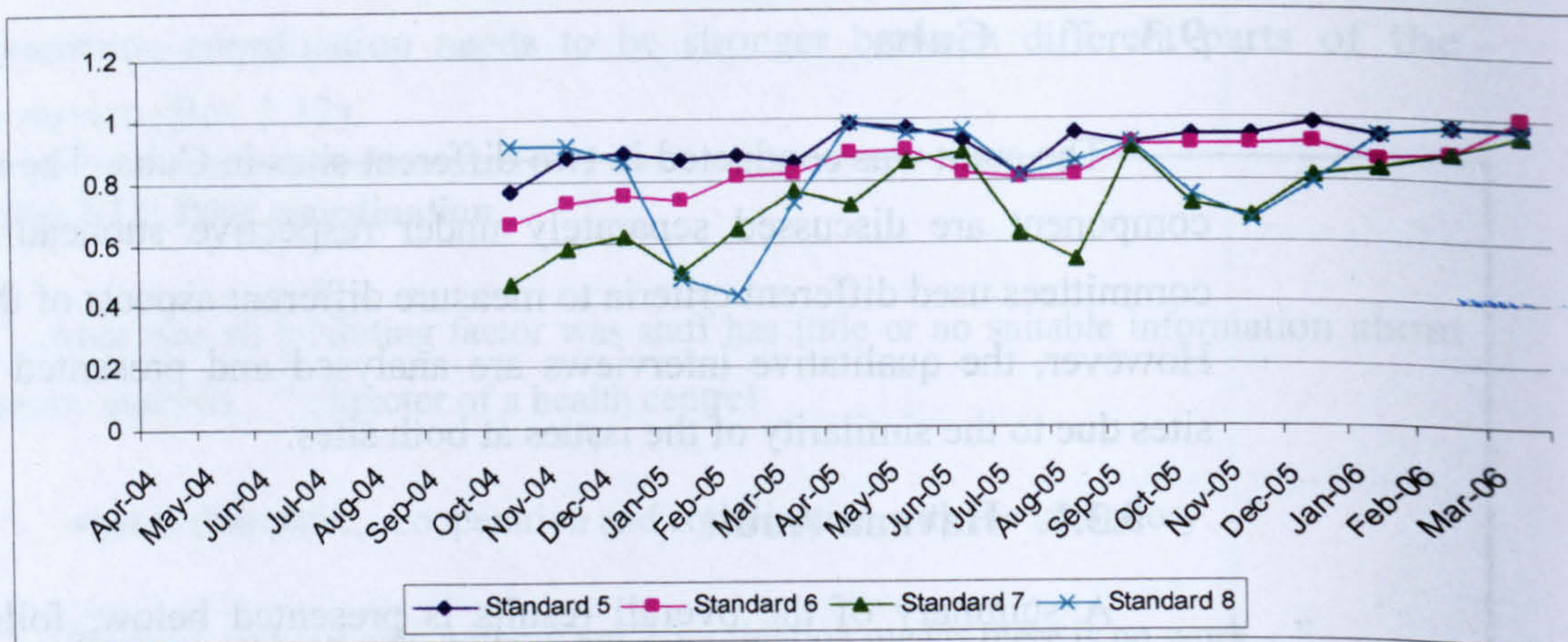
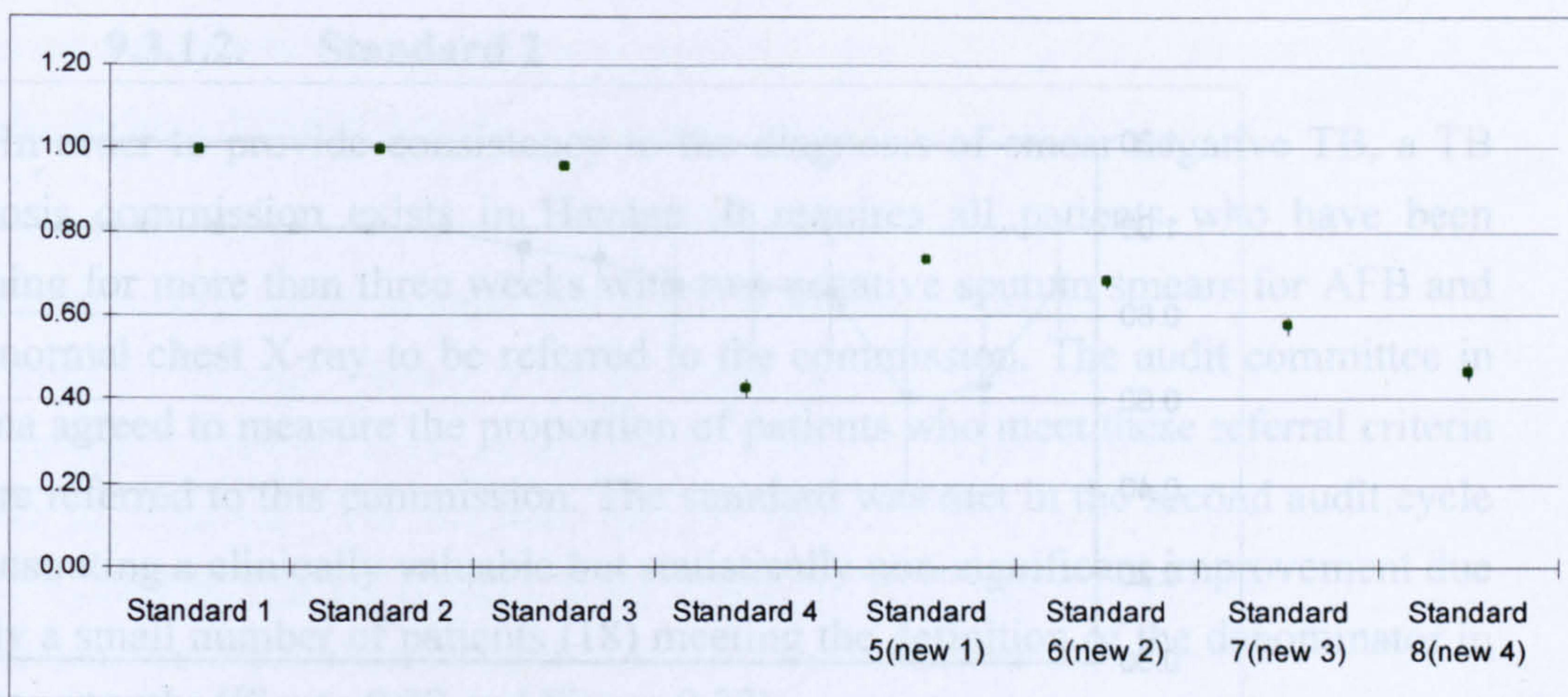


Figure 9.28: A comparison of trends for standards 5 to 8 in Havana, Cuba

Table 9.6: Absolute difference between the mean proportions of the first and the last six-month data collection period for all standards in Havana, Cuba

Standard	Mean proportion in the first cycle	Mean proportion in the last cycle	Difference (95% CI)	z	p value
1	0.78	1.00	0.21 (0.15 to 0.28)	6.11	less than 0.001
2	0.83	1.00	0.17 (-0.13 to 0.47)	1.08	ns
3	0.48	0.98	0.50 (0.46 to 0.54)	22.52	less than 0.001
4	0.85	0.92	0.06 (0.02 to 0.10)	3.14	less than 0.001
5	0.85	0.96	0.11 (0.08 to 0.14)	6.71	less than 0.001
6	0.75	0.92	0.17 (0.13 to 0.21)	7.73	less than 0.001
7	0.59	0.83	0.23 (0.18 to 0.29)	8.71	less than 0.001
8	0.74	0.86	0.12 (0.08 to 0.17)	5.26	less than 0.001



1

Figure 9.29: Relative difference between the mean proportions (95%CI) of the first and the last six-month data collection period for each standard in Havana, Cuba

9.3.1.1. Standard 1

The National TB programme guidelines in Cuba make it mandatory for all patients with cough for more than 21 days to have a chest X-ray. The facility to have a chest X-ray should exist at every polyclinic centre in Havana. Standard 1 was selected to measure the proportion of patients who have been coughing for 21 or more days and were also requested to have a chest X-ray. The agreed target was achieved in the second audit cycle, demonstrating a 20% *absolute* improvement and 100% *relative* improvement compared to the mean proportions in the first data collection period (Figure 9.30 and Figure 9.31).

The audit committee highlighted the main problems:

- Only three out of five health centres had X-ray equipment, and two of these sets of equipment were broken for a month in two health centres
- Existing X-ray equipment was also in a poor state
- Incomplete clinical data were recorded on X-ray requests, resulting in discarding of some requests
- There was only one radiologist reporting on the X-rays performed during this period. Moreover, he was not even working in the same municipality health authority where the audit took place

¹ Confidence intervals around means are very narrow, and therefore, do not appear in this figure

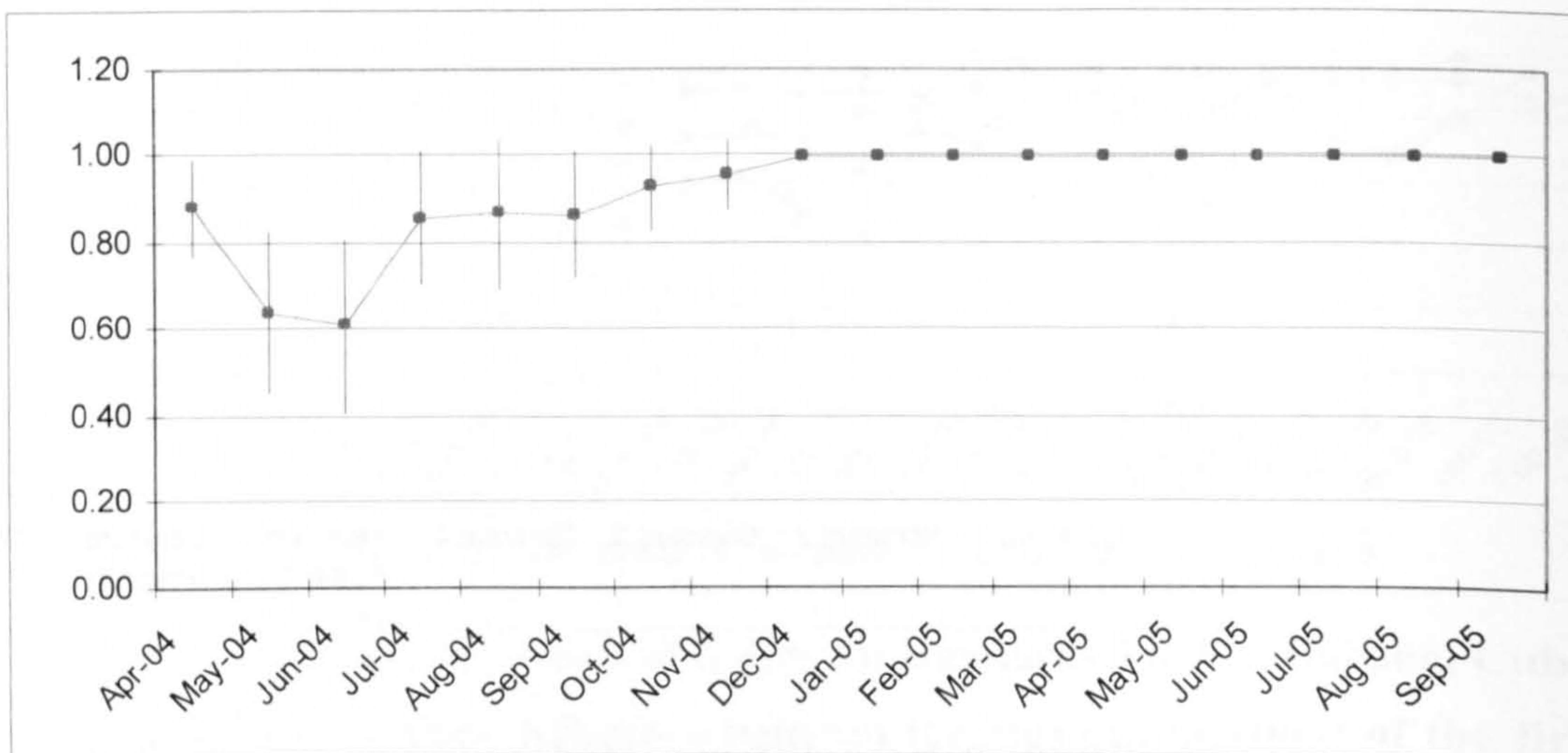


Figure 9.30: Trend line showing the proportions (95%CI) of patients meeting standard 1 for all health centres in Havana combined

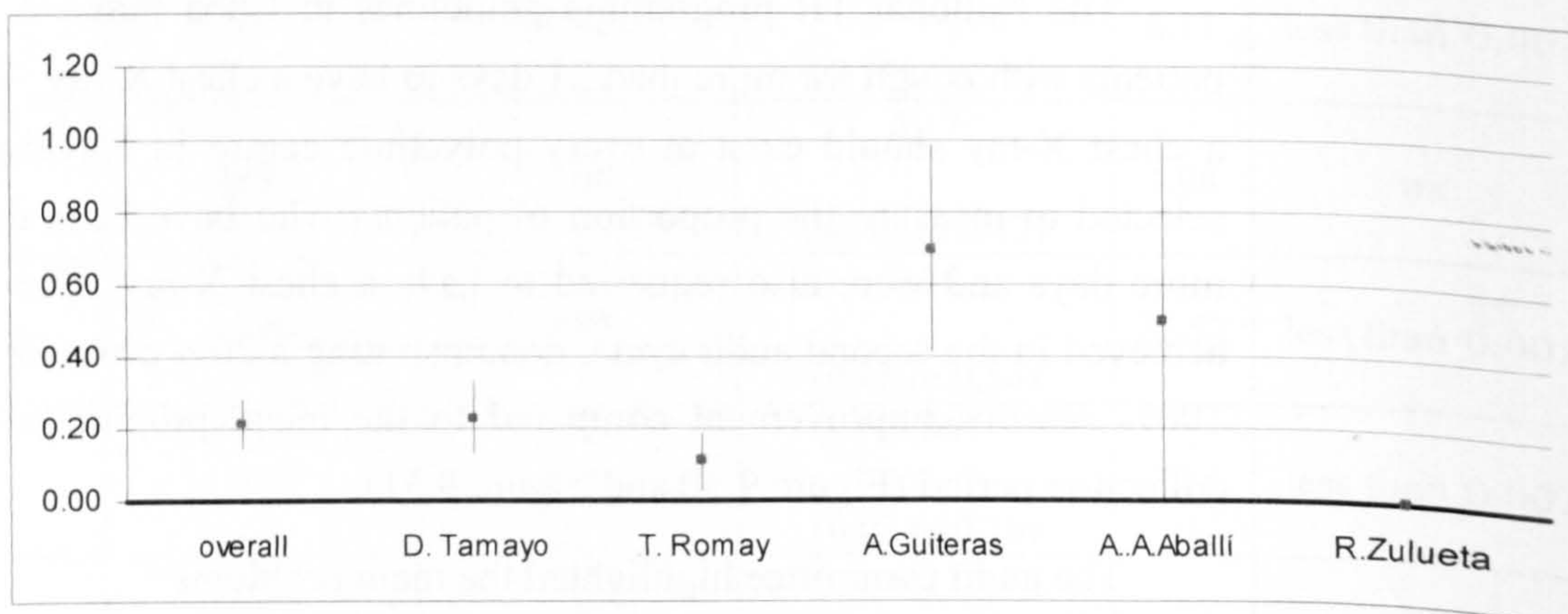


Figure 9.31: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 1 in each health centre in Havana, Cuba

During the first audit cycle, the committee proposed:

- To provide clinicians with training on completion of request forms
- To lobby health authorities to repair and provide X-ray equipment.
- That the health authorities incorporate radiology services into the municipality

By the end of the project, the situation was considerably improved. Despite the successive replacement of doctors, training of doctors was maintained. All health centres had access to X-ray facilities, as reflected in the results for this standard.

9.3.1.2. Standard 2

In order to provide consistency to the diagnosis of smear negative TB, a TB diagnosis commission exists in Havana. It requires all patients who have been coughing for more than three weeks with two negative sputum smears for AFB and an abnormal chest X-ray to be referred to the commission. The audit committee in Havana agreed to measure the proportion of patients who meet these referral criteria and are referred to this commission. The standard was met in the second audit cycle demonstrating a clinically valuable but statistically non-significant improvement due to only a small number of patients (18) meeting the definition of the denominator in eighteen months (Figure 9.32 and Figure 9.33).

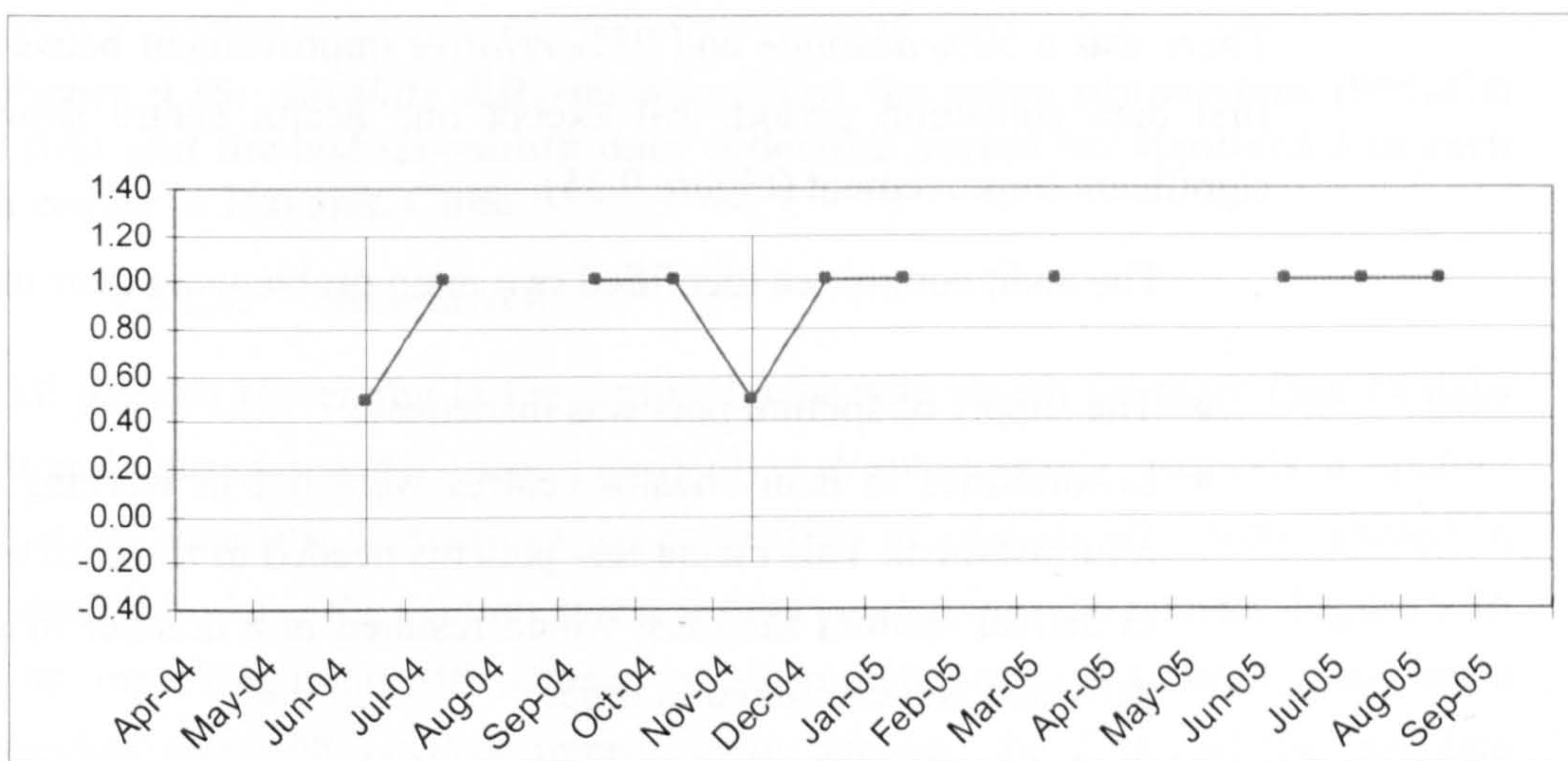


Figure 9.32: Trend line showing the proportions (95%CI) of patients meeting standard 2 for all health centres in Havana combined

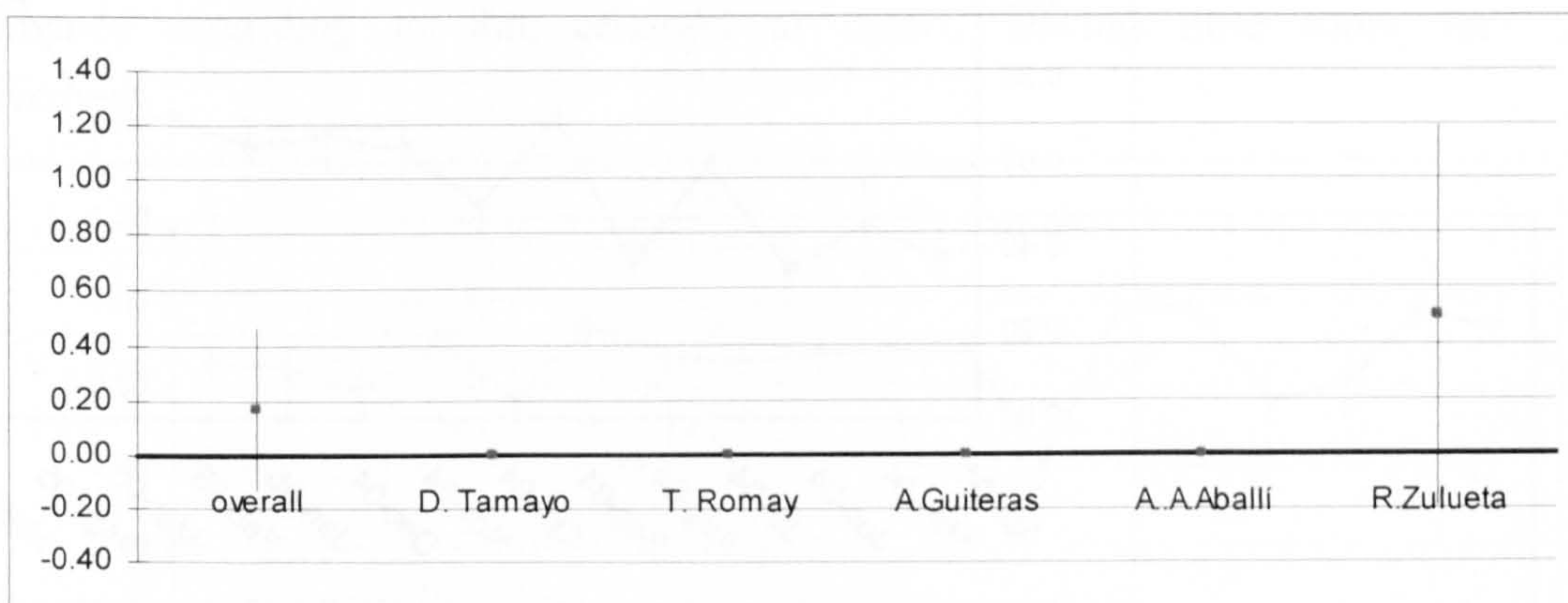


Figure 9.33: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 2 in each health centre in Havana, Cuba

The audit committee proposed to educate clinicians about the referral criteria and procedures related to referring to the Commission. Actions were taken by all

participating centres in this regard, and the members were reminded repeatedly in successive audit committee meetings to follow this recommendation.

9.3.1.3. Standard 3

Standard 3 was a measure of the number of patients with cough for more than two weeks who had at least two good quality sputum samples examined in the laboratory within 72 hours of collection. This was set to ensure that the required number of good quality sputum samples are delivered to the laboratories in polyclinics, and they are examined in a timely fashion to avoid any diagnostic delay. Figure 9.34 demonstrates that this standard meets the desired level in the second cycle and a remarkable improving trend in this standard over the course of the study. There was a 50% *absolute* and 95% *relative* improvement between the last and the first data collection period. All except one health centre showed a statistically significant improvement (Figure 9.35).

The audit committee identified two main problems in their initial meetings:

- The supply of sputum pots was inadequate
- Laboratories in many health centres were not in working order and needed refurbishment. This meant that patients needed to travel to other health centres to deliver sputum samples, which resulted in a number of samples not being delivered and examined in time.

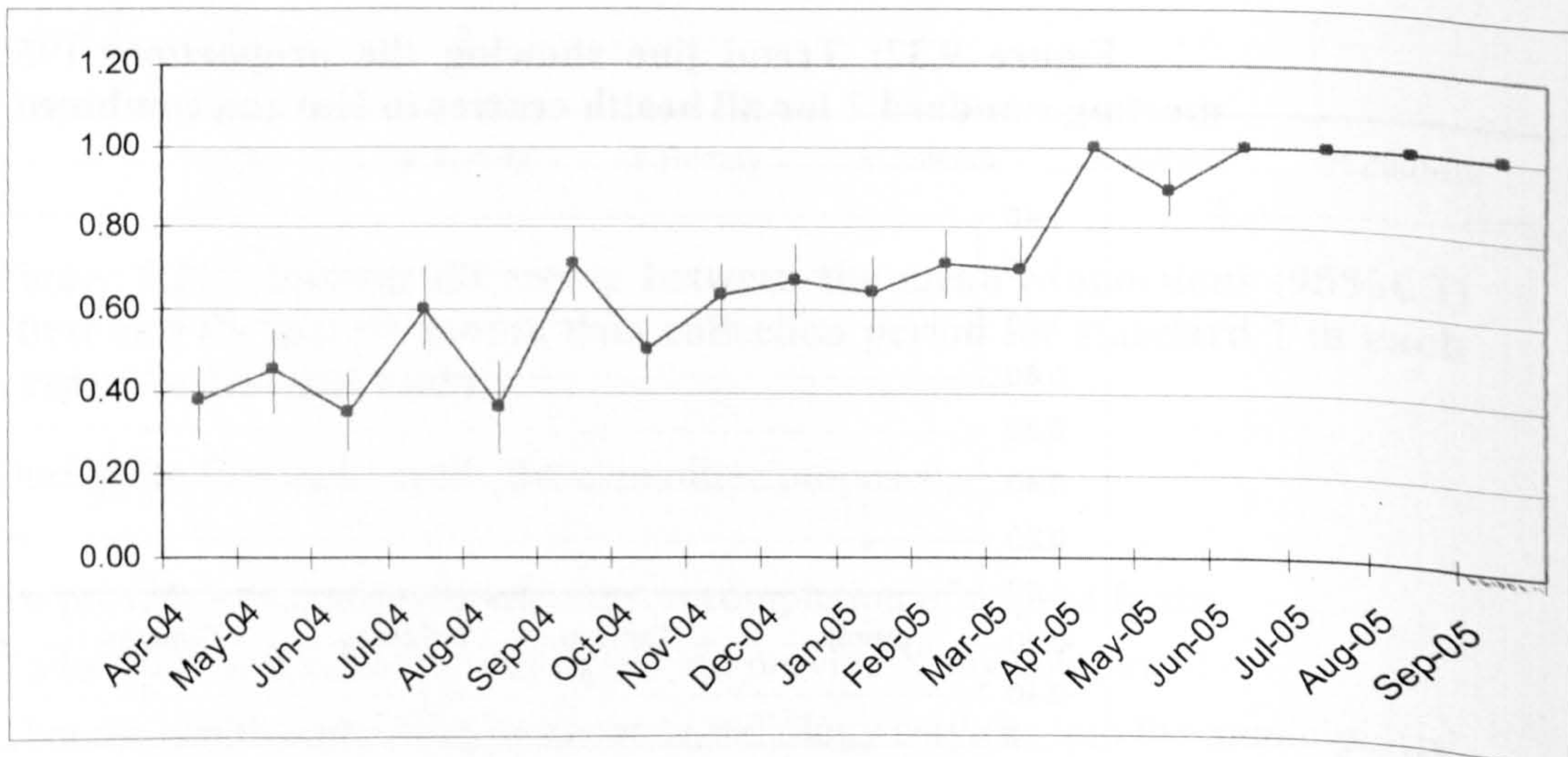


Figure 9.34: Trend line showing the proportions (95%CI) of patients meeting standard 3 for all health centres in Havana combined

The audit committee agreed to speak to health authorities to ensure a regular supply of the appropriate sputum pots to all health centres. In addition, during the audit cycle, a number of laboratory facilities in the health centres were refurbished. The audit committee noted at their final meeting that the situation had improved in

terms of the condition of the laboratories within the health centres, and the availability of sputum pots.

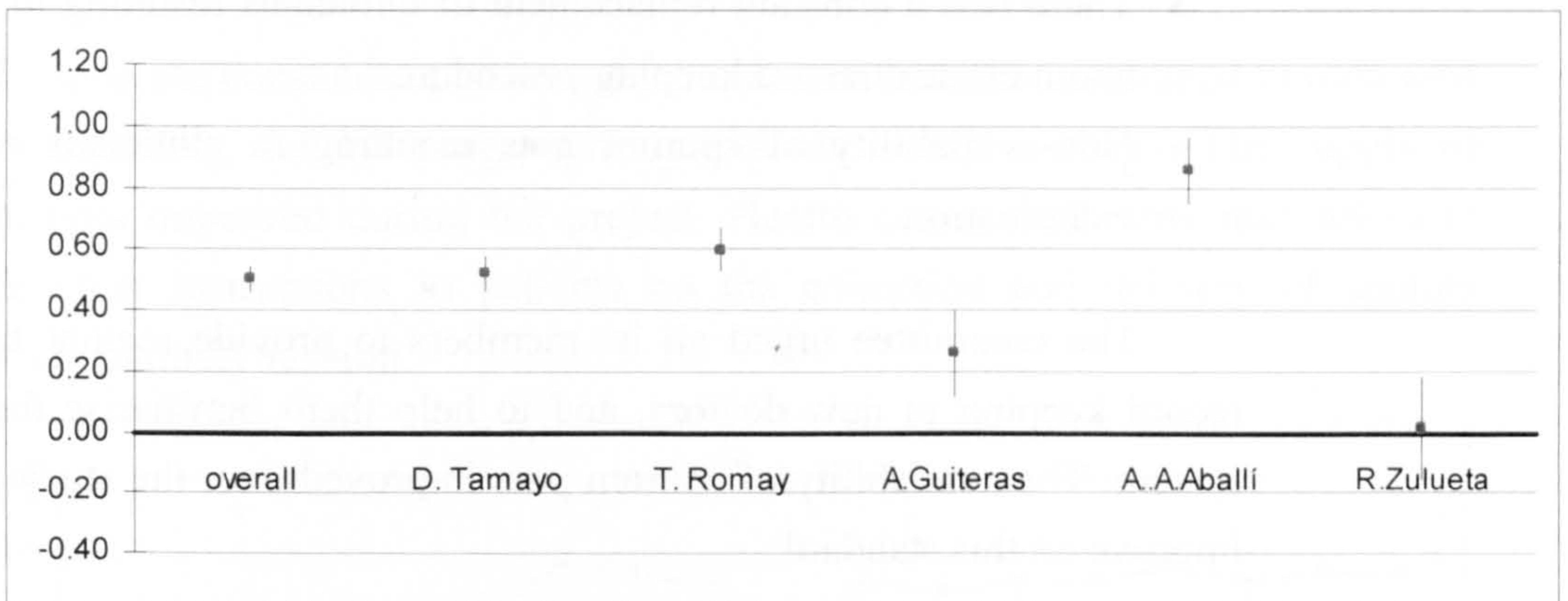


Figure 9.35: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 3 in each health centre in Havana, Cuba

9.3.1.4. Standard 4

All patients presenting to the family doctor with cough for more than 14 days are entered into a register. The family doctor subsequently requests a sputum examination. Standard 4 measures the proportion of patients who were entered in this register who have the sputum smear results entered into the register. Figure 9.36 shows an improving trend with some month-to-month variation. Overall, there was a 6% *absolute* and 43% *relative* improvement between the first and the last data collection periods. Three health centres also demonstrate statistically significant improvement (Figure 9.37). The other two health centres demonstrated optimal performance according to this criterion at outset, leaving little room for improvement.

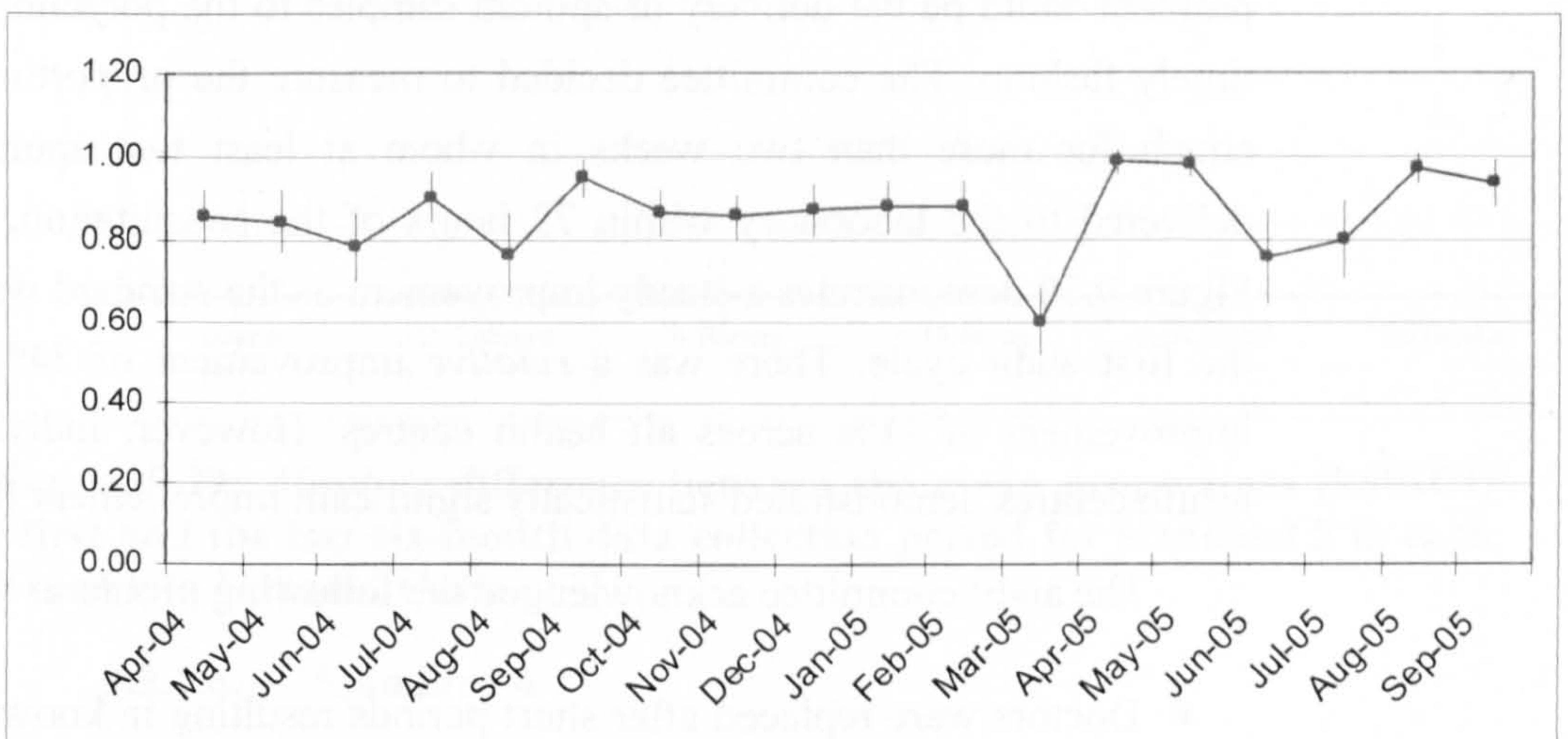


Figure 9.36: Trend line showing the proportions (95%CI) of patients meeting standard 4 for all health centres in Havana combined

The audit committee realised two problems with this standard

- There was a constant replacement of clinicians resulting in lack of awareness about clinical record keeping procedures
- Non-availability of sputum pots resulting in clinicians not requesting the examination

The committee urged all its members to provide regular training on clinical record keeping to new doctors, and to help them familiarise themselves with the system. The availability of sputum pots improved over the study period and helped improve on this standard.

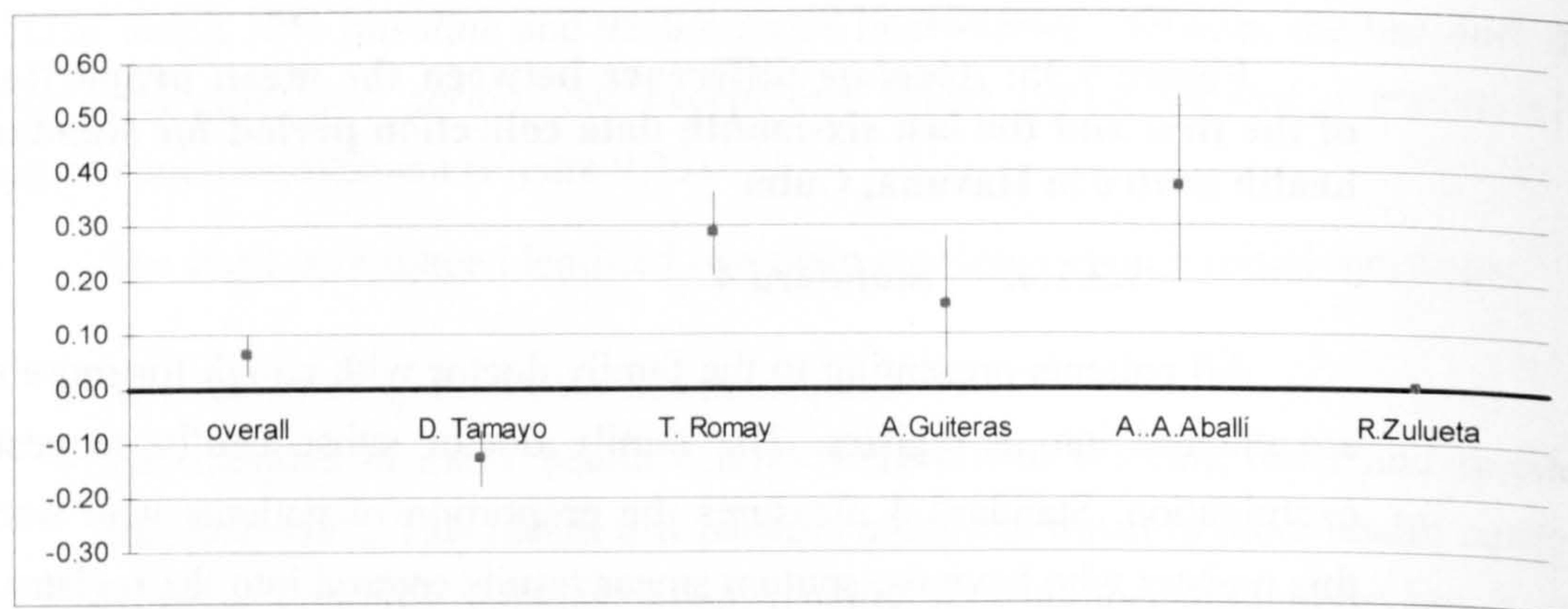


Figure 9.37: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 4 in each health centre in Havana, Cuba

9.3.1.5. Standard 5

After the first data feedback, the audit committee realised that part of the problem could be the delivery of sputum samples to the polyclinic laboratories in a timely fashion. The committee decided to measure the proportion of patients with cough for more than two weeks in whom at least two sputum samples were delivered to the laboratory within 72 hours of the consultation. The trend line in Figure 9.38 demonstrates a steady improvement as the standard was achieved within the first audit cycle. There was a *relative* improvement of 74% and an *absolute* improvement of 11% across all health centres. However, individually only three health centres demonstrated statistically significant improvement (Figure 9.39).

The audit committee acknowledged the following problems within the system:

- Doctors were replaced after short periods resulting in knowledge and training gaps about the TB programme guidelines
- Sputum pots were unavailable for collecting samples

- Improvement depended on patients' motivation to deliver the sample to the laboratory in time

Despite the constant replacements, committee members continued to train new doctors regarding the TB programme guidelines and procedures. The supply of sputum pots improved during the project. Health centre staff were also asked to provide clear instructions to patients on the collection and delivery of sputum samples in a timely fashion.

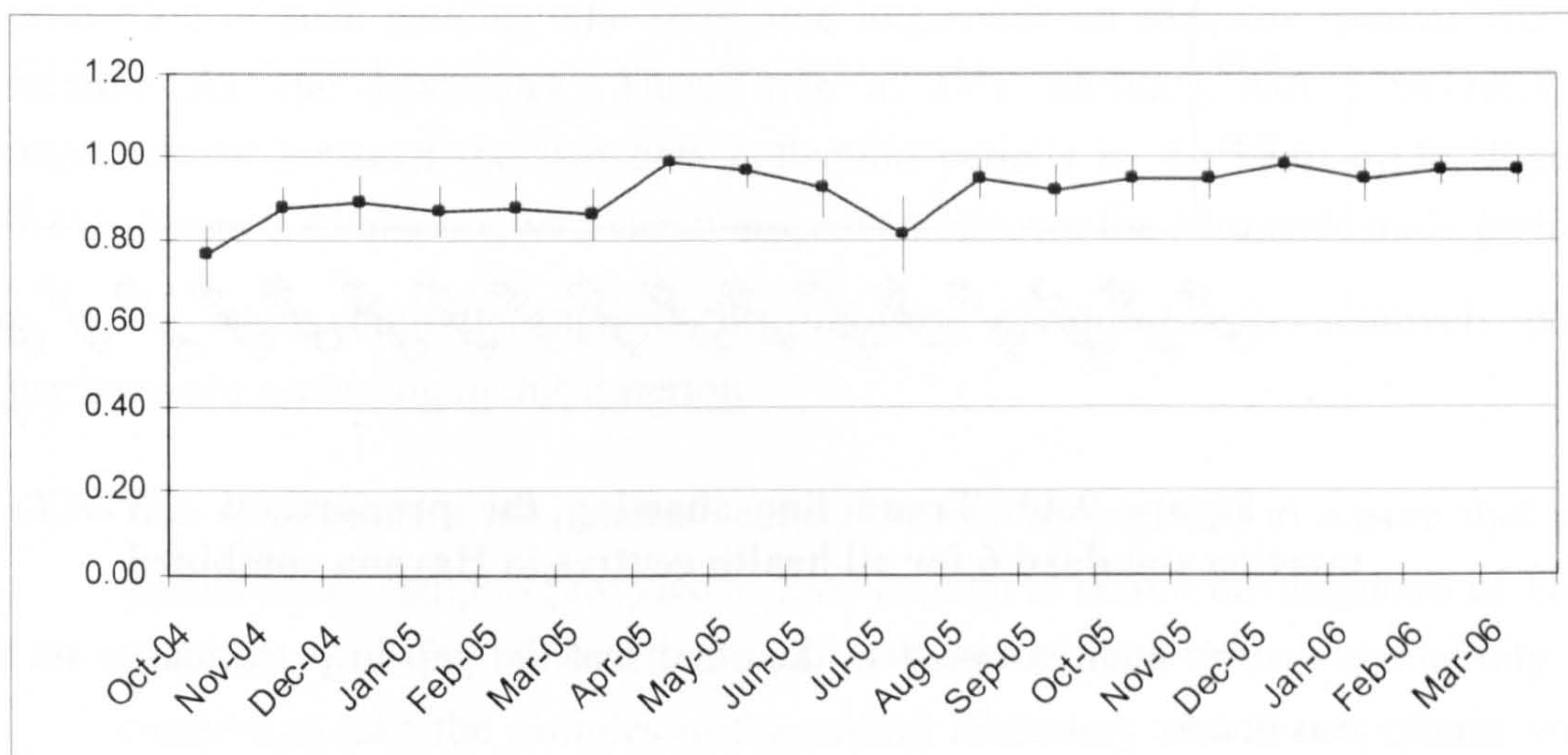


Figure 9.38: Trend line showing the proportions (95%CI) of patients meeting standard 5 for all health centres in Havana combined

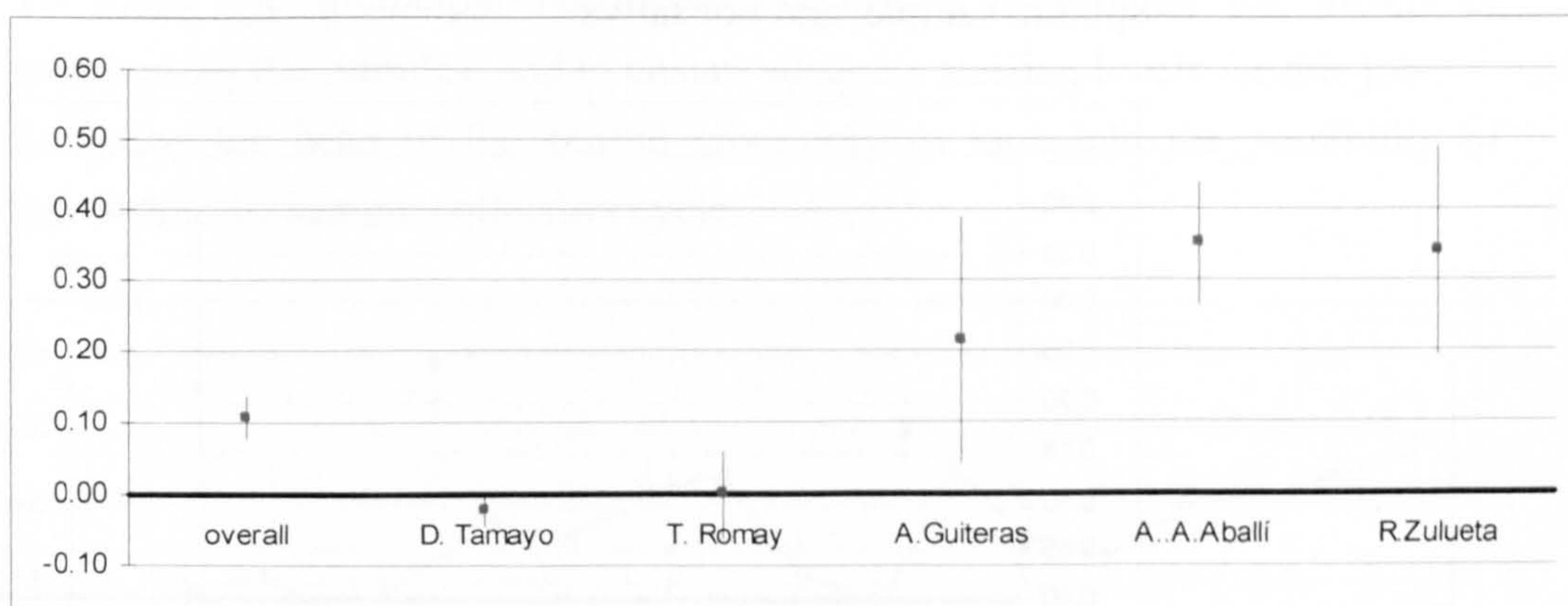


Figure 9.39: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 5 in each health centre in Havana, Cuba

9.3.1.6. Standard 6

The audit committee agreed to measure the proportion of patients who need to have a sputum examination, and deliver a good quality sputum that can be utilised for examination in the laboratory. Figure 9.40 shows a steady improvement during

the first cycle, but results remained short of the desired level. A 17% *absolute* and 68% *relative* improvement was observed between the first and last data collection periods in the audit cycle (Figure 9.41).

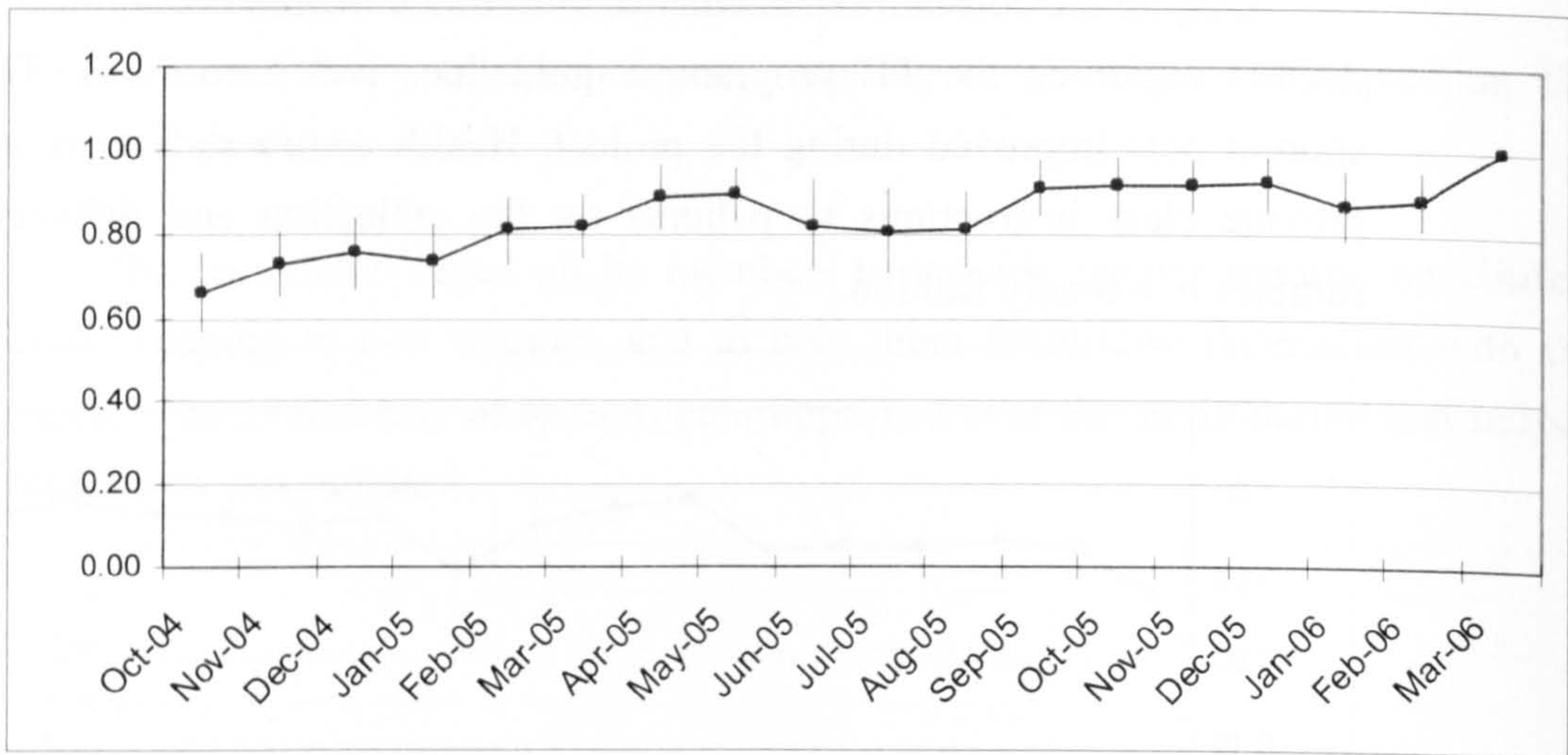


Figure 9.40: Trend line showing the proportions (95%CI) of patients meeting standard 6 for all health centres in Havana combined

The audit committee identified that the gap in performance on this standard was due to:

- Clinicians not receiving training on the importance of the quality of the sputum sample and its relationship with the yield of the sample
- Patients not receiving clear instructions on how to produce a good quality sputum sample, and not saliva

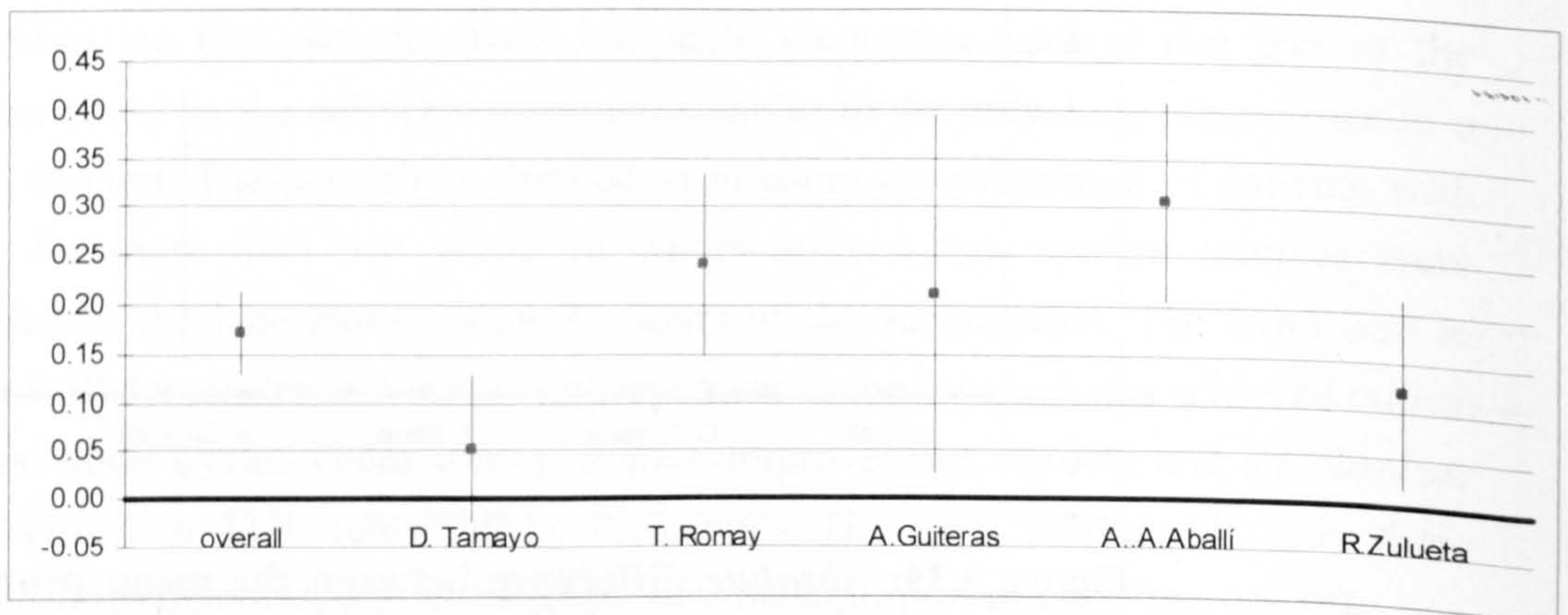


Figure 9.41: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 6 in each health centre in Havana, Cuba

Committee members continued to facilitate training in their respective health centres and encourage doctors to request good quality sputum samples on patients

with suspected TB. They were also given training on instructing patients to provide a good quality sputum sample.

9.3.1.7. Standard 7

In Havana, all patients with suspected TB are expected to have a sputum culture examination. However, these are carried out in the central laboratory and not in polyclinics. The quality of sputum specimen is crucial for the quality of culture examination. Standard 7 was agreed by the audit committee to measure the proportion of such patients who were able to provide an adequate sputum sample suitable for the laboratory. There was a 23% *absolute* and 57% *relative* improvement between the two data collection periods in the audit cycle (Figure 9.43). Figure 9.43 also shows a steady improvement over the 18 month study period.

The audit committee agreed the following reasons for the relatively poor performance according to this criterion.

- This is dependent on patients' education and cooperation to ensure that the quality of the samples provided is good enough to permit the diagnosis of TB
- Problems with the transportation of the samples, with limited availability of couriers to take the samples to the central laboratory and in accordance with the planned delivery cycles

The committee agreed to the following actions:

- To lobby the municipal healthcare authorities to provide the means of transporting the samples, and to ensure adequate staffing levels for this job
- To lobby the head of the central laboratory to look into the possibility of increasing the sample collection cycle

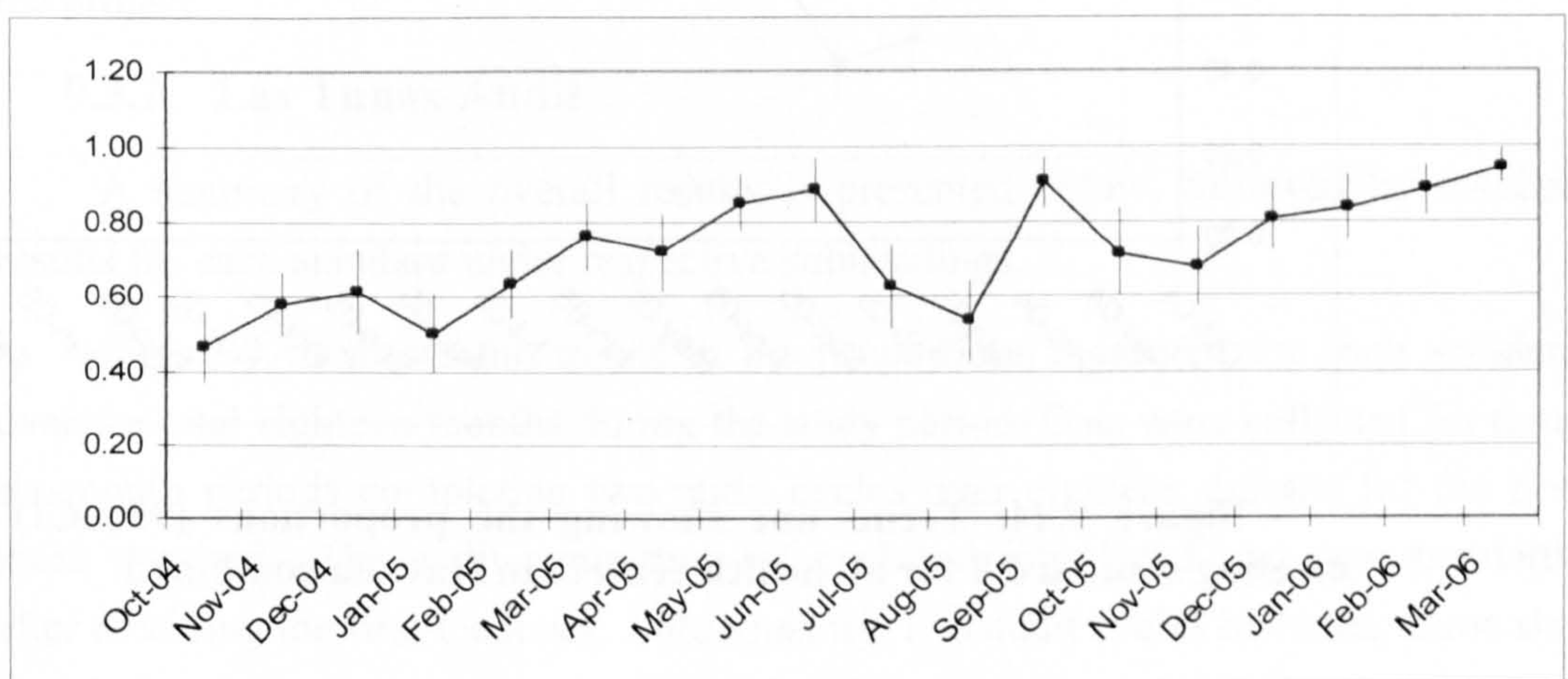


Figure 9.42: Trend line showing the proportions (95%CI) of patients meeting standard 7 for all health centres in Havana combined

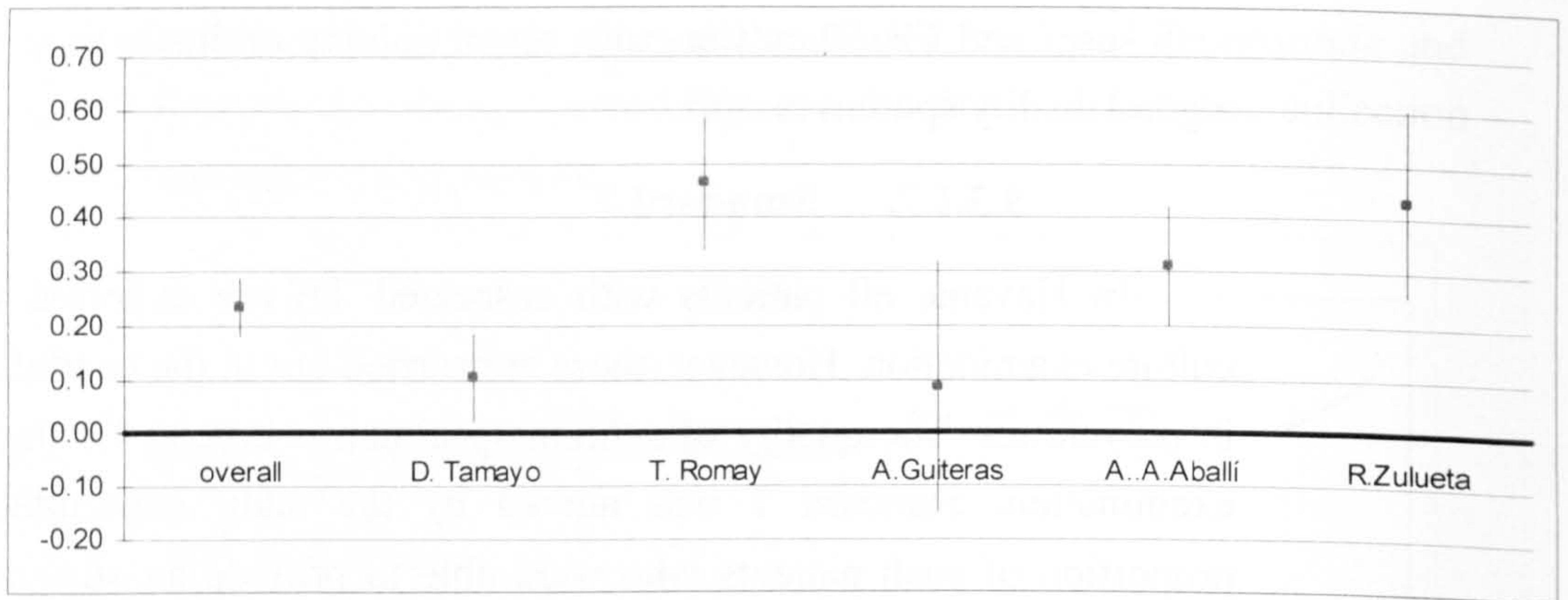


Figure 9.43: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 7 in each health centre in Havana, Cuba

9.3.1.8. Standard 8

The audit committee noticed that a number of medical requests for sputum examination were not entertained by the laboratories because of poor recording of clinical information on the medical request forms. The committee decided to measure this as standard 8, as the proportion of medical requests for sputum smear microscopy with complete clinical information. Figure 9.44 shows a gradually improving and steady trend during the second half of the audit cycle. There was a 12% *absolute* and 47% *relative* improvement between the two data collection periods in the audit cycle. However, improvement reached statistical significance for only two health centres (Figure 9.45).

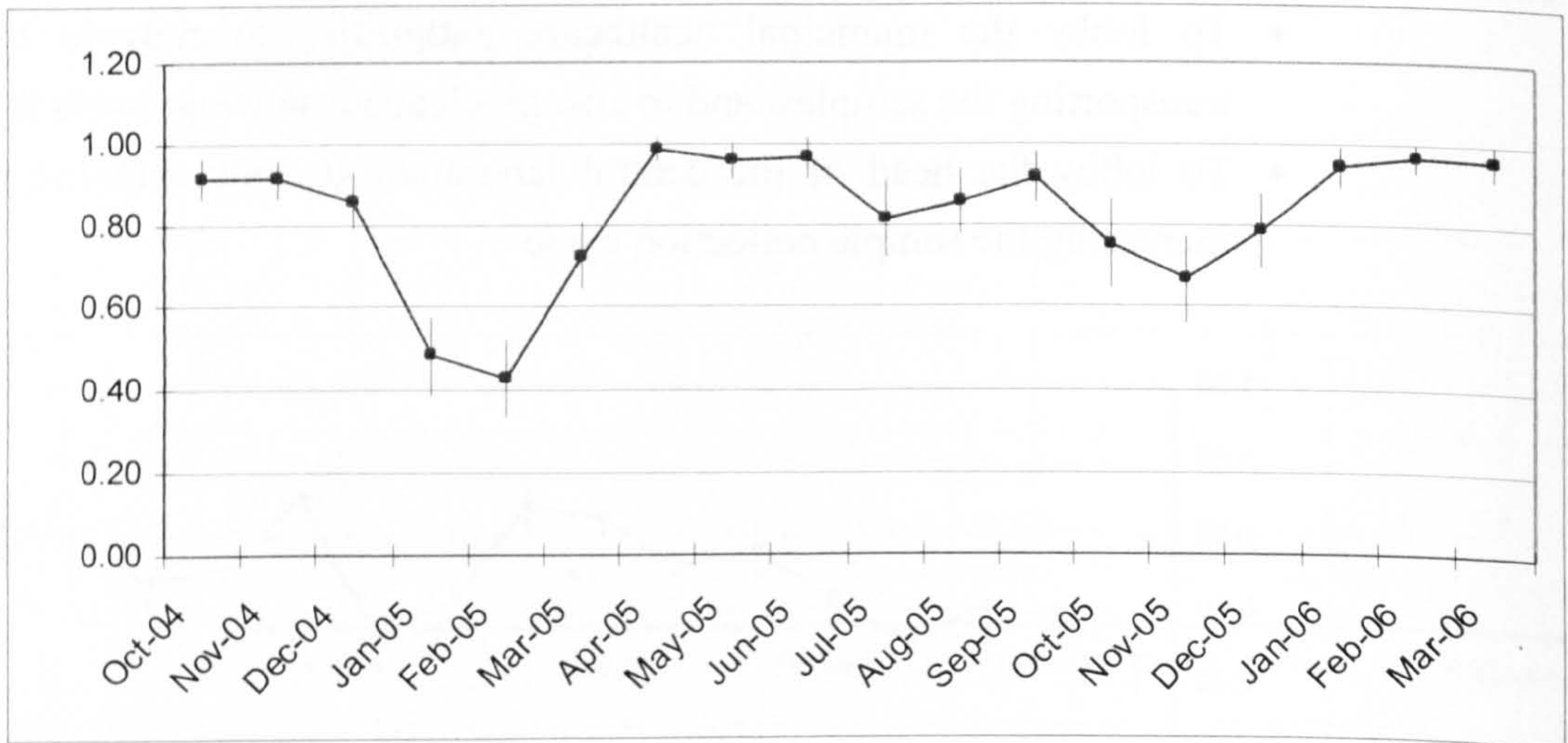


Figure 9.44: Trend line showing the proportions (95%CI) of patients meeting standard 8 for all health centres in Havana combined

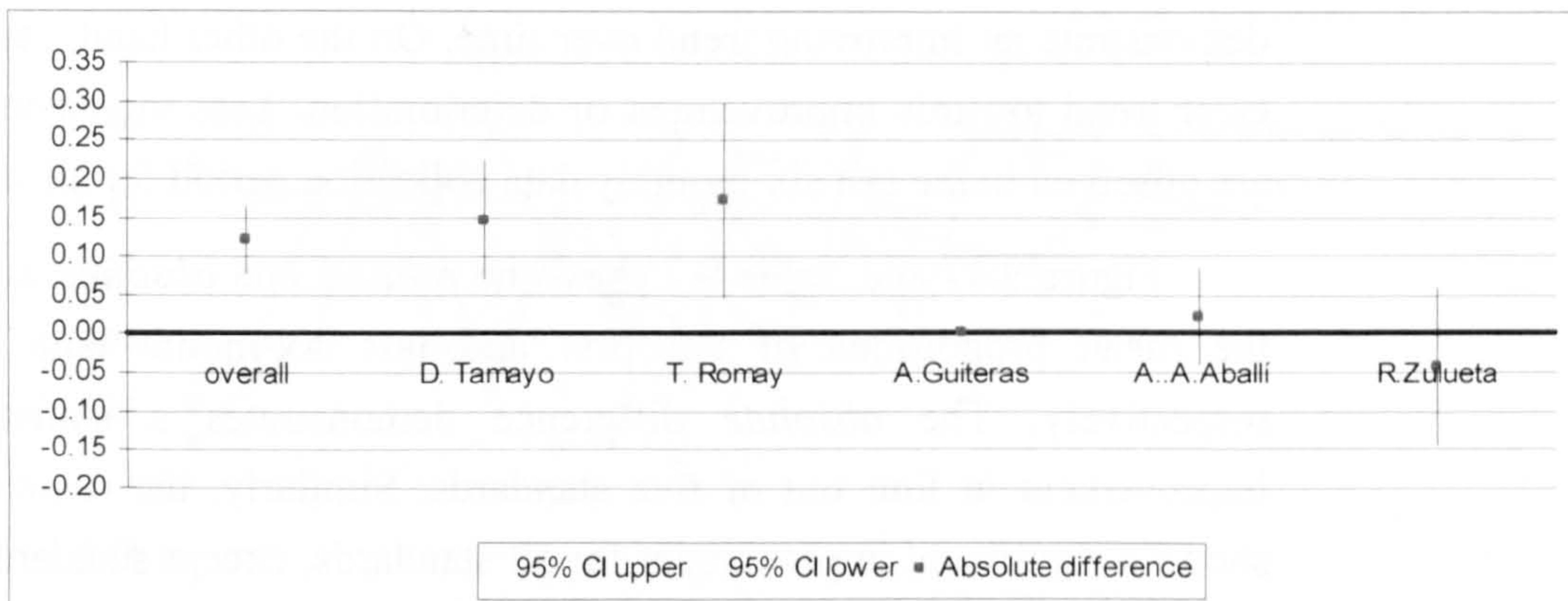


Figure 9.45: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 8 in each health centre in Havana, Cuba

The committee acknowledged that a problem existed with the complete recording of clinical information on the microscopy analysis requests. Members were asked to impress upon doctors and nurses the importance of correctly filling in the requests for improving the identification of positive cases.

9.3.1.9. Summary

In summary, two audit cycles including three data collection periods were completed for four audit standards and one cycle for the last four standards in Havana, Cuba. The audit committee met regularly and received feedback on a six monthly basis after each data collection period. Problem identification and action planning to implement solutions were done subsequently. The audit committee also met in between the six monthly feedbacks, to review progress against the action plans. Following clinical audit, there was an *absolute* improvement of statistical and clinical significance in seven out of eight standards and a *relative* improvement in all. In six out of the eight criteria, the agreed standards were reached by the end of the project.

9.3.2. Las Tunas-Audit

A summary of the overall results is presented below, followed by detailed results for each standard under respective subheadings.

Figure 9.46 shows the trends in the proportions measured for each standard over the total eighteen months during the study period. Data were collected for three six-month periods completing two audit cycles over eighteen months for the first three standards. The audit committee selected and introduced two new standards after receiving the first feedback. Subsequently, two audit cycles including three six-month data collection periods were completed for these new standards. At the end of each six-month data collection period, data were presented to the audit committee for feedback and action planning for improvement. Standards 1, 2, 4 and 5

demonstrate an improving trend over time. On the other hand, standard 3 shows no clear trend towards improvement or deterioration. Less month-to-month variations are observed in the last six-monthly data collection period for all standards.

Figure 9.47 and Table 9.7 show the *relative* and *absolute* differences between the mean proportions of the first and last six-month data collection period respectively. The *absolute* difference demonstrates a statistically significant improvement in four out of five standards. Similarly, the *relative* difference also shows a significant improvement for all standards, except standard 3. All standards reached the agreed level set by the committee at the end of the second cycle. It is also worth noting that standards 2 and 3 were already achieving the desired level doing the first data collection period.

Table 9.7: Absolute difference between the mean proportions of the first and the last six-month data collection period for all standards in Las Tunas, Cuba

Standard	Mean proportion in the first cycle	Mean proportion in the last cycle	Difference (95% CI)	z	p value
1	0.85	0.93	0.08 (0.05 to 0.11)	6.02	less than 0.001
2	0.88	0.92	0.04 (0.02 to 0.07)	3.34	less than 0.001
3	0.97	0.97	0.00 (-0.02 to 0.01)	-0.47	ns
4	0.92	0.98	0.06 (0.03 to 0.08)	4.73	less than 0.001
5	0.87	1.00	0.13 (0.03 to 0.23)	2.63	less than 0.05

9.3.2.1. Standard 1

The audit committee in Las Tunas agreed to measure the proportion of patients with cough of more than 14 days in whom the first sputum sample was submitted, investigated and reported within 48 hours of the medical consultation as standard 1. This was to ensure that sputum smears are done and reported in a timely fashion.

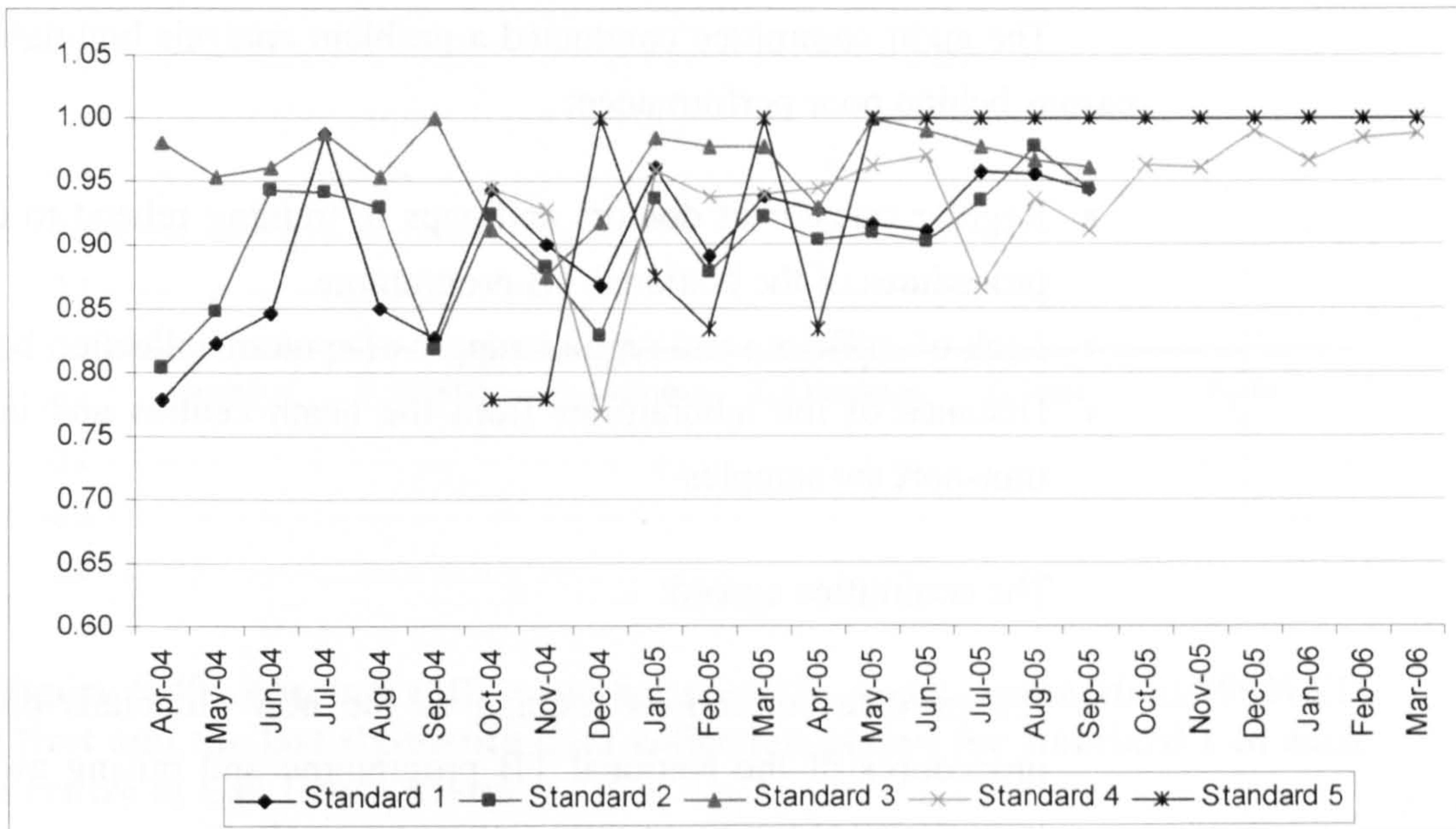
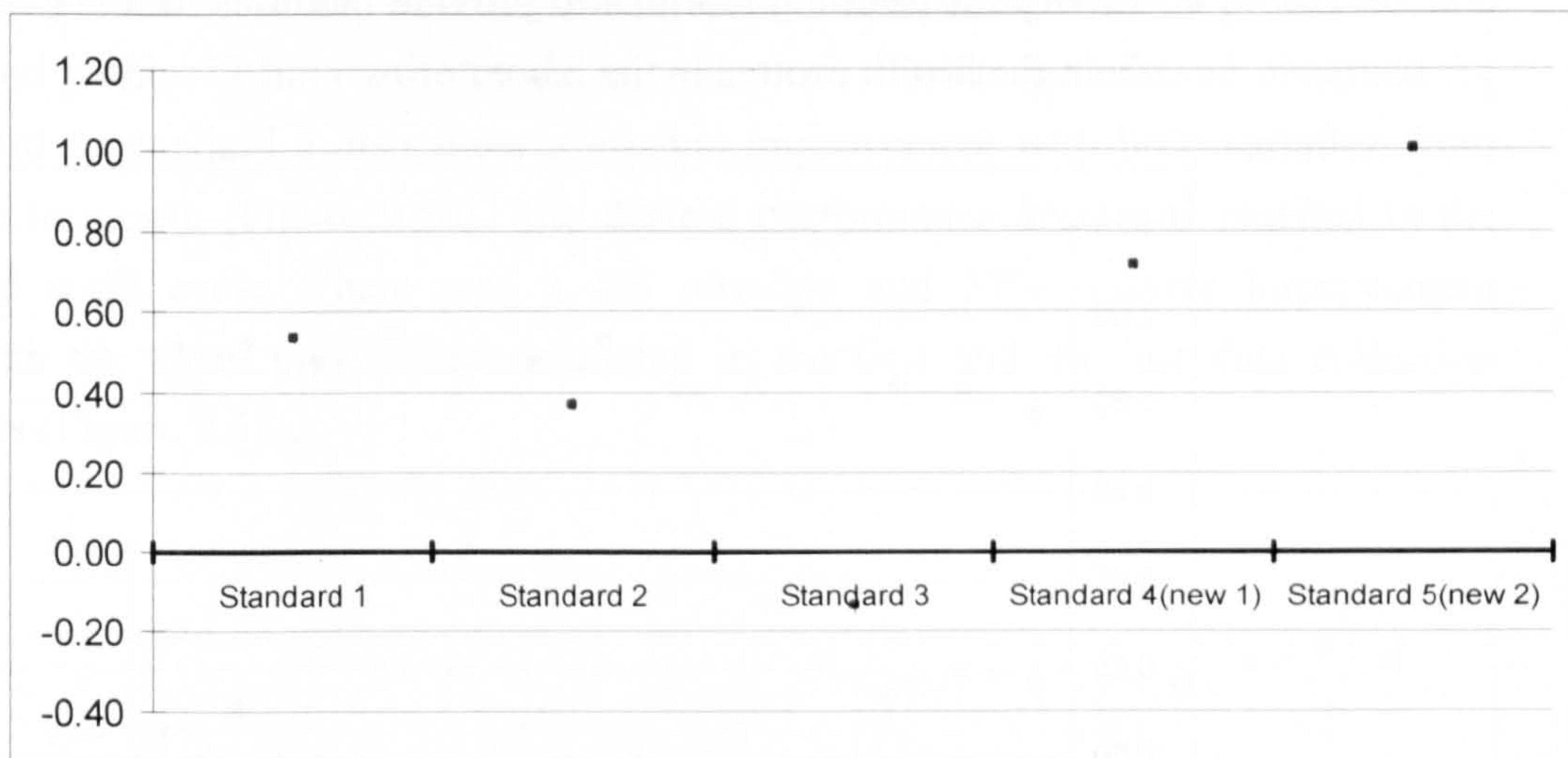


Figure 9.46: A comparison of trends for all standards in Las Tunas, Cuba



2

Figure 9.47: Relative difference between the mean proportions (95%CI) of the first and the last six-month data collection period for each standard in Las Tunas, Cuba

Figure 9.48 shows a gradually improving trend with little month-to-month variation. There was an 8% *absolute* and 54% *relative* improvement between the mean proportions estimated in the first and the last data collection periods. Only two centres achieved improvement of statistical significance (Figure 9.49). However, the desired level was reached in the second audit cycle.

² Confidence intervals around means are very narrow, and therefore, do not appear in this figure

The audit committee conducted a problem analysis highlighting the following reasons behind poor performance:

- Regular transfer of doctors and gaps in training related to the guidelines and procedures of the National TB programme
- Lack of sufficient and regular supply of sputum collection bottles
- Distance of the laboratories from the health centres and lack of facilities to transport the samples

The committee agreed:

- To provide continuous training to the new clinicians on the policies and procedures of the National TB programme and raising awareness about the importance of timely sputum smear examination
- To lobby health authorities to ensure constant and adequate supply of sputum collection bottles
- To request health authorities to provide facilities to transport sputum samples from the health centres to the laboratories

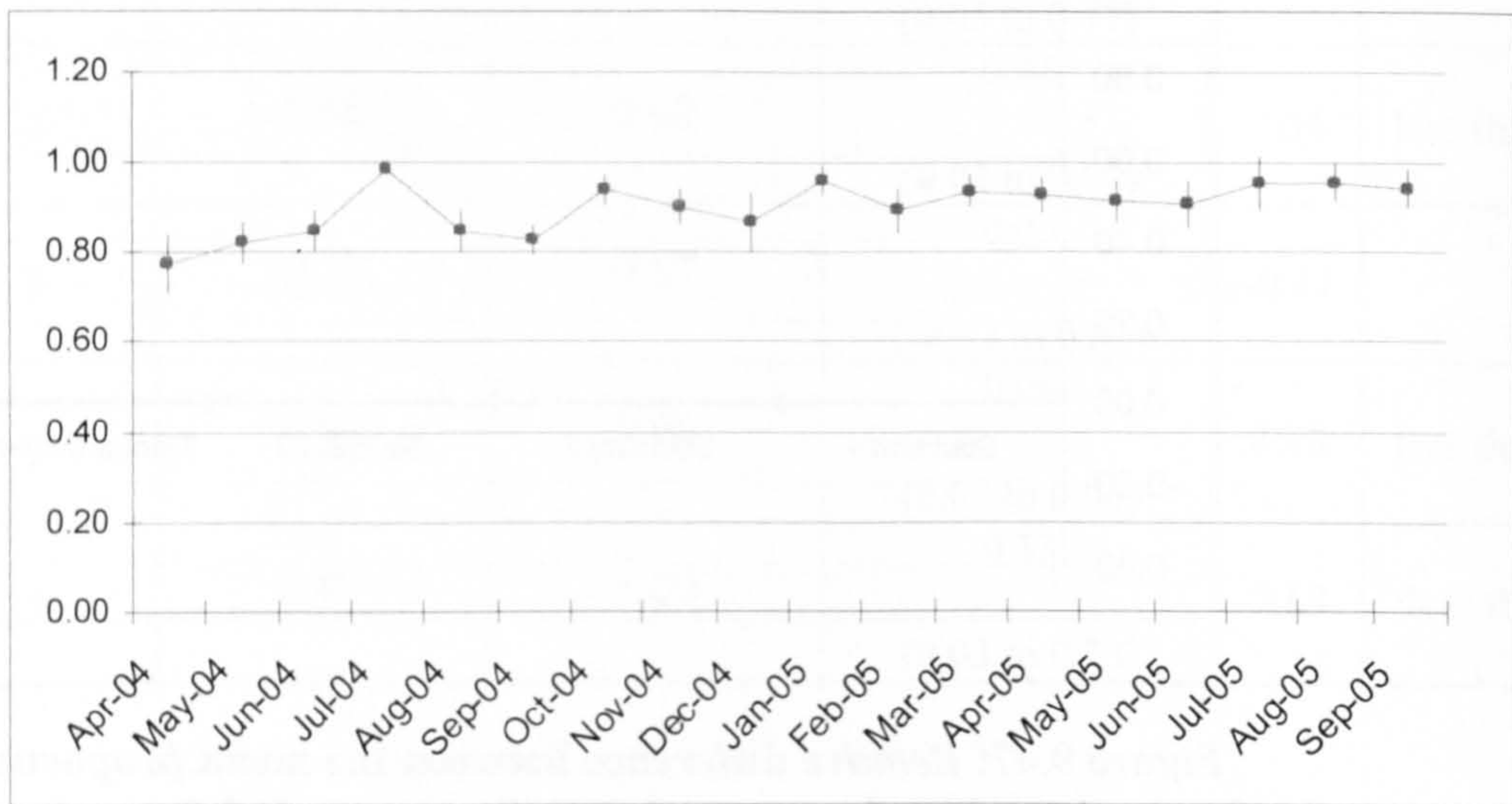


Figure 9.48: Trend line showing the proportions (95%CI) of patients meeting standard 1 for all health centres in Las Tunas combined

By the end of the project, the committee noted that the availability of sputum pots improved and regular training of new doctors took place without much delay.

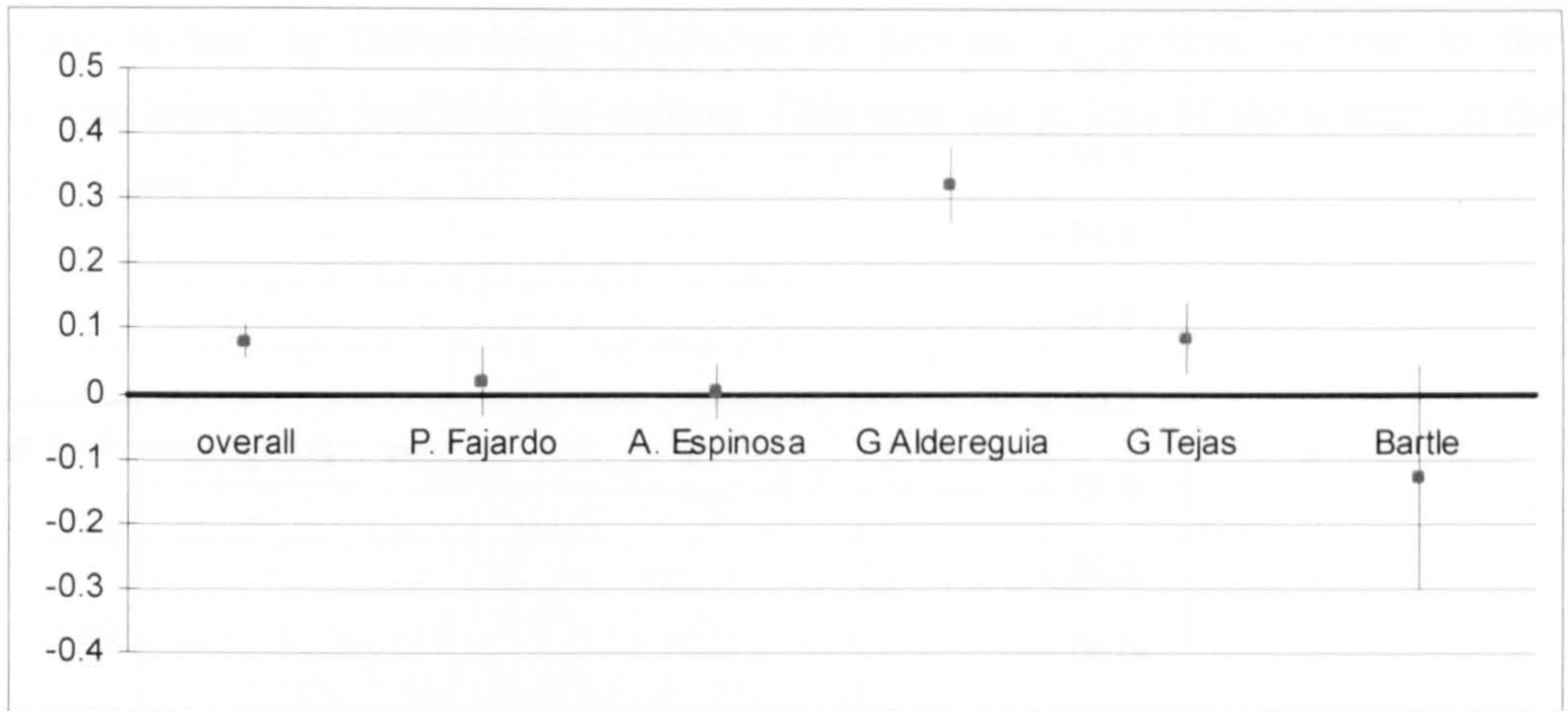


Figure 9.49: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 1 in each health centre in Las Tunas, Cuba

9.3.2.2. Standard 2

The second standard was set to measure the proportion of patients with cough for more than 2 weeks who had their second sample submitted, processed and reported within 72 hours of medical consultation. Similar to the trend observed for standard 1, standard 2 also show a gradual improvement with little variation from month to month (Figure 9.50). The desired performance level was reached in the second audit cycle. There was a 4% *absolute* and 37% *relative* improvement between the mean proportions estimated in the first and the last data collection periods (Figure 9.51).

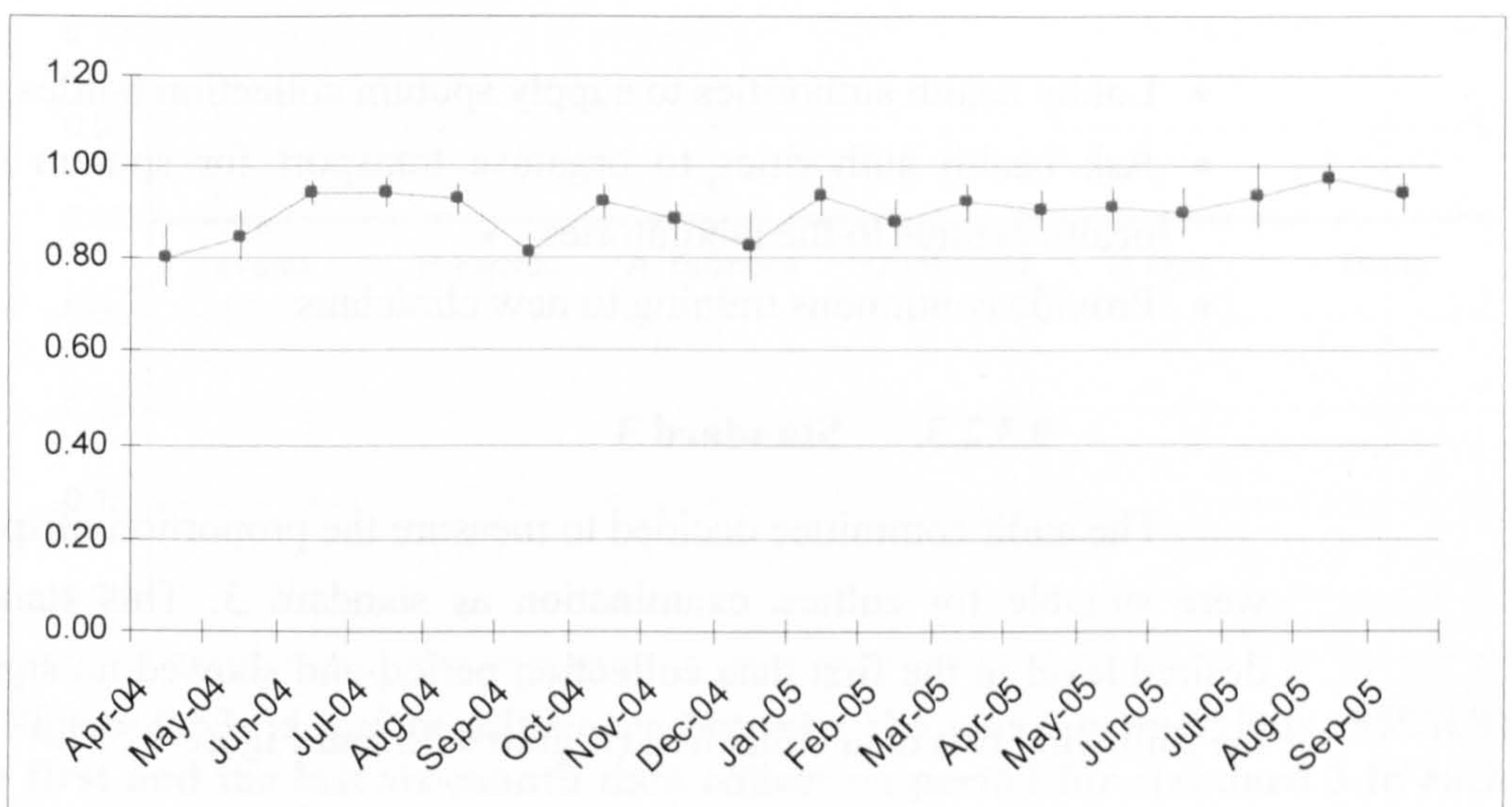


Figure 9.50: Trend line showing the proportions (95%CI) of patients meeting standard 2 for all health centres in Las Tunas combined

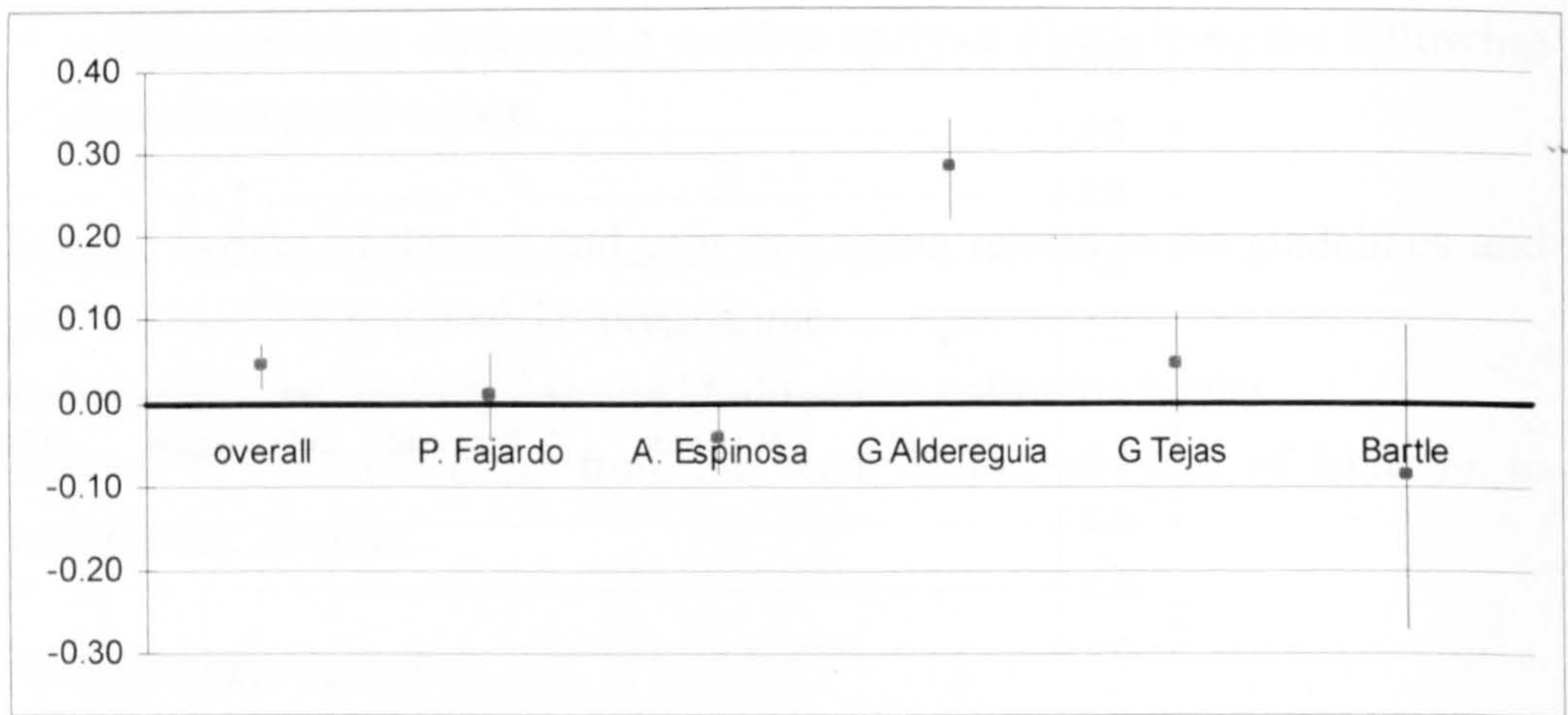


Figure 9.51: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 2 in each health centre in Las Tunas, Cuba

As for to standard 1, the audit committee highlighted a number of reasons behind poor performance:

- Insufficient and irregular supply of sputum collection bottles
- Laboratories were far from the health centres, and limited facilities to transport the samples resulted in delay
- Doctors were regularly transferred and this created resources gaps as mentioned previously

The audit committee agreed to:

- Lobby health authorities to supply sputum collection bottles regularly
- Ask health authorities to organise transport for sputum samples from the health centres to the laboratories
- Provide continuous training to new clinicians

9.3.2.3. Standard 3

The audit committee decided to measure the proportion of sputum samples that were suitable for culture examination as standard 3. This standard achieved its desired level in the first data collection period and showed no significant change in the following two data collection (Figure 9.52 and Figure 9.53).

The audit committee concluded that the poor standard observed initially was down to:

- Lack of clinicians' knowledge about the importance of a good quality sputum sample and their failure to instruct patients to deliver an adequate sample

- Patients had to travel long distances to provide a sputum sample to the laboratories with facilities for culture. This resulted in loss of the quality of the specimen

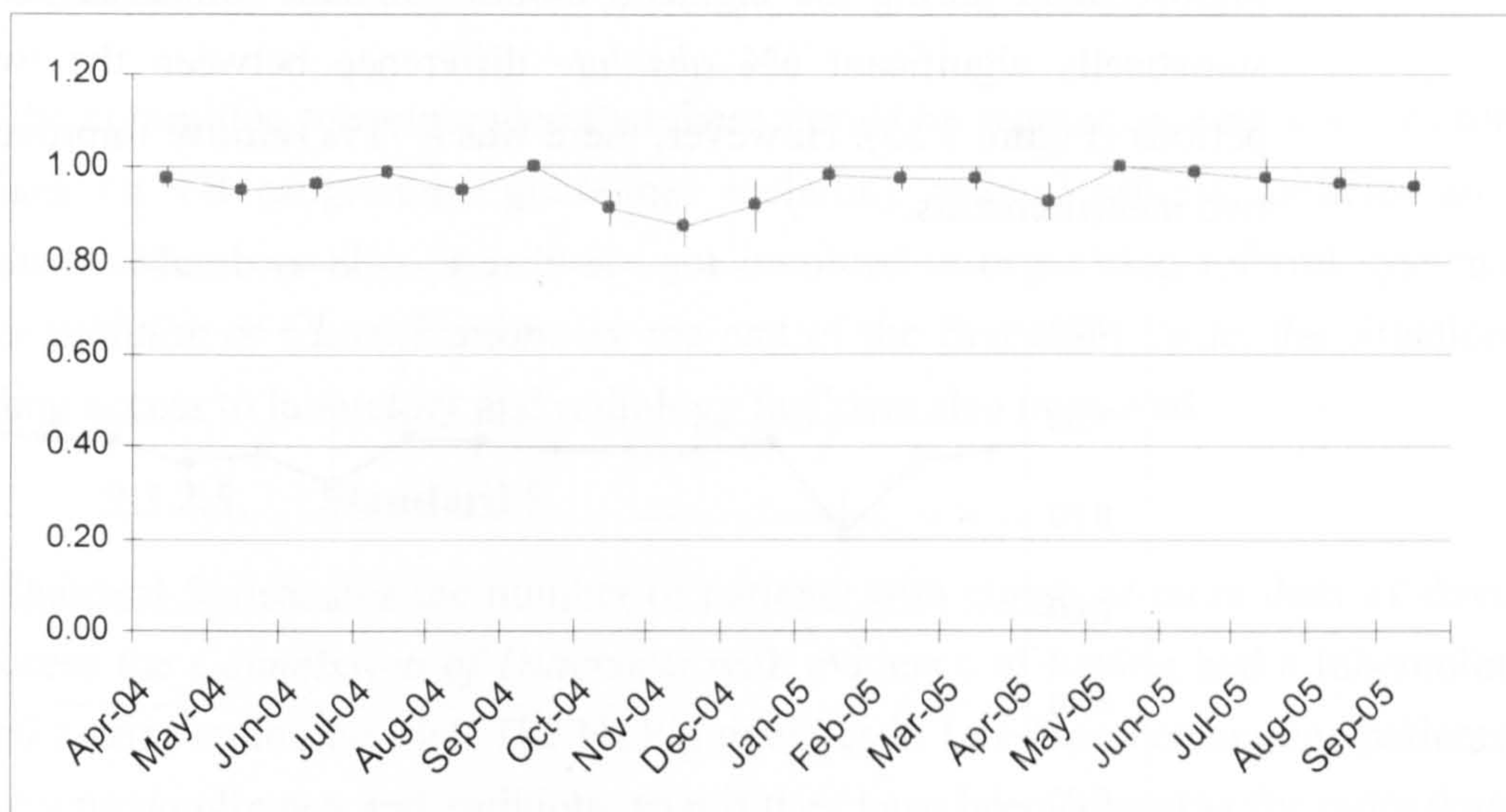


Figure 9.52: Trend line showing the proportions (95%CI) of patients meeting standard 3 for all health centres in Las Tunas combined

In their recommendations, the committee emphasised that doctors should be made aware of the importance of the sample quality, and training should be provided to give clear instructions to patients on providing a good quality sputum for culture to the laboratory.

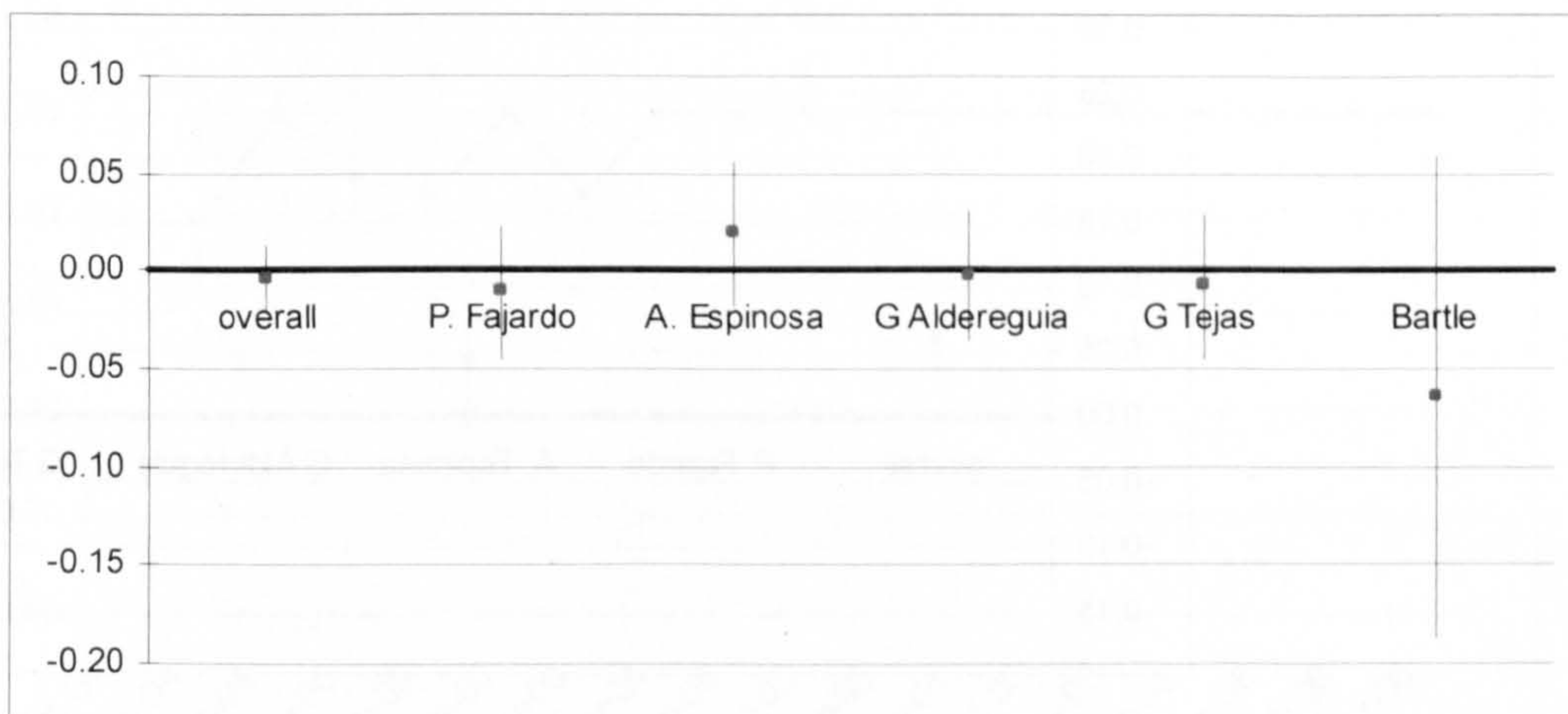


Figure 9.53: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 3 in each health centre in Las Tunas, Cuba

9.3.2.4. Standard 4

The TB programme in Las Tunas makes it mandatory that all patients with cough of more than 14 days should have a *Consultation of Classification* with a chest X-ray and two sputum smear examinations. This consists of an assessment by

a chest physician, who assesses the probability of smear negative TB diagnosis based on the initial investigations. Standard 4 measures the proportion of patients complying with the above guidance. The trend line in Figure 9.54 shows improvement during the eighteen months of data collection period. There was a statistically significant 6% *absolute* difference between the two data collection periods (Figure 9.55). However, there was a 71% *relative* improvement between the two measurements.

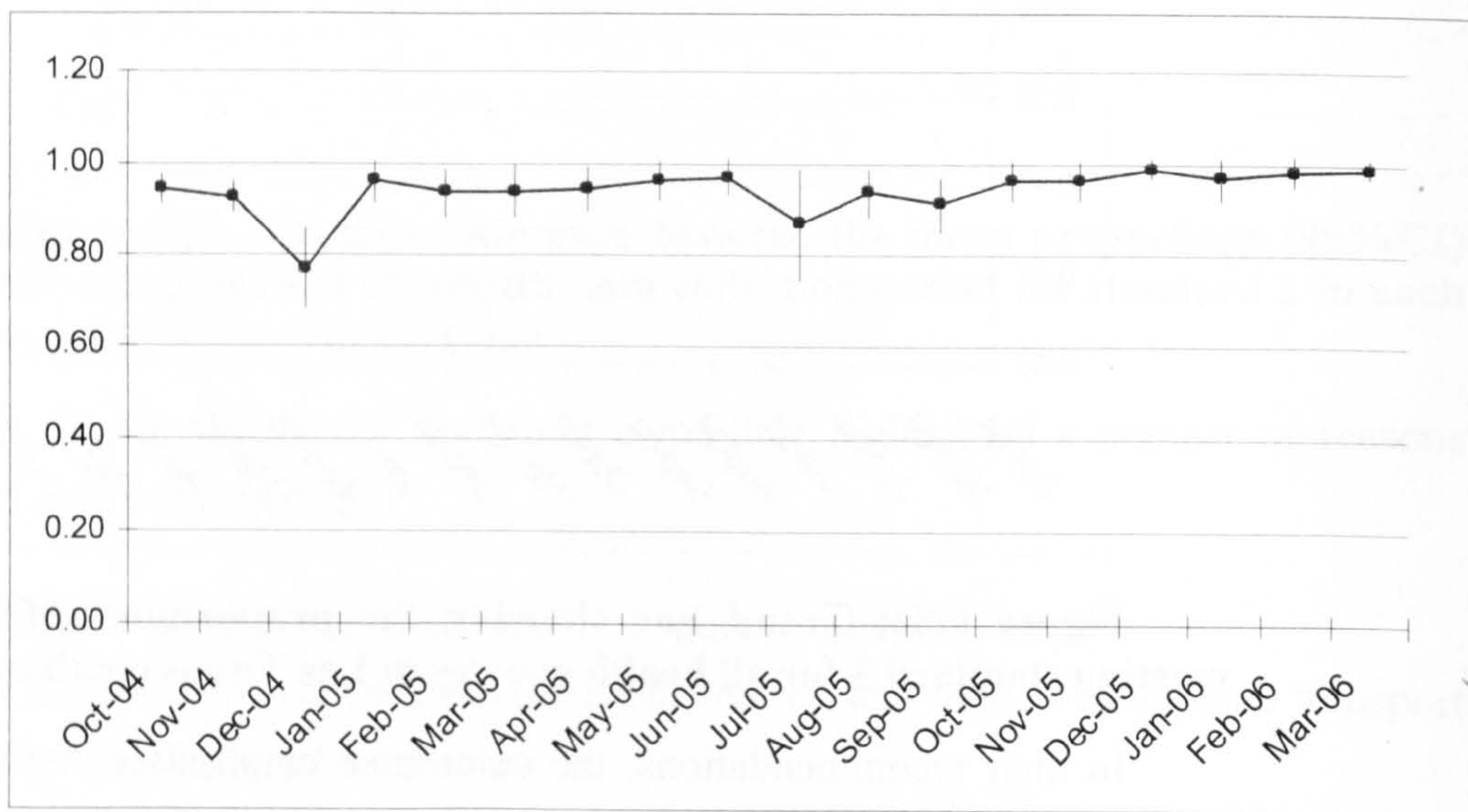


Figure 9.54: Trend line showing the proportions (95%CI) of patients meeting standard 4 for all health centres in Las Tunas combined

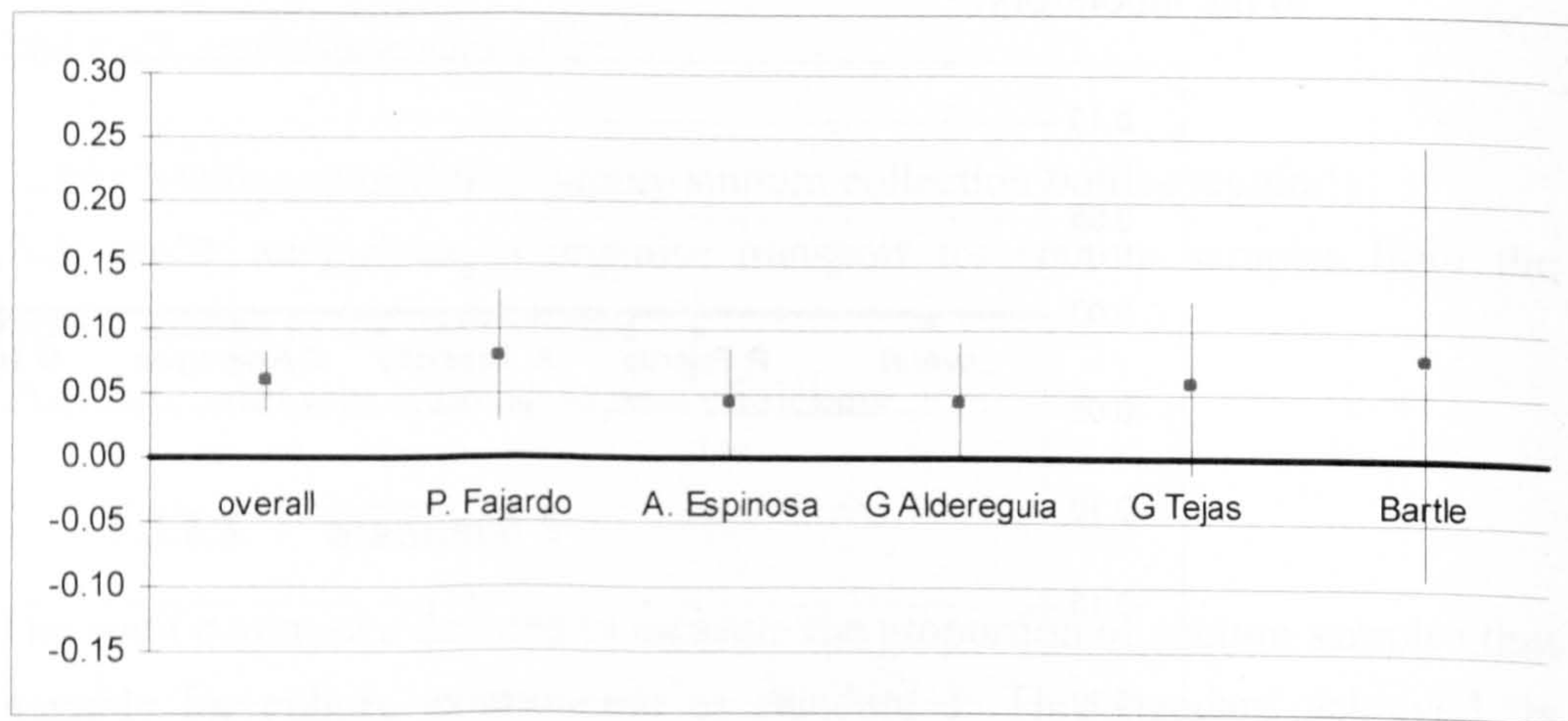


Figure 9.55: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 4 in each health centre in Las Tunas, Cuba

The audit committee identified three problems:

- Initially the referral system for *Consultation of Classification* was not properly established and general practitioners were not aware of the system

- Clinicians were not aware of the TB programme guidelines and the policies and procedures of the referral system
- Investigations could not be completed in time due to poor access to laboratory and radiology facilities

The committee recommended that there should be regular training sessions for clinicians on TB programme guidelines including referral criteria, policies and procedures. Members also proactively got involved in organising referral systems for *Consultation of Classification*. By the end of the first audit cycle, the situation regarding access to laboratory and radiology facilities also improved.

9.3.2.5. Standard 5

Standard 5 measures the number of patients with cough of more than 21 days that access the *Commission of Diagnosis* with evidence of having had a tuberculin test and a prior antibiotic trial. The NTP guidelines in Las Tunas encourage patients to have a tuberculin test and antibiotic trial if they have been coughing for more than 21 days prior to their referral to the *Commission of Diagnosis*. The trend line in Figure 9.56 demonstrates a gradual improvement over the audit cycle. There is a 100% *relative* improvement in the standard between the first and the second data collection periods. The improvement in the *absolute* difference was 13% reaching statistical significance (Figure 9.57).

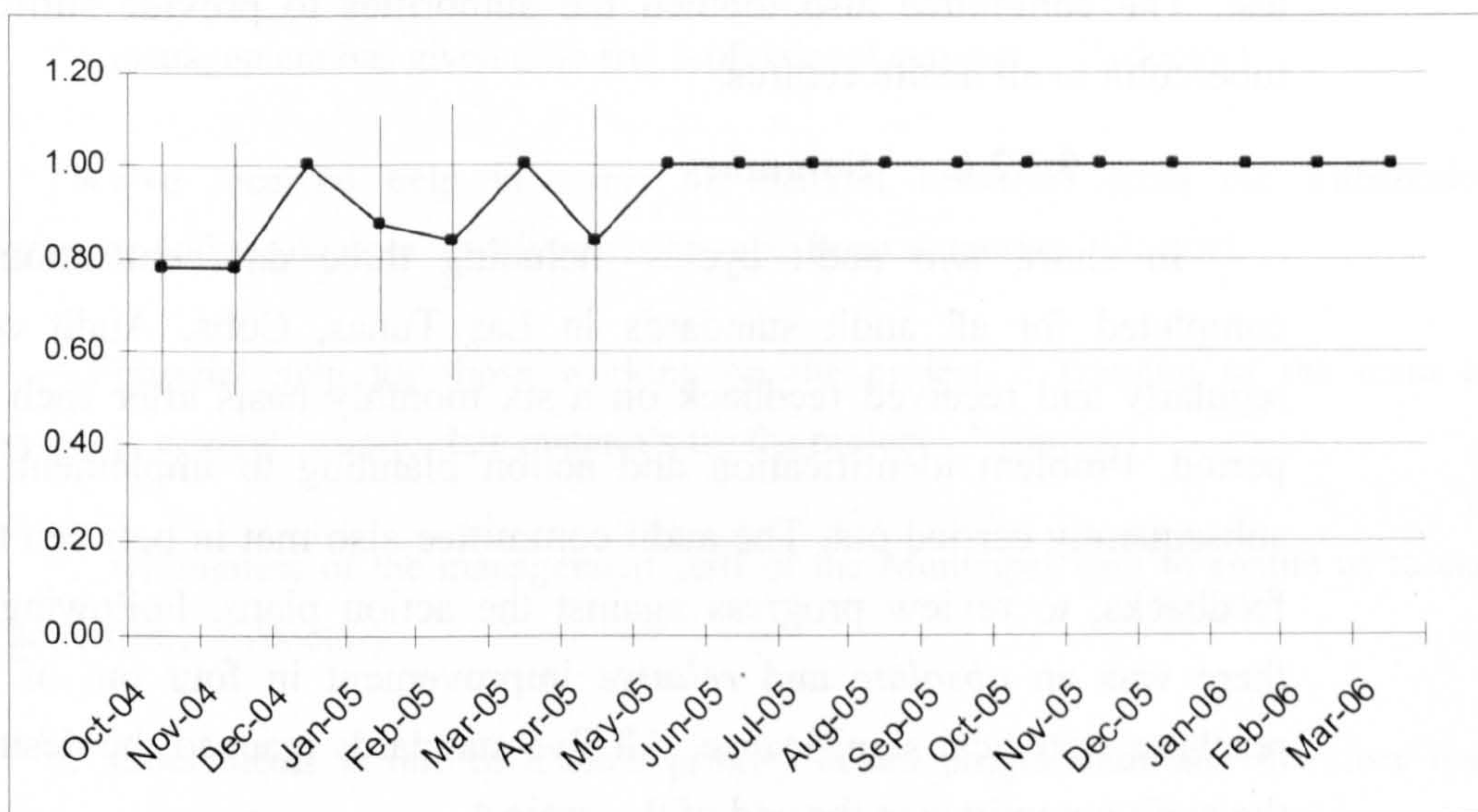


Figure 9.56: Trend line showing the proportions (95%CI) of patients meeting standard 5 for all health centres in Las Tunas combined

The committee identified three reasons for the poor performance observed in the first part of the audit cycle. These are as follows:

- Lack of awareness about the requirement of the tuberculin test as part of the national guidelines
- Primary health care centres do not always have staff trained in how to administer the tuberculin test
- Unreliable supply of tuberculin

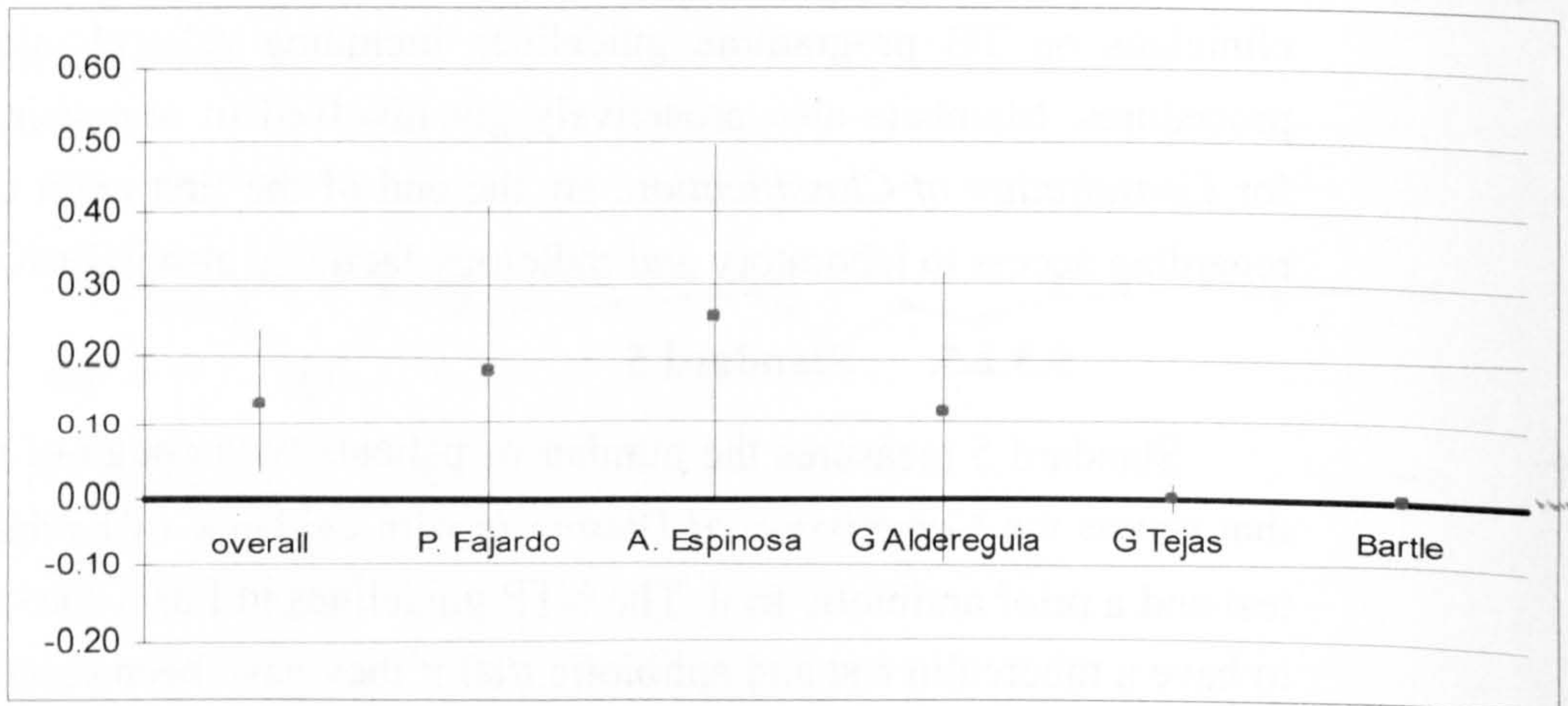


Figure 9.57: Absolute difference between the mean proportions (95%CI) of the first and the last six-month data collection period for standard 5 in each health centre in Las Tunas, Cuba

The audit committee raised these issues with the healthcare authorities and persuaded them to arrange training for nurses in the administration of the tuberculin test. The committee also lobbied the authorities to provide sufficient supply of tuberculin to all health centres.

9.3.2.6. Summary

In short, two audit cycles including three data collection periods were completed for all audit standards in Las Tunas, Cuba. Audit committees met regularly and received feedback on a six monthly basis after each data collection period. Problem identification and action planning to implement solutions were subsequently carried out. The audit committee also met in between the six monthly feedbacks, to review progress against the action plans. Following clinical audit, there was an *absolute* and *relative* improvement in four out of five standards, reaching statistical significance. All five standards reached the desired level set by the audit committee at the end of the project.

The following sub-section presents the findings of the qualitative interviews conducted in June and July 05 in both Havana and Las Tunas, which will help to illuminate above results

9.3.3. Analysis of the qualitative interviews conducted in Cuba

Fourteen health care professionals were interviewed in the ten health centres that took part in the project. All interviewees were members of the two audit committees in Havana (8) and Las Tunas (6). All but one interviewee was female, with a median age of 38.5. There were eight doctors, four nurses and two laboratory technicians. They had been in their post for a median of 12.5 years. A summarised thematic analysis is described as follows:

9.3.3.1. Facilitating factors

9.3.3.1.1. Programme support

In general, health professionals felt that the quality improvement intervention received help and support from the TB programme and senior health services management. TB programme co-ordinators not only took part in all audit committee meeting but also facilitated the discussions. This ownership by the TB programme and senior management was considered to be a major factor in achieving improvement (Box 3.1).

Box 3.1: Programme support

“...but as far as the project’s concerned, we’ve received help and support. So far there haven’t been any restrictions” (doctor)

“...management has given time and professional support” (doctor)

“We’ve received help in terms of material resources from the Tuberculosis Programme and the doctors’ involvement has also been supported” (doctor)

“..Financial help for those working on the project ...Training of the team and everyone in general....up-to-date materials for the project...” (doctor)

“...willingness of the management staff of the Municipal Unit to enable us to carry out activities....” (doctor)

“...tuberculosis is one of Cuba’s priority health programmes and therefore many activities are facilitated...” (doctor)

“...help from administration...” (nurse)

“...support from administration and active involvement of the infirmary staff...” (nurse)

9.3.3.1.2. Opportunity for training and professional development

The quality improvement process was perceived as an opportunity by many health care professionals as an opportunity to access further training. Several professionals commented that this process created many opportunities for professional development. Interviewees did not reflect any differential level of access towards such opportunities (Box 3.2).

Box 3.2: Opportunity for training and professional development

“...Opportunities for further training and qualifications: access to Masters and distance learning courses is facilitated...” (doctor)

“...had a really positive effect as it has created more incentives for staff to get further training and qualifications... training is very good as it provides us with the tools we need to be able to take action...” (doctor)

“...The possibilities of obtaining further training and qualifications that are open to all medical and paramedical staff...” (doctor)

“...facilitating factors...professional development... existing directives have helped me. Getting further training and qualifications ...” (lab technician)

“..the opportunity to take part in projects and courses...facilitating factor...” (nurse)

“...responsible for the activity and for implementing change and it prepares and trains the other members of the group in order to harmonise criteria ...” (nurse)

9.3.3.1.3. Participatory leadership

Interviewees generally thought that participatory team leadership had been key to their successes. Leaders who understood the strength and weaknesses of their team members, made staff feel valued. They also motivated the staff by taking part in the audit process themselves (Box 3.3).

Box 3: Participatory leadership

“...A leader would make it difficult to assist improvement if ...s/he didn't give time to the team ...” (doctor)

“...must know when to give credit and motivate staff and when to give constructive criticism ...” (doctor)

“...S/he should not impose change but try to convince them that the changes that are going to be introduced will bring about improvement ...” (technician)

“...I would encourage them...I would help them whenever they had problems ...” (nurse)

9.3.3.1.4. Appreciation of the link between quality improvement initiatives and direct benefit to the patients

A number of responses in the interviews suggested that health professionals were able to appreciate the link between this initiative designed to improve quality, and direct benefit to patients. Some interviewees commented that they were able to see improvements during the project (Box 3.4).

Box 3.4: Appreciation of the link between quality improvement initiatives and direct benefit to the patients

"... I've personally been really motivated by the audit project ...they've provided us with guidelines for improvement..." (lab technician)

"...the existence of new services for the population..." (nurse)

"... Support the team by taking into account that the results will justify the direction taken..." (nurse)

"... Encouraging factors...results of the work carried out..." (nurse)

"... have helped to improve the delivery of service are related to changes agreed after resolving problems that were compromising the quality of an optimum medical service..." (doctor)

"...Improvement is inhibited when you see evidence of problems linked to professional practice which could be resolved by getting further training and qualifications that would contribute to bringing change..." (doctor)

"...I would be motivated by achieving good results..." (nurse)

9.3.3.1.5. Better working environment

During the project, several health centres in Cuba went through refurbishment. Health professionals welcomed these developments and saw these as facilitators in their role in providing a better service to their patients (Box 3.5).

Box 3.5: Better working conditions

"...the refurbishment of the healthcare centres facilitated..." (doctor)

"...have benefited from improvements to the healthcare centre...There are better working conditions now ..." (doctor)

"... Refurbishment means we now have optimum conditions in the workplace..." (lab technician)

"...facilitating factor...the refurbishment of the healthcare centres..." (nurse)

9.3.3.1.6. Shared goals

A number of health professionals shared common goals and objectives with their managers, including people from the TB programme. This was one of the main contributory factors towards the improvement process (Box 3.6).

Box 3.6: Shared goals

"... There haven't been any guidelines that have hindered the project..." (doctor)

"... Yes the audit team is very important because it supports the National Tuberculosis Programme and we've worked everywhere..." (doctor)

"... the fact that the infirmary staff has also accepted the project and cooperate with it..." (doctor)

"... Teams are characterized by work which has a shared mission and goal..." (nurse)

"... You unify criteria and everyone has the same vision and goal..." (nurse)

"... Our services have facilitated unity between those working in audit and their management..." (nurse)

9.3.3.1.7. Good communication and inter-personal skills

Several interviewees felt that the communication and inter-personal skills were the key to effective teamwork, to bring about improvement in a system that relies on numerous partners from various disciplines. Some professionals stressed the importance of teaching communication skills on a regular basis (Box 3.7).

Box 3.7: Good communication and inter-personal skills

"...yes, teamwork has improved. You can exchange ideas within the team..." (doctor)

"... Team members should have good interpersonal skills and be motivated...."
(doctor)

"...communication problems between workers, guidelines can be misinterpreted and, in this sector...“Communication skills” should be given more importance on degree courses..." (doctor)

"... lack of information and communication should be discussed and explained every time a change is introduced..." (technician)

"... the directives could improve things if they were properly followed and there was effective communication..." (nurse)

9.3.3.1.8. Recentralisation

In Las Tunas, recentralisation of TB services had taken place just before the project. Many interviewees working in the health centres there saw that as a facilitating factor towards improving care towards patients with suspected tuberculosis.

9.3.3.2. Limiting factors

9.3.3.2.1. Lack of resources

According to the interviewees, lack of resources has been a strong impediment in bringing improvement according to agreed quality standards. This was often down to the lack of sputum collection pots, microscopes and reagents used in slide preparation (Box 3.8).

Box 3.8: Lack of resources

"...inhibitory factor... When material resources are not available in time..." (doctor)

"... Problems with some resources (e.g. scarcity of some reagents, specimen bottles, RX chasses)..." (doctor)

"... Sometimes the collection of specimens is delayed because there aren't any specimen bottles..." (doctor)

"...for solutions but both the lack of material resources and work pressures undoubtedly have an impact on professional ethics, e.g. not having paper to write the patient's details on and then referring him/her..." (doctor)

"... the supply of material resources (specimen bottles) has sometimes been temporarily affected..." (doctor)

"... The lack of reagents, of glassware, of utensils...we don't have enough disinfectant..." (lab technician)

"... Lack of a laboratory which has the appropriate conditions...Lack of a microscope to study TB..." (nurse)

9.3.3.2.2. Poor coordination

Some professionals felt that the lack of coordination between different components of the health service e.g. primary and secondary care often inhibited improvement (Box 3.9).

Box 3.9: Poor coordination

"...Lack of coordination between healthcare and management...there isn't an organisation in charge of collecting information and this hinders improvement because you have to give the information to various different entities..." (doctor)

"...There are so many programmes and sub-programmes and everyone wants to control their own programme...integration helps Primary and Secondary Care to tackle the healthcare problem. Greater integration would enable us to make more progress..." (doctor)

"...Inhibitory factors...poor conditions in the workplace..." (lab technician)

9.3.3.2.3. Rapid staff turnover

During the project, a number of health care professionals were moved to other places. A large number of doctors and nurses went to work on international secondments. This was seen as a big impediment to improvement and resulting in wastage of training and preparing professionals to invest in quality improvement (Box 3.10).

Box 3.10: Rapid staff turnover

".. Inhibitory factors...staff turnover in Primary Care...." (doctor)

"... Staff turnover because this means that you have to train new staff..." (doctor)

"... discouraging factors...staff turnover..." (doctor)

9.4. Conclusions

I measured 24 criteria in four study sites, in three Latin American countries over a period of 24 months. 15 out of 24 criteria showed statistically significant *absolute* improvement whilst two showed deterioration (Figure 9.58). Seven criteria showed no significant change. Out of 15 improved criteria, 11 were from the two study sites in Cuba, two from Bolivia and two from Peru. The range of improvement was from 4 to 50% with a median of 12%. *Relative* improvement was more marked, as 17 out of 24 criteria showed significant improvement (Figure 9.59). Three criteria deteriorated, whilst four showed no significant change. Out of the 17 which improved, 12 were from the two study sites in Cuba, three from Bolivia and two from Peru. The range of improvement ranged from 6 to 100% with a median of 51%.

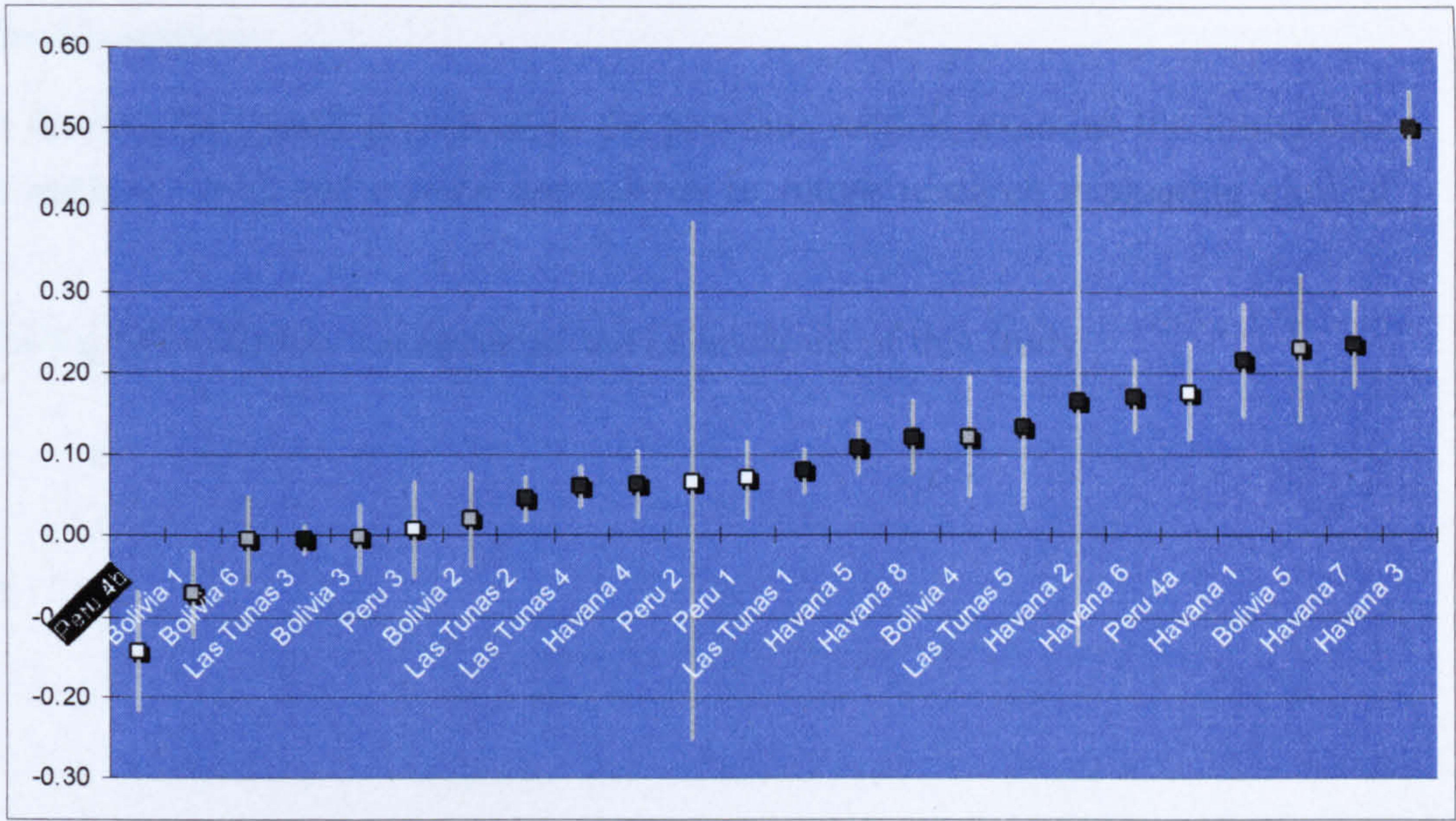


Figure 9.58: A comparison of *absolute* improvement in all criteria across all the three Latin American countries

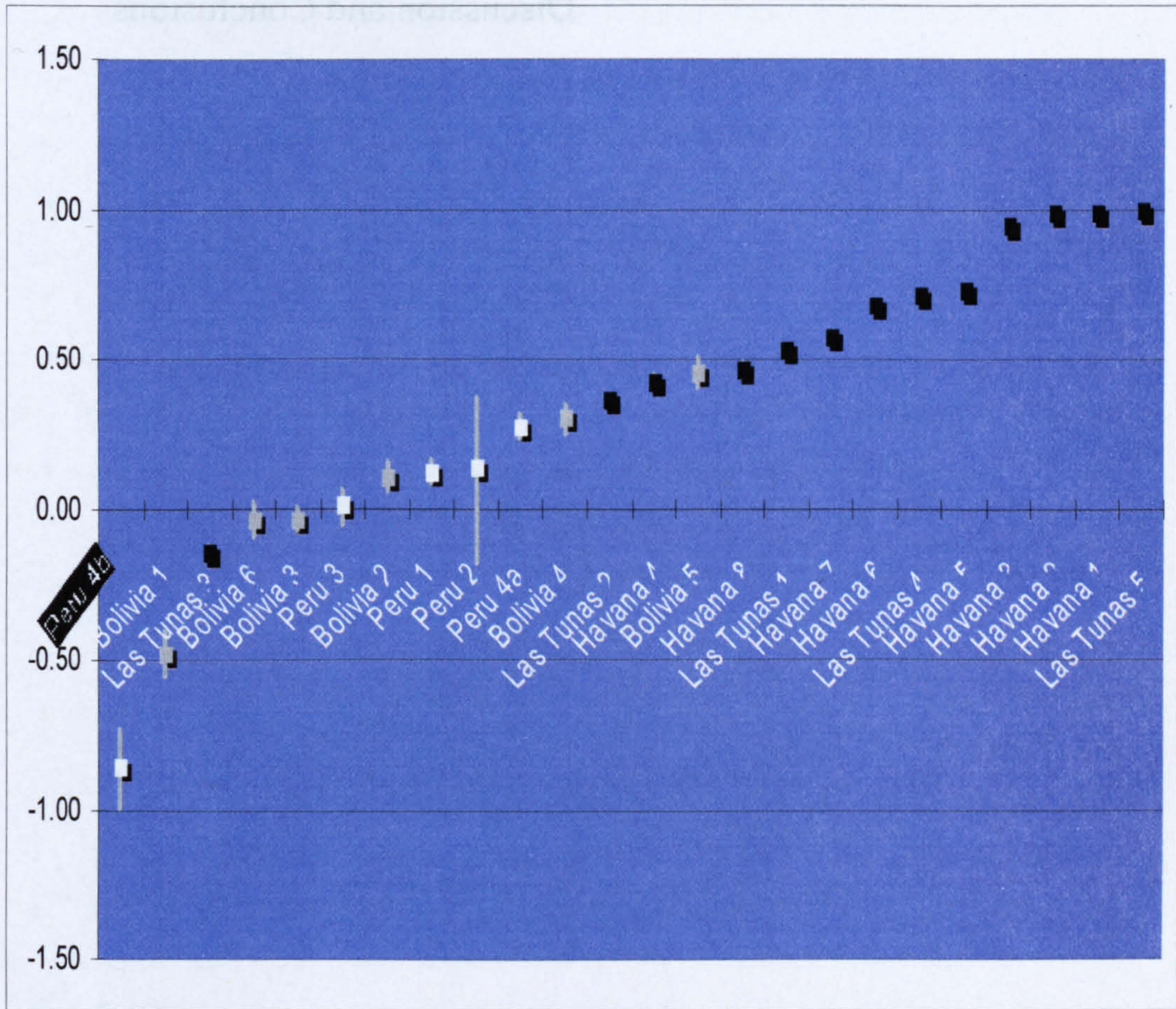


Figure 9.59: A comparison of *relative* improvement in all criteria across all the three Latin American countries

Discussion and Conclusions

In this section:

I discuss the results presented in the previous section, examine the limitations of the methods used and outline approaches to future research evaluating clinical audit

In the final chapter, I summarise the conclusions of this study

Chapter 10 Discussion

The first section of this chapter discusses the methodological limitations and constraints faced during data collection, analysis and interpretation of results. I then summarise the results, following which, there is a discussion highlighting similarities and differences between the results obtained in the three countries. I then discuss the key issues emerging from the results. In the final section of the chapter, I discuss the research implications of this study and propose some approaches relevant to future evaluations of clinical audit.

10.1. Methodological limitations of this study

Before discussing the results of the study in detail, some of the methodological constraints faced during the project are detailed below. Some of these were already discussed in detail in the methods (see page 162) and are revisited here in the light of my experience. A number of issues, however, emerged during the data collection and analysis stage.

10.1.1. External validity of the results

Audit is a complex intervention, which consists of multiple interdependent components. Moreover, audit is a highly context dependent intervention. Its effectiveness depends upon personalities, relationships, professional and organisational structures, and processes (Kerrison, Packwood & Buxton, 1993). It is inherently difficult, therefore, to generalise results from trials of audit interventions carried out in selected circumstances to audit in general (Lord & Littlejohns, 1997). The results from the qualitative interviews highlight this and draw attention to differences between study sites. I have endeavoured to understand and present the *context* within which the audit intervention took place at each site by describing the interaction between health professionals, and between the environment and the organisations they were working in, through these narratives. This information from the qualitative component of the analysis can help to overcome problems with generalisability to other settings.

Evaluation requires some standardisation of the intervention under review, but standardisation is likely to influence and change its nature (Lord & Littlejohns, 1997). Audit by definition is required to have clinical ownership, which introduces local modification of the processes, and takes control of the intervention away from the evaluator. This intervention in the four study sites was subject to similar modification, which was justified to contextualise the audit to local circumstances.

However, this occurred at the cost of standardisation. The contextual narrative for each site is likely to help in understanding the reasons and nature of modifications.

It has been proposed that standardisation of a complex intervention (such as clinical audit) in terms of its components would be an oversimplification (Hawe, Shiell & Riley, 2004). In such interventions, it should be the function and aim of the intervention, which should be standardised and not the process. This would allow the intervention to be tailored to the local context, and to retain its integrity, if based on the principles of the hypothesised process of change.

10.1.2. Lack of controls

In each of the study sites, the intervention was introduced in all participating health centres, and no controls were selected. Therefore, the interrupted time series and the before-and-after design were the only practical study designs. In evaluative terms, it is never possible to isolate the effects of the intervention from confounding factors without a truly equivalent control group. However, selecting some health centres as controls within the study sites was not only impractical, but may also have raised questions about the validity of the results for the reasons described below.

Health centres in the study sites were part of the same district administration and an intervention in some centres, especially one that influenced health systems, would have contaminated control health centres. A number of these health centres, especially those in urban settings, were in close proximity and had internal referral systems, which would have made contamination likely.

Selection of more study sites in addition to the intervention sites would have required more resources. Each study site would have required additional facilitators and revised data collection systems, given the complex nature of the intervention and the outcomes measure to determine its effectiveness.

The variables measured in this study were developed and agreed by the clinicians as audit criteria, and were not part of the routine monitoring system of the local TB programmes. Modifications were introduced in the clinical record keeping system in almost all health centres in Bolivia, and in many health centres in the other study sites. These changes, often requiring time intense effort, were introduced to conduct audit as well as research. The selection of the audit criteria and the modified data collection systems were considered to be part of the audit intervention. It would not have been possible to collect similar data from the “control” health centres without introducing audit criteria and modifying their data collection systems. The introduction and measurement of these newly developed criteria (which I considered to be part of the intervention) itself would have influenced change in the control sites. ‘Feedback’ would have been the only

component of the audit intervention for which the effect could have been observed in the intervention centres compared to control centres.

10.1.3. Defining and measuring the impact of audit

I learned that defining and measuring the impact of clinical audit can be challenging and far from straightforward for a number of reasons which are described below.

The ultimate aim of clinical audit is clearly to improve the quality of patient care. However, what do we mean by quality? Good quality care must be that which is clinically effective, but other dimensions, such as equity, efficiency and humanity are also important (Maxwell, 1984). Defining the goals of clinical audit can be surprisingly difficult and dependent on which professional group is determining these goals and where their values lie. I followed the standard guidelines to develop multidisciplinary audit committees. Nevertheless, audit committees predominantly consisted of clinicians working in these centres. By virtue of their position in the health centres, they often dominated discussions and the decision-making process. This created a situation where the majority of the selected audit criteria and standards had a bias towards clinical effectiveness at the expense of other dimensions of quality. It is likely that the standards would have been different if selected by committees more representative of TB programme co-ordinators or patients.

The aim of the research group conducting this study, as discussed in the methods chapter was to assess the effectiveness of clinical audit in improving the quality of diagnostic care provided to patients with suspected TB and patients with smear negative TB. I accepted the criteria selected by the audit committees as the markers of quality and do not attempt to develop and measure the impact of clinical audit using indicators other than the ones selected by the committees. A purist view might be that a set of separate indicators should be developed and measured to assess the impact of clinical audit according to the objectives of the study to counteract potential bias created by audit committees' selection of audit criteria considered and measured as quality of care. However, my inability to find any previous examples in the literature where such an approach had been developed and applied indicated that this might be too fraught with difficulties and challenges to do it in practice.

This study could not determine sustainability of audit effectiveness over the longer term. Such an estimation would have required measurement of the audit criteria over a prolonged period after cessation of audit activity. Other studies have also indicated this difficulty and empirical evidence of the effectiveness of audit

over the longer term does not exist, even in studies done in developed countries (Robinson, Thompson & Black, 1998).

This study assessed the effectiveness of the intervention through measuring change in clinical practice and not in clinical outcomes. Change in clinical practice is used as a proxy measure for change in clinical outcomes. I justify this by the assumption that the majority of the audit criteria selected were based on evidence that a change in clinical practice would influence clinical outcomes.

In committee meetings, there was also strong support for measuring and improving the quality of care for patients with suspected pulmonary TB, and not just for patients with suspected smear negative TB. This contrasted with the original project proposal, which specifically talked about the quality of the diagnosis of smear negative TB patients. Patients that are suspected to have smear negative TB usually constitute a subset of a bigger cohort of “sintomaticos respiratorios”, or patients with suspected pulmonary TB. The improvement in diagnostic quality also benefits those who are diagnosed (correctly) as not having smear negative TB; and availability of sputum microscopy remains the corner stone of diagnostic process, so the two diagnostic groups cannot be separated. In addition, in terms of health impact, the intervention is more likely to be successful if addressing the quality of care of a larger group of patients.

Clinical audit seeks to improve patient care in ways other than just the direct changes in clinical practice e.g., indirect effects through professional education and team development. However, turning these abstract goals into measurable outputs can be difficult (Lord & Littlejohns, 1997). Evidence collected through interviews and minutes of the audit committee meetings points to a number of such positive spin offs from the audit. This is also evidenced by the continuation of audit in two study sites even after the completion of the project. In retrospect, such spin offs need to be counted towards the effectiveness of such interventions and estimated through appropriate outcomes.

10.1.4. Issue of clinical significance and statistical significance

The estimation of sample size for an audit differs slightly from the sample size calculations for research. The number needed in the sample for an audit criterion is determined by two factors (NICE, 2002):

- The degree of confidence wanted in the findings (the same as for research)
- Resource constraints

It is recommended that the sample chosen for audit should be small enough to allow data collection in a timely fashion, but large enough to be

representative(Copeland, 2005). Research variables are often selected on the basis of the availability of a sufficient sample size required to provide a statistically significant difference. On the other hand, selection of audit criteria is essentially based on clinical significance and their relevance to the quality of clinical care. Sample size in clinical audit is also limited to the occurrence of a specific event under observation in the participating health centres within the specified period. For example, standard 2 in Lima, Peru was selected because clinicians felt that this was an issue of high clinical importance, despite being relevant only to a small subset of patients with suspected tuberculosis.

An alternative method called rapid-cycle sampling has been introduced recently(Alemi et al, 2000). It involves the use of small samples, with many repeated data collections to monitor serious fluctuations in clinical performance. The cycle is completed quickly with small sized data collections, and reliability is improved by repeating the process.

10.1.5. Differentiation between intervention and research activity

In evaluating complex interventions such as clinical audit, the person who facilitates the implementation of the intervention, often also evaluates the effectiveness of the intervention. This creates a dilemma in distinguishing the effect of the intervention from the activities carried out as part of the research(Black, 1992). It also makes it more difficult to define the intervention for future implementation in policy and practice.

In this project, the four audit co-ordinators (two in Cuba and one each in Peru and Bolivia) were responsible for facilitating audit committee meetings, as well as providing assistance in selecting audit criteria, data collection, feedback, problem analysis and development of action plans. In addition, they were also acting as the research co-ordinators for each site. This carried extra responsibilities of qualitative and quantitative data collection, communicating with the other researchers in the project and managing the research project and its finances. An evaluation requiring an economic assessment of exact inputs and output would have been problematic. Since the audit co-ordinator is part of the intervention, it would have been desirable to differentiate that role from the research role at the outset. In retrospect, a description of the roles and activities of an audit co-ordinator should have been drafted.

10.1.6. Failure to capture variations in individual health centres

Chapter 9 highlighted that there were variations in performance, and differences in the observed improvements between health centres within each study site. However, due to small sample size, these differences failed to reach statistical

significance. For that reason, this study could not detect any patterns of significance within the individual sites. Nevertheless, the differences between the performances of the health centres were part of the audit feedback process. Evidence from the UK suggests that clinicians are more likely to pay attention and act upon feedback on their performance, if it is provided in comparison with their peers and colleagues (Fraser & Gosling, 1985). Therefore, a comparative analysis was relevant to health professionals representing individual health centres (as noted during the meetings) despite not being statistically significant. In addition, the interviews did not explore the reasons for better or worse relative performance between health centres. Such inquiries were not built in the interview questions or analytical strategy mainly because all health centres in individual sites were regarded as one case study unit and the differences between individual sub-unit (health centres) were not explored.

10.1.7. Limited potential for improvement

Audit committees in all study sites selected criteria using a standardised method (see methods chapter). However, for several criteria the baseline performance was found to be close to the desired level during the first data collection cycle. For these criteria, there was less scope to demonstrate a statistically significant *absolute* difference between the before-and-after performances. I, therefore, estimated the *relative* difference between the proportions of patients meeting specified criteria during the first and the last data collection periods. This removes the effect of differences in the baseline performance for various criteria to some extent. Moreover, according to the diffusion of innovations theory, change is harder to achieve after a certain level (Sanson-Fisher, 2004). The difference observed between improvements for different criteria may possibly be due to differences in the rate of change at different levels of performance.

10.1.8. The data collection system and its influence on outcomes

Clinical audit uses the routinely collected data within health systems to measure clinical performance. There is an underlying assumption that there will be a basic minimum routinely collected data set within the health system, which will provide sufficient information to measure the numerator and the denominator agreed for each audit criteria. These assumptions are usually valid in high resource health systems. However, in resource poor settings the routine data collection system is often non-existent. This study found that on numerous occasions, the existing data collection system was insufficient to measure performance of any clinical relevance. The respective audit committees decided that the data collection system would be improved where deficient, and introduced where absent to provide the basic infrastructure for conducting clinical audit. This introduced significant delay in

introducing audit. It is difficult to distinguish the influence of introducing or modifying the data collection system from the effect of the audit and feedback without controls. It is expected that the influence of changes to the data collection system should be reflected in the first data collection, and any subsequent improvements would be due to the audit and feedback. However, it is also possible that such changes have a delayed effect, which produced a gradual change in the system.

10.1.9. Time series and modelling

Time series analyses have been used to assess the magnitude and statistical significance of any shifts in data series following quality improvement interventions (Hand, Plsek & Roberts, 1995). Data are analysed by comparing pre- and post-intervention trends in a change in intercept (or level) and a change in slope (or trend) of each variable. In this study, it was not possible to test significance of time series changes using ordinary least square regression. This is because the individual data points were not independent, and are more likely to be correlated with data points closer in time than those further removed (Cook & Campbell, 1979). An autoregressive integrated moving average (ARIMA) model and the related modelling techniques could have been used. However, it was decided not to use such modelling techniques and not to perform a time series analyses. When monthly data for each health centre for individual criteria were plotted to observe trends, there was considerable variation between successive time points. The ARIMA model measures change from one time point to the next for each health centre, and builds a mathematical model that produces a summation of all individual changes. However, if the data vary considerably from one point to the next, it fails to estimate and reflect real change. In this situation, it does not offer any clear advantage over the alternative technique used. The only implication of not using the ARIMA model is that I was not able to use data collected monthly throughout the audit cycles and therefore was not able to capture all changes taking place during that period.

10.1.10. Limited information about changes during intervention

By definition, the before-and-after design can only detect changes in performances before and after the intervention. It fails to assess any temporary changes during the project, and their influence on the overall impact of the intervention. I calculated the difference between the mean proportion of patients meeting each criterion in the first and the last six-month data collection period. This takes account of two-thirds of the data collected in Bolivia and Cuba and half of that collected in Peru. It can be argued that this approach took account of the most important data collection period in the audit cycle, and changes occurring in the middle of the cycle should not influence the overall outcomes of the study. In

addition, I observed that in certain instances, especially data collected from Cuba, there was reduced variation and visible improvement by the end of the data collection period, making it even less important to take account of the performance in the middle six months period.

10.2. Summary of results

This section provides a discussion of the summarised results (Table 10.1) which have been presented in detail in chapter 9. For each country, I provide a list of salient findings followed by a number of contextual issues that may have played a key part in how clinical audit influenced clinical practice in each country. Some of these were characteristic to one study site, others were either common in two or more sites. Some factors facilitated clinical audit to influence and bring improvement, and others impeded its effectiveness.

10.2.1. Peru

In Peru, clinical audit was implemented in eight health centres in Lima, constituting one study site, over a period of 24 months. During this period, three audit cycles were completed including four six-month data collection periods and feedback sessions. There was an absolute improvement of statistical significance in two out of five criteria (1 and 4a). None of the criteria reached the standards agreed by the committee. There were wide variations in results achieved in different health centres.

10.2.1.1. What went well?

- Peru was the only site where three audit cycles were completed within the two-year period. This reflects effective project management and facilitation of the audit intervention on the part of the participants in Peru. Several lessons can be learned from this experience to help in developing a practical model of implementing clinical audit in a TB programme setting.
- Despite numerous difficulties faced by the audit committee (see results chapter), some improvement was secured. Committee meetings were well attended and members demonstrated their motivation through active participation. Problem analyses were detailed and action plans were followed through.
- The audit team in Peru held meetings within official working hours and ensured that committee members were given official leave from work to attend meetings.
- The study site in Peru lost its audit facilitator in the middle of the project. However, a new facilitator was swiftly appointed and the audit process kept its momentum without any break in data collection.

10.2.1.2. What went wrong?

- Audit in Peru had strong clinical ownership but less involvement of the TB programme. Selected criteria were biased towards clinical priorities and were sometimes in conflict with the programme targets (see standard 1 in Results chapter for details). The TB programme had developed its own guidance for diagnosing and managing TB, which was not accepted fully by clinicians and, therefore, only partially implemented. There were clear disagreements between clinicians working in the health centres about some aspects of the guidance. Clinicians also pointed to a lack of clarity in the guidance for managing patients with suspected tuberculosis with negative smears.
- Clinicians' perceptions of patients' beliefs and attitudes plays a major role in determining professional behaviour. In the interviews, clinicians acknowledged that they deviated from evidence-based practice due to their perceptions of patients' reactions to a specific clinical decision. While these issues were acknowledged, few actions were planned to address them. It is possible that despite feedback on performance, clinicians continued to behave in a manner that they perceived desirable from patients' perspective (see pages 242 and 247 in results chapter for details).
- Certain interventions implied as desirable by the chosen criteria could only be implemented through patients bearing extra cost in terms of repeat visit fees, loss of wages, transportation costs etc. Initially, the committee members failed to recognise that such recommendations would be problematic to implement. After the first cycle, however, they realised that these issues were mostly beyond their control.
- There was a clear lack of coordination at the interface between laboratories and clinicians. This was due to the absence of a service design that could prevent patients from "falling through the net". This was responsible for some of the poor performance observed. Some of these issues, although identified through the audit cycle, were not resolved even by the end of the project.
- Political interference resulting in constant staff changes and preferential treatment of some staff members was seen as a major limiting factor in bringing improvement as highlighted in the interviews.

10.2.2. Bolivia

In Bolivia, clinical audit was implemented in eight health centres in Cochabamba as one study site over a period of 24 months. During this period, two audit cycles were completed including three six-month data collection periods and feedback sessions. There was an *absolute* improvement of statistical significance in two (4 and 5) out of six criteria. However, *relative* improvement was observed in three (2, 4 and 5) out of six five criteria. By the end of the project, only one criterion reached the agreed standard.

10.2.2.1. What went well?

- Clinical audit generated a number of training activities specifically around TB and more generally about evidence-based medicine. Interviewees and audit committee members acknowledged that this quality improvement initiative had created opportunities for staff to develop themselves professionally and keep up to date with current guidance on TB management.
- Participants also saw the link between audit and quality improvement through their experience of implementing audit. As highlighted in the interviews, there was a general recognition that clinical audit made them reflect on their practice and strive for improvement. There was evidence from our survey that participants saw this as a worthwhile exercise.
- Committee members identified that patients' beliefs and attitudes play a key role in influencing clinical practice and one of the key interventions would be to influence patients' knowledge, beliefs and attitude through patient education. In an effort to improve certain standards where patients' perceptions are likely to have played a key role, committee members planned and executed a number of actions to educate and monitor patients.
- Audit facilitation also involved translating TB programme clinical guidance into user-friendly clinical tools such as desktop guides, care pathways plotted in the clinical notes, charts with patient pathways and algorithms. These tools were found useful in implementing evidence and acted as a reminder for clinicians in following TB guidance.

10.2.2.2. What went wrong?

- A number of health centres did not have a system for patient registration and clinical record keeping. A lot of time and effort was spent to try to establish a data collection system in those centres. Even when a system of clinical record keeping was established, it had a number of problems due to logistical issues within the centres, as evidenced by lack of improvement in the first standard.
- Some of the criteria were selected where performance was already close to the optimal agreed level with little opportunity to bring a visible improvement. Selection process for the audit criteria occasionally failed to take account of the opportunity for demonstrating improvement when considering various issues for audit.
- Audit activity was not entirely integrated within the TB programme and clinicians often referred to the lack of programme support in quality improvement initiatives. Unlike Peru, criteria selected by the audit committee were not in direct conflict with the TB programme objectives. However, more improvement could have been achieved had the TB programme participated in the audit activity directly.

- Frequent changes in health care staff, managers and ultimately policies were also recognised as a key limiting factor in Bolivia. Like Peru, interviewees pointed towards preferential treatment towards certain members of staff within the health service leading to incompetence and frustration.
- Lack of coordination between health centres and laboratories appeared as a major constraint in improving certain related standards.

10.2.3. Cuba

In Cuba, clinical audit was implemented in five health centres in Havana and Las Tunas as two study sites over a period of 18 months. There was a delay in the start of the project due to human resource issues. Four criteria were selected in Havana at the start of the project. Subsequently four more criteria were added after the first audit cycle. Similarly, two more criteria were added in Las Tunas after completing the first cycle on the initial three criteria. Therefore, two audit cycles were completed for all criteria in Havana and in Las Tunas. In Havana, there was an absolute improvement in seven out of eight criteria and a relative improvement in all criteria. In Las Tunas, four out of five criteria showed a statistically significant absolute as well as relative improvement. Six out of eight criteria in Havana reached the standards agreed by the committee at the end of the project. Similarly, all five criteria reached the agreed standards in Las Tunas. There were fewer variations compared to elsewhere in the changes observed between different health centres in both sites.

10.2.3.1. What went well?

- Clinical audit activity was fully integrated within the TB programme both in Havana and in Las Tunas. The National TB programme approved the audit plan as part of this research activity at outset. The district TB co-ordinators chaired and facilitated audit committee meetings, thereby endorsing full support to the audit process. This provided a good collaborative model between TB programme managers and clinicians in securing quality improvement with shared objectives. TB programme support and direct involvement in clinical audit was a key factor in the improvements observed in both study sites.
- Refurbishment of a number of health centres was another supportive development that took place during the time of project. This brought in better resources in terms of equipment and disposable items that helped clinicians in improving service provision.
- As in Bolivia, audit activity stimulated a number of training activities, workshops and seminars that were appreciated by the health care staff as evidenced by interviews.

- Clinicians were also able to observe improvements taking place as a direct result of the audit activity. This was found to be a key motivational factor and facilitator in improving clinical practice.

10.2.3.2. What went wrong?

- During the time of the project, several thousand health care staff were seconded to Venezuela as part of a national co-operation programme between the two governments. This affected clinical audit as the majority of the staff participating in the audit activity left for Venezuela. This not only delayed the process but also necessitated several induction sessions for new members, revision of committees and revision of audit criteria selected.
- Laboratory equipment, disposable items such as sputum pots, slides and reagents were in insufficient supply at the beginning of the project. However, the refurbishment programme mentioned above rectified this problem.
- As in Bolivia, a number of criteria in Las Tunas were selected where a near optimal performance from the start made it difficult to demonstrate improvement.
- Lack of coordination between health centres and laboratories was a key limiting factor in improving relevant standards.

10.2.4. Similarities and differences across the three countries

Putting the above country-specific summaries together:

- Clinical audit was most effective in improving standards of care provided to patients with suspected tuberculosis in Cuba. In Bolivia, audit has produced mixed results, with some clear improvement in certain areas but less so in others. In Peru, clinical audit failed to improve performance according to all except one of the criteria measured.
- Integration of clinical audit within the district TB programme was seen as one of the most important facilitating factors in bringing change. TB programme support was most obvious in Cuba, less in Bolivia and least in Peru. Lack of shared goals and objectives between the TB programme and clinicians was a key factor in the failure of audit activity to show sizeable improvements.
- The appreciation of a visible relationship between audit activity and real improvements was a key motivational factor for clinicians to change practice as seen in both Cuba and Bolivia.
- Similarly, provision of opportunities for training and education and user-friendly tools (pathways, algorithms, charts etc.) as part of the audit activity was seen a vehicle for promoting and motivating clinicians to change practice both in Cuba and Bolivia.

Table 10.1: Results and inferences in the three Latin American countries

Results and other inferences	Peru	Bolivia	Cuba
Audit cycles completed	3	2	2
Major changes and modifications made in the clinical record keeping system	Partial (in some health centres)	Yes (in almost all health centres)	Minimal (few alterations)
Statistically significant improvement in audit criteria (<i>absolute</i>)	2 out of 5 (40%)	2 out of 6 (33%)	11 out of 13 (85%)
Statistically significant improvement in audit criteria (<i>Relative</i>)	2 out of 5 (40%)	3 out of 6 (50%)	12 out of 13 (92%)
Performance reaching agreed standards by the end of the project	Nil out of 5 (0%)	1 out of 6 (17%)	11 out of 13 (85%)
Selection of criteria where performance was close to the desired level at the start	Nil out of 5 (0%)	3 out of 6 (50%)	8 out of 13 (62%)
TB programme involvement in the audit activity	None	Partial	Full
Agreement on targets and guidelines between clinicians and TB programme managers	Little	Partial	To a large extent
Many strategies for improvement beyond clinicians' control	Yes	Some	Some
Clinicians related improvements to the audit activity	Not stated by clinicians	Stated by clinicians	Stated by clinicians
Clinicians exploited training opportunities through audit	Not mentioned	Mentioned frequently	Mentioned
Poor coordination between clinicians and laboratories	Yes	Yes	Yes
Perception of patients beliefs influencing professional practice	Identified but no strategy suggested	Identified and strategies suggested	Not identified as an issue
Lack of resources (premises, equipment etc.)	Yes	Yes	Yes (but addressed later through another initiative)
Political interferences, staff changes and favouritism	Yes	Yes	No (only staff changes)

- Both in Bolivia and Las Tunas, selection of the audit criteria followed a systematic process. However, criteria were often selected in clinical areas where performance was already optimal or close to the desired level. Due to lack of baseline data, audit committees did not have the opportunity to determine which criteria are most likely to demonstrate improvement. This led to a missed opportunity of measuring some other aspects of care where feedback could have made bigger improvements.
- Absence of a foolproof system and coordination at the interface between laboratories and clinicians is a major determinant of poor performance in diagnosing TB. In all

study sites, lack of coordination between the laboratories and health centres was identified as a key deterrent to improvement.

- Clinicians' perceptions of patients' beliefs and attitudes play a key role in influencing professional practice as observed in both Peru and Bolivia. However, this was better recognised as a key issue in Bolivia and a number of their planned actions were aimed at patient education and behaviour.
- Lack of resources, ranging from a clinical information management system to laboratory dispensable items was a major limiting factor highlighted in all three countries. This was addressed only in Cuba (coincidentally) through the refurbishment programme.
- Political interference leading to rapid staff changes and favouritism was a key restraining factor to improvements, shared by the participants in both Peru and Bolivia.

Some of these issues are discussed in more detail and in the context of existing literature in the following subsections.

10.2.5. Clinical audit and the TB programme

One of the key inferences from this research is that clinical audit appears to be more effective in settings where it is implemented as an integrated component of the TB programme. In Peru, clinical audit had a lot of support from health professionals but little involvement from the TB programme. In Cuba, the TB programme was fully engaged in the initiative, whilst in Bolivia its involvement was partial. There is also a strong case for TB programmes to incorporate an integrated model of quality improvement interventions, to meet targets and international standards set by the WHO and other professional bodies (WHO, 2006). It would be worthwhile to understand where quality features in TB control programmes at present.

The current DOTS strategy provides a framework to meet the global targets for TB control. However, despite the widening coverage of DOTS programmes, only 22 countries have so far been able to achieve these targets (WHO, 2005a). It is, therefore, reasonable to question whether national TB programmes (NTP) include adequate systems for quality assurance to bring about improvements required to meet these target (Siddiqi, Walley & Newell, 2006).

Currently the DOTS strategy emphasises quality improvement through:

Quality assurance(QA) within microscopy by means of regular training, supervision and rechecking

Monitoring reports of case finding, smear conversion and treatment outcomes

Regular supervision to ensure that the operational policies of NTPs are implemented

These measures can improve some aspects of care but do not engage clinicians in improving others, especially clinical care related to diagnosing and managing TB. TB programmes have placed emphasis on translating evidence into guidelines, protocols and educational materials, which is necessary but not sufficient to establish standardised clinical practice (Dick et al, 2004). As discussed in previous chapters, clinical audit provides a continuous quality improvement process that engages clinicians, and is often needed to stimulate change in professional behaviour. It ensures clinical engagement in quality improvement of any aspects of care. Health care professionals themselves identify areas for improvement, stimulate necessary change and evaluate the effects of their actions. These may include ensuring compliance with standardised care pathways; patient-centred care; identifying and cutting delays; implementing prescribed quality assurance more rigorously; and if necessary, setting up new locally agreed measures.

In the introductory chapters, I have shown that the experience of such measures in developing countries has been limited for reasons that are only partially understood. Lack of resources is a major constraint, but this makes it even more imperative to adopt quality improvement measures to ensure clinical effectiveness and cost-effectiveness.

This study of implementing clinical audit to improve diagnostic care of suspected TB patients in three Latin American countries, has provided proof of principle insight into the feasibility of implementing such quality improvement processes. Similar research, combined with the operational knowledge of TB programme managers, can help in developing a quality improvement package that can be added to the current DOTS strategy. This can then be piloted under TB control programme settings at various sites. An evaluation of such pilots can inform decisions whether to include processes for improving the quality of clinical care in future revisions of the DOTS strategy.

10.2.6. Guidelines

Lack of systematically developed and disseminated clinical guidelines prior to the implementation of clinical audit in these study sites could be an important factor in the mixed results achieved in this project.

In the last decade, as clinical audit became routine practice, guidelines seeking to influence and regulate clinical activity also gained a new cultural ascendancy in health systems on both sides of the Atlantic (Hurwitz, 1994). Clinicians saw guidelines as a remarkable tool to improve practice and clinical outcomes, and policy makers accepted it as an innovative approach to reduce variation in care and inefficiencies in the system (Feder, 1994). As a result, a lot of attention in the UK

and USA remained focussed on producing guidelines. Reviews on the impact of guidelines have helped to understand the barriers to guidelines implementation (Grimshaw & Russell, 1993). A systematic process of developing and disseminating guidelines highlights a number of steps to ensure that these produce an impact (Thomson, Lavender & Madhok, 1995). However, it was realised that other strategies would be required to increase the likelihood of adoption. Comparative feedback on performance was considered to be a powerful stimulus to change, preferably if linked to the cyclical process of audit, with implementation of change and subsequent review. In short, developed countries introduced clinical audit as a tool to implement clinical guidelines that had already gained a lot of popularity and familiarity in the health service.

In developing countries, a number of factors (see introduction chapter) are responsible for the gap between the evidence and practice. Most research is either irrelevant to the problems of developing countries, or is not accessible to clinicians there. Many countries are just beginning to adopt evidence translated into guidelines. Disease control programmes in developing countries are ready to adopt such guidelines, due to better resources and closer links with international agencies. However, clinical guidelines in disease control programmes in developing countries are often developed by expert groups in WHO and Universities in developed countries. These are usually not context specific and lack sufficient detail to assist clinicians in adopting these in practice. Moreover, they are usually not readily available in user-friendly formats to clinicians working in primary care. This situation is different from developed countries where e.g. in the UK, most guidelines are developed and disseminated using a systematic process involving local health professionals with an understanding of the local context.

In this study, TB programme guidelines for diagnosing and managing TB existed in Bolivia and Peru. However, these were adapted WHO guidelines, which were not grounded in the local context. They were also not available in user-friendly formats and lacked sufficient detail to be used by clinicians. Therefore, clinical audit was introduced in a setting where guidelines were not developed systematically or implemented in the health centres. Since the main purpose of the audit intervention was to influence clinicians to adopt clinical guidelines, absence of these did not help the situation.

One of the lessons is that future researchers and policy makers need to prepare the ground before introducing quality improvement tools in health systems where both evidence and quality assurance are relatively new concepts. This can be done by investing in developing and disseminating clinical guidelines in a systematic way.

A more preferable approach would be to first develop and implement integrated care pathways (Campbell, Hotchkiss, Bradshaw & Porteous, 1998). An integrated care pathway determines locally agreed multidisciplinary standards based on evidence, where available, for a specific patient group. These are task orientated care plans with detailed essential steps in the care of patients with a specific clinical problem and describe the patient's expected clinical course. They offer a systematic process of developing and implementing local clinical protocols of care, building on evidence based clinical guidelines. They can also identify the reasons why clinical care falls short of adopted standards. Development of the pathway is done first through a critical evaluation of all aspects of current clinical practice and review of the available evidence. This is followed by the development of locally agreed pathways. Pathways are more likely to be implemented if those who will be using them are involved in developing them. Adherence to pathways is facilitated as these form part or all of the patient's record and are available for review when clinical decisions are being made.

10.2.7. Selection of criteria

Existing literature provides some key examples of a systematic approach to developing audit criteria (Fraser, Khunti, Baker & Lakhani, 1997; Hearnshaw et al, 2001). Fraser et al describe a six-stage systematic method for developing audit criteria. These are: selection of a topic, identification of key elements of care, focused literature reviews, prioritization of the criteria on the strength of the evidence and impact on outcomes, preparation of full documentation, and peer review (Fraser et al, 1997). Hearnshaw et al used a consensus development technique to identify a list of 23 desirable characteristics of audit criteria (Hearnshaw et al, 2001). They argue that the use of this list can help in improving the cost-effectiveness of quality improvement activities in health care settings. It is also important to have the correct balance of clinicians and managers in the audit committee to ensure ownership by both disciplines (Hearnshaw et al, 2001). This study also adopted a systematic approach towards selecting audit criteria based on the list of the desirable characteristics of these criteria (see methods chapter). Despite employing a methodical approach, the study found numerous problems in selecting audit criteria.

Whilst clinicians participating in audit committees were very proficient in identifying key elements of care, their grasp of the current literature of effectiveness may not be up to date. The committee members conducted no focused literature reviews due to resource and time constraints prior to the selection of the audit criteria. Their assessment of the strength of the evidence base for the selected criteria was uninformed on most occasions.

Similarly, members also struggled to estimate the overall health impact of the various criteria considered for the audit, and to prioritise a short list on that basis. Such decisions are usually informed by an estimate of the likely number of patients in the denominators and the effect of changes in clinical practice on the clinical outcomes under study. Committee members did not have such information available to them before the selection.

Before selecting audit criteria, clinicians had little evidence of baseline performance. For several criteria, clinical performance was found to be sufficiently high after the first data collection, leaving little room for improvement. The selection of the audit criteria themselves might have influenced clinicians' practice well before the feedback of their comparative performance was provided.

In several instances, where clinicians regarded a change in the clinical performance feasible through simple measures, it later turned out to be far more challenging. It was only after repeatedly conducting problem analyses based on the feedback provided, that committees fully appreciated the disincentives and constraints to the change process within the health system.

Clinicians also struggled to assess the measurability of the audit criteria without being fully aware of what can be measured through existing routine data collection systems (see page 325 for further discussion on this).

Committees dominated by clinicians are more likely to highlight and focus on the clinical issues that they feel important in their transactions with patients. They are less likely to prioritise criteria entirely based on efficient use of resources and the ones more in line with the objectives and targets of the TB programme. Ideally, objectives of the clinicians and the programme managers should be similar. However, in reality they can often be in different directions. I found this to be a major issue in Peru and to a certain extent also in Bolivia, where some of the programme activities proved a disincentive to meeting standards set by the respective audit committees (see page 253 for further details).

The current research literature also reflect that the criteria set are often not based on agreed desirable characteristics, and highlights difficulties faced by other researchers which are similar to those in this study(Hearnshaw et al, 2002;Hearnshaw et al, 2003).

A detailed review of the methods used for selecting audit criteria has shown that in particular the selection process often omits many of the desirable characteristics of audit criteria(Hearnshaw et al, 2002). A significant proportion of criteria in my study were not based on evidence of effectiveness. Even when audit

criteria development did involve a review of the research literature, only few attempted to assess the quality of the literature (Hearnshaw et al, 2003). Experts were consulted in only a minority of cases. Moreover, patients and carers were rarely consulted.

It has been argued that inappropriate selection of audit criteria is an important factor in the failure of demonstrating the beneficial effect of clinical audit. Given the difficulties highlighted above, it is likely that this may have been a factor in the mixed results achieved in this study. Hearnshaw et al in their review of audits conducted in the UK found several similar issues in the selection of audit criteria (Hearnshaw et al, 2003). Proposed solutions to address these are as follows:

A lack of available literature upon which to base criteria because of scarce literature available on a particular clinical topic and lack of an evidence-based approach in a certain clinical disciplines. The solutions centred on gathering expert opinion and resources to do focused literature reviews.

Validity issues including the clarity of the audit criteria and the quality of data drawn from the audit. Solutions included acknowledging the need to define criteria that are more explicit, clarifying the numerators and denominators for data collection and using another data source for triangulation.

Problem with coordination between different professional groups to agree audit criteria. Recommended solutions highlighted the value of establishing regular formal meetings.

Problems with accessing literature included problems in physically accessing libraries and locating identified citations. Solutions included availability of internet and access to free online academic resources.

One of the solutions produced by a government agency in the UK (called the National Institute of Health and Clinical Excellence [NICE]) with the responsibility of developing clinical guidance is the publication of proposed audit criteria with each guidance issued (National Institute of Health and Clinical Excellence,). Clinicians are encouraged to select some of these criteria to audit their practice. This can help in saving resources and selecting appropriate criteria. In a TB programme, setting a similar approach can be adopted. All guidance issued by the TB programmes can be accompanied by a list of proposed evidence based audit criteria. The respective audit committees can prioritise certain criteria from these lists.

In summary, there were numerous problems in selecting audit criteria. However, these were similar to the issues faced by other researchers in this field. Professionals involved in audit programmes may be able to use information from this account to improve methods to select audit criteria.

10.2.8. Cost-effectiveness of audit

This study did not measure the cost-effectiveness of the audit intervention. Therefore, despite demonstrating the effectiveness of clinical audit in improving certain aspects of clinical performance, it is difficult to comment on its real value for money. Interventions similar to clinical audit are often implemented aiming to remove some of the inefficiencies in the system. However, these interventions themselves come with a cost(Severens, 2003). Whilst in some studies audit has produced improvements in the quality of care, concern has been expressed about the cost-effectiveness of such interventions(Black, 1992). According to a recent systematic review, there is only a weak evidence base to support decisions about strategies to influence clinical practice on the basis of their cost-effectiveness(Grimshaw et al, 2004).

One of the pre-requisites of the cost-effectiveness of interventions designed to change clinical practice is that the practice for which improved performance is required is itself cost-effective(Sculpher, 2000). However, even when the knowledge of the benefits of a particular clinical practice is well established, assessing the cost-effectiveness of interventions designed to influence that practice is not a straightforward business. In an attempt to assess the cost-effectiveness of thrombolytic therapy for patients with acute myocardial infarction, Robinson et al highlighted a number of potential methodological problems in estimating the cost-effectiveness of interventions with well-established effectiveness(Robinson, 1995;Robinson et al, 1998).

To control for other confounding factors which can influence clinical practice besides clinical audit

To estimate accurate costing of the intervention, including the cost of managing extra patients because of improved compliance

Sample size, often limited by the occurrence of events in a certain time frame, can influence the statistical precision of the results obtained

Assumptions about the changes in the clinical performance over longer time periods after the intervention

Validity of using process measures as proxies for clinical outcomes

In addition, the cost of a complex intervention such as clinical audit may vary according to the context, and so the results of a cost-effectiveness study may not be generalisable.

It has been suggested that the cost of audit intervention needs to estimate not only the fixed and variable cost of implementing the audit but also the cost of increased utilisation of the clinical practice under study. Effectually, cost-

effectiveness of such interventions would be a function of the effectiveness of the targeted clinical practice and the incremental change in the level of practice produced by the audit. The cost-effectiveness of interventions to change clinical practice would be expressed in terms of the intervention cost plus the treatment costs per optimally treated patient (Severens, 2003). The incremental ratio can be estimated by comparing the costs and effectiveness of different strategies. Based on these principles, Mason et al have developed a model to estimate overall policy cost-effectiveness (Mason et al, 2001). This model distinguishes between the treatment cost-effectiveness (the net cost and benefit of treatment when applied) and the policy cost-effectiveness (which combines treatment cost-effectiveness with the cost and magnitude of change achieved by a quality improvement method) (Severens, 2003). Other models, such as one based on the assessment of cost-utility analysis using quality of life adjusted years, have also been used and recommended for evaluations in future (Robinson et al, 1998).

Future research attempting to evaluate the effectiveness of quality improvement interventions such as clinical audit needs to adopt one of the recommended models for its economic evaluation. Potential threats to the validity of the economic evaluation for such interventions need to be recognised and addressed as much as possible.

10.2.9. Systems and resources to support implementation of evidence

This study raises some challenging issues about the extent to which an intervention aimed at changing professional practice can bring improvement by itself own. Audit is designed to influence clinical practice, and does not have much influence on the rest of the health system to support and facilitate change. Even with their full commitment, clinicians in the audit committee frequently felt incapable of changing the system to support the specific clinical practice they were trying to influence e.g. clinicians tried to abolish a fee for the second visit for patients who wanted to report after receiving their sputum results (see page 249 for details). This study also identified a number of issues impacting on clinical practice which were beyond the control of the health service e.g. patients working on daily wages failing to come for a second visit due to fear of losing earnings. Clinical audit has shown to be likely to be effective in bringing change in clinical practice, if introduced alongside other interventions to improve quality that works at different levels, within the health system (Grol, 2001b). However, evaluating the effectiveness of clinical audit would be even more complex and difficult to numerous confounders when introduced as a part of a multifaceted intervention. It is generally acknowledged that if clinicians are aware of the evidence and are willing to change, an environment conducive to change is likely to be beneficial (Grol & Grimshaw, 2003). A key

challenge for policymakers in this area is to create an environment which facilitates health professionals to pursue quality of care.

Garner et al summarised efforts in bringing evidence into practice in developing countries and argued that the implementation of evidence into practice is a complex process and a systematic approach should be adopted based on the following four activities(Garner et al, 2004).

Increase awareness about the potential health gains from adopting research based knowledge into policy and practice

Identify target groups and individuals with specific roles in implementing evidence into practice

Support health professionals in assessing their clinical practice and bringing it in line with the current evidence e.g. through clinical audit

Establishing or strengthening national health technology assessment bodies with management systems in health care to ensure that guidelines are implemented and monitored

Among the developed countries, UK and USA have introduced a number of initiatives to improve the quality of care and bring evidence into practice. Some of these interventions have used principles of Total Quality Management, which is capable of working at different levels (Iles & Sutherland, 2001). One such initiative in the UK was the establishment of a national agency NICE, which produces and disseminates a number of clinical guidelines and technology appraisals on major topics and innovations. A study assessing the influence of this body claims that the implementation of NICE guidance has been variable(Sheldon et al, 2004). Guidance was adopted where there was strong professional support, good management systems to monitor implementation and no extra cost to the service. In one of the most comprehensive reviews on such initiatives, Ferlie et al argue that these are unlikely to achieve their objectives unless explicit consideration is given to a multilevel approach to change(Ferlie & Shortell, 2001). Such an approach will consist of the following four levels, which are interdependent on each other and the effect is more likely to be sustainable if these are implemented together:

Individual approaches, based on the diffusion of innovations model, entails education and training, educational outreach, performance feedback etc. Such approaches have been shown to be ineffective if implemented in isolation

Team approaches include clinical audit, collaboratives, pathway redesigns, guidelines development, implementation etc. However, teams need to be

developed to benefit from such initiatives, and organisational culture is crucial in supporting such development.

Organisational initiatives including continuous quality improvement, total quality management, quality improvement cycle, clinical governance, knowledge management and transfer. Such initiatives can be very effective if the organisational culture supports change through its decision-making processes, policies and human resource management.

Larger system/national level schemes include national agencies to summarise and disseminate evidence (e.g. NICE), national bodies to monitor performance (Commission for Health Improvement in the UK), and accreditation and licensing authorities especially in systems where significant health care is provided through private care. Such initiatives have less effect when they appear to compromise clinicians' autonomy in the decision-making process and if structures and processes do not exist at other levels to support them.

In addition, there are a number of other elements, which are essential to bringing improvement and change in the organisation, and these need to be fostered throughout (Ferlie & Shortell, 2001). They include, participatory leadership at all levels, supportive organisational culture and information technology. This study gives mixed results and identifies some key barriers to improvement through clinical audit. It reinforces the notion that quality improvement interventions are interdependent on other such interventions, working at different levels. Despite their efficacy in improving care, they are likely to be ineffective if introduced in isolation. The audit intervention was introduced (especially in Peru and Bolivia) in almost a vacuum of quality improvement initiatives, and its only partial success reflects very strongly that such interventions cannot work effectively unless other initiatives at different levels are introduced simultaneously, and cross cutting themes like leadership development and a supportive organisational culture are fostered throughout.

10.3. Research implications

In this section, I discuss the research implications of this study under three sub-sections:

Earlier I discussed some of the methodological difficulties faced during the study. In the first sub-section, I highlight some of the desirable attributes of studies designed to evaluate clinical audit in future. This is mainly based on the lessons learned during this study.

In the second sub-section, I summarise and present some examples from the existing literature on the alternate approaches to evaluating complex interventions like clinical audit.

In the final subsection, I make some recommendations on both methodological and research content issues for future researchers planning to evaluate clinical audit under such settings.

10.3.1. Evaluation of clinical audit

From my experience in this project, I learned that the evaluation of complex interventions such as clinical audit poses numerous methodological challenges. Evaluation requires careful design, with particular attention to aspects described below.

Clinical audit is a complex intervention that relies on the context of its application for it to be effective. An evaluation that does not take account of the context is likely to fail in developing our understanding of such interventions. I set out to use mixed methods to understand the interaction between the context and the intervention. While I was able to identify some barriers and facilitators to clinical audit that may have influenced its impact in the four different settings, my approach clearly lacked the sophistication to deal with the complexity of the interaction. An evaluation that takes account of the context in which the intervention is implemented and tries to understand the complex interaction between the two is likely to be more useful than a more simplistic approach.

Complex interventions are subject to adaptation depending upon contextual settings. This takes away the standardisation of the components of an intervention and allows it to be modified in order to increase local ownership. Such modifications can take place with or without losing the basis and core principles of the intervention. Simple evaluation models are often too crude to assess the impact of such non-standardised interventions and do not allow policy makers to infer conclusions in the face of these contextual modifications. Evaluation using techniques that can cope with such modifications, and assess whether intervention was successful in retaining its core principles, is likely to help policy makers in making confident judgments about the effectiveness of clinical audit.

A controlled design is clearly desirable in evaluating complex interventions. However, such studies need to be feasible and justifiable for their usually higher resource requirements. Controlled studies for clinical audit also need to be carefully designed to avoid contamination and need to have the sophistication to distinguish between the impacts of the audit and the effects of other confounders such as

introducing a data collection process. One approach would be to conduct a feasibility study to assess the effective implementation of the intervention.

One of the challenges for evaluation of complex interventions is the selection of appropriate outcome measures. Clinical outcomes are usually desirable but are often difficult to measure. For clinical audit, despite success in influencing clinical practice, the expected improvements in clinical outcomes may not be forthcoming within the lifetime of the study.

Studies measuring change in clinical practice often end up measuring outcomes, which are the same as the criteria selected by the audit committee. However, as audit criteria are selected by audit committees with different objectives and not researchers, this approach can introduce potential bias. An evaluation that measures variables, which are not influenced directly by audit committee decisions and are able to capture the impact of other externalities, is likely to carry greater validity. I was able to observe some of these externalities in this study e.g. improved staff morale, but did not have the research tools to quantify these.

Another problem with adopting the research outcomes which are the same as the audit criteria, is selecting a "fit for purpose" sample size. For research, sample size needs to be justified in terms of statistical significance. However, for clinical audit, committees may decide on a sample size that is feasible to collect, carries clinical meaning but is not statistically powerful. As discussed in previous sections, rapid cycle sampling may be able to resolve this issue. Further research is needed to judge the feasibility of this approach. This study also provides an estimate of variance around the mean for various audit criteria, which can assist sample size calculations for future evaluation.

Existing approaches to the selection of audit criteria do not consider their ability to demonstrate a statistically significant change in practice within the period of an audit cycle. When evaluating the impact of audit, criteria selection needs to be more rigorous to be able to demonstrate such improvement. This approach need not necessarily reduce local ownership, and by applying a stricter framework to audit criteria selection, it will enhance the rigour of not only the evaluation but also the quality of clinical audit.

A routine clinical data collection system is essential to conduct audit. In countries where clinical audit originated and evaluated, such systems universally exist. However, the situation is often different in low-resource settings, as observed in Bolivia and Peru. In these settings where some reformation of routine clinical record keeping was essential prior to the implementation of audit, an evaluation

needed to distinguish between the impact of these two interventions (unless developing a data collection system is considered as part of the audit intervention).

I anticipated a number of problems with selecting an uncontrolled quasi-experimental design such as a before-and-after study and time series modelling (see methods chapter). Some of these problems e.g. slow diffusion of intervention and *maturation* became clearer after the study. Any before-and-after study that only assesses the impact of an intervention at two points in time is going to be insensitive to diffusion. On the other hand, statistical modelling based on a time series design may not be valid in dealing with small samples at different health centres, and with large variations between successive time points.

One of the difficulties with randomised controlled trial of clinical audit is that they may remove professional preference from the equation. Clinical audit like other contextual interventions is dependent on the motivation of professionals who are involved in the audit. Any evaluation based on randomisation between intervention and control sites needs to be able to deal with this issue.

Examination of the effectiveness of audit needs to include an economic evaluation to judge the cost-benefit. The evidence on the cost-effectiveness of clinical audit is not strong even in developed countries. It is even more important in resource-poor settings to have an economic evaluation built into an evaluation of clinical audit.

10.3.2. Evaluating complex interventions - examples from the literature

A complex intervention in health care is defined as a therapeutic or preventative intervention that is made up a number of components that seem essential to the proper functioning of the intervention, although the “active ingredient” of the intervention that is effective is difficult to specify (Campbell et al, 2000;MRC, 2000). Such an intervention comprises of interacting components acting at various levels. Clinical audit meets the definition of a complex intervention by virtue of it being a multi-component intervention. In order to inform future research it is worth reviewing some examples and guidance on evaluating complex interventions in the current literature. This will help to develop an appropriate framework for evaluating clinical audit as proposed in the next section.

10.3.2.1. MRC framework for developing and evaluating complex interventions

The MRC proposes a series of phases of developing and evaluating a complex framework in their guidance (Campbell et al, 2000;MRC, 2000) (Figure 10.1). These phases are:

Theoretical
Modelling
Exploratory trial
Main trial
Long-term implementation

The first phase is aimed at establishing the theoretical basis and plausibility of an intervention. Information is also obtained to understand the organisational constraints and the professionals' beliefs that may facilitate or inhibit the change process. If the intervention is "well established" in other settings then this may not be necessary.

The modelling phase relates to developing an intervention on paper and defining its various components. It may also involve conducting a preliminary qualitative study to inform the development of the intervention.

The exploratory trial phase is aimed at evaluating the implementation of the intervention to inform the main trial. Studies in this phase would involve testing the feasibility of implementation and controlling the intervention. Information to establish appropriate measurable outcomes, controls, sample size etc. can also be gathered for the main trial.

The next, phase involves conducting a randomised controlled trial with detailed attention to the randomisation process, appropriate outcome measures, potential biases and suitable sample size to give adequate power to the study.

The long-term implementation phase is usually an observational study that has a surveillance function to inform the effective long-term implementation and potential adversities of the intervention.

The MRC framework advocates that the randomised control trial remains the gold standard, even for complex interventions. However, conducting trials in this phased approach is likely to overcome some of the common objections directed against RCTs in complex interventions. The MRC framework requires an investment of time and resources at the beginning of an implementation effort, in order to understand the contexts in which the intervention will be implemented and, therefore, maximize the probability of success (Sales & Helfrich, 2006). A study in which the MRC framework was applied, concluded that the exploratory phase was useful to understand the context and build a model for a controlled trial (Blackwood, 2006). However, outcomes must be determined carefully to reflect both the constant and variable components of the intervention in order to assess its effectiveness.

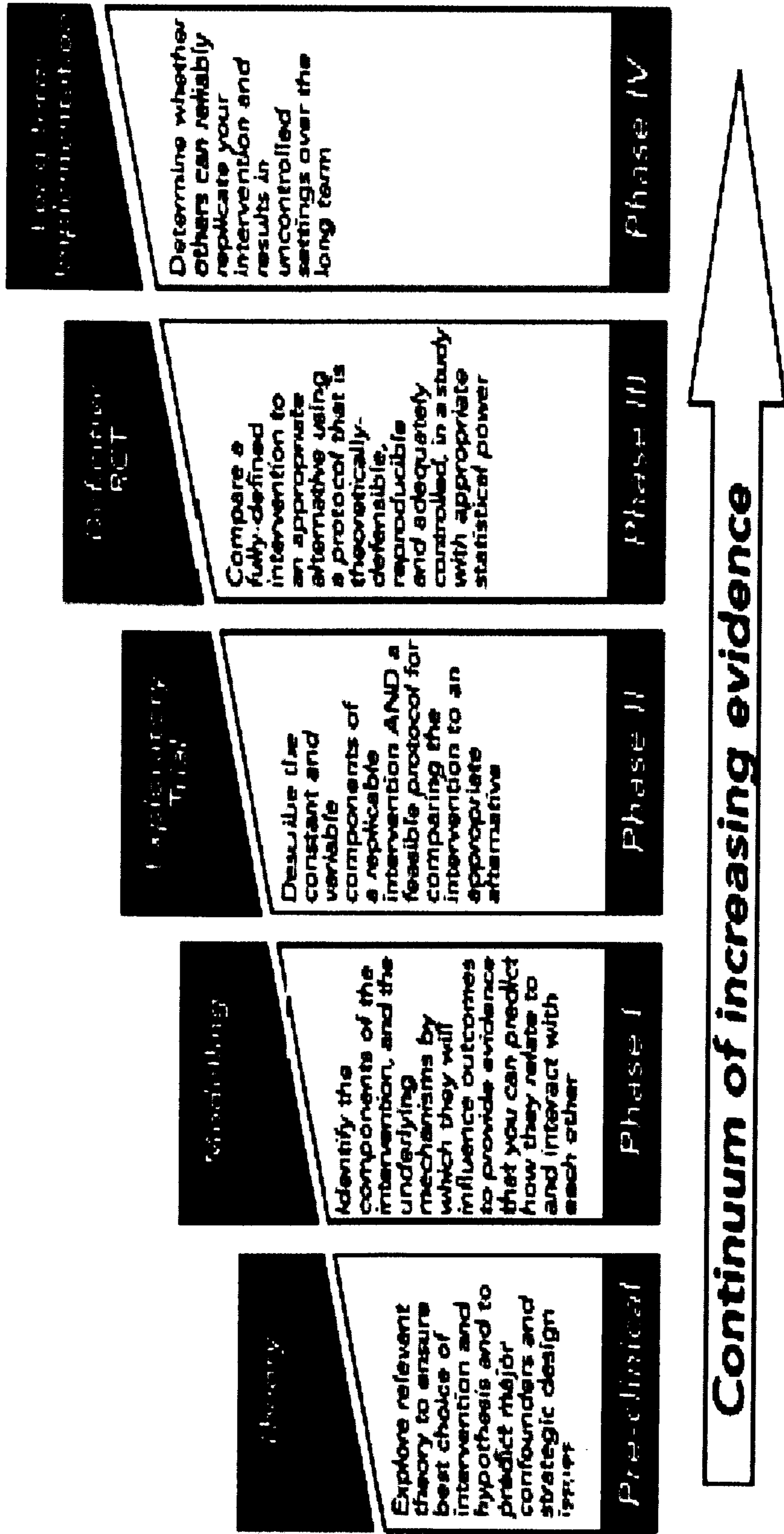


Figure 10.1: Medical Research Council framework for evaluating complex interventions

The programme of work described in this thesis corresponds to the first three phases of the MRC framework namely, developing and piloting intervention and evaluation methods. The information obtained thus far is useful to inform the design of a randomised controlled trial.

The intervention implemented in the three countries was implemented with variable levels of integration with the TB programme. My findings can be used to determine which model is more likely to engage all stakeholders and is likely to be more effective in stimulating improvements. This study also gives information about the prerequisites for implementation of audit. These include development and dissemination of evidence based locally acceptable clinical guidelines and policies, and a “fit for purpose” clinical record keeping system in place prior to the intervention. There were also difficulties with selecting “audit criteria” using the standard methods. The intervention itself requires certain structures to be in place and resources to be allocated prior to implementation of the audit cycle. I found that the standard steps necessary to establish clinical audit could generally be implemented and monitored successfully in the study sites.

This study helps to address some of the key design issues relating to internal and external validity of a prospective large trial. These have been discussed in detail in previous sections.

10.3.2.2. An integrated quantitative and qualitative approach

Bradley et al have proposed another approach to evaluation which also includes a feasibility study prior to a major trial (Bradley et al, 1999). However, they argue for using explicit integrated quantitative and qualitative methods to inform the theory, processes and context of the intervention and place less emphasis on study design issues during the exploratory phase.

Interventions need to be defined at three levels of understanding, and the exploratory studies need to inform each of these levels. These are: (i) the evidence and theory that informs the intervention, (ii) the tasks and processes involved in applying the theoretical principles, and (iii) the people with whom, and context within which, the intervention is implemented. Quantitative components of the exploratory study can be used to determine whether an intervention, developed on the basis of existing evidence, can be effectively implemented. This can help to define appropriate outcomes, likely effect size and to judge if the intervention is worthy of substantive evaluation. The qualitative approach takes account of the people delivering or being affected by the intervention and the context in which the effectiveness of the intervention is determined. This helps to correct some theoretical assumptions and modify some of the processes and tasks of the

interventions. Bradley et al argue for formalising the “usual hidden learning curve” of implementation in order to inform future intervention designs more explicitly.

Another study illustrates how modelling an intervention can help in gaining a better understanding of the intervention and its potential effects (Rowlands, Sims & Kerry, 2005). The authors argue that the individual components of the intervention together with the interaction between the intervention and the context within which it will be applied need to be defined, to gain an understanding of how these might influence the outcomes of the study. This also enables researchers to decide which outcomes will best demonstrate changes brought about by the intervention.

This study used interviews to explain the findings of the quantitative component and to understand barriers and facilitators in implementing clinical audit. Findings from the qualitative component were helpful in improving the processes of the intervention, defining pre-requisites of clinical audit and establishing an understanding of the context in which audit can be implemented and evaluated more effectively.

10.3.2.3. Process evaluation in RCTs of complex interventions

A “social model” of RCT has also been proposed for evaluating the effectiveness of a complex intervention (Oakley et al, 2006). This consists of a process evaluation within trials that: (i) determines the views of participants on the intervention, (ii) examines how the intervention is implemented, (iii) distinguishes between the components of the interventions, (iv) investigates the contextual issues and (v) studies the variable effects on different study groups. The data for the process evaluation can be both quantitative and qualitative and utilise on-treatment and subgroup analyses to understand the context. Such an evaluation needs to specify prospectively a set of process research questions and to identify the processes to be studied, the methods to be used and procedures for integrating process and outcome data.

The authors, by using the example of their trial to evaluate the effectiveness of sex education in schools, outline a method to identify key processes and collect relevant data. They also propose a two-stage process of data analysis, firstly analysing outcomes and secondly combining the process and outcome measures. This approach is argued to maximise ability to interpret data and understand the context in which the intervention is implemented.

Power et al propose that process evaluation should also take place during the feasibility study, where a formative evaluation should inform the design of the intervention and subsequent trial (Power et al, 2004). In their study in Zimbabwe, a

process evaluation during a feasibility study changed the composition of their intervention in preparation for a subsequent evaluation in a larger trial.

10.3.2.4. Standardising complex interventions

Hawe et al proposed a controlled trial design for evaluating complex interventions but suggest an innovative approach to standardising the interventions (Hawe et al, 2004). Their argument is that standardising all components of an intervention in all sites is too reductionist when applied to complex interventions. The integrity of a complex intervention depends on its evidence of fit with the underlying theory and principles of the hypothesised change process. It needs also to be adaptable in different settings, while maintaining its function. The authors argue, therefore, that interventions need to be tailored to the local context, and standardisation should focus on the function and not individual components of interventions.

10.3.2.5. The stepped wedge trial design

The MRC advocates a cluster-randomised trial as an appropriate and desirable design for evaluating complex interventions. However, it is often not practical, feasible and at times ethical to conduct such a trial, particularly in developing countries. For instance, in situations where a programme is implemented gradually depending on a country's logistical and financial situation, it is not possible to influence programmes to be rolled out to suit the trial design. Where the intervention is highly likely to be useful, it may be unethical to withhold it from some districts. In other cases, it may not be possible to implement programmes in multiple districts simultaneously. Cluster randomised trial may also not be suitable where a relatively long period is required to detect improvements e.g. public health programmes.

The stepped wedge trial design, first introduced by Cook and Campbell and endorsed by other researchers, offers a possible solution to these difficulties (Cook & Campbell, 1979; Habicht, Victora & Vaughan, 1999). An intervention is rolled out sequentially in the participating clusters over a number of equally spaced time-periods (Brown, Patil & Lilford, 2006). The number of clusters included each time is usually dependent on the financial and logistical constraints of the programme. However, randomisation can be used for allocation at each time interval. At the end of the trial, all clusters will have received the intervention. Data on the outcomes is collected at regular intervals throughout the study and the analysis involves a comparison of the data points between intervention and control clusters in the wedge.

There is a potential loss of power in this design compared to a parallel controlled study due to fewer numbers of clusters at time period. However, this may

be offset by measuring outcomes over a longer period. This would be particularly useful for interventions where it is likely that the health impact will be detectable only after a prolonged period.

The step wedge design may be useful in evaluating quality improvement interventions, which are unlikely to be implemented in one go, such as clinical audit in a vertical programme in developing countries. There is opportunity to use a stepped wedge design to assess the effectiveness of clinical audit, if the programme decides to implement it sequentially. However, it can create political difficulties if the evaluation concludes that a programme is ineffective, if it has already been rolled out as part of policy in a country. It should be mentioned that this design is relatively new and has not been widely tested in different settings.

10.3.2.6. Qualitative evaluation

Up to now, I have mainly discussed possible ways of evaluating clinical audit, which involve some form of clinical trial. I have also discussed ways of combining qualitative and quantitative approaches to evaluating complex interventions. In this sub-section, I discuss some qualitative methods that have been proposed for evaluating complex interventions. Qualitative approaches to evaluation are used classically to elucidate why an intervention has been successful or unsuccessful rather than simply quantifying its success. Qualitative approaches may involve data collection from various sources to produce best approximations to the otherwise invisible relationships between cause and effect (Lord & Littlejohns, 1997). The following discussion is by no means exhaustive, but highlights some examples where such methods have been used effectively.

One approach, the case study, has been discussed already in detail in the methods. This uses a number of information sources to understand the “how” and “why” questions while implementing an intervention. In my study, I used this approach to complement the findings of the quantitative study, and to understand one particular aspect of clinical audit implementation. It has been argued, that the case study design can also be used more comprehensively without accompanying a quantitative study to evaluate complex interventions.

10.3.2.7. Systems approach

Lord et al evaluated an audit programme in the UK using methods based on systems theory (Lord & Littlejohns, 1995). According to this approach, one designs systems that are based on sound theory but are adaptive to “real world” situations. Evaluation compares these “ideal adaptive models” with the structures and processes of the current system and makes a judgement on that basis. A systems approach was used to describe the current audit programme in one health authority and to compare

this with a number of prescriptive approaches. It described how audit had evolved in isolation in the local health economy in the hands only of health professionals, and discussed how this could be adapted to a number of other approaches, where audit has been implemented within the wider managerial context of the NHS organisation. The information was collected through local workshops, interviews, document reviews, and published reports. The alternative perspectives of how clinical audit should work were articulated through conceptual models(Lord & Littlejohns, 1995). This example provides an interesting and useful approach to the future evaluation of audit in TB programme settings to judge if these are implemented as an integrated component of the TB programme within the wider context of organisations.

10.3.2.8. Realistic evaluation

The realistic evaluation has been suggested as a solution to the methodological limitations of experimental approaches to evaluation and for developing realistic theories(Redfern, Christian & Norman, 2003). This relatively new approach has its roots in realist tradition in philosophy; this stresses the mechanics of explanation and demonstrates that the use of explanatory strategies can add to the body of scientific knowledge(Pawson & Tilley, 1997). The explanations of a realistic evaluation are built on an axiomatic base that proposes, “causal outcomes follow from mechanisms acting in contexts” (Figure 10.2). It argues that specific mechanisms acting in specific contexts produce specific outcomes.

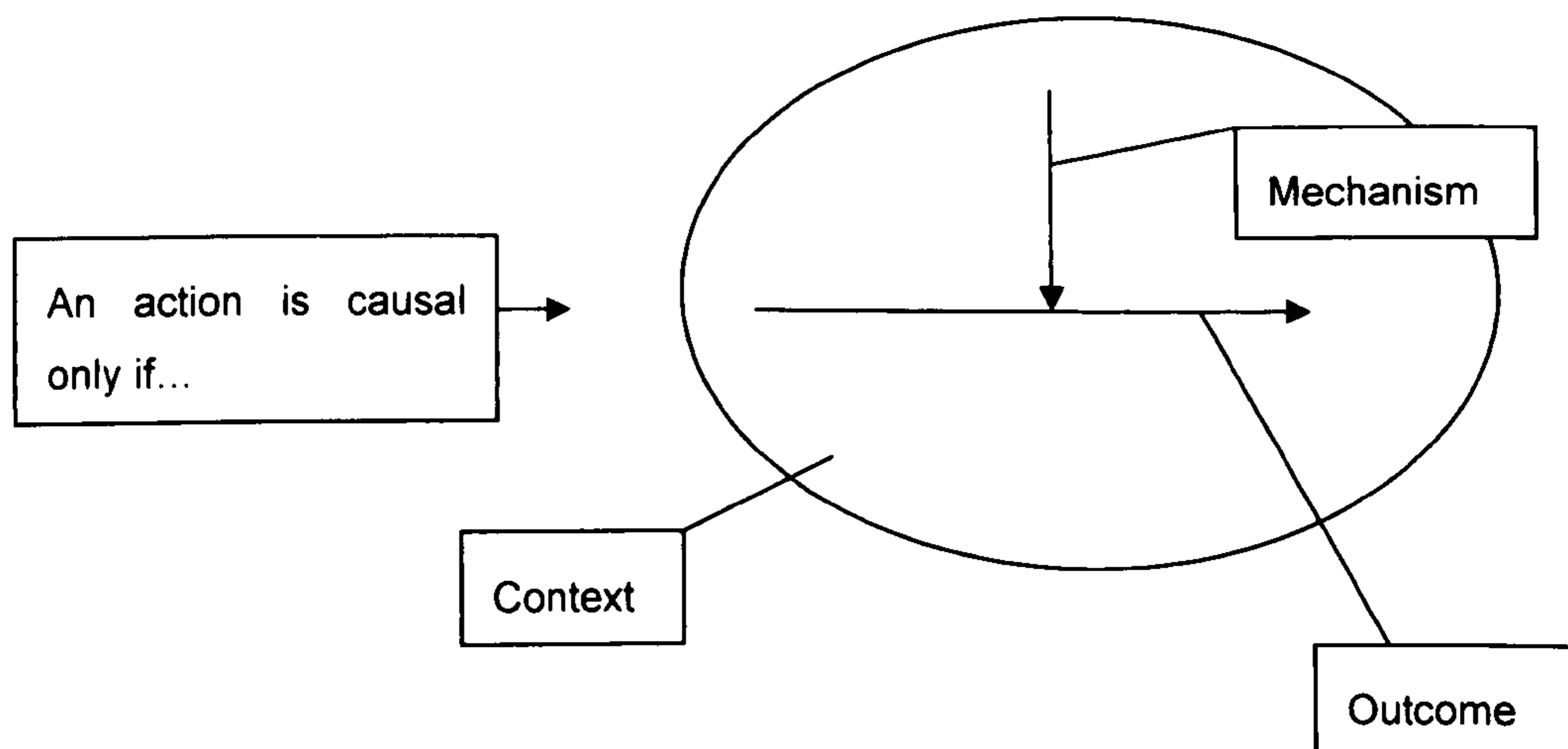


Figure 10.2: Realistic Evaluation

Realistic evaluation follows the classic wheel of science consisting of Theory→ Hypothesis→ Observations→ Empirical Generalization(Pawson & Tilley, 1997). However, it has a unique way of understanding the ingredients of theory. It argues that theories must be framed in terms of explanatory propositions about how mechanisms act in context to produce outcomes. A hypothesis is built, based on

which ingredients in the programme are likely to produce change in which specific population sub-group, under what conditions.

Observations are made with a pluralist approach using a whole range of qualitative and quantitative methods. These observations are analysed to generate “specifications” instead of generalisations. Realistic evaluation questions the notion of research findings being generalisable and implies that things only happen in a particular way because of particular mechanisms in particular contexts. I was unable to find many examples where this approach had been used in evaluating health services delivery and organisation. However, realistic evaluation seems to offer an attractive approach to evaluating complex interventions in health care.

10.3.3. Recommendations for future research

This project is one of the first attempts to evaluate the effectiveness of clinical audit in Latin America. Diagnostic care for TB was selected because of the high potential public health impact of improving quality of care. Logical next steps would be to evaluate clinical audit applying it to other aspects of TB care in other settings as well as to apply it to other conditions of public health importance.

Another logical progression of this work would be to assess the cost-effectiveness of clinical audit in a TB programme setting. One of the key questions for future research is whether clinical audit can generate sufficient health and efficiency gains to offset the cost of implementing it in the TB programme over and above the existing supervision and monitoring arrangements. I propose a mixed methods approach using a controlled trial design combined with a case study approach for this. This project has been an exploratory study to assess the feasibility of conducting such a trial.

The stepped wedge trial design offers a useful approach to evaluate the effectiveness of clinical audit in a programme setting. This design offers certain advantages, which makes it more relevant to conducting evaluation in settings where a country’s TB control programme decides to roll out clinical audit sequentially over a certain period.

A controlled trial needs to be accompanied by a strong qualitative component focussing on a process evaluation. Such an evaluation examines the views of the stakeholders on the intervention and comment on how the intervention is implemented. It distinguishes between different components of the interventions and relates these components to the relevant outcomes. The evaluation need to investigate the contextual issues and study the variable effects on different study groups.

In this chapter, I have summarised the results of this study and highlighted some key methodological limitations challenging its internal and external validity. I also highlighted some of the key issues that need to be taken into account by policy makers whilst implementing such quality improvement initiatives. I have also provided some examples from the literature of various methods that have been recently developed to evaluate complex interventions, which may overcome some of the limitations faced in this project.

The final chapter summarises the conclusions of this study.

Chapter 11 Conclusions

Researchers have been interested in developing and evaluating interventions aimed at influencing professional practice as a means of improving quality of clinical care, bringing evidence into practice and making health systems more efficient. Sufficient evidence has accumulated in the last two decades in developed countries to assist policy makers in introducing such interventions. However, the evidence of its effectiveness in low and middle-income countries remains weak due to the scarcity and methodological limitations of published research in this area.

Clinical audit is one such intervention. It is defined as an ongoing process to improve the quality of health care through critical examination of current performance against agreed standards, leading to the identification and utilisation of opportunities for bringing practice closer to that standard. Clinical audit has the potential to improve quality of care in resource-poor health systems, where adherence to evidence-based guidelines is generally poor and pressure to provide care under resource constraints is high. However, in common with other interventions aimed at influencing clinical practice, the evidence for its effectiveness is weak.

I, therefore, in this project set out to investigate the effectiveness of clinical audit in changing the practice of health care professionals in poorly resourced health systems, using the management of tuberculosis as an example. The patient pathway under consideration was the provision of care to patients with suspected tuberculosis from the point of first contact with the health service to their final diagnosis (referred to as diagnostic care).

I conducted a before-and-after quasi-experimental study to evaluate the effectiveness of clinical audit in four study sites in three Latin American countries, Peru, Bolivia and Cuba. I also used qualitative research methods to explore factors that impede or facilitate change among health care professionals' clinical behaviour (reflected by change in processes of care), following the introduction of clinical audit.

Three audit cycles were completed in eight health centres in Peru over a period of two years. Similarly, in Bolivia, eight health centres took part, completing two audit cycles. In Cuba, clinical audit was implemented in five health centres in Havana and Las Tunas completing two audit cycles.

Clinical audit was most effective in improving standards of care provided to patients with suspected tuberculosis in Cuba. In Bolivia, audit has produced mixed results with some

clear improvement in certain areas but less so in others. In Peru, clinical audit failed to improve performance according to all except one of the criteria measured.

I measured 24 audit criteria, out of which 15 showed statistically significant *absolute* improvement, whilst two showed deterioration. Seven criteria showed no significant change. Out of 15 improved criteria, 11 were from the two study sites in Cuba, two from Bolivia and two from Peru. The range of improvement was from 4 to 50% with a median of 12%.

Out of 24 audit criteria, 12 reached the agreed standards after two years. 11 of these were chosen in Cuba, one in Bolivia and none in Peru. Three audit criteria in Bolivia and eight in Cuba were found to have baseline performance close to the desired level leaving little opportunity for clinical audit to demonstrate improvement.

I found that the integration of clinical audit within the district TB programme is one of the strongest facilitating factors in bringing change. Audit was more effective in Cuba where audit was jointly led by TB programme managers and clinicians and was integrated in the programme in contrast to Peru where it was led primarily by clinicians with little involvement of TB programme managers. In Cuba, audit criteria were more aligned with the TB programme objectives as compared to Peru where some of the audit criteria were in conflict with programme targets.

Improvements were more apparent where change strategies were perceived not to be beyond clinicians' control and a link with improvement with quality of care was visible. Clinicians showed motivation to change where the intervention was accompanied by training events and user-friendly educational materials.

Poor coordination between clinicians and laboratories, perception of patients' beliefs influencing professional practice, lack of resources, political interferences, staff changes and favouritism were some of the other constraints in bringing improvements through clinical audit.

The pre-requisites of clinical audit such as nationally agreed evidence-based clinical guidance, a routine clinical record system that can be used for audit data collection and an audit support unit only existed in some study sites. This resulted in considerable delay and resource use in implementing audit and contributed towards lack of improvements observed in certain study sites.

This study helped to develop the research methods necessary to any future evaluation of clinical audit in resource-poor settings, by indicating the preferred approaches for selecting appropriate sample size, audit criteria and outcomes to assess the effectiveness of the audit

intervention. The study also highlights that audit, as a complex intervention, needs to be evaluated using innovative evaluation designs that can help to understand the context in which it is implemented. Currently, there is no guidance on implementing audit in TB control programme settings. This study informs the development of an evidence-based audit intervention, which addresses issues of implementation, for a TB control programme setting. My research demonstrates that clinical audit can be implemented in resource-poor settings, and has the potential to be effective in influencing clinical practice under favourable organisational environments. However, further research is required to establish the effectiveness of clinical audit in developing countries, in not only improving quality of care, but also generating sufficient health and efficiency gains to offset the cost of its implementation.

References

- Aber, V. R., Allen, B. W., Mitchison, D. A., Ayuma, P., Edwards, E. A., & Keyes, A. B. (1980). Quality control in tuberculosis bacteriology. 1. Laboratory studies on isolated positive cultures and the efficiency of direct smear examination. *Tubercle*. 61, pp. 123-133.
- Adamolekun, B., Mielke, J. K., & Ball, D. E. (1999). An evaluation of the impact of health worker and patient education on the care and compliance of patients with epilepsy in Zimbabwe. *Epilepsia*. 40, pp. 507-511.
- Akel, M. & Hamadeh, G. (1999). Quality of diabetes care in a university health center in Lebanon. *International Journal for Quality in Health Care* 11, pp. 517-521.
- Al Marri, M. R. & Kirkpatrick, M. B. (2000). Erythrocyte sedimentation rate in childhood tuberculosis: is it still worthwhile? *Int.J.Tuberc.Lung Dis* 4, pp. 237-239.
- Alausa, K. O., Osoba, A. O., Montefiore, D., & Sogbetun, O. A. (1977). Laboratory diagnosis of tuberculosis in a developing country 1968-1975. *Afr.J.Med Med Sci*. 6, pp. 103-108.
- Alderson, P. & Roberts, I. (2000). Should journals publish systematic reviews that find no evidence to guide practice? Examples from injury research. *BMJ* 320, pp. 376-377.
- Alderson, P. (1998). Theories in health care and research: The importance of theories in health care. *BMJ* 317, pp. 1007-1010.
- Alemi, F., Neuhauser, D., Ardito, S., Headrick, L., Moore, S., Hekelman, F., & Norman, L. (2000). Continuous self-improvement: systems thinking in a personal context. *Jt.Comm J Qual.Improv.* 26, pp. 74-86.
- Angunawela, I. I., Diwan, V. K., & Tomson, G. (1991). Experimental evaluation of the effects of drug information on antibiotic prescribing: a study in outpatient care in an area of Sri Lanka. *Int.J.Epidemiol.* 20, pp. 558-564.
- Arif, K., Ali, S. A., Amanullah, S., Siddiqui, I., Khan, J. A., & Nayani, P. (1998). Physician compliance with national tuberculosis treatment guidelines: a university hospital study. *International Journal of Tuberculosis & Lung Disease*. 2, pp. 225-230.
- Aris, E. A., Bakari, M., Chonde, T. M., Kitinya, J., & Swai, A. B. (1999). Diagnosis of tuberculosis in sputum negative patients in Dar es Salaam. *East Afr.Med.J.* 76, pp. 630-634.
- Armstrong, D., Reyburn, H., & Jones, R. (1996). A study of general practitioners' reasons for changing their prescribing behaviour. *BMJ* 312, pp. 949-952.
- Avorn, J. & Soumerai, S. B. (1983). Improving drug-therapy decisions through educational outreach. A randomized controlled trial of academically based "detailing". *The New England Journal of Medicine* 308, pp. 1457-1463.
- Awan, A. K., Awan, A. H., & Akhtar, R. (1989). Medical audit by peer review and competitive self-appraisal as tools for promoting efficiency: a case study in Lahore, Pakistan. *International Journal of Gynaecology & Obstetrics*. 30, pp. 27-32.

- Axt-Adam, P., van der Wouden, J. C., & van der Does, E. (1993). Influencing behavior of physicians ordering laboratory tests: a literature study. *Med Care* 31, pp. 784-794.
- Baker, R., Hearnshaw, H., & Robertson, N. (1999). Implementing change with clinical audit. First, John Willey & Sons Ltd, Chicester.
- Balas, E. A., Boren, S. A., Brown, G. D., Ewigman, B. G., Mitchell, J. A., & Perkoff, G. T. (1996). Effect of physician profiling on utilization. Meta-analysis of randomized clinical trials. *J Gen. Intern Med* 11, pp. 584-590.
- Banda, H., Kang'ombe, C., Harries, A. D., Nyangulu, D. S., Whitty, C. J., Wirima, J. J., Salaniponi, F. M., Maher, D., & Nunn, P. (2000). Mortality rates and recurrent rates of tuberculosis in patients with smear-negative pulmonary tuberculosis and tuberculous pleural effusion who have completed treatment. *Int.J.Tuberc.Lung Dis.* 4, pp. 968-974.
- Banda, H., Harries, A., Welby, S., Boeree, M., Wirima, J., Subramanyam, V., & Maher (1998). Prevalence of tuberculosis in TB suspects with short duration of cough. *Trans R Soc Trop Med Hyg* 92, pp. 161-163.
- Bandura, A. (1986). *Social Foundations of Thought and Action: A Social Cognitive Theory*. Prentice Hall, New Jersey.
- Bankole, J. O., Lawal, O. O., & Adejuyigbe, O. (2003). Surgical audit in the developing countries. [Review] [16 refs]. *West African Journal of Medicine.* 22, pp. 76-78.
- Baral, N., Koner, B. C., Lamsal, M., Niraula, I., & Dhungel, S. (2001). Thyroid function testing in eastern Nepal and the impact of CME on subsequent requests. *Tropical Doctor.* 31, pp. 155-157.
- Barron, S. (1991). Audit in Obstetrics. *British Journal of Obstetrics & Gynaecology.* 98, pp. 1065-1072.
- Bassili, A., Zaki, A., Zaher, S. R., El Sawy, I. H., Ahmed, M. H., Omar, M., Omar, T., Bedwani, R. N., Davies, C., & Tognoni, G. (2000). Quality of care of children with chronic diseases in Alexandria, Egypt: the models of asthma, type I diabetes, epilepsy, and rheumatic heart disease. Egyptian-Italian Collaborative Group on Pediatric Chronic Diseases. *Pediatrics.* 106, p. E12.
- Bauchner, H., Simpson, L., & Chessarre, J. (2001). Changing physician behaviour. *Archives of Disease in Childhood* 84, pp. 459-462.
- Behar, P., Wagner, M. B., Freitas, I., Auler, A., Selistre, L., Fossatti, L., & Asquidamini, S. (2000). Assessing the antimicrobial prescription request process in a teaching hospital in Brazil: regulations and training. *Brazilian Journal of Infectious Diseases.* 4, pp. 76-85.
- Behr, M. A., Warren, S. A., Salamon, H., Hopewell, P. C., Ponce, d. L., Daley, C. L., & Small, P. M. (1999). Transmission of Mycobacterium tuberculosis from patients smear-negative for acid-fast bacilli. *Lancet* 353, pp. 444-449.
- Bennett, J. W. & Glasziou, P. P. (2003). Computerised reminders and feedback in medication management: a systematic review of randomised controlled trials. [Review] [47 refs]. *Medical Journal of Australia.* 178, pp. 217-222.
- Berger, A. (1998). Why doesn't audit work? *BMJ* 316, pp. 875-876.
- Bergman, N. J. (1995). A "treatment score" for primary and pulmonary tuberculosis. *Cent.Afr.J.Med.* 41, pp. 1-6.

Bernal-Delgado, E., Galeote-Mayor, M., Pradas-Arnal, F., & Peiro-Moreno, S. (2002). Evidence based educational outreach visits: effects on prescriptions of non-steroidal anti-inflammatory drugs. *Journal of Epidemiology & Community Health*. 56, pp. 653-658.

Berner, E. S., Baker, C. S., Funkhouser, E., Heudebert, G. R., Allison, J. J., Fargason, C. A., Jr., Li, Q., Person, S. D., & Kiefe, C. I. (2003). Do local opinion leaders augment hospital quality improvement efforts? A randomized trial to promote adherence to unstable angina guidelines. *Medical Care*. 41, pp. 420-431.

Berwick, D. M. (2003). Disseminating Innovations in Health Care. *JAMA: The Journal of the American Medical Association* 289, pp. 1969-1975.

Bexell, A., Lwando, E., von Hofsten, B., Tembo, S., Eriksson, B., & Diwan, V. K. (1996). Improving drug use through continuing education: a randomized controlled trial in Zambia. *Journal of Clinical Epidemiology*. 49, pp. 355-357.

Bharat, V., Das, N. K., Mohanty, B., Jha, A. C., Chawla, S. C., Dash, B., & Mohanty, R. (2003). Reduction of mechanical heart valve thrombosis through a clinical audit. *Journal of Heart Valve Disease* 12, pp. 362-369.

Bhutta, Z. (2003). Practising just medicine in an unjust world. *BMJ* 327, pp. 1000-1001.

Black, N. (1992). The relationship between evaluative research and audit. *Journal of Public Health* 14, pp. 361-366.

Black, N. (1996). Why we need observational studies to evaluate the effectiveness of health care. *BMJ* 312, pp. 1215-1218.

Blackwood, B. (2006). Methodological issues in evaluating complex healthcare interventions. *J Adv.Nurs.* 54, pp. 612-622.

BMJ (1992). Medical audit in general practice. I: Effects on doctors' clinical behaviour for common childhood conditions. North of England Study of Standards and Performance in General Practice. *BMJ* 304, pp. 1480-1484.

Bojalil, R., Guiscafre, H., Espinosa, P., Viniegra, L., Martinez, H., Palafox, M., & Gutierrez, G. (1999). A clinical training unit for diarrhoea and acute respiratory infections: an intervention for primary health care physicians in Mexico. *Bulletin of the World Health Organization*. 77, pp. 936-945.

Boonstra, E., Lindbaek, M., Klouman, E., Ngome, E., Romoren, M., & Sundby, J. (2003). Syndromic management of sexually transmitted diseases in Botswana's primary health care: quality of care aspects. *Tropical Medicine & International Health*. 8, pp. 604-614.

Borbas, C., Morris, N., McLaughlin, B., Asinger, R., & Gobel, F. (2000). The role of clinical opinion leaders in guideline implementation and quality improvement. [Review] [33 refs]. *Chest*. 118, p. Suppl-32S.

Bordley, W. C., Chelminski, A., Margolis, P. A., Kraus, R., Szilagyi, P. G., & Vann, J. J. (2000). The effect of audit and feedback on immunization delivery: a systematic review. [Review] [26 refs]. *American Journal of Preventive Medicine*. 18, pp. 343-350.

Bowling, A. (2002). Research methods in health-Investigating health and health services. second, Open University Press, Buckingham.

Bradley, F., Wiles, R., Kinmonth, A. L., Mant, D., & Gantley, M. (1999). Development and evaluation of complex interventions in health services research: case study of the

- Southampton heart integrated care project (SHIP). The SHIP Collaborative Group. *BMJ*. 318, pp. 711-715.
- Brooks, A. J., Phipson, M., Potgieter, A., Koertzen, H., & Boffard, K. D. (1999). Education of the trauma team: video evaluation of the compliance with universal barrier precautions in resuscitation. *European Journal of Surgery*. 165, pp. 1125-1128.
- Brown, C., Patil, P., & Lilford, R. (2006). The Stepped Wedge Trial Design: A review of the literature.,
- Brown, C. A., Belfield, C. R., & Field, S. J. (2002). Cost effectiveness of continuing professional development in health care: a critical review of the evidence. [Review] [27 refs]. *BMJ*. 324, pp. 652-655.
- Brown, L. D., de Negri, B., Hernandez, O., Dominguez, L., Sanchack, J. H., & Roter, D. (2000). An evaluation of the impact of training Honduran health care providers in interpersonal communication. *International Journal for Quality in Health Care*. 12, pp. 495-501.
- Bruchfeld, J., Aderaye, G., Palme, I. B., Bjorvatn, B., Kallenius, G., & Lindquist, L. (2000). Sputum concentration improves diagnosis of tuberculosis in a setting with a high prevalence of HIV. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 94, pp. 677-680.
- Bugalho, A. & Bergstrom, S. (1993). Value of perinatal audit in obstetric care in the developing world: a ten-year experience of the Maputo model. *Gynecologic & Obstetric Investigation*. 36, pp. 239-243.
- Buntinx, F., Winkens, R., Grol, R., & Knottnerus, J. A. (1993). Influencing diagnostic and preventive performance in ambulatory care by feedback and reminders. A review. *Family Practice* 10, pp. 219-228.
- Campagne, G., Garba, A., Barkire, H., Vera, C., Boulanger, D., & Chippaux, J. P. (2000). [Quality control during ultrasonographic evaluation of morbidity due to *Schistosoma haematobium* in Niger]. [French]. *Medecine Tropicale*. 60, pp. 35-41.
- Campbell, D. (1975). Degrees of freedom and the case study. *Comparative Political Studies* 8, pp. 178-185.
- Campbell, H., Hotchkiss, R., Bradshaw, N., & Porteous, M. (1998). Integrated care pathways. *BMJ* 316, pp. 133-137.
- Campbell, L. (2001). Audit of referral of aids patients from hospital to an integrated community-based home care programme in Kwazulu-Natal, South Africa. *Southern African Journal of HIV Medicine* 6, pp. 9-11.
- Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter, D., & Tyrer, P. (2000). Framework for design and evaluation of complex interventions to improve health. *BMJ*. 321, pp. 694-696.
- Cantillon, P. & Jones, R. (1999). Does continuing medical education in general practice make a difference? *BMJ* 318, pp. 1276-1279.
- Carter, A. O., Battista, R. N., Hodge, M. J., Lewis, S., Basinski, A., & Davis, D. (1995). Report on activities and attitudes of organizations active in the clinical practice guidelines field. *CMAJ Canadian Medical Association Journal*. 153, pp. 901-907.

Causse, R., Chouaid, C., Callaert, S., Le Paih, M. F., Cohen, R., & Thebault, A. (1998). [Impact of a multidisciplinary approach for monitoring prescribing of antibiotics in a hospital]. [French]. *Presse Medicale*. 27, pp. 1371-1375.

Chareonkul, C., Khun, V. L., & Boonshuyar, C. (2002). Rational drug use in Cambodia: study of three pilot health centers in Kampong Thom Province. *Southeast Asian Journal of Tropical Medicine & Public Health*. 33, pp. 418-424.

Chauhan, S. P., Magann, E. F., McAninch, C. B., Gherman, R. B., & Morrison, J. C. (2003). Application of learning theory to obstetric maloccurrence. *J Matern.Fetal Neonatal Med*. 13, pp. 203-207.

Cheater, F., Baker, R., Hearnshaw, H., Robertson, N., Hicks, N., Oxman, A., & Flottorp, S. (2004). Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes (Protocol for a Cochrane Review). *The Cochrane Library* 1.

CIA (2005). <http://www.cia.gov/cia/publications/factbook/>.

Cibere, J., Sibley, J. T., & Haga, M. (2002). Rheumatologists' adherence to guidelines for misoprostol use in patients at high risk for nonsteroidal antiinflammatory drug gastropathy. *Journal of Rheumatology*. 29, pp. 339-346.

Cohen, S. J., Halvorson, H. W., & Gosselink, C. A. (1994). Changing Physician Behavior to Improve Disease Prevention. *Preventive Medicine* 23, pp. 284-291.

Colebunders, R. & Bastian, I. (2000). A review of the diagnosis and treatment of smear-negative pulmonary tuberculosis. *Int.J.Tuberc.Lung Dis*. 4, pp. 97-107.

Conner, M. & Norman, P. (1996). Predicting health behaviour. Conner & Norman. 1, Open University Press, Buckingham.

Cook, T. & Campbell, D. (1979). Quasi-experimentation: Design and Analysis Issues for Field Settings. Rand McNally, Chicago.

Copeland, G. (2005). A Practical Handbook for Clinical Audit. NHS Clinical Governance Support Team, London.

Costello, A. & Zumla, A. (2000). Moving to research partnerships in developing countries. *BMJ* 321, pp. 827-829.

Cowie, R. L. & Escreet, B. C. (1980). The diagnosis of pulmonary tuberculosis. *S.Afr.Med J*. 57, pp. 75-77.

Crabtree, B. F., Ray, S. C., Schmidt, P. M., O'Connor, P. J., & Schmidt, D. D. (1990). The individual over time: time series applications in health care research. *J Clin.Epidemiol*. 43, pp. 241-260.

Cranney, M., Warren, E., Barton, S., Gardner, K., & Walley, T. (2001). Why do GPs not implement evidence-based guidelines? A descriptive study. *Family Practice* 18, pp. 359-363.

David, M. M., Sherri, P., V., & Jonathan, L. B. (2004). Design and Analysis of Group-Randomized Trials: A Review of Recent Methodological Developments. *American Journal of Public Health* 94, p. 423.

- Davis, D. (1998). Does CME work? An analysis of the effect of educational activities on physician performance or health care outcomes. *Int J Psychiatry Med* 28, pp. 21-39.
- Davis, D. A. & Taylor-Vaisey, A. (1997). Translating guidelines into practice. A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. *Canadian Medical Association Journal* 157, pp. 408-416.
- Davis, D. A., Thomson, M. A., Oxman, A. D., & Haynes, R. B. (1995). Changing physician performance. A systematic review of the effect of continuing medical education strategies.[see comment]. *JAMA*. 274, pp. 700-705.
- Davis, D. A., Thomson, M. A., Oxman, A. D., & Haynes, R. B. (1992). Evidence for the effectiveness of CME. A review of 50 randomized controlled trials. *JAMA: The Journal of the American Medical Association* 268, pp. 1111-1117.
- Davis, D., O'Brien, M. A. T., Freemantle, N., Wolf, F. M., Mazmanian, P., & Taylor-Vaisey, A. (1999). Impact of Formal Continuing Medical Education: Do Conferences, Workshops, Rounds, and Other Traditional Continuing Education Activities Change Physician Behavior or Health Care Outcomes? *JAMA: The Journal of the American Medical Association* 282, pp. 867-874.
- De Castro, M. S., Kopittke, L., Fuchs, F. D., & Tannhauser, M. (1999). Evidence of inappropriate use of vancomycin in a university affiliated hospital in Brazil. *Pharmacoepidemiology & Drug Safety* 8, pp. 405-411.
- DeCherney, G. S. (1999). Accelerating acceptance. *Physician Executive*. 25, pp. 32-38.
- Diallo, I., Fall, C., Ndiaye, P., Ndiaye, S., Wone, I., & Diakhate, M. (2002). [Impact of algorithms on abusive prescriptions of parental drugs at the health post level in the Tambacounda health district, Senegal]. [French]. *Sante*. 12, pp. 301-306.
- Dick, J., Lewin, S., Rose, E., Zwarenstein, M., & Walt, H. (2004). Changing professional practice in tuberculosis care: an educational intervention. *J Adv.Nurs*. 48, pp. 434-442.
- Dickey, L. L., Gemson, D. H., & Carney, P. (1999). Office system interventions supporting primary care-based health behavior change counseling. [Review] [78 refs]. *American Journal of Preventive Medicine*. 17, pp. 299-308.
- Donner, A. & Klar, N. (2004). Pitfalls of and Controversies in Cluster Randomization Trials. *American Journal of Public Health* 94, pp. 416-422.
- Duley, L. & Farrell, B. (2002). Clinical trials. Duley & Farrell. BMJ Books, London.
- Eddy, D. M. (1982). Clinical policies and the quality of clinical practice. *The New England Journal of Medicine* 307, pp. 343-347.
- Edwards, P. R., Lunt, D. W., Fehrsen, G. S., Lombard, C. J., & Steyn, K. (1998). Improving cost-effectiveness of hypertension management at a community health centre. *South African Medical Journal*. 88, pp. 549-554.
- Fairall, L. R., Zwarenstein, M., Bateman, E. D., Bachmann, M., Lombard, C., Majara, B. P., Joubert, G., English, R. G., Bheekie, A., van, R. D., Myers, P., Peters, A. C., & Chapman, R. D. (2005). Effect of educational outreach to nurses on tuberculosis case detection and primary care of respiratory illness: pragmatic cluster randomised controlled trial. *BMJ*.331(7519):750-4.

- Fairhurst, K. & Huby, G. (1998). From trial data to practical knowledge: qualitative study of how general practitioners have accessed and used evidence about statin drugs in their management of hypercholesterolaemia. *BMJ*. 317, pp. 1130-1134.
- Farmer, A., Legare, F., McAuley, L., Thomas, R., Harvey, E., McGowan, J., Grimshaw, J., & Wolf, F. (2004). Printed educational materials: effects on professional practice and health care outcomes (Protocol for a Cochrane Review). *The Cochrane Library*.
- Feder, G. (1994). Clinical guidelines in 1994. *BMJ* 309, pp. 1457-1458.
- Ferlie, E. B. & Shortell, S. M. (2001). Improving the quality of health care in the United Kingdom and the United States: a framework for change. *The Milbank Quarterly* 79, pp. 281-315.
- Finkelstein, J. A., Davis, R. L., Dowell, S. F., Metlay, J. P., Soumerai, S. B., Rifas-Shiman, S. L., Higham, M., Miller, Z., Miroshnik, I., Pedan, A., & Platt, R. (2001). Reducing antibiotic use in children: a randomized trial in 12 practices. *Pediatrics*. 108, pp. 1-7.
- Fleiss, J., Levin, B., & Paik, M. (2003). *Statistical Methods for Rates and Proportions*. Third, John Wiley & Sons, New Jersey.
- Fleuren, M., Wiefferink, K., & Paulussen, T. (2004). Determinants of innovation within health care organizations: literature review and Delphi study. *Int J Qual Health Care*. 16, pp. 107-123.
- Flores, R., Robles, J., & Burkhalter, B. R. (2002). Distance education with tutoring improves diarrhea case management in Guatemala. *International Journal for Quality in Health Care* 14, pp. 47-56.
- Foulds, J. & O'Brien, R. (1998). New tools for the diagnosis of tuberculosis: The perspective of developing countries. *International Journal of Tuberculosis & Lung Disease* 2, pp. 778-783.
- Fourie, B. & Weyer, K. (2000). Trials of anti-tuberculosis treatment as a diagnostic tool in smear-negative tuberculosis are of questionable benefit. *International Journal of Tuberculosis & Lung Disease* 4, p. 997.
- Fraser, R. C. & Gosling, J. T. (1985). Information systems for general practitioners for quality assessment: II. Information preferences of the doctors. *Br Med.J (Clin.Res.Ed)*. 291, pp. 1544-1546.
- Fraser, R. C., Khunti, K., Baker, R., & Lakhani, M. (1997). Effective audit in general practice: a method for systematically developing audit protocols containing evidence-based review criteria. *Br J Gen.Pract.* 47, pp. 743-746.
- Freemantle, N., Harvey, E. L., Wolf, F., Grimshaw, J. M., Grilli, R., & Bero, L. A. (2000). Printed educational materials: effects on professional practice and health care outcomes. [Review] [11 refs]. *Cochrane Database of Systematic Reviews*. p. CD000172.
- Freemantle, N., Nazareth, I., Eccles, M., Wood, J., Haines, A., & Evidence-based, O. t. (2002). A randomised controlled trial of the effect of educational outreach by community pharmacists on prescribing in UK general practice.[erratum appears in Br J Gen Pract 2002 Sep;52(482):767]. *British Journal of General Practice*. 52, pp. 290-295.
- Garfield, R. & Santana, S. (1997). The impact of the economic crisis and the US embargo on health in Cuba. *American Journal of Public Health* 87, pp. 15-20.

Garfield, R. Health care in Cuba and the manipulation of humanitarian imperatives. *The Lancet* 364, p. 1007.

Garner, P., Kale, R., Dickson, R., Dans, T., & Salinas, R. (1998). Getting research findings into practice: Implementing research findings in developing countries. *BMJ* 317, pp. 531-535.

Garner, P., Meremikwu, M., Volmink, J., Xu, Q., & Smith, H. (2004). Putting evidence into practice: how middle and low income countries "get it together". *BMJ* 329, pp. 1036-1039.

Gebre, N., Karlsson, U., Jonsson, G., Macaden, R., Wolde, A., Assefa, A., & Miorner, H. (1995). Improved microscopical diagnosis of pulmonary tuberculosis in developing countries. *Trans R Soc Trop Med Hyg* 89, pp. 191-193.

Gifford, D. R., Holloway, R. G., Frankel, M. R., Albright, C. L., Meyerson, R., Griggs, R. C., & Vickrey, B. G. (1999). Improving adherence to dementia guidelines through education and opinion leaders. A randomized, controlled trial. *Annals of Internal Medicine*. 131, pp. 237-246.

Gonzalez, E., Armas, L., Baly, A., Galvez, A., Alvarez, M., Ferrer, G., & Mesa, A. C. (2000). [Economic and social impact of the National Tuberculosis Control Program (NTCP) on the Cuban population]. *Cad.Saude Publica* 16, pp. 687-699.

Graham, I. D. & Logan, J. (2004). Translating Research: Innovations in Knowledge Transfer and Continuity of Care. *Canadian Journal of Nursing Research* 36, pp. 89-103.

Graham, W., Wagaarachchi, P., Penney, G., McCaw-Binns, A., Antwi, K. Y., & Hall, M. H. (2000). Criteria for clinical audit of the quality of hospital-based obstetric care in developing countries. *Bull. World Health Organ* 78, pp. 614-620.

Greco, P. J. & Eisenberg, J. M. (1993). Changing physicians' practices. *The New England Journal of Medicine* 329, pp. 1271-1273.

Green, J. & Thorogood, N. (2004). *Qualitative Methods for Health Research*. 1, SAGE Publications Ltd, London.

Green, J. & Britten, N. (1998). Qualitative research and evidence based medicine. *BMJ* 316, pp. 1230-1232.

Green, L. & Kreuter, M. (1980). *Health education planning: An diagnostic approach*. Mayfield Publishing Company, California.

Green, L. & Kreuter, M. (1991). *Health promotion planning: an educational and environmental approach*. Mayfield Publishing Company, London.

Greene, J. A. (2004). An ethnography of nonadherence: culture, poverty, and tuberculosis in urban Bolivia. *Cult. Med. Psychiatry* 28, pp. 401-425.

Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., & Kyriakidou, O. (2004). Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q.* 82, pp. 581-629.

Greer, A. L. (1988). The state of the art versus the state of the science. The diffusion of new medical technologies into practice. *Int J Technol. Assess. Health Care* 4, pp. 5-26.

Grilli, R. & Lomas, J. (1994). Evaluating the message: the relationship between compliance rate and the subject of a practice guideline. *Med Care* 32, pp. 202-213.

Grimshaw, J., Campbell, M., & Eccles, M. (2000). Experimental and quasi-experimental designs for evaluating guideline implementation strategies. *Family Practice* 17, p. S11-S16.

Grimshaw, J. M., Eccles, M. P., Walker, A. E., & Thomas, R. E. (2002). Changing physicians' behavior: what works and thoughts on getting more things to work. *J Contin. Educ. Health Prof.* 22, pp. 237-243.

Grimshaw, J. M. & Russell, I. T. (1993). Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* 342, pp. 1317-1322.

Grimshaw, J. M., Shirran, L., Thomas, R., Mowatt, G., Fraser, C., Bero, L., Grilli, R., Harvey, E., Oxman, A., & O'Brien, M. A. (2001). Changing provider behavior: an overview of systematic reviews of interventions. *Medical Care*. 39, p. Suppl-45.

Grimshaw, J. M., Thomas, R. E., MacLennan, G., Fraser, C., Ramsay, C. R., Vale, L., Whitty, P., Eccles, M. P., Matowe, L., Shirran, L., Wensing, M., Dijkstra, R., & Donaldson, C. (2004). Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol. Assess.* 8, p. iii-72.

Grol, R. (2001a). Successes and failures in the implementation of evidence-based guidelines for clinical practice. *Medical Care*. 39, p. Suppl-54.

Grol, R. (1997). Personal paper: Beliefs and evidence in changing clinical practice. *BMJ* 315, pp. 418-421.

Grol, R. (2001b). Improving the Quality of Medical Care: Building Bridges Among Professional Pride, Payer Profit, and Patient Satisfaction. *JAMA: The Journal of the American Medical Association* 286, pp. 2578-2585.

Grol, R. & Grimshaw, J. (2003). From best evidence to best practice: effective implementation of change in patients' care. *The Lancet* 362, pp. 1225-1230.

Guadagnoli, E., Soumerai, S. B., Gurwitz, J. H., Borbas, C., Shapiro, C. L., Weeks, J. C., & Morris, N. (2000). Improving discussion of surgical treatment options for patients with breast cancer: local medical opinion leaders versus audit and performance feedback. *Breast Cancer Research & Treatment*. 61, pp. 171-175.

Habeenzu, C., Lubasi, D., & Fleming, A. F. (1998). Improved sensitivity of direct microscopy for detection of acid-fast bacilli in sputum in developing countries. *Trans R Soc Trop Med Hyg* 92, pp. 415-416.

Habicht, J. P., Victora, C. G., & Vaughan, J. P. (1999). Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. *International Journal of Epidemiology* 28, pp. 10-18.

Hadiyono, J. E., Suryawati, S., Danu, S. S., Sunartono, & Santoso, B. (1996). Interactional group discussion: results of a controlled trial using a behavioral intervention to reduce the use of injections in public health facilities. *Social Science & Medicine*. 42, pp. 1177-1183.

Haines, A. & Jones, R. (1994). Implementing findings of research. *BMJ* 308, pp. 1488-1492.

Hand, R., Plsek, P., & Roberts, H. V. (1995). Interpreting quality improvement data with time-series analyses. *Qual. Manag. Health Care*. 3, pp. 74-84.

Hargreaves, N. J., Kadzakuanja, O., Whitty, C. J., Salaniponi, F. M., Harries, A. D., & Squire, S. B. (2001). 'Smear-negative' pulmonary tuberculosis in a DOTS programme: poor outcomes in an area of high HIV seroprevalence. *Int.J.Tuberc.Lung Dis.* 5, pp. 847-854.

Harries, A. D., Banda, H. T., Boeree, M. J., Welby, S., Wirima, J. J., Subramanyam, V. R., Maher, D., & Nunn, P. (1998a). Management of pulmonary tuberculosis suspects with negative sputum smears and normal or minimally abnormal chest radiographs in resource-poor settings. *Int.J.Tuberc.Lung Dis.* 2, pp. 999-1004.

Harries, A. D., Hargreaves, N. J., Kumwenda, J., Kwanjana, J. H., & Salaniponi, F. M. (2000). Trials of anti-tuberculosis treatment in areas of high human immunodeficiency virus prevalence in sub-Saharan Africa. *Int.J.Tuberc.Lung Dis* 4, pp. 998-1001.

Harries, A. D., Hargreaves, N. J., Kwanjana, J. H., & Salaniponi, F. M. (2001). Clinical diagnosis of smear-negative pulmonary tuberculosis: an audit of diagnostic practice in hospitals in Malawi. *Int.J.Tuberc.Lung Dis.* 5, pp. 1143-1147.

Harries, A. D., Kamenya, A., Subramanyam, V. R., Maher, D., Squire, S. B., Wirima, J. J., Nyangulu, D. S., & Nunn, P. (1997). Screening pulmonary tuberculosis suspects in Malawi: testing different strategies. *Trans.R.Soc.Trop.Med.Hyg.* 91, pp. 416-419.

Harries, A. D., Maher, D., & Nunn, P. (1998b). An approach to the problems of diagnosing and treating adult smear-negative pulmonary tuberculosis in high-HIV-prevalence settings in sub-Saharan Africa. *Bull.World Health Organ* 76, pp. 651-662.

Harrison, A., Karim, S. A., Floyd, K., Lombard, C., Lurie, M., Ntuli, N., & Wilkinson, D. (2000). Syndrome packets and health worker training improve sexually transmitted disease case management in rural South Africa: randomized controlled trial. *AIDS.* 14, pp. 2769-2779.

Harrison, A., Wilkinson, D., Lurie, M., Connolly, A. M., & Karim, S. A. (1998). Improving quality of sexually transmitted disease case management in rural South Africa. *AIDS.* 12, pp. 2329-2335.

Hawe, P., Shiell, A., & Riley, T. (2004). Complex interventions: how "out of control" can a randomised controlled trial be? *BMJ.* 328, pp. 1561-1563.

Hazra, A., Tripathi, S. K., & Alam, M. S. (2000). Prescribing and dispensing activities at the health facilities of a non-governmental organization. *National Medical Journal of India.* 13, pp. 177-182.

Hearnshaw, H., Harker, R., Cheater, F., Baker, R., & Grimshaw, G. (2002). A study of the methods used to select review criteria for clinical audit. Vol 6 (1). *Health Technology Assessment*,

Hearnshaw, H. M., Harker, R. M., Cheater, F. M., Baker, R. H., & Grimshaw, G. M. (2001). Expert consensus on the desirable characteristics of review criteria for improvement of health care quality. *Quality and Safety in Health Care* 10, pp. 173-178.

Hearnshaw, H. M., Harker, R. M., Cheater, F. M., Baker, R. H., & Grimshaw, G. M. (2003). Are audits wasting resources by measuring the wrong things? A survey of methods used to select audit review criteria. *Quality and Safety in Health Care* 12, pp. 24-28.

Heiby, J. R. (1998). Quality improvement and the integrated management of childhood illness: lessons from developed countries. *Jt.Comm J Qual Improv.* 24, pp. 264-279.

Heineck, I., Ferreira, M. B., & Schenkel, E. P. (1999). Prescribing practice for antibiotic prophylaxis for 3 commonly performed surgeries in a teaching hospital in Brazil. *AJIC: American Journal of Infection Control*. 27, pp. 296-300.

Heller, R. F., D'Este, C., Lim, L. L., O'Connell, R. L., & Powell, H. (2001). Randomised controlled trial to change the hospital management of unstable angina.[see comment][comment]. *Medical Journal of Australia*. 174, pp. 217-221.

Hermida, J. & Robalino, M. E. (2002). Increasing compliance with maternal and child care quality standards in Ecuador. *International Journal for Quality in Health Care*. 14, p. Suppl-34.

Hesketh, T. M., Zhu, W. X., & Zheng, K. H. (1994). Improvement of neonatal care in Zhejiang Province, China through a self-instructional continuing education programme. *Medical Education*. 28, pp. 252-259.

Hodgkin, P. (1996). Medicine, postmodernism, and the end of certainty. *BMJ* 313, pp. 1568-1569.

Hogerzeil, H. V. (1995). Promoting rational prescribing: an international perspective. [Review] [77 refs]. *British Journal of Clinical Pharmacology*. 39, pp. 1-6.

Hong, S. W., Ching, T. Y., Fung, J. P., & Seto, W. L. (1990). The employment of ward opinion leaders for continuing education in the hospital. *Med Teach*. 12, pp. 209-217.

Horton, R. (2003). Medical journals: evidence of bias against the diseases of poverty. *The Lancet* 361, pp. 712-713.

Hulscher, M. E., Wensing, M., Grol, R. P., van der, W. T., & van Weel, C. (1999). Interventions to improve the delivery of preventive services in primary care. *Am.J Public Health* 89, pp. 737-746.

Hurwitz, B. (1994). Clinical guidelines: proliferation and medicolegal significance. *Quality and Safety in Health Care* 3, pp. 37-44.

Iles, V. & Sutherland, K. (2001). Managing Change in the NHS. Organisational Change. A Review for Health Care Managers, Professionals and Researchers.

Illsley, R. (1980). Professional or public health? Sociology in health and medicine. The Rock Carling Fellowship monograph. Nuffield Provincial Hospitals Trust, London.

International society for quality in health care (2003).
<http://www.isqua.org.au/isquaPages/General.html>.

Jamtvedt, G., Young, J. M., Kristoffersen, D. T., O'Brien, M. A., & Oxman, A. D. (2006). Audit and feedback: effects on professional practice and health care outcomes. *Cochrane.Database.Syst.Rev.* p. CD000259.

Jamtvedt, G., Young, J. M., Kristoffersen, D. T., Thomson O'Brien, M. A., & Oxman, A. D. (2003). Audit and feedback: effects on professional practice and health care outcomes.[update of Cochrane Database Syst Rev. 2000;(2):CD000259; PMID: 10796520]. [Review] [204 refs]. *Cochrane Database of Systematic Reviews*. p. CD000259.

Johnston, G., Crombie, I. K., Davies, H. T., Alder, E. M., & Millard, A. (2000). Reviewing audit: barriers and facilitating factors for effective clinical audit. [Review] [90 refs]. *Quality in Health Care*. 9, pp. 23-36.

Johnston, M. E., Langton, K. B., Haynes, R. B., & Mathieu, A. (1994). Effects of Computer-based Clinical Decision Support Systems on Clinician Performance and Patient Outcome: A Critical Appraisal of Research. *Annals of Internal Medicine* 120, pp. 135-142.

Kafuko, J., Zirabamuzale, C., & Bagenda, D. (1999). Rational drug use in rural health units of Uganda: effect of national standard treatment guidelines on rational drug use. *International conference on improving use of medication*.

Kanaya, A. M., Glidden, D. V., & Chambers, H. F. (2001). Identifying pulmonary tuberculosis in patients with negative sputum smear results. *Chest* 120, pp. 349-355.

Kelley, E., Geslin, C., Djibrina, S., & Boucar, M. (2001). Improving performance with clinical standards: the impact of feedback on compliance with the integrated management of childhood illness algorithm in Niger, West Africa. *International Journal of Health Planning & Management*. 16, pp. 195-205.

Kelley, E., Kelley, A. G., Simpara, C. H., Sidibe, O., & Makinen, M. (2003). The impact of self-assessment on provider performance in Mali. *International Journal of Health Planning & Management*. 18, pp. 41-48.

Kerrison, S., Packwood, T., & Buxton, M. (1993). Monitoring medical audit. pp. 155-177. King's Fund Institute, London.

Kim, T. C., Blackman, R. S., Heatwole, K. M., Kim, T., & Rochester, D. F. (1984). Acid-fast bacilli in sputum smears of patients with pulmonary tuberculosis. Prevalence and significance of negative smears pretreatment and positive smears post-treatment. *Am.Rev.Respir.Dis.* 129, pp. 264-268.

Kim, Y. M., Rimon, J., Winnard, K., Corso, C., Mako, I. V., Lawal, S., Babalola, S., & Huntington, D. (1992). Improving the quality of service delivery in Nigeria. *Studies in Family Planning*. 23, pp. 118-127.

Kirkman, M. S., Williams, S. R., Caffrey, H. H., & Marrero, D. G. (2002). Impact of a program to improve adherence to diabetes guidelines by primary care physicians.[see comment]. *Diabetes Care*. 25, pp. 1946-1951.

Kitson, A., Harvey, G., & McCormack, B. (1998). Enabling the implementation of evidence based practice: a conceptual framework. *Quality and Safety in Health Care* 7, pp. 149-158.

Kotler, P. (1984). Social marketing of health behaviour. Frederickson LW, Solomo LJ, & Brohony KA. Plenum Press, New York.

Krause, G., Borchert, M., Benzler, J., Heinmuller, R., Kaba, I., Savadogo, M., Siho, N., & Diesfeld, H. J. (1999). Rationality of drug prescriptions in rural health centres in Burkina Faso. *Health Policy & Planning*. 14, pp. 291-298.

Kupets, R. & Covens, A. (2001). Strategies for the implementation of cervical and breast cancer screening of women by primary care physicians. [Review] [28 refs]. *Gynecologic Oncology*. 83, pp. 186-197.

Larsen, J. (1992). Reducing the perinatal mortality rates in developing countries. *Tropical Doctor* 22, pp. 49-51.

Lauzardo, M. & Ashkin, D. (2000). Phthisiology at the dawn of the new century. *Chest* 117, pp. 1455-1473.

Lawrence, T. (1999). A stage-based approach to behaviour change. In *Evidence-Based Health Promotion*. John Wiley & Sons, Chichester.

Le Grand, A., Hogerzeil, V., & Haaijer-Ruskamp, F. (1999). Review Article. Intervention research in rational use of drugs: a review. *Health Policy and Planning* 14, pp. 89-102.

Lenfant, C. (2003). Clinical Research to Clinical Practice -- Lost in Translation? *The New England Journal of Medicine* 349, pp. 868-874.

Levy, H., Feldman, C., Sacho, H., van der, M. H., Kallenbach, J., & Koornhof, H. (1989). A reevaluation of sputum microscopy and culture in the diagnosis of pulmonary tuberculosis. *Chest* 95, pp. 1193-1197.

Lipsey, M. W. & Wilson, D. B. (1993). The efficacy of psychological, educational, and behavioral treatment. Confirmation from meta-analysis. *Am.Psychol.* 48, pp. 1181-1209.

Lobo, C. M., Frijling, B. D., Hulscher, M. E., Bernsen, R. M., Braspenning, J. C., Grol, R. P., Prins, A., & van der Wouden, J. C. (2002). Improving quality of organizing cardiovascular preventive care in general practice by outreach visitors: a randomized controlled trial.[see comment]. *Preventive Medicine.* 35, pp. 422-429.

Lococ, L., Dopson, S., Chambers, D., & Gabbay, J. (2001). Understanding the role of opinion leaders in improving clinical effectiveness. [Review] [33 refs]. *Social Science & Medicine.* 53, pp. 745-757.

Logan, J. & Graham, I. D. (1998). Towards a comprehensive interdisciplinary model of health care research use. *Science Communication* 20, pp. 227-246.

Loke, Y. K., Hwang, S. L., & Tan, M. H. (1997). Delays in thrombolytic therapy in acute myocardial infarction: an audit from the east coast of peninsular Malaysia. *Annals of the Academy of Medicine, Singapore.* 26, pp. 285-289.

Lomas, J. (1993a). Making clinical policy explicit. Legislative policy making and lessons for developing practice guidelines. *Int J Technol.Assess.Health Care* 9, pp. 11-25.

Lomas, J. (1993b). Diffusion, dissemination, and implementation: who should do what? *Ann.N.Y.Acad.Sci.* 703:226-35; discussion 235-7., pp. 226-235.

Long, R. (2001). Smear-negative pulmonary tuberculosis in industrialized countries. *Chest* 120, pp. 330-334.

Lord, J. & Littlejohns, P. (1995). Links between clinical audit and contracting systems. *Int J Health Care Qual Assur.* 8, pp. 15-24.

Lord, J. & Littlejohns, P. (1997). Evaluating healthcare policies: the case of clinical audit. *BMJ* 315, pp. 668-671.

Lucas, R. E. & Oberli, H. (1997). An audit to assess the impact of a strategy to reduce inappropriate red cell transfusions at Honiara Hospital. *Tropical Doctor.* 27, pp. 97-99.

Mahabir, D. & Gulliford, M. C. (1999). A 4-year evaluation of blood pressure management in Trinidad and Tobago. *Journal of Human Hypertension.* 13, pp. 455-459.

Maher, D., Chalet, P., Spinaci, S., & Harries AD (1997). Treatment of Tuberculosis: Guidelines for National Programmes. second, pp. 13-17. World Health Organisation, Geneva.

- Major, S., Salti, I., Masri, A., Van Lerberghe, W., Boelaert, M., & Khogali, M. (1998). Managing diabetes mellitus in a Lebanese primary care centre. Working towards change. *Journal Medical Libanais - Lebanese Medical Journal*. 46, pp. 182-188.
- Mallet, H. P., Njikam, A., & Scouflaire, S. M. (2001). [Evaluation of prescription practices and of the rational use of medicines in Niger]. [French]. *Sante*. 11, pp. 185-193.
- Mancey-Jones, M. & Brugha, R. F. (1997). Using perinatal audit to promote change: a review. [Review] [42 refs]. *Health Policy & Planning*. 12, pp. 183-192.
- Mandelblatt, J. & Kanetsky, P. A. (1995). Effectiveness of interventions to enhance physician screening for breast cancer. *J Fam.Pract.* 40, pp. 162-171.
- Marquez, L. (2001). helping healthcare providers perform according to standards. 2. Quality Assurance Project, USAID,
- Marrero, A., Caminero, J. A., Rodriguez, R., & Billo, N. E. (2000). Towards elimination of tuberculosis in a low income country: the experience of Cuba, 1962-97. *Thorax* 55, pp. 39-45.
- Mason, J., Freemantle, N., Nazareth, I., Eccles, M., Haines, A., & Drummond, M. (2001). When is it cost-effective to change the behavior of health professionals? *JAMA*.286(23):2988-92.
- Maxwell, R. J. (1984). Quality assessment in health. *Br Med.J (Clin.Res.Ed)*. 288, pp. 1470-1472.
- McBurney, D. (1994). Research Methods. 3, Brooks/Cole, Pacific Grove,CA.
- McDonald, C. J. (1976). Protocol-based computer reminders, the quality of care and the non-perfectability of man. *The New England Journal of Medicine* 295, pp. 1351-1355.
- Mittman, B. S., Tonesk, X., & Jacobson, P. D. (1992). Implementing clinical practice guidelines: social influence strategies and practitioner behavior change. *QRB Qual Rev.Bull.* 18, pp. 413-422.
- Molina, S., I, Lopez, P. C., & Alonso, H. R. (2003). [An ecologic study on tuberculosis in a Cuban municipality]. *Cad.Saude Publica* 19, pp. 1305-1312.
- Moongtui, W., Gauthier, D. K., & Turner, J. G. (2000). Using peer feedback to improve handwashing and glove usage among Thai health care workers. *AJIC: American Journal of Infection Control*. 28, pp. 365-369.
- Morrell, C. & Harvey, G. (2002). The clinical audit handbook: improving the quality of healthcare. Bailliere Tindall & co, London.
- Morris, C. D., Bird, A. R., & Nell, H. (1989). The haematological and biochemical changes in severe pulmonary tuberculosis. *Q.J.Med* 73, pp. 1151-1159.
- Mosteller, F. (1981). Innovation and evaluation. *Science* 211, pp. 881-886.
- Mowatt, G., Foy, R., Grimshaw, GM., & Sobrevilla, A. (2004). Local consensus processes: effects on professional practice and health care outcomes (Protocol for a Cochrane Review). *The Cochrane Library* 1.

Mowatt, G., Grimshaw, J. M., Davis, D. A., & Mazmanian, P. E. (2001). Getting evidence into practice: the work of the Cochrane Effective Practice and Organization of care Group (EPOC). *J Contin. Educ. Health Prof.* 21, pp. 55-60.

MRC (2000). A framework for the development of RCTs for complex interventions to improve health.

Mugford, M., Banfield, P., & O'Hanlon, M. (1991). Effects of feedback of information on clinical practice: a review. *BMJ* 303, pp. 398-402.

Naikoba, S. & Hayward, A. (2001). The effectiveness of interventions aimed at increasing handwashing in healthcare workers - a systematic review. [Review] [32 refs]. *Journal of Hospital Infection.* 47, pp. 173-180.

National Institute of Health and Clinical Excellence <http://www.nice.org.uk/>.

Nazareth, I., Freemantle, N., Duggan, C., Mason, J., & Haines, A. (2002). Evaluation of a complex intervention for changing professional behaviour: the Evidence Based Out Reach (EBOR) Trial. *Journal of Health Services & Research Policy.* 7, pp. 230-238.

NHS CRD (1994). Implementing clinical practice guidelines: can guidelines be used to improve clinical practice. 8, pp. 1-12. The Royal Society of Medicine Press Limited, London.

NHS CRD (1999). Getting evidence into practice. 5, The Royal Society of Medicine Press Limited, London.

NHS CRD (2001). Undertaking Systematic Reviews of Research on Effectiveness. 4. University of York, York.

NHS CRD (2003). The effects of clinical practice guidelines on patient outcomes in primary care. *Database of Abstracts of Reviews of Effectiveness.*

NICE (2002). Principles for best practice in clinical audit. Radcliffe Medical Press Ltd, Oxford.

Nicholas, D. D., Heiby, J. R., & Hatzell, T. A. (1991). The Quality Assurance Project: introducing quality improvement to primary health care in less developed countries. *Qual Assur. Health Care* 3, pp. 147-165.

Nilsson, G., Hjemdahl, P., Hassler, A., Vitols, S., Wallen, N. H., & Krakau, I. (2001). Feedback on prescribing rate combined with problem-oriented pharmacotherapy education as a model to improve prescribing behaviour among general practitioners. *European Journal of Clinical Pharmacology.* 56, pp. 843-848.

Norman, P. (1995). Social learning theory and the prediction of attendance at screening. *Psychology & Health* 5, pp. 231-239.

Nyirenda, T. E., Harries, A. D., Banerjee, A., & Salaniponi, F. M. (1999). Accuracy of chest radiograph diagnosis for smear-negative pulmonary tuberculosis suspects by hospital clinical staff in Malawi. *Trop. Doct.* 29, pp. 219-220.

O'Connell, M. (1975). Max Horkheimer *Critical Theory*. Continuum. New York.

O'Rourke, K. (1995). The effect of hospital staff training on management of obstetrical patients referred by traditional birth attendants. *International Journal of Gynaecology & Obstetrics.* 48, p. Suppl-102.

- Oakley, A., Strange, V., Bonell, C., Allen, E., & Stephenson, J. (2006). Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 332, pp. 413-416.
- Obua, C., Ogwal-Okeng, J. W., Waako, P., Aupont, O., & Ross-Degnan, D. (2004). Impact of an educational intervention to improve prescribing by private physicians in Uganda. *East African Medical Journal.Suppl*:S17-24.
- Ochoa, E. G., Perez, L. A., Gonzalez, J. R. B., Escobar, J. C., Corrales, R. R., & Suarez, G. A. (1996). Prescription of antibiotics for mild acute respiratory infections in children. *Bulletin of the Pan American Health Organization* 30, pp. 106-117.
- Ogden, J. (2003). Some Problems With Social Cognition Models: A Pragmatic and Conceptual Analysis. *Health Psychology* 22, p. 424.
- Opello, W. & Rosso, S. (1999). *The Nation-State and Global Order: A Historical Introduction to Contemporary Politics*. Lynne Rienner, Colorado.
- Oxman, A. D., Thomson, M. A., Davis, D. A., & Haynes, R. B. (1995). No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *Canadian Medical Association Journal* 153, pp. 1423-1431.
- Pariante, A., Prevost, J., Montaut, N., Quesnel-Tueux, N., Boulet, J. M., Gasnier, Y., Mangon, C., Malet, M., & Merlet, M. (1998). [Improvement of prescriptions for serum tumor markers in a general hospital].[see comment]. [French]. *Presse Medicale*. 27, pp. 153-156.
- Parry, C. M. (1993). Sputum smear negative pulmonary tuberculosis. *Trop.Doct.* 23, pp. 145-146.
- Pawson, R. & Tilley, N. (1997). *Realistic Evaluation*. Sage Publications, London.
- Pelly, T., Moore, D. A., Gilman, R., & Evans, C. (2004). Recent tuberculosis advances in Latin America. *Curr.Opin.Infect.Dis.* 17, pp. 397-403.
- Perez-Cuevas, R., Guiscafne, H., Munoz, O., Reyes, H., Tome, P., Libreros, V., & Gutierrez, G. (1996). Improving physician prescribing patterns to treat rhinopharyngitis. Intervention strategies in two health systems of Mexico. *Social Science & Medicine*. 42, pp. 1185-1194.
- Petersen, K. F. & Urbanczik, R. (1982). [Microscopic and cultural methods for the laboratory diagnosis of tuberculosis. A short historical review (author's transl)]. *Zentralbl.Bakteriol.Mikrobiol.Hyg [A]* 251, pp. 308-325.
- Piaget, J. (1970). *The science of education and the psychology of the child* New York. Grossman, New York.
- Pisacane, A. (1985). Reduction of child hospital mortality in Mozambique through a nurse training programme. *Annals of Tropical Paediatrics*. 5, pp. 7-10.
- Power, R., Langhaug, L. F., Nyamurera, T., Wilson, D., Bassett, M. T., & Cowan, F. M. (2004). Developing complex interventions for rigorous evaluation--a case study from rural Zimbabwe. *Health Educ.Res.* 19, pp. 570-575.
- Prochaska, J. O. & DiClemente, C. C. (1983). Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin.Psychol.* 51, pp. 390-395.
- Redfern, S., Christian, S., & Norman, I. (2003). Evaluating change in health care practice: lessons from three studies. *J Eval.Clin.Pract.* 9, pp. 239-249.

Reerink, I. H. & Sauerborn, R. (1996). Quality of primary health care in developing countries: recent experiences and future directions. *International Journal for Quality in Health Care*. 8, pp. 131-139.

Revere, D. & Dunbar, P. J. (2001). Review of computer-generated outpatient health behavior interventions: clinical encounters "in absentia". [Review] [90 refs]. *Journal of the American Medical Informatics Association*. 8, pp. 62-79.

Ripouteau, C., Conort, O., Lamas, J. P., Auleley, G. R., Hazebroucq, G., & Durieux, P. (2000). Effect of multifaceted intervention promoting early switch from intravenous to oral acetaminophen for postoperative pain: controlled, prospective, before and after study.[see comment]. *BMJ*. 321, pp. 1460-1463.

Robinson, M. B. (1995). Economic evaluation of quality assurance programmes. *Int.J Health Care Qual Assur*. 8, pp. 8-12.

Robinson, M. B., Thompson, E., & Black, N. A. (1998). Why is evaluation of the cost effectiveness of audit so difficult? The example of thrombolysis for suspected acute myocardial infarction. *Quality and Safety in Health Care* 7, pp. 19-26.

Roger, E. (1995). *Diffusion of Innovations*. New York Free Press, New York.

Ross-Degnan, D., Soumerai, S. B., Goel, P. K., Bates, J., Makhulo, J., Dondi, N., Sutoto, Adi, D., Ferraz-Tabor, L., & Hogan, R. (1996). The impact of face-to-face educational outreach on diarrhoea treatment in pharmacies. *Health Policy and Planning* 11, pp. 308-318.

Rosser, L. H., Jr. & Kleiner, B. H. (1995). Using management information systems to enhance health care quality assurance. [Review] [28 refs]. *Journal of Management in Medicine*. 9, pp. 27-36.

Roter, D., Rosenbaum, J., de Negri, B., Renaud, D., DiPrete-Brown, L., & Hernandez, O. (1998). The effects of a continuing medical education programme in interpersonal communication skills on doctor practice and patient satisfaction in Trinidad and Tobago. *Medical Education*. 32, pp. 181-189.

Rowlands, G., Sims, J., & Kerry, S. (2005). A lesson learnt: the importance of modelling in randomized controlled trials for complex interventions in primary care. *Family Practice* 22, pp. 132-139.

Ruangkanchanasetr, S. (1993). Laboratory investigation utilization in pediatric out-patient department Ramathibodi Hospital. *J.Med Assoc.Thai*. 76 Suppl 2:194-208., pp. 194-208.

Rycroft-Malone, J., Kitson, A., Harvey, G., McCormack, B., Seers, K., Titchen, A., & Estabrooks, C. (2002). Ingredients for change: revisiting a conceptual framework. *Quality and Safety in Health Care* 11, pp. 174-180.

Saizy-Callaert, S., Causse, R., Furhman, C., Le Paih, M. F., Thebault, A., & Chouaid, C. (2003). Impact of a multidisciplinary approach to the control of antibiotic prescription in a general hospital. *Journal of Hospital Infection*. 53, pp. 177-182.

Salazar-Lindo, E., Chea-Woo, E., Kohatsu, J., & Miranda, P. R. (1991). Evaluation of clinical management training programme for diarrhoea. *Journal of Diarrhoeal Diseases Research*. 9, pp. 227-234.

Sales, A. E. & Helfrich, C. D. (2006). Value in development of complex interventions. *Am J Manag.Care*. 12, pp. 253-254.

- Samb, B., Henzel, D., Daley, C. L., Mugusi, F., Niyongabo, T., Mlika-Cabanne, N., Kamanfu, G., Aubry, P., Mbagala, I., Larouze, B., & Murray, J. F. (1997). Methods for diagnosing tuberculosis among in-patients in eastern Africa whose sputum smears are negative. *Int.J.Tuberc.Lung Dis.* 1, pp. 25-30.
- Samb, B., Sow, P. S., Kony, S., Maynard-Badiane, M., Diouf, G., Cissokho, S., Ba, D., Sane, M., Klotz, F., Faye-Niang, M. A., Mboup, S., Ndoye, I., Delaporte, E., Hane, A. A., Samb, A., Coulaud, J. P., Coll-Seck, A. M., Larouze, B., & Murray, J. F. (1999). Risk factors for negative sputum acid-fast bacilli smears in pulmonary tuberculosis: results from Dakar, Senegal, a city with low HIV seroprevalence. *Int.J.Tuberc.Lung Dis.* 3, pp. 330-336.
- Sanghavi, D. M., Gilman, R. H., Lescano-Guevara, A. G., Checkley, W., Cabrera, L. Z., & Cardenas, V. (1998). Hyperendemic pulmonary tuberculosis in a Peruvian shantytown. *Am.J.Epidemiol.* 148, pp. 384-389.
- Sanson-Fisher, R. W. (2004). Diffusion of innovation theory for clinical change. *Med.J Aust.* 180, p. S55-S56.
- Santoso, B., Suryawati, S., & Prawaitasari, J. E. (1996). Small group intervention vs formal seminar for improving appropriate drug use.[erratum appears in Soc Sci Med 1996 Jul;43(1):I]. *Social Science & Medicine.* 42, pp. 1163-1168.
- Sauerborn, R., Nougara, A., & Diesfeld, H. J. (1989). Low utilization of community health workers: results from a household interview survey in Burkina Faso. *Soc Sci.Med* 29, pp. 1163-1174.
- Scally, G. & Donaldson, L. J. (1998). Looking forward: Clinical governance and the drive for quality improvement in the new NHS in England. *BMJ* 317, pp. 61-65.
- SCHARR (2004). <http://www.phru.nhs.uk/~casp/casp.htm>.
- Schultz, C. (2002). An audit of the management of asthma in an urban health centre in Yemen. *Primary Care Respiratory Journal* 11, pp. 52-53.
- Schwartz, R., Soumerai, S., & Avorn, J. (1999). physician motivation for non-specific drug prescribing. *Social Science & Medicine* 28, p. 577.
- Sculpher, M. (2000). Evaluating the cost-effectiveness of interventions designed to increase the utilization of evidence-based guidelines. *Family Practice* 17, p. S26-S31.
- Severens, J. L. (2003). Value for money of changing healthcare services? Economic evaluation of quality improvement. *Quality and Safety in Health Care* 12, pp. 366-371.
- Sevy Court, J., Pelaez, S. O., rteaga Yero, A. L., Armas, P. L., Borroto, G. S., & Gonzalez Ochoa, C. E. (2003). [Tuberculosis in Havana City, 1995-1999]. *Rev.Saude Publica* 37, pp. 326-332.
- Shea, S., DuMouchel, W., & Bahamonde, L. (1996). A meta-analysis of 16 randomized controlled trials to evaluate computer-based clinical reminder systems for preventive care in the ambulatory setting.[see comment]. *Journal of the American Medical Informatics Association.* 3, pp. 399-409.
- Sheldon, T. & Chalmers, I. (1994). The UK Cochrane Centre and the NHS Centre for reviews and dissemination: respective roles within the information systems strategy of the NHS R&D programme, coordination and principles underlying collaboration. *Health Econ.* 3, pp. 201-203.

Sheldon, T. A., Cullum, N., Dawson, D., Lankshear, A., Lawson, K., Watt, I., West, P., Wright, D., & Wright, J. (2004). What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. *BMJ* 329, p. 999.

Sherri, P., V, David, M. M., Jessica, B. J., & Jonathan, L. B. (2004). Design and Analysis of Group-Randomized Trials: A Review of Recent Practices. *American Journal of Public Health* 94, p. 393.

Shin, S., Furin, J., Bayona, J., Mate, K., Kim, J. Y., & Farmer, P. (2004). Community-based treatment of multidrug-resistant tuberculosis in Lima, Peru: 7 years of experience. *Social Science & Medicine* 59, pp. 1529-1539.

Siddiqi, K., Walley, J., Khan, M. A., Shah, K., & Safdar, N. (2006). Clinical guidelines to diagnose smear-negative pulmonary tuberculosis in Pakistan, a country with low-HIV prevalence. *Trop. Med Int Health*. 11, pp. 323-331.

Siddiqi, K., Walley, J., & Newell, J. (2006). Quality in TB control. *Int J Tuberc. Lung Dis*. 10, p. 354.

Siriwardena, A. N., Rashid, A., Johnson, M. R., & Dewey, M. E. (2002). Cluster randomised controlled trial of an educational outreach visit to improve influenza and pneumococcal immunisation rates in primary care.[see comment][erratum appears in Br J Gen Pract 2002 Oct;52(483):855]. *British Journal of General Practice*. 52, pp. 735-740.

Skinner, B. (1953). Science and human behaviour. Macmillan, New York.

Smith, J. B., Coleman, N. A., Fortney, J. A., Johnson, J. D.-G., Blumhagen, D. W., & Grey, T. W. (2000). The impact of traditional birth attendant training on delivery complications in Ghana. *Health Policy and Planning* 15, pp. 326-331.

Smith, W. R. (2000). Evidence for the Effectiveness of Techniques To Change Physician Behavior. *Chest* 118, pp. 8S-17.

Smits, P. B. A., Verbeek, J. H. A. M., & de Buissonje, C. D. (2002). Problem based learning in continuing medical education: a review of controlled evaluation studies. *BMJ* 324, pp. 153-156.

Solomon, D. H., Hashimoto, H., Daltroy, L., & Liang, M. H. (1998). Techniques to improve physicians' use of diagnostic tests: a new conceptual framework. *JAMA: The Journal of the American Medical Association* 280, pp. 2020-2027.

Soumerai, S. B. & Avorn, J. (1990). Principles of educational outreach ('academic detailing') to improve clinical decision making. *JAMA: The Journal of the American Medical Association* 263, pp. 549-556.

Steinberg, E. P. (2003). Improving the quality of care--can we practice what we preach? *The New England Journal of Medicine* 348, pp. 2681-2683.

Stocking, B. (1992). Promoting change in clinical care. *Quality in Health Care* 1, pp. 56-60.

Stone, E. G., Morton, S. C., Hulscher, M. E., Maglione, M. A., Roth, E. A., Grimshaw, J. M., Mittman, B. S., Rubenstein, L. V., Rubenstein, L. Z., & Shekelle, P. G. (2002). Interventions that increase use of adult immunization and cancer screening services: a meta-analysis. *Annals of Internal Medicine* 136, pp. 641-651.

- Strauss, A. & Corbin, J. (1990). *Basics of Qualitative Research: Grounded theory Procedures and Techniques*. Sage Publication, London.
- Suarez, P. G., Watt, C. J., Alarcon, E., Portocarrero, J., Zavala, D., Canales, R., Luelmo, F., Espinal, M. A., & Dye, C. (2001). The dynamics of tuberculosis in response to 10 years of intensive control effort in Peru. *J.Infect.Dis.* 184, pp. 473-478.
- Tessema, T. A., Bjune, G., Assefa, G., & Bjorvat, B. (2001). An evaluation of the diagnostic value of clinical and radiological manifestations in patients attending the addis ababa tuberculosis centre. *Scand.J.Infect.Dis.* 33, pp. 355-361.
- Thamlikitkul, V., Danchaivijitr, S., Kongpattanakul, S., & Ckokloikaew, S. (1998). Impact of an educational program on antibiotic use in a tertiary care hospital in a developing country. *Journal of Clinical Epidemiology.* 51, pp. 773-778.
- Thomas, A. (2006). Measures to improve detection of smear positive patients under programme.
- Thomson O'Brien, M. A., Freemantle, N., Oxman, A. D., Wolf, F., Davis, D. A., & Herrin, J. (2001). Continuing education meetings and workshops: effects on professional practice and health care outcomes.[comment]. [Review] [73 refs]. *Cochrane Database of Systematic Reviews.* p. CD003030.
- Thomson O'Brien, M. A., Oxman, A. D., Davis, D. A., Haynes, R. B., Freemantle, N., & Harvey, E. L. (2000a). Educational outreach visits: effects on professional practice and health care outcomes. [Review] [19 refs]. *Cochrane Database of Systematic Reviews.* p. CD000409.
- Thomson O'Brien, M. A., Oxman, A. D., Haynes, R. B., Davis, D. A., Freemantle, N., & Harvey, E. L. (2000b). Local opinion leaders: effects on professional practice and health care outcomes. [Review] [9 refs]. *Cochrane Database of Systematic Reviews.* p. CD000125.
- Thomson, R. (1998). Quality to the fore in health policy---at last. *BMJ* 317, pp. 95-96.
- Thomson, R., Lavender, M., & Madhok, R. (1995). Fortnightly Review: How to ensure that guidelines are effective. *BMJ* 311, pp. 237-242.
- Tu, K. & Davis, D. (2002). Can we alter physician behavior by educational methods? Lessons learned from studies of the management and follow-up of hypertension. [Review] [35 refs]. *Journal of Continuing Education in the Health Professions.* 22, pp. 11-22.
- Tumwikirize, W. A., Ekwaru, P. J., Mohammed, K., Ogwal-Okeng, J. W., & Aupont, O. (2004). Impact of a face-to-face educational intervention on improving the management of acute respiratory infections in private pharmacies and drug shops in Uganda. *East African Medical Journal.Suppl:*S25-32.
- Valdivia, M. (2002). Public health infrastructure and equity in the utilization of outpatient health care services in Peru. *Health Policy and Planning* 17, pp. 12-19.
- van Bokhoven, M. A., Kok, G., & van der Weijden, T. (2003). Designing a quality improvement intervention: a systematic approach. *Quality and Safety in Health Care* 12, pp. 215-220.
- Vandenbroucke, J. P. (2004). When are observational studies as credible as randomised trials? *The Lancet* 363, pp. 1728-1731.

Vos, J., Gumodoka, B., van Asten, H. A., Berege, Z. A., Dolmans, W. M., & Borgdorff, M. W. (1994). Changes in blood transfusion practices after the introduction of consensus guidelines in Mwanza region, Tanzania. *AIDS*. 8, pp. 1135-1140.

Wagaarachchi, P. T., Graham, W. J., Penney, G. C., McCaw-Binns, A., Yeboah, A. K., & Hall, M. H. (2001). Holding up a mirror: changing obstetric practice through criterion-based clinical audit in developing countries. *International Journal of Gynaecology & Obstetrics*. 74, pp. 119-130.

Walker, G. J., Ashley, D. E., & Hayes, R. J. (1988). The quality of care is related to death rates: hospital inpatient management of infants with acute gastroenteritis in Jamaica. *Am.J Public Health* 78, pp. 149-152.

Watson, M., Gunnell, D., Peters, T., Brookes, S., & Sharp, D. (2001). Guidelines and educational outreach visits from community pharmacists to improve prescribing in general practice: a randomised controlled trial. *Journal of Health Services & Research Policy*. 6, pp. 207-213.

Watson, M. C., Bond, C. M., Grimshaw, J. M., Mollison, J., Ludbrook, A., & Walker, A. E. (2002). Educational strategies to promote evidence-based community pharmacy practice: a cluster randomized controlled trial (RCT). *Family Practice*. 19, pp. 529-536.

Weeks, A. D., Alia, G., Ononge, S., Otolorin, E. O., & Mirembe, F. M. (2005). A criteria-based audit of the management of severe pre-eclampsia in Kampala, Uganda. *International Journal of Gynaecology & Obstetrics*. 91(3):292-7; discussion 283-4.

Weeks, A. D., Alia, G., Ononge, S., Mutungi, A., Otolorin, E. O., & Mirembe, F. M. (2003). Introducing criteria based audit into Ugandan maternity units. *BMJ* 327, pp. 1329-1331.

Wennberg, J. & Gittelsohn (1973). Small area variations in health care delivery. *Science* 182, pp. 1102-1108.

Wensing, M. & Grol, R. (1994). Single and combined strategies for implementing changes in primary care: a literature review. [Review] [100 refs]. *International Journal for Quality in Health Care*. 6, pp. 115-132.

Wensing, M., van der, W. T., & Grol, R. (1998). Implementing guidelines and innovations in general practice: which interventions are effective? *Br.J Gen.Pract.* 48, pp. 991-997.

Whitehead, D. (2001). A social cognitive model for health education/health promotion practice. *Journal of Advanced Nursing* 36, p. 417.

WHO (1980). United Nations/World Health Organization Meeting on Socio-Economic Determinants and Consequences of Mortality, Mexico City, 19-25 June 1979. *Popul.Bull.* pp. 60-74.

WHO (2003a). <http://www.paho.org>.

WHO (2003b). The World Health Report 2003 Shaping the future. WHO, Geneva.

WHO (2004). World Health Report 2004. WHO, Geneva.

WHO (2005a). Global Tuberculosis Control: Surveillance, Planning, Financing. WHO Report 2005. WHO, Geneva.

WHO (2005b). www.who.int.

- WHO (2006). International standards for tuberculosis care. *Wkly.Epidemiol.Rec.* 81, pp. 43-47.
- Wickstrom, G. & Bendix, T. (2000). The "Hawthorne effect"--what did the original Hawthorne studies actually show? *Scand.J Work Environ.Health* 26, pp. 363-367.
- Wilcke, J. T., Askgaard, D. S., Nybo, J. B., & Dossing, M. (1998). Radiographic spectrum of adult pulmonary tuberculosis in a developed country. *Respir.Med.* 92, pp. 493-497.
- Wilkinson, D. (1997). Reducing perinatal mortality in developing countries. *Health Policy & Planning.* 12, pp. 161-165.
- Wilkinson, D., De Cock, K. M., & Sturm, A. W. (1997). Diagnosing tuberculosis in a resource-poor setting: the value of a trial of antibiotics. *Trans.R.Soc.Trop.Med.Hyg.* 91, pp. 422-424.
- Wilkinson, D., Newman, W., Reid, A., Squire, S. B., Sturm, A. W., & Gilks, C. F. (2000). Trial-of-antibiotic algorithm for the diagnosis of tuberculosis in a district hospital in a developing country with high HIV prevalence. *Int.J.Tuberc.Lung Dis.* 4, pp. 513-518.
- Wilkinson, D. & Sturm, A. W. (1997). Diagnosing tuberculosis in a resource-poor setting: The value of sputum concentration. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 91, pp. 420-421.
- Williamson, K. B., Gunderman, R. B., Cohen, M. D., & Frank, M. S. (2004). Learning Theory in Radiology Education. *Radiology* 233, pp. 15-18.
- Wilson, D., Nachega, J., Morroni, C., Chaisson, R., & Maartens, G. (2006). Diagnosing smear-negative tuberculosis using case definitions and treatment response in HIV-infected adults. *Int J Tuberc.Lung Dis.* 10, pp. 31-38.
- Wise, J. (1998). WHO identifies 16 countries struggling to control tuberculosis. *BMJ* 316, p. 957.
- Yanagisawa, N., Takahashi, M., Namiki, M., Okajima, S., Ichinose, Y., & Toyama, K. (1996). [Study of erythrocyte sedimentation rate in patients with pulmonary tuberculosis]. *Kansenshogaku Zasshi* 70, pp. 955-962.
- Yin, R. (1994). *Case Study Research: Design and Methods.* second, SAGE Publications, Thousand Oaks.
- Zwar, N., Wolk, J., Gordon, J., Sanson-Fisher, R., & Kehoe, L. (1999). Influencing antibiotic prescribing in general practice: a trial of prescriber feedback and management guidelines. *Family Practice.* 16, pp. 495-500.
- Zwar, N. A., Wolk, J., Gordon, J. J., & Sanson-Fisher, R. W. (2000). Benzodiazepine prescribing by GP registrars. A trial of educational outreach. *Australian Family Physician.* 29, pp. 1104-1107.

Appendix 1

Search strategy for the literature review to determine the effectiveness of interventions to change clinical practice in developing countries

1. exp *education,continuing/
2. (education\$ adj2 (programme\$ or intervention? or meeting? or session? or strateg\$ or workshop? or visit?)).tw.
3. (behavio?r\$ adj2 intervention?).tw.
4. *pamphlets/
5. (leaflet? or booklet? or poster or posters).tw.
6. ((written or printed or oral) adj information).tw.
7. (information\$ adj2 campaign).tw.
8. (education\$ adj1 (method? or material?)).tw.
9. *advance directives/
10. outreach.tw.
11. ((opinion or education\$ or influential) adj1 leader?).tw.
12. facilitator?.tw.
13. academic detailing.tw.
14. consensus conference?.tw.
15. *guideline adherence/
16. practice guideline?.tw.
17. (guideline? adj2 (introduc\$ or issu\$ or impact or effect? or disseminat\$ or distribut\$)).tw.
18. ((effect? or impact or evaluat\$ or introduc\$ or compar\$) adj2 training programme\$).tw.
19. *reminder systems/
20. reminder?.tw.
21. (recall adj2 system\$).tw.
22. (prompter? or prompting).tw.
23. algorithm?.tw.
24. *feedback/ or feedback.tw.
25. (feedback adj1 (loop? or control? or regula\$ or mechanism? or inhib\$ or system?

or circuit? or sensory or visual or audio\$ or auditory)).tw.

26. 23 not 24

27. chart review\$.tw.

28. ((effect? or impact or records or chart?) adj2 audit).tw.

29. compliance.tw.

30. marketing.tw.

31. or/1-22,26-30

32. randomized controlled trial.pt.

33. controlled clinical trial.pt.

34. intervention studies/

35. experiment\$.tw.

36. (time adj series).tw.

37. (pre test or pretest or (posttest or post test)).tw.

38. random allocation/

39. impact.tw.

40. intervention?.tw.

41. chang\$.tw.

42. evaluation studies/

43. evaluat\$.tw.

44. effect?.tw.

45. comparative studies/

46. animal/

47. human/

48. 46 not 47

49. or/32-45

50. 49 not 48

51. (less-developed adj countr\$).mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]

52. (third-world adj countr\$).mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]

53. under-developed countr\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]

54. developing countr\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]

55. poor\$ countr\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]

56. less developed countr\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]

57. under developed countr\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]

58. less developed nation\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
59. third world nation\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
60. under developed nationand.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
61. developing nation\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
62. poor\$ nation\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
63. exp Developing Countries/
64. poor\$ econom\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
65. third world econom\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
66. developing econom\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
67. under developed econom\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
68. less developed econom\$.mp. [mp=ti, ab, sh, tn, ot, dm, mf, hw, rw]
69. or/51-68
70. (Afghanistan or Albania or Algeria or Andorra or Angola or Antigua or Barbuda or Argentina or Armenia or Azerbaijan or Bahamas or Bangladesh or Barbados or Belarus or Belize or Benin or Bhutan or Bolivia or Bosnia or Herzegovina or Botswana or Brazil or Bulgaria or Burkina or Faso or Burma or Burundi or Cambodia or Cameroon or Chad or Chile or China or Colombia or Comoros or Congo or Rica or Croatia or Cuba or Djibouti or Timor or Ecuador or Egypt or Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gambia or Georgia or Ghana or Guatemala or Guinea or Haiti or Honduras or India or Indonesia or Iran or Iraq or Kazakhstan or Kenya or Kiribati or Korea or Kyrgyzstan or Laos or Latvia or Lebanon or Lesotho or Liberia or Libya or Liechtenstein or Lithuania or Madagascar or Malawi or Malaysia or Maldives or Mali or Mauritania or Mauritius or Mexico or Micronesia or Moldova or Mongolia or Morocco or Mozambique or Myanmar or Namibia or Nauru or Nepal or Nicaragua or Niger or Nigeria or Pakistan or Palau or Panama or Papua or Paraguay or Peru or Philippines or Rwanda or Samoa or Senegal or Serbia or Montenegro or Sierra Leone or Slovakia or Slovenia or Solomon or Somalia or South Africa or Lanka or Sudan or Suriname or Swaziland or Syria or Taiwan or Tajikistan or Tanzania or Thailand or Togo or Tonga or Trinidad or Tobago or Tunisia or Turkmenistan or Tuvalu or Uganda or Ukraine or Uruguay or Uzbekistan or Vanuatu or Venezuela or Vietnam or Yemen or Zaire or Zambia or Zimbabwe).tw.
71. 69 or 70

72. *audit/ or audit.tw.

73. (31 or 72) and 50 and 71

74. remove duplicates from 73

Appendix 2

Some examples of how audit is understood in many health systems around the globe

Clinical audit, in developed countries usually mean an ongoing process to improve the quality of health care through the ongoing critical examination of current performance against agreed standards, leading to the identification and utilisation of opportunities for bringing practice closer to that standard.

A sentinel event or critical incident audit has been practiced in many developing countries especially in obstetrics care. Usually the sentinel event is either a maternal or peri-natal death. This audit usually entails examination of case notes, interviews with relevant health care professional and relevant family members. In developed countries this process has evolved into confidential enquiries into maternal and infant deaths.

Audit in some health systems is merely referred to an examination, review and verification of all financial accounts and dealings between health purchasers and providers.

In some countries it is referred as a performance management tool exercised by the ministry of health in a centralised fashion in order to monitor the performance according to indicators set by the government.

Appendix 3

INCO Project WP3- Qualitative interviews

First set of qualitative interviews will be conducted in Cochabamba during the months of March and April 2005. Currently eight health centres are involved in the audit cycle from various parts of the district. Two persons will be interviewed from each centre (sixteen interviews in total), one will be the member of the audit committee and other not a member of the committee but another health professional working in the health centre involved in care of "sintomaticos respiratorius". It is proposed that a minimum of four nurses should also be included among the people being interviewed.

Activities required

- A training session with the interviewer by Anna; Raul and Kamran 22-23rd of March 05
- A pilot interview session with the interviewer 24th of March 05
- To sort out the funding issue by 15th of April 05(Bolivia or Nuffield)
- To book time with the interviewees for the month of May 05 (2 hours each person). It would be appropriate to try to cover one health centre and to do two interviews in one day.
- Interviews to commence in May 05 and completed in mid June 05
- Interviewer will use the following interviewer's guide to conduct the interviews
- During the month of May and June, interviewer will have one-to-one weekly meetings with Anna to discuss any problems during the interview
- Interviewer will hand write the responses on separate sheets of paper if necessary
- After completing the interview, interviewer will write the responses in a word file specific for each interview.
- These files will then be translated in English (in Bolivia but cost paid by Nuffield) - June
- The English translation will be validated and checked by Anna and the interviewer End of June
- The translated files (electronic versions) will be sent to Nuffield where these will be analysed and the results of the analysis will be fed back and presented in the forthcoming international meeting in Bolivia.

Background Note for Interviewers

The purpose of this note is to help interviewer in conducting their interviews during the qualitative phase of WP3. Selection of interviewees and other details were already described above. This document will provide a structure for the interviews.

Purpose of the interviews

Clinical audit or cycle of quality improvement is a process in which the current performance of the health professionals is compared against agreed standards of high quality care. The results of this comparison are fed back to these professionals prompting them to develop an action plan for change. The measurements are repeated after sufficient interval and cycle of feeding back and action planning continues until optimal performance is reached. The main purpose of this survey is to establish factors that facilitate or impede improvement in professional performance following the introduction of clinical audit.

Who is to be interviewed?

Health professionals who are to be interviewed are either directly or indirectly involved in the implementation of clinical audit. Some interviewees are members of the audit committee, which means that they were directly involved in setting standards, receiving feedback and developing action plans and recommendations. Others would have been indirectly involved which means that they were working in the same health centre involved in the delivery of care. Their performance would have also been measured and fed back to them indirectly but they would not have taken a direct role in the audit committee in setting standards and developing action plan.

Both groups are likely to bring a different perspective to the interviews.

Type of interviews

Open and structured

These interviews are open in order to allow the interviewee to express their thoughts but also structured to keep the interviewee focused. The interview is divided into two sections. First section (questions A-D) asks general questions

about factors that help or inhibit improvement in the performance during audit cycle. The second section (questions E-H) asks more specific question relating to each standard and inquiring about the factors that helped or inhibited the achievement of these particular standards.

Separate sheets are attached with this guide and each one relates to one question. It is advised not to spend more than 10-15 minutes on each question. Each sheet provides the:

- ✚ Initial question
- ✚ Alternative question, if there is no (or inadequate) response to the initial questions
- ✚ High level or prompt questions once the discussion progresses or comes to a halt
- ✚ Kind of answers interviewers would be looking for
- ✚ Space for writing their response and highlighting salient issues raised in the discussion

Before starting the interview

- Introduce yourself
- Check that the interviewee has spared one and a half to two hours for the interview
- Check that interviewee is unlikely to be disturbed during the interview by other members of staff telephone calls etc.
- Explain the background and the purpose of the interview
 - You may say “I believe that you have been involved in the audit cycle project aiming to improving quality of health care to patients who are ‘sintomaticos respiratorious’
 - You can also say “Have you heard about the audit cycle project that your health centre has been involved with an aim to improve the quality of health care.....”
 - You may then say, “The purpose of these interviews is to find out the factors that may have helped improving quality during audit cycle and also other factors that may have inhibited the improvement process....”
- Explain the format of interview
 - You may say, “I am hoping that you would express your real opinions and thoughts about the process of audit cycle....”
 - You may also say, “I have structured the interview around 8 questions but if you feel that there is something important which is not covered please say so....”
 - You need to say, “the interview has two sections; first section ask general.....and the second section ask more specific....”
- Explain that the information will be kept confidential and the results of these interviews will be anonymous

- Make sure that the interviewee has understood the above two points
- If necessary repeat the background

During the interview

- Ask the question and check if the person has understood the question
- Ask alternative question or prompt questions as necessary
- First listen then write
- Write in the interviewee's own words in the response section but write your own assessment in the salient feature section
- If the interviewee is drifting away from the topic, please bring him back
- Ensure that you have explored enough using the high level and prompt question but never try to put words into the interviewee's mouth
- Try to be polite, sensitive and a good listener

After the interview (checklist)

- Make sure that you have completed the cover sheet with the basic information
- Make sure that all questions have been asked, explored and answered
- Make sure to say thank you to the interviewee
- Now try to put the written responses and the salient features in a word file specific to the interviewee

COVER SHEET

Basic details of the interviewee

✚ Name:-----

✚ Sex:----- Age:-----

✚ Health centre:-----

✚ Position in the health centre:-----

✚ Years in that post:-----

✚ Part of the audit committee-----

Question A:

Please say, "As you know that the aim of the clinical audit is to improve quality of care. This sometimes requires more resources, change in the system but also sometimes require changing the way we practice clinical medicine e.g. doing X-rays at a certain point or prescribing antibiotics or not etc."

Then ask, "During this audit process, what has helped you to change your clinical practice and what made it difficult?"

Alternatively you can ask, "What factors in the system helped you to adapt to the standards set by the audit committee and what made it difficult?"

Other prompt questions can be "what is in your working environment, other staff members, patients, resources, and system that will encourage you to adopt new standards and what will discourage you?"

You will be expecting to hear the following replies

- ⬇ "Only if the resources are made available..."
- ⬇ "If senior professionals change then it will help us to change ..."
- ⬇ "If the change is rewarded, we will adopt readily..."

Please write the **response** below (use additional sheet if necessary)

Please provide a list of **salient issues** highlighted in the above response

↓ -----

↓ -----

↓ -----

↓ -----

↓ -----

Question B:

Please say, "Politics at all levels (national, with in the health service or in our local work place) may affect the way we work"

Then ask, "During the implementation of audit cycle, what influence does politics (at different levels) play in helping or hindering in improving quality of care?"

Alternatively you can ask, "Do you think politics, whether it is of national or local level makes it difficult or easy for you to improve care? How?"

Other prompt questions can be "What is it about politics that help you to improve quality or stop you from improvement? Does national politics has any thing to do with your clinical practice. Does politics in the health service effects change in you practice? How does the local politics in your health centre influence improvement in working practice"

You will be expecting to hear the following replies

- ⬇ "Political appointments make it difficult..."
- ⬇ "Constant changes in the system do not help..."
- ⬇ "Political allegiances often play a part..."

Please write the **response** below (use additional sheet if necessary)

Please provide a list of **salient issues** highlighted in the above response

↓ -----

↓ -----

↓ -----

↓ -----

↓ -----

Question C:

Please say, "Health care is delivered more effectively by team work between health professionals. Similarly, team work may also be important to improve quality of care"

Then ask, "Do you think that during the process of audit cycle teams are important to bring improvement? What kind of team work will help you or make it difficult for you to bring improvement?"

Alternatively, you can ask, "We work together as a team to improve health care in audit cycle process. What are the characteristics of a team that will assist improvement and what will make it difficult?"

Other prompt questions can be "When you are working together with other doctors and nurses, what help would you expect from them as a team that will facilitate improvement. What sort of problems your colleagues can create that will make it difficult to bring improvement"

You will be expecting to hear the following replies

- ⬇ "It will help if whole team work together..."
- ⬇ "Some colleagues make it very difficult because..."
- ⬇ "Clear roles and responsibility will help..."

Please write the **response** below (use additional sheet if necessary)

Please provide a list of **salient issues** highlighted in the above response

↓

↓

↓

↓

↓

Question D:

Please say, "A good leader can help in bringing improvement in the system and a bad leader can make it very difficult for individuals to bring improvement"

Then ask, "In your opinion, what makes a good leader that facilitates improvement in the system during audit cycle and what makes a bad leader that will block any efforts for improvement".

Alternatively, you can ask, "If you are the leader of your organisation (health facility) how will you ensure that individuals are facilitated in improving the quality of care and what will you avoid."

Other prompt questions can be "What can your boss (chief) do to help you in bringing improvement? What does your boss (chief) do that makes it difficult for you to bring improvement?"

You will be expecting to hear the following replies

- "My boss has a blaming attitude which....."
- "A leader who encourages creativity....."
- "I will make sure that resources are available to support change....."

Please write the **response** below (use additional sheet if necessary)

Please provide a list of **salient issues** highlighted in the above response

↓ -----

↓ -----

↓ -----

↓ -----

↓ -----

Question E

This question relate to Standard 1 of the audit cycle, which is “.....”

What things helped you to achieve this standard in your centre and what things made it difficult for you to achieve this standard?

Please write the **response** below (use additional sheet if necessary)

Please provide a list of **salient issues** highlighted in the above response

↓ -----

↓ -----

↓ -----

↓ -----



Question F

This question relate to Standard 2 of the audit cycle, which is “.....”

What things helped you to achieve this standard in your centre and what things made it difficult for you to achieve this standard?

Please write the **response** below (use additional sheet if necessary)

Please provide a list of **salient issues** highlighted in the above response

- ↓ -----
- ↓ -----
- ↓ -----
- ↓ -----



Question G

This question relate to Standard 3 of the audit cycle, which is “.....”

What things helped you to achieve this standard in your centre and what things made it difficult for you to achieve this standard?

Please write the **response** below (use additional sheet if necessary)



Please provide a list of **salient issues** highlighted in the above response

↓

↓

↓

↓

↓

Question H

This question relate to Standard 4 of the audit cycle, which is “.....”

What things helped you to achieve this standard in your centre and what things made it difficult for you to achieve this standard?

Please write the **response** below (use additional sheet if necessary)

Please provide a list of **salient issues** highlighted in the above response

↓ -----

↓ -----

↓ -----

↓ -----

↓ -----