

**Integrating the prevention and management of type 2 diabetes
in real world settings.**

**Thesis submitted for the degree of Doctor of Philosophy by published
work**

The University of Sheffield

ScHARR

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March 2013

Acknowledgements

I would like to thank my academic advisor Professor Elizabeth (Liddy) Goyder for her support and advice in carrying out this work. Liddy has been an inspirational person for me over the last nine years, encouraging me to evolve and develop my skills and knowledge. She has thoroughly supported my ambition to carry out a PhD. She has been there for me at difficult times in my life, never losing faith in my capabilities.

Professor Alicia O’Cathain has also supported my ambition to carry out a PhD, and has provided advice and support throughout my research career. Alicia has been the crucial link between those of us that are carrying out a PhD by publication at SchARR.

I would also like to thank the co-authors of the papers that are included in this work. I enjoyed working and collaborating with the study teams and learned so much from them.

Many thanks to Dr. Jackie Goode and Dr. Emma Knowles, who have trodden this path before me, and have given me the benefit of their experiences, as well as continued support. Ongoing support has also been provided by my colleagues in SchARR.

My family have been behind me on this journey, and I would like to thank them for listening to me patiently, and probably wondering when all this was going to end!

Howard, my partner, has taken an interest in my work and my writing, encouraging me to take time to think. Howard has offered interesting ideas and perspectives, and has been my inspiration as a person, showing me that worrying is pointless. Thank you so much Howard.

Abstract

Despite a vast amount of epidemiological data documenting the 'epidemic' of type 2 diabetes and extensive randomised controlled trials evidence of effective interventions, there is a contrast between this wealth of quantitative research and the relatively underdeveloped qualitative understanding of how type 2 diabetes impacts upon patients and health care professionals. We therefore seem no closer to understanding how to effectively tackle the massive burden this represents for both patients and the health service.

The publications discussed here represent a body of work consisting of five first author publications (2005-2012) that explore interventions and patient and health professional perspectives regarding the prevention of and care management for type 2 diabetes.

Two main methods are used in the studies represented by the papers. These are primary qualitative research (three publications) and evidence synthesis (two publications) for public health guidance. The qualitative methods used in two primary studies and one evidence synthesis allow the perspectives of service users and professionals to be assessed in relation to public health interventions and health care. The remaining evidence synthesis examines how large scale diabetes prevention interventions can be tailored for use in the community.

A major theme that links the publications is transferability of care management and prevention ideals to life in the real world. The Chronic Care Model (CCM) provides an optimum framework for such adaptations. However, whilst NHS policies and the CCM focus on patient engagement, it is clear that much needs to be done in recognising and addressing the feasibility of prevention and care strategies in practice.

The thesis discusses how disparities between idealism and the 'life world' of patients might be addressed, adding to current debates about shared understanding and the importance of taking into account behavioural influences that might undermine or enhance the achievement of shared goals.

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Abbreviations

BME	Black and Minority Ethnic
BMI	Body Mass Index (kg / m ²)
CCM	Chronic Care Model
CHD	Coronary Heart Disease
DPP	Diabetes Prevention Program
DPS	Diabetes Prevention Study
EPP	Expert Patient Programme
EPPI-Centre	Evidence for Policy and Practice Information and Co-ordinating Centre
GP	General Practitioner
GPwSI	General practitioners with a special interest
HbA _{1c}	Glycosylated haemoglobin
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
IT	Information Technology
MSc	Masters in Science
LCHW	Lay Community Health Worker
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence
PDG	Programme Development Group
PCT	Primary Care Trust
PHCC	Public Health Collaborating Centre
QOF	Quality Outcomes Framework
RCT	Randomised Controlled Trial
YMCA	Young Men's Christian Association

1. Introduction

This thesis charts the culmination of published work representing nine years of experience in the field of public health research. Whilst I have carried out research in other topic areas, the majority of my peer reviewed publications as well as reports have explored ways of reducing the burden of type 2 diabetes.

The contribution of this work lies in furthering understanding of the importance of a model for diabetes prevention and health promotion activities that integrates the needs of patients with the ideals of providers. The Chronic Care Model (CCM) (Wagner 1996) provides a framework for integrative care which can also be utilised for prevention (Glasgow *et al* 2001). The work here critically discusses both diabetes care delivery and prevention within the CCM framework. Primary and secondary research methods that were utilised are presented in relation to their methodology as well as their usefulness for addressing the research aims.

All included publications have been peer-reviewed and are in the public domain through medical, nursing and public health journals. In addition to the papers included here, further related work has been incorporated into NICE guidance on prevention of type 2 diabetes which can be found on the NICE website:
<http://guidance.nice.org.uk/PH35>.

Section 2 provides a brief overview of my career path and interest in health services research, and in particular, type 2 diabetes and qualitative methods.

In section 3, I introduce the public health and policy background for my research and why this can have significant impact for individual patients as well as for population health.

In section 4, I present the five included published works in chronological order, along with their associated methods and my role in the studies. I highlight the impact that the publications have had on clinical and research practices.

Section 5 presents a critical appraisal of my body of work in the context of the CCM and broader literature.

Section 6 is a discussion of the main issues arising from the work as well as limitations of the papers and the thesis.

I reflect on the potential impact that my professional background may have had on the work in section 7.

In section 8, I conclude the thesis and highlight aspects of research and practice that could be explored following the findings from this thesis.

2. Background

I have a nursing background and came to research relatively late in my career path. My clinical experience provided me with communication skills and an understanding of health care issues that have contributed to my research practice with patients and clinicians. Research was an important element of the BSc Psychology curriculum and my interest in qualitative methods has continued throughout my time at SchARR where I completed the MSc in Health Service Research.

The majority of my research studies have been in the field of type 2 diabetes, however I have also worked on projects in the field of emergency care and on public health reviews relating to the prevention of alcohol misuse, weight management in pregnancy, and walking and cycling interventions. In the research environment one often has to work within a range of topic areas according to successful funding.

The NICE Public Health Collaborating Centre (PHCC) was developed at SchARR in 2008 as a result of a grant from the National Institute of Health and Clinical Excellence (NICE). I joined the PHCC as a reviewer with the brief to produce a specified number of reviews to inform public health guidance. From this work I began have gained knowledge and skills in evidence synthesis.

Table 1: Published works and associated studies

Article	Related study and Funding source	Setting and population	Sample	Research methods	Duration of study
<p>Changing roles, changing responsibilities and changing relationships: an exploration of the impact of a new model for delivering integrated diabetes care in general practice. <i>Quality in Primary Care</i> 2005 13: 85-90</p>	<p>Evaluation of Specialist support for Diabetes Care Services (SSDCS) pilot.</p> <p>Sheffield Health and Social Care Research Consortium.</p>	<p>Range of Diabetes Specialists employed in Sheffield based Hospital Clinics.</p> <p>General Practitioners.</p>	<p>Consultants (n=6)</p> <p>General Practitioners (n=6)</p> <p>Diabetes Specialist Nurses (n=3)</p>	<p>Semi-structured face-to-face interviews</p>	<p>June 2003 – September 2003</p>
<p>Meeting the educational needs of people at risk of diabetes-related amputation: a vignette study with patients and professionals. <i>Health Expectations</i> 2005 8: 324-333</p> <p>Patient and professional perspectives on</p>	<p>Barriers to effective foot-care in people with Type 2 Diabetes.</p> <p>DH Public Health Career Scientist Award.</p> <p>Sheffield Health and Social Care Research Consortium.</p>	<p>Diabetes Specialists employed in Sheffield based Hospital Clinics.</p> <p>General Practitioners and Practice nurses employed in primary care practices.</p> <p>Patients with type 2 diabetes related foot complications.</p>	<p>Consultant Diabetologists (n=2)</p> <p>Vascular surgeons (n=1)</p> <p>General Practitioners (n=2)</p> <p>Nurses (n=3)</p> <p>Podiatrists (n=3)</p> <p>Orthotists (n=3)</p> <p>Dieticians (n=1)</p>	<p>Semi-structured face-to-face interviews using a vignette technique.</p>	<p>September 2003 – April 2004</p>

prescribed therapeutic footwear for people with diabetes: A vignette study. <i>Patient Education and Counseling</i> 2006; 64: 167-172			Patients (n=15)		
What are the barriers to primary prevention of type 2 diabetes in black and minority ethnic groups in the UK? A qualitative evidence synthesis. <i>Diabetes Research and Clinical Practice</i> 2011; 93: 150-158	Public Health Collaborating Centre (PHCC) evidence reviews to inform NICE public health guidance. National Institute for Health and Clinical effectiveness (NICE).	Papers that assessed the barriers and facilitators to implementing community level lifestyle interventions for black and minority ethnic groups in the UK.	Number of included papers = 13 Total number of participants across studies = > 898 (not reported in one study)	Evidence synthesis of studies using qualitative methods.	September 2009 – July 2010
Can diabetes prevention programs be translated effectively into real world settings and still deliver improved outcomes? A synthesis of evidence” <i>Diabetic Medicine</i> 2013; 30: 1	Public Health Collaborating Centre (PHCC) evidence reviews to inform NICE public health guidance. National Institute for Health and Clinical effectiveness (NICE).	Papers that compared community based diabetes prevention programme content and outcomes to those from major prevention trials.	Number of included papers = 19 (17 studies).	Evidence synthesis of studies.	September 2010 – July 2011

3. Type 2 Diabetes and the Chronic Care Model

3.1 The extent of the problem: Type 2 diabetes

It is estimated that 2.9 million people in the UK are diagnosed with diabetes, with around 90% of these diagnosed with type 2 diabetes. According to QOF statistics, the average prevalence of type 2 diabetes across the UK is 4.45% (Diabetes UK 2011). Many more people are likely undiagnosed, and incidence is increasing due to changes in lifestyle. Prevalence is increasing due to higher incidence rates as well as better survival. Having type 2 diabetes increases the chances of cardiovascular disease and its associated mortality (Alberti *et al* 2007). Diabetes can also lead to complications such as neuropathy, nephropathy and retinopathy, which impact on quality of life. Five percent of health care costs in the UK are attributable to diabetes and medication alone takes up 7% of the NHS drugs budget (Waugh *et al* 2007).

3.2 Risk factors

Individual risk for type 2 diabetes is associated with raised BMI (particularly above 30 kg / m²) and / or waist circumference (over 80cm in woman and 94cm in men) and increasing age. Type 2 diabetes is also associated with raised blood pressure and serum cholesterol. Risk is higher in those with a familial history of type 2 diabetes, and certain groups such as African-Caribbean, Black African and South Asian are at increased risk, possibly due to higher rates of obesity and lower physical activity levels. In the UK, the Bangladeshi / Pakistani population prevalence is the highest, at 8.9 per 100 compared with 1.7 in Whites. African-Caribbean prevalence is 5.3 and Indian or African Asian is 4.7 per 100 (Oldroyd *et al* 2005). It is therefore potentially possible, through changing modifiable factors such as BMI, to prevent diabetes and its precursors.

3.3 Prevention of diabetes-related complications

The aims of care management for people who live with type 2 diabetes include reducing the risk of complications such as retinopathy, nephropathy, neuropathy, renal disease and coronary heart disease. A relatively recent rise in global prevalence of type 2 diabetes has created an impetus for research into prevention of complications in order to limit financial and health related costs for the future.

This has included long term assessment of intensive therapies, mainly pharmacological. Much of this research has been carried out in the UK as part of the 20 year UKPDS trial. One of the many findings from the trial was that tight control of HbA_{1c} levels can delay complications (Stratton *et al* 2000). A large body of research has since been published that assesses clinical management of diabetes, including optimum medication regimes and the encouragement of adherence. However the mainstay of diabetes management (with or without the use of medication regimes) is to encourage maintenance of optimum lifestyle behaviours to limit the elevation of blood glucose levels.

3.4 Prevention of type 2 diabetes

Prevention of type 2 diabetes also requires modification of lifestyle behaviours and as such shares some similarities with the aims of care management (Glasgow *et al* 2001). Strategies for prevention have been trialled in a number of studies worldwide, most notably the Diabetes Prevention Program (DPP) in the US (DPPRG 2002), and the Diabetes Prevention Study (DPS) in Finland (Lindstrom *et al* 2003). The US trial had a larger sample than the DPS, with both using a protocol based on behavioural change in diet, physical activity, and management of weight, delivered over a set period of time by experienced personnel. Risk reduction for diabetes in the intervention arm of the DPP was 58%, compared with the control arm. Mean weight loss was 5.6kg compared to 0.2kg in the controls at 2.8 years follow-up (DPPRG 2002). The DPP and DPS trials included only those at high risk of diabetes, i.e. having Impaired Glucose Tolerance (IGT), and there has been speculation as to whether targeting should be broader, for example at population level (Simmons *et al* 2006).

3.5 The Chronic Care Model

3.5.1 History and development of the CCM

In 1996, Edward Wagner reflected on the care that was being delivered in the US for people with chronic illness such as type 2 diabetes (Wagner *et al* 1996). Care was often fragmented and based on treating individuals rather than based on an integrated system with a shared goal. He envisaged a model that started with an established evidence base (guidelines) from which care could be planned for specific groups of people. The model also necessitated the re-design of general practices to utilise the

range of available roles so that a structured appointment system could be set up and patients followed up at regular intervals.

The model required that patients receive education and behavioural interventions to enable them to manage their own condition, provided by experts with access to decision support from which they could assist in chronic disease management where necessary. Information in the form of outcomes would be gathered and used for monitoring purposes so that progress could be fed back to the patient.

The main message was that care for chronic illness is different from that of acute conditions in its continuous interactions over time, and also in its aims. Such care could be improved if practitioners across the country and globally delivered structured, evidence based care and support, monitoring self-management efforts of patients and encouraging regular assessments.

The initial model was used to inform diabetes improvement within a co-operative care scheme in the US, with positive results. A revised version was named the Chronic Care Model following a series of expert reviews (Wagner *et al* 1999).

3.5.2 Elements of the CCM

The Chronic Care Model (CCM) consists of six elements that are recognised as important factors in the successful chronic care and prevention management (Wagner *et al* 1999). These are:

1. An overall health care organization that is linked with the community. This includes effective leadership, as well as incentives and resources to implement quality care for chronic illness.
2. The care organisation supports the delivery system which is designed such that practice members with a range of roles work together for the shared goal of quality integrated care. Physician care might be delegated to nurses, and innovative ways of managing care such as group sessions might be used.
3. Clinical information systems support the management of patient information, such as a registry of patients with the same chronic illness. This is particularly important for population-based programmes. Information systems can be used

to alert practitioners to the results of important elements of care, or to contact people that might require specific attention as well as creating appointment reminders.

4. Systematic decision support assists practitioners in their clinical decision-making and informs them of new therapies. Evidence based protocols and guidelines, as well as advice from specialists can be accessed.
5. Support for patient self-management is enhanced by a collaborative approach between patient and practitioner and comprises psychosocial support for the patient and carer as well as identification of goals and problem solving.
6. Links to available community resources can provide access to resources not generally available within the health system.

Wagner *et al* (2001) also proposed that productive interactions be developed between informed and active patients (and their carers) with resourced and expert healthcare providers. This is facilitated by implementation of the six elements as well as time to facilitate quality management through care plans that reflect a patient-centred approach.

3.5.3 Transferability of the CCM to the UK health system

The majority of CCM literature comes from the US, where health system funding differs from that of the UK. However, there are similarities in that diabetes is managed and prevented using the same general principles, whatever the setting. Whilst the detail of policy and health care delivery may vary across different populations, the common factor is that the system needs to be organised, integrated, linked with other systems and resources, and in line with patient and provider requirements.

Elements of the CCM are evident within UK policies and system delivery, as discussed in the thesis. The development of chronic care clinics in UK general practice was cited by Wagner *et al* (2001) as an example of the type of primary care re-organisation that is outlined in the CCM. This thesis highlights how the CCM principles can be applied within the UK and elsewhere, as well as some of the barriers to its application.

3.5.4 How the CCM relates to the included publications

Table 2 presents each element of the Chronic Care Model and its relevance to the context and findings of the five publications discussed in this thesis. The table shows that, in addition to chronic disease management, the elements are relevant to the prevention of chronic illness.

Table 2: Elements of the Chronic Care Model as they relate to the included articles

CCM Elements	Management of Type 2 Diabetes	Prevention of Type 2 Diabetes
An overall health care organization that is linked with the community	<p>Publication 1 NHS policies have encouraged community care. Secondary care personnel support staff in primary care. Leadership in primary care.</p> <p>Publication 2 Policies for improved care and self-management for T2DM.</p>	<p>Publication 4 Prevention in hard to reach groups requires policies that encourage and fund culturally sensitive interventions.</p> <p>Publication 5 Population prevention requires organisation to support delivery in community settings.</p>
A re-designed delivery system	<p>Publication 1 Professional roles and the system of care delivery have been adapted for delivery in primary care.</p> <p>Publication 2 Improved education for patients requires continuous systematic delivery, wherever the setting.</p>	<p>Publication 4 Interventions and facilities for T2DM prevention need to be accessible (physically, socially and financially) to the target group.</p> <p>Publication 5 Interventions delivered in primary care require a system that can identify patients at risk, deliver theoretically based interventions and monitor progress.</p>
Clinical information systems	<p>Publication 1 Optimal information</p>	<p>Publication 4 Communication between</p>

	<p>systems are required for sharing information across traditional boundaries.</p> <p>Publication 2</p> <p>Clinical information systems are required to register and follow up patients.</p>	<p>geographically distant teams would benefit from improved information systems.</p> <p>Publication 5</p> <p>Clinical information systems can be used to deliver preventive interventions directly to service users and support attendance.</p>
Systematic decision support	<p>Publication 1</p> <p>Evidence based clinical information is required for primary care teams to provide specialist care.</p> <p>Publication 2</p> <p>There is a need for consistency of clinical information in primary care.</p>	<p>Publication 4</p> <p>Health professionals require decision support for screening and prescribing interventions.</p> <p>Publication 5</p> <p>Prevention in primary care requires decision support for identifying at risk individuals and designing interventions.</p>
Support for patient self-management	<p>Publication 1</p> <p>The scheme aims to better support self-management in the community.</p> <p>Publication 2</p> <p>Self-management support can impact on the risk of complications.</p> <p>Publication 3</p> <p>Shared decision making can encourage the acceptability of an intervention.</p>	<p>Publication 4</p> <p>Advice and motivation support is required to maintain intervention goals.</p> <p>Publication 5</p> <p>Interventions that best support patients in prevention trials provide motivational strategies to achieve and maintain goals.</p>
Links to available community resources	<p>Publication 2</p> <p>Community resources such as chiropody clinics can be used where there</p>	<p>Publication 4</p> <p>Community resources such as gyms and swimming pools can</p>

	<p>are gaps in NHS provision.</p> <p>Publication 3</p> <p>Suggesting commonly available footwear styles that patients can access easily can increase acceptance.</p>	<p>provide access to culturally sensitive activities.</p> <p>Publication 5</p> <p>Prevention strategies can use community facilities such as churches to best reach the target populations,</p>
<p>Productive interactions between informed and active patients and resourced and expert healthcare providers</p>	<p>Publication 1</p> <p>The scheme aimed to increase productive interactions between service users and increasingly expert providers in local areas.</p> <p>Publication 2</p> <p>Interactions that are not productive are a barrier to patient education and self-management.</p> <p>Publication 3</p> <p>Concordance; empowering patients to become involved in product suggestions and design.</p>	<p>Publication 4</p> <p>Productive interactions and informed patients require that providers understand the diverse requirements of service users.</p> <p>Publication 5</p> <p>Tailored interventions require that service users discuss their preferences with trained intervention providers such as nurses, dieticians and fitness experts.</p>

3.6 Contribution of this body of work

The work presented here presents my contribution to the body of research relating to disease management and prevention of type 2 diabetes in the context of the Chronic Care Model as well as critical assessments of intervention implementation. In doing so it addresses the main elements of the Chronic Care Model and extends the knowledge base through my findings, particularly in relation to how self management aims and productive interactions between patients and providers might be a challenge in reality. It provides a detailed synthesis of how diabetes care and prevention might move from a generalised evidence base toward the more idiosyncratic requirements of the target population.

The work draws on primary qualitative research methods as well as evidence synthesis, both of which are evolving to better address the issues of external validity in designing public health interventions. The combined impact of the work has been to inform health care practice, public health guidance, health care research and health care training. For a summary of the characteristics of the studies represented in the publications, see Table 1 on pages 10 and 11.

4. Summaries of included publications and related studies.

The following lists the included publications together with a summary of the studies from which they derive. It needs to be stated here that this is not an exhaustive list of my first author publications, nor are these my only publications in the field of type 2 diabetes. One publication that assessed the impact of diabetes service delivery change on patient experiences (Johnson *et al* 2006) was omitted from this thesis due to its association with my MSc dissertation.

4.1 Publications

Publication 1: Johnson M., Goyder E. Changing roles, changing responsibilities and changing relationships: an exploration of the impact of a new model for delivering integrated diabetes care in general practice. *Quality in Primary Care* 2005 13: 85-90

The 'shared care' concept was developed, through DH policies, to provide diabetes care on a broader, more community based scale and to reduce the rising demand in secondary care. The delivery system as well as the roles of those working within it therefore needed to adapt so that expert and organised diabetes care could be accessed in primary care.

The publication is based on an evaluation of a local shared diabetes care pilot scheme. The main aim was to explore the experiences of practitioners in implementing the pilot and to assess whether the scheme might be worth rolling out to other practices. The scheme involved identifying patients that were receiving their routine care in hospital clinics, and might be suitable for general practice based care. General practitioners and practice nurses were supported in the expansion of their roles by consultants and diabetes specialist nurses through regular meetings. Practices that were involved had at least one general practitioner with a special interest in diabetes, as well as a support from a particular team of specialists (consultant and nurse) at the hospital.

I found that teams had to be formed between secondary care and primary care practitioners, and that traditional professional boundaries had to be negotiated in order to facilitate collaboration. In primary care, teams were required to expand their roles, expertise and skills to provide routine care for patients with diabetes.

Publication 2: Johnson M., Newton P., Jiwa M., Goyder E. Meeting the educational needs of people at risk of diabetes-related amputation: a vignette study with patients and professionals. *Health Expectations* 2005 8: 324-333

and:

Publication 3: Johnson M., Newton P., Goyder E. Patient and professional perspectives on prescribed therapeutic footwear for people with diabetes: A vignette study. *Patient Education and Counseling* 2006; 64: 167- 172

The study aimed specifically to identify the care needs of people with diabetes-related foot complications. I used a vignette approach to elicit views from patients and professionals, comparing the issues voiced by the two groups. A number of professionals representing a range of roles were interviewed based in both primary care and hospital based clinics. Patients were contacted from different geographical areas in Sheffield to ensure that views from a diverse population were represented, although only one non-white participant agreed to participate. There is often a mismatch between trying to be inclusive during recruitment, and actually achieving a range of views that includes diverse populations. All the patients had long standing type 2 diabetes and were recruited from the foot clinic at two local hospitals.

There was a copious amount of data collected from this study. The two published papers report on separate issues that were pertinent to the interviewees. One was the giving and receiving of health education, a vital component for self-management. The second main issue was patient and provider experiences around the prescribed use of special shoes for the diabetic foot.

Publication 4: Maxine Johnson, Emma Everson-Hock, Roy Jones, Helen Buckley Woods, Nick Payne, Elizabeth Goyder. What are the barriers to primary prevention of type 2 diabetes in black and minority ethnic groups in the UK? A qualitative evidence synthesis. *Diabetes Research and Clinical Practice* 2011; 93: 150-158

This paper was based on a review I carried out with the ScHARR Public Health Collaborating Centre. Findings were used in the development of Public Health Guidance by the National Institute of Health and Clinical Excellence (NICE 2011). Community interventions that aimed to prevent type 2 diabetes were assessed, with a particular focus on people from black and ethnic minority groups.

For this programme, I carried out a mapping review to scope the literature and found only a small amount of potential effectiveness evidence that fitted the inclusion criteria. Previous systematic reviews had also found scarce effectiveness evidence. This highlights the point made by Glasgow *et al* (2003) pertaining to the research practice gap and the need for evaluations of interventions that are appropriate to the target population. There was slightly more evidence relating to low socio-economic groups, which was synthesised in a separate report. In Black and Minority Ethnic (BME) groups, a reasonable amount of evidence was available relating to barriers and facilitators to implementation, which I synthesised with a focus on applicability to the UK setting.

Publication 5: Maxine Johnson, Roy Jones, Crystal Freeman, Helen Buckley Woods, Michael Gillett, Nick Payne, Elizabeth Goyder. Can diabetes prevention programs be translated effectively into real world settings and still deliver improved outcomes? A synthesis of evidence. *Diabetic Medicine* 2013; 30: 1.

The second piece of NICE guidance relating to prevention of type 2 diabetes in individuals (NICE 2012) included four reviews that were carried out by the Public Health Collaborating Centre (PHCC) team. This paper represents the third of such reviews, examining the transferability of large diabetes prevention trials such as the Diabetes Prevention Program (DPP) in the US and the Diabetes Prevention Study (DPS) in Finland into community settings such as general practice.

The review included papers that reported prevention strategies in community (or 'real world') settings using a protocol based on one of the major trials. The intervention was to prevent type 2 diabetes in those already identified as at risk using a range of parameters such as BMI, blood glucose level, or high diabetes risk score using a recognised tool.

The paper describes the necessary modifications in delivering prevention strategies with limited resources, such as group educational classes rather than individual sessions. It also combines the findings to highlight the potential benefits of modified strategies as well as the reported limitations.

4.2 My role and contribution to carrying out the studies and writing the publications

Work that led up to writing the papers was shared with team members, particularly in terms of reviews carried out for publication 4 and publication 5, where an information specialist and two reviewers necessarily contributed to carrying out the initial work. For the publications I conceptualised initial ideas and wrote the first draft of all five papers, following discussions with co-authors regarding appropriate target journals. I continued to re-draft the articles, integrating the contributions of co-authors. I facilitated the article submission process, with input from co-authors, through to final publication. Therefore I estimate that my contribution to writing all five publications was 90%.

This section provides a detailed account of this contribution as well as the impact that the studies and publications have had in practice.

4.2.1 Primary research

For the first study (Publication 1) I attended meetings with those involved in initiating the pilot study to learn about the aims and progress of the programme. Along with the study Principle Investigator (PI) I designed the study, developing a topic guide and a strategy for accessing potential interviewees. This mainly involved contacting one diabetes specialist nurse for contacts at the hospitals as well as lead general practitioners that were participating in the pilot to request their participation. The GPs were instrumental in helping to recruit other members of their team such as practice nurses. I carried out all the interviews and analysed the data along with the PI of the study. I presented findings from the study to team members to obtain their feedback points.

For the study presented in publications 2 and 3, service user interviewees had long-standing diabetes-related foot complications and were attending the foot clinic at one of the major hospitals. A vignette approach was chosen to allow service users to comment about a story without having necessarily to relate to their own experiences. Practitioners with experience of caring for service users at foot clinics or in the community were interviewed using the same vignette so that responses could be compared.

I led in designing the vignette, which portrayed a character with type 2 diabetes and his trajectory from diagnosis to developing a lesion on his foot. To ensure that the story reflected typical behaviour I also consulted literature about people with diabetes and presented initial drafts of the to a panel of diabetes care professionals and a lay person with diabetes, making several edits before finalising.

Vignette interviewing differs from traditional interviews in that the scenario entices the participant to consider what is going on in the story and to respond to it. In this way, actions themselves are not presented, but knowledge and beliefs are:

“By projecting situations onto hypothetical characters and asking the interviewee to put themselves in the protagonist’s shoes, sensitive data...can be obtained in an indirect, non-confrontational manner” (Jenkins et al 2010a p. 9).

Jenkins *et al* (2010a) highlight an example where the interviewee uses his own experience to fill in what could happen in the story (for example the actor could take someone else’s urine sample instead of his own for testing). This allows the patient to project the action onto the actor rather than owning it. To maximise internal validity, the situation depicted within the vignette needs to be genuine, in other words, as close to typical behaviour as possible (Gould 1996).

I carried out all the interviews with patients and health professionals and transcribed the data into written form; I found that this allowed me to become familiar with the narratives of the participants through repeated listening. A researcher with previous experience in qualitative diabetes research assisted with the data analysis. Analysis of interview data for the two studies was carried out using the ‘Framework’ approach. This approach was initially developed by the Institute of Social and Community Planning Research (SCPR) for use in applied policy research (Ritchie & Lewis 2003). The approach is particularly useful when answers are required fairly quickly to inform policy making and practice (Ritchie & Spencer 2002). Increasingly, funders require findings within a short time-frame, making more traditional ethnographic methods inappropriate. Framework allows transparency since the data management and analysis charts that are generated can be shared with other researchers as well as funders. The method can be taken further to develop theory though this is usually not the aim of the research, nor is there often the time available in which to do this.

Following the development of charts using the Framework method, themes were discussed with project team members at length before focusing on the main issues for service users and professionals. The themes are explored in more detail in section 7. For both studies I presented findings to the associated steering groups and attended to their feedback prior to publication.

4.2.2 Secondary research

For the third and fourth studies I led review teams that included an information specialist, systematic reviewers and economic modellers to identify the effectiveness and cost-effectiveness of prevention strategies in those at high risk for type 2 diabetes. The two sets of reviews related to programmes carried out over a two year period. The first programme focussed on preventing diabetes in high risk groups such as those from low socio-economic backgrounds and ethnic groups at risk from diabetes. It examined community interventions aimed at the group level whilst the second examined prevention interventions for individuals identified as high risk, for example with raised BMI or blood glucose levels.

Publication 4 relates to one review from the first programme and Publication 5 relates to one review from the second programme. For both programmes I led a team of reviewers in sifting citations that were collated in Reference Manager following the searches. Together we also made decisions about inclusion / exclusion, data extraction, and quality assessment.

For publication 4, qualitative data from included papers in the review (those that best addressed the research question) were synthesised. Evidence synthesis methods are developing and are relatively new to the research agenda. As with qualitative methodology, many variations on the theme of synthesising qualitative data have been described which are mainly derived from primary research methods (see Dixon Woods *et al* 2004). The process is similarly time-consuming and entails a number of challenging decisions regarding inclusion and quality, the results of which may not be acceptable to purists but allow the work to be carried out pragmatically (Lloyd Jones 2004).

The main debates in this field include:

- Adequate quality assessment of qualitative studies and whether or not 'poor' studies ought to be excluded.
- Methods of synthesising qualitative findings that have been derived from a range of study types (for example interviews, focus groups and observation) as well as different analysis techniques (such as Grounded Theory, Discourse Analysis, Thematic Analysis, etc.).
- Ways of integrating qualitative findings with quantitative findings so that a research question can be addressed more thoroughly.
- Decisions about when to stop searching for new papers. The concept of 'data saturation' within the qualitative paradigm can be useful in limiting duplication of work.

Tight timescales limited the degree to which in depth qualitative analysis could be carried out on the included studies. The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-centre) has adopted the 'thematic analysis' approach to carrying out evidence synthesis (Thomas & Harden 2008). At the Public Health Collaborating Centre, we also adopted this method, though we are exploring the development of innovative methods for examining key literature where the information base is vast.

In a similar way to 'Framework', thematic analysis allows findings to be synthesised within relatively short time periods. It can be carried out on any type of study though it is stated to be limited in the ability to generate theory (Dixon Woods *et al* 2004), mainly because an *a priori* framework is applied to the data. In reality, interesting themes that do not fit with the framework are usually saved and commented upon, and so could be analysed in more depth at a later stage.

For Publication 5, synthesis was carried out of evidence from studies that reported the methods and results of studies translating the protocols of large prevention trials (in this case the DPP and the DPS) into smaller evaluations that better reflected usual practice, or that used community settings such as the YMCA and churches to recruit individuals.

The content of the interventions were similar to the larger studies but were modified so it was important to assess the impact of modification on outcomes. I extracted data

relating to the content and delivery of interventions as well as the follow up times and outcomes. I then compared these with the DPP and DPS outcomes which included incidence of diabetes, changes in blood glucose levels, weight, BMI and waist circumference.

For both review programmes, key issues that might affect the implementation of interventions to prevent diabetes were highlighted as 'evidence statements'. The statements were then considered by the PDG in their development of recommendations to inform NICE public health guidance (NICE 2011; NICE 2012). I was responsible for creating reports and submitting them to NICE by pre-specified dates, as well as for presenting findings to the Programme Development Group (PDG) at regular meetings in either London or Manchester. The PDG comprised experts in the field, including consultant physicians, primary care physicians, researchers, economists, and lay members. The aim of the discussions was to facilitate the PDG role in developing recommendations. Each member of the PDG contributed their own perspective on the topic of diabetes prevention. Agreed recommendations were then used in the development of Public Health Guidance published by the National Institute of Health and Clinical Excellence (NICE 2011; NICE 2012).

4.3 Impact of the studies and publications

Study 1: Publication 1

This study:

- Allowed team members who were involved in hospital-based and community-based diabetes care to evaluate the progress of the pilot study. From this evaluation, decisions could be made regarding whether and how to proceed with shared care in the future, and whether there should be any changes to implementation.
- Reporting findings back to the teams allowed discussion regarding individual and integrated roles.

Publication 1 has been cited in an Australian review of integrated approaches in primary care (Tiemann *et al* 2006) as well as a discussion of the nursing contribution to chronic disease management (Forbes & While 2009).

Study 2: Publications 2 and 3

This study:

- Allowed health professionals and service users to express their beliefs about foot-care for type 2 diabetes.
- Feedback to the health care teams allowed practice to be assessed in relation to the beliefs and needs of service users.

Publication 2 has been cited in 13 publications relating to self-care, patient education, shared decision making, foot care and footwear, and research methods.

Publication 3 has had the following impact:

- I was an invited speaker at the 4th International Biomechanics of the Lower Limb in Health Disease & Rehabilitation, Satellite Conference.
- I was informed that the findings inspired practice change at one hospital.
- It was used as a discussion piece as part of a Masters Course in podiatry.
- It has been cited in 10 publications relating to a range of topics including patient education, shared decision making, foot-care, the acceptability and use of prescribed footwear and clothing and self-identity.

Study 3 and 4: Publications 4 and 5

The two programmes carried out for NICE (that include the reviews presented in publications 4 and 5) have:

- Allowed the most recent evidence relating to diabetes prevention to be assessed, with particular reference to at risk groups and individuals.
- Synthesised evidence about how prevention might be carried out, focussing on recent trials, their components and how they might translate into 'real world' settings.
- Informed two public health guidance documents:
 1. National Institute for Health and Clinical Excellence. Preventing type 2 diabetes: population and community-level interventions in high-risk groups and the general population 2011.
 2. National Institute for Health and Clinical Excellence. Preventing type 2 diabetes: Risk identification and interventions for individuals at high risk 2012.

5. Toward an integrated model for implementing type 2 diabetes management and prevention activities in the real world.

The Chronic Care Model was first developed in the US (Wagner 1996) where health care systems differ from the UK National Health Service. However the premise of an integrated care model for chronic illness can be applied to UK settings. The following section synthesises and critically discusses my five publications in relation to the six elements of Chronic Care Model as well as to the broader literature.

5.1: The overall health care organization

The studies represented by the five included publications were carried out within the context of policy developments within the NHS and reflect the impact of organisational structure on care management and preventive efforts. Changes to health care organisation have taken place in recent years that focus on the transfer of care in the UK to community settings. Primary Care Trusts (PCTs) were developed to replace Health Authorities in order to facilitate 'front line' delivery of care in the community. The aim was to "shift the balance of power" away from central government and included *"The development of GP specialists able to provide more complete care for patients outside hospital and in a primary care setting"* (DH 2001 p. 24). The introduction of the Quality Outcomes Framework (QOF) provided a financial incentive for general practices to become involved in the prevention and management of a range of conditions including type 2 diabetes (DH 2011). Further changes are planned for the commissioning and delivery of diabetes care and prevention as PCTs are to be replaced by local GP commissioning groups in 2013.

Recent NHS policies call for improvements in diabetes care in order to prevent complications, and for strategies to prevent diabetes occurring. The National Service Frameworks for Diabetes (DH 2001) set out 12 standards for the prevention and care of type 2 diabetes, including identification and monitoring of people at risk from diabetes, as well as reduction of inequalities relating to those at risk. For those with diabetes, standards include empowerment and shared decision making regarding care and self-care. In terms of monitoring however, the National Diabetes Audit (2012) shows that only 56% of people in England with type 2 diabetes received the recommended nine annual checks. The extent to which annual assessments are

carried out varies with type (with blood pressure being most commonly assessed and albumin / creatinine least commonly checked) as well as by PCT.

5.2: Redesigning delivery systems

5.2.1 Delivering diabetes and prevention care in community settings

As a result of recent organisational and financial strategies, many services have moved from hospitals to primary care settings. This shift also aimed to improve access for users and reduce demand in secondary care (Goyder *et al* 1998; Sibbald *et al* 2007). As prevalence of type 2 diabetes is rapidly increasing, it was predicted that there would be insufficient resource in secondary care to provide for all those diagnosed with the disease (Kirby 2002). A systematic review of early shared care schemes for diabetes showed outcomes were favourable where primary care provided systematic care with appropriate support (Greenhalgh 1994).

I examined the impact of such delivery redesign on interactions between secondary and primary care teams as well as on health care professional roles and responsibilities. Transferring diabetes care and prevention strategies across traditional settings is not a simple process and there are challenges to implementing strategies designed in one context to a different setting (Garfield *et al* 2003). In terms of delivering routine diabetes management in community settings (publication 1), a potential barrier included the ability of secondary and primary care teams to work together. Pro-active collaboration between secondary and primary care teams was used as a way of overcoming this barrier. Face-to-face meetings encouraged information sharing and allowed traditional boundaries to be eroded. This kind of collaboration requires trust and shared values to achieve common goals (Gilson 2003) such as ensuring that routine care is not compromised by changes in service delivery.

5.2.1.1 Accessibility and acceptability for patients

As well as interviewing practitioners I also interviewed patients about the shift in their routine diabetes care from hospital to the community (Johnson *et al* 2006), finding that apart from ease of access, the most important aspect was the relationship with the practitioners, regardless of where the care was delivered.

Lawton *et al* (2009) found that similar shifts in care were met with both positive and negative feedback from patients. Apart from the issue of accessibility, patients perceived the shift as a positive step, showing that blood glucose levels must be relatively stable. In contrast a negative perception was that the shift indicated a resource issue at the hospital, or a punishment for having good control of blood glucose levels.

5.2.2 Extending Professional Roles in Primary Care Settings

A particular feature of diabetes shared care is that traditional generalist roles are extended to provide quality care for routine cases. Publication 1 shows that extended skills for primary care practitioners can be transferred through regular meetings with specialists. In particular, specialist nurses were able to support general practitioners and practice nurses in initiating patients onto insulin where they have previously controlled their type 2 diabetes by adjusting their diet and taking oral medication.

5.2.2.1 From General Practitioner to Specialist GP

General practitioners with a special interest (GPwSI) were first described in The NHS Plan (2000). The role of the GPwSI was originally to work beyond their generalist scope of practice in a particular area to reduce the burden on specialist services. Since 2009 the role has required accreditation through the Royal College of General Practitioners which stipulates a number of competencies relating to the management of type 2 diabetes and its complications (RCGP 2012).

The broader literature points to patient and professional ambivalence about the specialist role as a contradiction of the philosophy of general practice (Moffat *et al* 2006). For some patients in our study (publications 2 & 3), there was a perceived lack of professional expertise in managing type 2 diabetes, particularly in general practice. For patients this lack of knowledge and skills was a weak link in the system, combining with their own lack of understanding of potential adverse consequences.

A range of service delivery options is described in the literature, with some GPs providing specialist care within their practice, and others forming separate specialist centres covering larger geographical areas (Nocon *et al* 2004). Specialist centres, as well as larger practices and practices that are outside deprived areas, may be more likely to provide podiatry and dietetic care (Khunti *et al* 2001).

In publication 1, general practitioners had a special interest in managing type 2 diabetes and were aware of the extra commitment to training that this required for themselves as well as for practice nurses, who carried out much of the routine assessments in dedicated clinics.

5.2.2.2 From Practice Nurse to Nurse Practitioner

Whilst general practitioners were positive about their role in shared care, in publication 1 practice nurses were concerned about the extra workload that might result from carrying out care that was formerly the responsibility of the hospital. Diabetes was not the only condition that was addressed in specific primary care clinics. Prescribing insulin for patients formerly controlling their diabetes with oral medication was also daunting for some, whilst others were more willing to take the challenge.

Prescribing insulin is not a simple undertaking as not only does the nurse need to be knowledgeable about the appropriate dosage and type of insulin, the patient also has to be trained in self-injection, a task that many fear as disruptive to daily life, potentially painful, as well as socially stigmatising (Hunt 1997). Professionals may also be wary of encouraging a move to insulin due to the perception that this is the last resort and that blood glucose control is no longer viable (Tan *et al* 2011), or that the patient may not comply with their insulin regime, or may become at risk from hypoglycaemia (Haque *et al* 2005).

5.2.2.3 The importance of leadership

Whilst there was evidence of collaboration between secondary and primary care settings in publication 1, there were also clear issues around maintaining independence and autonomy in primary care. Primary care teams usually had a strong leader due to a continued special interest in type 2 diabetes. This meant that one particular GP in the practice was championing the change, and was leading the rest of the team in this endeavour. Leaders are an important source of support during times of change; the Royal College of General practitioners specifies leadership as one of the four main characteristics of the GPwSI. Leadership is required to bring the multidisciplinary team together as well as maintain care delivery in accordance with National Frameworks 2007 (<http://www.rcgp.org.uk/clinical-and-research/clinical-resources/gp-with-a-special-interest-gpws-i-accreditation.aspx>).

Strong leadership may also create a motivational environment when developing diabetes prevention programmes. There is evidence that championing facilitates engagement and commitment to a programme, particularly in the early stages (Moffat *et al* 2006)

5.2.3 Modifying prevention programmes for community settings

As previously discussed, prevention of type 2 diabetes is dependent upon identifying those at risk and providing suitable interventions. Trials of diabetes prevention programmes such as the DPP, DPS, Indian Diabetes programme and Da Qing Programme (DDPRG 2009; Lindstrom *et al* 2003; Ramachandran *et al* 2006; Pan *et al* 1997) have shown that risk for diabetes can be reduced using an intensive behavioural protocol. There is no example of such a large scale study within the UK.

I assessed the impact of transferring the protocols of such trials to more modest settings, mainly in the US but also in Australia and Scandinavia. I reviewed the findings of studies that were based on two large trials (DDPRG 2009; Lindstrom *et al* 2003) as at the time of reporting I could find no published studies based on other trials (publication 5). The reviewed programmes used a modified DPP or DPS protocol to increase feasibility and acceptability in community settings where scale of resources cannot match that of the large trials. Settings included the YMCA and churches as well as primary care and clinics, with the aim of bringing the intervention to the community.

Though meta-analysis was not appropriate due to the heterogeneity of study characteristics, findings from the smaller scale studies were promising, particularly in terms of achieving weight management, which is a strong indicator for reducing the risk of type 2 diabetes. The relatively short duration of the studies was a limitation to assessing maintenance of such achievements and there was significant drop out in some studies, whilst others retained most of the original sample. It may be that whilst smaller scale interventions lack the robustness of large samples and intensive protocols, they are better able to reach the individual needs of those at risk within the community. This is an important factor to consider in population based interventions, especially when designing health care and prevention strategies for hard to reach groups.

In publication 4 I reviewed the barriers to modifying preventive interventions for BME groups. I found that some settings, such as gymnasiums and swimming pools, lacked

appropriate facilities, particularly for Muslim women. Preventive strategies were more acceptable when delivered in settings that were familiar to the target population, and involved community leaders.

Delivering diabetes prevention programmes in community settings for BME groups was found to be hampered where differing agendas could not be reconciled. A lack of communication between teams and diminished communication pathways were reported as particular barriers as well as engrained attitudes that created entrenched positions.

5.3: Modern clinical information systems

Effective communication systems are essential to effective communication between different health care settings as well as to facilitating communication between health care settings and patients. However, effective Information Technology (IT) systems have not been designed or used to their full advantage (Garfield *et al* 2003). A national strategy in the UK to implement a number of interconnected IT systems as part of the NHS Plan (DH 2000) to provide a National Programme for IT (NPfIT) included the aim to localise care delivery as specified in “*Shifting the balance of power*” (DH 2001) as well as improve information systems in order to implement the National Service Frameworks (Brennan 2006). The NPfIT has been beset by financial issues, lack of communication between the main partners and reticence by NHS staff (Hendy *et al* 2005).

Interviewees for publication 1 informed me that improved IT systems would be a valuable asset in effective communication between primary and secondary care settings. However the effectiveness of such communication was reported to be variable in terms of IT systems, which were not compatible, as well as content, which was often vague or incomplete. Modern communication systems can prompt providers to record information that is sufficiently detailed when transferring care across settings. However at the time of reporting this kind of system was not available and much transferred information was handwritten.

Another advantage of integrated IT systems is the ability to monitor appointments and prompt reminders for patients that do not attend. This recall system was one of the items identified as important for the success of shared care schemes (Greenhalgh *et al* 2004), and was also discussed in practitioner interviews as a positive factor in

encouraging attendance for appointments (publications 2 & 3). Professionals were concerned that if patients do not attend appointments it is difficult to monitor their self management and control of blood glucose levels, leading to potential complications. This also applies to prevention programmes where reminders ensure that patients are notified regularly to attend for assessments.

It was anticipated at the time of carrying out the studies in 2003-5 that the planned NHS integrated IT system might improve the situation. However, seven years after the study was completed, such streamlining of communication systems has still not been fully achieved, mainly due to complexities that arise when attempting to implement a standardised system in a diverse organisation (Sheikh *et al* 2011).

The concept of integrated IT systems attracts some criticism, as the sharing of patient information across settings has raised concerns about data confidentiality (Brennan 2006). Standardising patient information has been criticised for its potential to objectify the expertise of health care practitioners (Crossley 2000).

More recently, IT systems have being developed as a means of delivering health promotion materials directly to patients (publication 5).

5.4: Systematic decision support

The Chronic Care Model recommends adequate clinical information as support for chronic disease management. The systematic integration of care guidelines has been shown to improve provider behaviour in terms of quality for chronic disease management (Wagner *et al* 2001).

5.4.1 Guideline development

Guidelines for the management of type 2 diabetes (for example NICE 2008) tend to be necessarily broad due to the range of patient / treatment interactions. Concerns are exacerbated by the complexity of available options for treatment of hyperglycaemia. Therefore whilst such guidelines may provide a helpful algorithm for use in managing diabetes, knowledge will develop through experience in caring for a diverse range of patients.

In terms of diabetes prevention, I have been involved in providing evidence that informs the development of guidelines for risk assessment and lifestyle interventions (publications 4 and 5), and am acutely aware of the complexity associated with these objectives. One particular barrier to creating useful algorithms is the definitions of 'pre-diabetes' and diabetes which have historically shifted in terms of relationship with HbA1c levels and continue to vary in reliability according to the chosen blood glucose assay. The definition of 'pre-diabetes' can also be confusing for patients:

“Either you have diabetes or you think you haven't., so this pre-diabetes is not something I have met...so it leaves you in no man's land” (Patient; Troughton 2008: p. 90).

Such limitations to the development of useful guidance and knowledge are a barrier to the robust implementation of integrated care and prevention strategies. In particular they impact on extended professional roles that have developed to provide more comprehensive care and prevention programmes in the community.

5.5 Self-management support for patients

The diagnosis and trajectory of type 2 diabetes are anything but clear cut, with risk for diabetes, 'pre-diabetes' and a diagnosis of type 2 diabetes occurring on a continuum through which individuals can move in either direction. However once a patient is identified as 'at risk' through consistently raised blood glucose levels, there needs to be a support system in place so that patients can in the main manage their own condition. As Wagner *et al* (2001) state, the concept of self-management is relatively new, contrasting as it does with traditional didactic education.

The work that I carried out with patients and practitioners to identify why prevalence of diabetes and its complications continues to grow despite awareness of the causes and potential preventive strategies shows that in principle, self-management is recognised as beneficial to all concerned. The aims of self-management are to empower patients in their own self care and in doing so relieve the burden to health care resources.

However in reality the challenge for patients and those caring for them is fraught with environmental, social, cultural, psychological, financial and emotional barriers. Support and understanding from practitioners is therefore essential, from diagnosis of pre-diabetes or diabetes onwards. The following section discusses the impact of diagnosis and the challenges that patients face in their efforts to prevent or manage diabetes.

5.5.1 Impact of diagnosis

Diagnosis of type 2 diabetes is not a clear cut episode; where patients do experience symptoms of varying content and degree they may not realise or believe that they relate to a chronic illness. There is much uncertainty generally for people experiencing the onset of chronic illness, where experiences do not conform to common sense descriptions associated with a particular condition (Bury 1982). The 'insidious' nature of the onset of chronic illness (Bury 1982) is typified by type 2 diabetes. Symptomless for potentially years, the condition can be doing its damage unknown to the host, so that even when it is known that blood glucose levels are raised, patients may not feel that lifestyle change is urgent.

I spoke to patients (publications 2 & 3) who recalled consultations wherein type 2 diabetes controlled by diet was described as 'mild', perhaps, from the practitioner's point of view, compared to type 1 diabetes and insulin treated type 2 diabetes. They recalled a lack of awareness at diagnosis about the condition and its consequences:

"When I first got it, I was er, 'Oh, it's only diabetes'. I didn't know anything about it, and I just thought it were another illness" (female patient, publication 2; p.328)

The trajectory of chronic illness cannot be discussed as a predictable, linear entity. Rather, it is a shifting dynamic process that involves a dialectic relationship between the person and their 'world' (Paterson 2001). There can be disbelief and perhaps a 'holding on' to wellness, as illustrated by Paterson (2001) in her model of shifting perspectives of chronic illness. Wellness in the foreground is described as an attempt to integrate self-identity with the disease identity and the perspectives of others regarding the disease. This perspective allows the individual to avoid the role of victim and instead assume some control over circumstances.

Conversely, there may be a tendency to focus on the illness, characterising the associated burdens. A new diagnosis may trigger either response. According to Paterson (2001), those who take a wellness in the foreground stance still need to attend to the demands of the disease, or risk progression of the disease.

The range of responses from patients that I spoke to (publications 2 & 3) showed that not only did some people emphasise wellness, they needed to continue life as 'normal' despite advice to change their behaviour. For example, resting in order to assist the healing of foot complications was perceived as neglecting 'normal' activities and tasks:

“When I’m in the house and I’m resting...obviously I do, but as long as there’s things to do, you know, I can’t neglect everything else ‘cos of that, ‘cos it’s not going to rule my life, that’s not what it’s all about is it?” (male patient, publication 2; p.330)

The shift from ‘wellness’ to ‘illness’ symbolised by a diagnosis has been referred to as ‘biographical disruption’ (Bury 1982). This term, which has since been critiqued, is based upon the idea that ‘ontological security’ and trust that the future will continue in a reasonable predictable way, is disrupted by events such as chronic illness (Giddens 1991).

In publications 2 & 3 it was clear that daily life had been disrupted by the diagnosis of diabetes, yet the disruption was fragmented and possibly incremental. For some, self-management was associated with individual responsibility expressed in regard to diabetes control and complication prevention, though there was a stated lack of awareness of what was happening to them early enough to prevent foot complications.

“..I didn’t realise, it’ll not happen to me, but it has, everything’s happened.... I know when I were younger, I neglected myself, I really did, and now I’m paying for it”. (female patient, publication 2; p.328)

The main aims of self-management and prevention of diabetes, as has already been acknowledged, are to maintain or restore blood glucose levels, mainly through lifestyle behaviour modification. From the interviews I carried out it was unclear how much support was offered for self-management, particularly at the time of diagnosis.

5.5.2 The reality of carrying out lifestyle behaviour change

Prevention of diabetes and its complications can be achieved by keeping a tight control of blood glucose levels (DCCT 1993; UKDPS 1998). This requires patients to self-monitor their lifestyle, particularly dietary intake and physical activity. Individuals who require insulin also need to ensure that a balance is achieved between medication and dietary intake / physical activity. To achieve this, timely and appropriate training and advice is needed as well as ongoing support from trusted, knowledgeable professionals. For example, the DESMOND self-management programme for people newly-diagnosed with type 2 diabetes has been shown to improve positive health beliefs as well as affect weight management (Davies *et al* 2008) Patients require motivation to carry out and maintain lifestyle modifications, not just over weeks and months, but for the rest of their lives.

Patients that I interviewed (Publications 2 & 3) varied in terms of diabetes duration. Many had foot complications that potentially could have been avoided if optimum self-monitoring and self-care had been carried out from diagnosis. Some felt let down by health care services in the past, and some felt they had let themselves down. In either case they reflected on how things could have been different.

Some of the barriers to carrying out lifestyle behaviour advice are now discussed. They include entrenched habits, optimism about the future, deviation from 'rules' and issues of identity.

5.5.2.1 Habitual behaviours and optimism

Self-management skills and knowledge of interviewees (publications 2 & 3) had accumulated from numerous interactions with health professionals as well as from their own experiences. However, patients found it challenging to integrate these into their daily life. One potential reason for this is a tendency toward default or learned behaviours, combined with a sense of optimism about the future (Thaner & Sunstein 2009).

In order to change, it is theorised that individuals need to replace deep-rooted behaviours with new ones. This is the basis of theories of change such as the Health Belief Model (Rosenstock *et al* 1988), and Stages of Change, or trans-theoretical theory (Prochaska & Norcross 2001). However for change to be effective, it needs to be encouraged at a point where the individual is ready to take on the change, and interventions need to be congruent with the health beliefs of the person. It is possible that patients that I spoke to were not ready to change until they perceived a real threat from their diabetes.

5.5.2.2 Deviation from the rules

The vignette used in interviews with patients illustrated a number of potential consequences that were often met with derision. Patients were clear that people needed to 'do as they were told' if they did not want to sustain vascular complications. I spoke to patients who indicated that rules relating to self management were to be followed, otherwise negative consequences would follow. However, our interviewees confessed to breaking the rules despite the knowledge that this was counter to the aims of promoting health. They cited health professionals as accomplices in their

deviant behaviour, for example, stating that the doctor told them that the odd piece of cake won't hurt. The concept of deviance from the rules is also highlighted in a study by Lawton *et al* (2008) where one participant describes her behaviour as "*really naughty*" (p.50).

A developmental model (Thorne & Paterson 2001) illustrates how deviance might relate to the chronic illness trajectory, with 'childhood' being the early stages of the illness, and 'adolescence' the stage of rebellion. It may be that patients rebel against what appear to be stringent constraints on their normal life at a particular stage of the trajectory similar to rebellion at particular life stages.

5.5.2.3 Identity, self identity and stigma

The foot complication prevention study highlighted a particular aspect of self-management that patients resisted (publication 3). Foot ulceration was often addressed by prescribing therapeutic footwear in order to relieve pressure from the affected areas. To be effective, therapeutic footwear needs to be worn continually. However, prescribed footwear was mainly regarded as unattractive, particularly by women. One woman I spoke to was fond of high heels and reported that she felt distressed at having to wear prescribed footwear. There was evidence that she was balancing the perceived threat to her personal identity from wearing 'special shoes' against the health threat from wearing high heels. She continued to wear high heels but had to deal with the consequences.

According to Burr & King (2010), a woman's relationship with shoes is complex, taking into account comfort, practicality, but also sexuality and femininity. The analogy of life developmental stages can again explain resistance to sensible footwear. Belk (2003) explored the role of the shoe in rites of passage such as reaching adolescence, where parental attempts to enforce older children to wear 'sturdy' shoes are met with derision. Sensible shoes were associated with childhood and regarded as 'ugly' by adolescents, whilst high heels or designer shoes were the gateway to adulthood.

These findings resonate with patient narratives; in our study the term 'ugly' was used by some in relation to prescribed footwear, and with quite an emotional tone. Perhaps attempts by health professionals to encourage the use of 'sensible' shoes triggers automatic responses rooted in the patient's past history.

In Belk's study (2003), participants abused 'sensible' shoes in attempts to destroy them. Interviewees in our study did not go this far but some described ways that they had changed the shoes in order to suit the shape of their feet. This may also be an attempt to put the owner's stamp on the shoe, to make it their own. Prescribed footwear provoked social identity issues for our participants. For one woman, wearing such shoes meant that everyone could see that there was "*something wrong*". Special shoes for social occasions were associated with social stigma, either real or perceived. According to Goffman (1963), 'stigma' is a discounting by others due to a perception of difference. It is this discounting by others that individuals seek to avoid in their attempts to be unique, yet still acceptable to the group.

In a similar way, dietary restrictions were viewed by one interviewee (publication 3) as stigmatising when she attended social functions, a sign that one is somehow 'different'. There is temptation then to disregard self-management advice in order to avoid social exclusion or feelings of stigma.

In order to support self-management, the social and psychological impact of a diabetes diagnosis and challenges to lifestyle behaviour change for the individual need to be identified and addressed by professionals within the care plan. It is probably too idealistic to expect that self-management activities will be maintained continually, particularly as the prevention and optimal management of type 2 diabetes requires lifetime commitment in the face of the barriers discussed above.

5.6 Links to available community resources

Wagner *et al* (2001) identify access to community agencies as a cost-effective approach to delivering lifestyle interventions. In addition, modifications of diabetes prevention trials in primary care settings or in community settings require cultural sensitivity. Reviews that I carried out for NICE (2011) showed that awareness-raising and identification of at risk groups can be carried out by Lay Community Health Workers (LCHWs). The LCHW role is to provide a healthy living intervention that is understood by as well as delivered by the local community. Community led strategies aim to reduce the power differentials between care provider and receiver, so that interventions are more accessible, more acceptable and more empowering. They are particularly pertinent where health issues occur in traditionally hard to reach groups.

The context of type 2 diabetes prevention in Black and Minority Ethnic (BME) groups and deprived communities illustrates how resources such as churches can assist in making prevention interventions more accessible (see publication 4). For example, Project Dil was developed in Leicester to improve the effectiveness of Coronary Heart Disease (CHD) prevention in the South Asian community. The project, which trained 45 volunteers to deliver preventive educational programmes, was reported to have reached 2000 people by the end of the first 6 months (Farooqi & Bhavsar 2001). Similar projects are in evidence that target specific hard to reach groups and typically focus on prevention through improving diet and physical activity. The LCHW role has developed more rapidly in the US than in the UK, and in the UK the role has several titles and definitions (Kennedy *et al* 2008). This creates challenges when understanding and comparing the delivery of interventions, and as discussed previously, there is a dearth of evaluation of such roles.

Generally, the role of LCHW, however it is defined or whatever variation in title, provides a more immediate resource for the community, focussing on how to realistically motivate people to make changes within their situational constraints. LCHWs are not as pressured from workload as health professionals and therefore are able to spend more time and develop a rapport with clients (Kennedy *et al* 2008). Though a positive step, Grace (1991) argues that LCHW roles are at risk from becoming part of the establishment and that the empowerment role may be deactivated unless health improvement goals originate from within the community rather than from the health service agenda. This highlights a tension at the provider-user interface where health advice is not always welcome if it is perceived to originate from policy makers. Lay communities need to be aware of the risks inherent in particular behaviours so that they can make informed choices. LCHWs therefore need to balance respect for the cultural, social and psychological needs of the community with evidence-based health needs.

5.6.1 Barriers to diabetes prevention in hard to reach communities

5.6.1.1 Lack of available effectiveness evidence

A major issue for assessing the effectiveness of community interventions is the lack of published evaluations. Reviews that I carried out to inform guidance (NICE 2011) for diabetes prevention programmes for deprived and BME groups in the UK highlighted this dearth of evidence.

Only 12 relevant papers were identified for the review of prevention in deprived groups from searches carried out of relevant databases and grey literature between 1990 and 2009. Of these, three studies were randomised controlled trials (RCTs). The studies varied widely in their aims though they all used either dietary or physical activity interventions or both. There were no adverse effects of intervention but in the few (mainly physical activity) interventions that showed positive effects there were no particular characteristics that could be associated with effectiveness. The studies were generally short in duration therefore it cannot be ascertained whether the effects were maintained over time. These results and the lack of evidence for BME groups (publication 4) highlight the need for systematic evaluations of local interventions to be carried out and publicised so that best practice can be identified.

5.6.1.2 Cultural sensitivity

In publication 4, interventions that aimed to change behaviour in Black and Minority Ethnic (BME) groups were found to lack cultural sensitivity, despite acknowledgement in the literature of its importance (Stone *et al* 2005; Stone *et al* 2006). In particular, Muslim women were not catered for in terms of their gender, their child-caring responsibilities, or their religious beliefs. In order to encourage attendance, gyms needed to offer single sex classes, child care arrangements, and / or classes at suitable times in relation to school hours, and allow styles of dress that Muslim women find acceptable.

Language barriers were an issue not only in terms of accessing information and advice, but also when travelling to venues. Many women found travelling outside their local area daunting, and this also applied in deprived groups. The reviews I carried out highlighted the need for 'cultural tailoring' which takes into account the most important aspects for the target group such as religiosity, and perceptions of time (Kreuter *et al* 2003). The perception of time has salience when encouraging people to change their present behaviour to avoid problems in the future, therefore benefits that are delayed may need to be explained more fully to people who live mainly for the present.

Conceptualisation is an important aspect of cultural tailoring, as it distinguishes the meaning of concepts such as time, or 'exercise', and how they differ between groups. Physical activity is viewed for example as a part of everyday life in many cultures, rather than an activity performed in a purpose-built institution. Dietary change needs to

consider the symbolic associations that result for example, from reducing the fat content of a meal for guests. In some cultures this would incur shame on the host. The concept of a 'balanced meal' as we know it in the UK, is meaningless to the Somali community, who do not associate vegetables with nutritious value to the same extent as they do meat.

Yet cultural tailoring may not go far enough to really enhance acceptability and accessibility. It addresses the 'surface' structure, which would increase acceptability by making appropriate changes as outlined above, but not the 'deep' structure, which would involve the target group in intervention design and implementation (Reniscover *et al* 1999). Netto (2010) states that the conceptual basis for the health intervention needs to match that of the community. In other words, the intervention needs to be immersed within the culture from inception, attending to needs as expressed by members of the community, and delivered through that community.

5.6.2 Summary

The above sections show that the Chronic Care Model can provide a structure for integrated care, though within each element deficiencies and barriers to implementation need to be addressed. Globally there is evidence that large prevention programmes can be transferred to smaller settings, and within the UK there is evidence of the awareness that integration of chronic care and prevention, are necessary.

However findings from my work highlight gaps in understanding and in planning diabetes care and prevention for those in hard to reach groups. My work supports Wagner *et al* (2001) in showing that delivery redesign is necessary in order to increase accessibility and feasibility. However, transferring trial programmes and hospital care to primary care requires an adequate support system that includes training for those extending their roles as well as system organisation and IT systems that encourage the flow of communication between settings.

5.7 Productive interactions: Informed patients and pro-active providers

The Chronic Care Model specifies that for each of the six elements discussed above, there need to be productive interactions between informed and active patients (and their carers) with resourced and expert healthcare providers (Glasgow & Emmons 2007). In this section I critically discuss the concept of 'expert' patients as well as the

interaction between patients and informed providers through a critique of 'concordance'.

5.7.1 The 'Expert Patient'

The idea that patients need to be informed about and active in the prevention or self-care of their chronic illness is epitomised in the Expert Patient Programme (EPP) which was developed from the Chronic Disease Self-Management Program (Lorig *et al* 1999) in the US. Aims of the programme in the NHS were that individuals with chronic illness would be trained to manage their own condition and therefore be directed away from service use (Rogers 2009). This ideal is aligned with aforementioned strategies to reduce the demand on the NHS that include extended roles of health professionals.

In the case of EPP, the role of the patient is extended so that they become less dependent upon health services and more expert in managing their own condition. Patient -professional interactions thus become 'meetings between experts' (Fox & Ward 2006). However, Rogers *et al* (2009) conclude that patients face tensions between the aims of the programme and their own diversity of experience.

In one of my study interviews (publication 3) a participant described herself as an 'Expert Patient'. The interview was distinctive compared to other patient narratives in the tendency for extended talk about services and their impact rather than personal experiences of managing a chronic illness. In terms of accrued knowledge the perspective was similar to that of a health professional. This clearly has advantages for the patient in her interactions with practitioners, though as noted above, having expertise does not guarantee a consensus regarding decision making about care. A well informed patient may have strong views about treatment or self-management that do not conform to current guidelines.

The assumption that an expert patient will manage their condition as directed by practitioners is summed up as the paradox that "*...patient expertise both assumes compliance and a degree of taking control of management of health*" (Fox *et al* 2005 p. 1300) by evoking 'empowerment' that emanates from dominant ideologies such as the medical model. The issue of compliance presents a further challenge to productive interactions and is addressed in the next section.

5.7.2 Compliance, adherence and concordance

An area that has been much researched in terms of how best to improve uptake of interventions is that of adherence or compliance (Chatterjee 2006). Both terms are falling out of favour due to the implication that the professional is telling the patient what to do, and if the patient fails to adhere, they are culpable for deterioration in health (Thorne & Paterson 2001). Similarly, Thaler and Sunstein (2009) refer to the role of 'planner' and 'doer' in behaviour motivation. Professionals can be seen in the role of 'planners', providing advice based on scientific evidence. Whilst on the surface patients or 'doers' might agree with the advice, they behave more impulsively when faced with the challenge of carrying out such behaviours in different social situations. It is here, as discussed previously, where the issues of habitual behaviour, deviation and identity are likely to thwart attempts at behaviour change.

A gap then appears to reside in the over-emphasis of logical rationales for behaviour change in the face of shifting, dynamic influences on actual behaviour. The concept of concordance attempts to bridge the gap, with particular reference to reality as the 'life-world' of the patient. According to Mischler (1984), "*the voice of the life-world refers to the patient's contextually-grounded experiences of events and problems in her life*" (p.104). In contrast, the medical voice reflects 'technical interest' and a 'scientific attitude' which tends to strip away the social context of illness.

Concordance embraces joint decision-making and patient-centred care, the focus of recent NHS policymaking (Bissell *et al* 2004). Practitioners do not intend to ignore the patient's life-world, or to be inconsistent in attending to the life-world (Barry *et al* 2001). Indeed, recent efforts to prevent type 2 diabetes increasingly utilise interventions that are tailored to service user preferences and daily life (publications 4 & 5).

The concepts of patient centred care and concordance are made explicit in publications 2 and 3 respectively as a potential way forward in addressing the seemingly disparate perspectives given by professionals and patients during the interviews. Specifically, the requirements of the patient's life-world need to be taken into account by professionals so that agreed objectives can be developed to enhance healthcare. This supports Bissell *et al* (2004)'s conclusions that patients need to be involved at all levels of care, including the design of interventions.

In the case of prescribed footwear (publication 3), there was some way to go toward providing patients with shoes that they were prepared to wear. Following publication I received a communication from the orthotic community stating that they are now providing designs similar to shop-bought trainers in a move toward greater acceptability.

The concept of concordance has been critiqued, in a similar way to the concept of 'Expert Patient', for its basis within the domain of medical dominance, in attempting to improve the rate of medication-taking in people who are self-caring, but through the idealism of shared decision making (Segal 2007). Segal (2007) points out the disparate backgrounds of patients that are encouraged to engage in shared decisions about their health with medical professionals, many of whom are not equipped educationally (or otherwise) to do so.

It is therefore important that practitioners attend to patient narratives in the context of the person and their ideologies. Narratives of illness shift with time and across situations (Lawton *et al* 2008) and are, according to Williams (1984) reconstructed according to "workings of the discursive consciousness". Attending to such narratives may assist professionals in understanding some of the resistances that they observe from patients under their care.

5.7.3 Summary

In relation to the Chronic Care Model, challenges exist in managing and preventing chronic illness even where patients are well informed, empowered a shared decision making approach is taken. Professionals are duty bound to reduce perceived risk to patients, whereas patients may feel more empowered by not reducing that particular (health) risk, and choosing to reduce a different one (for example, the perceived risk to their sense of control, to their sense of identity or to their sense of belonging). In the context of encouraging patient decision making, the balancing of risks (medical objectives versus the life-world of the service user) needs to be discussed during the lay-professional consultation.

6. Discussion

This thesis presents my contribution to the scientific literature around diabetes prevention and care management through the perspective of an integrated care model such as the Chronic Care Model developed by Wagner *et al* (1996). Through five peer reviewed publications I argue that attending to integrated systems is essential but insufficient in itself for optimal prevention and care of diabetes, and that productive interactions between active patients and expert providers are beset by a range of challenges. I have presented a number of these challenges in relation to the broader literature.

Globally, there is evidence that diabetes prevention and its related weight management can be successful through intensive behavioural interventions. These programmes apply psychological strategies and underscore the need for individual tailoring. They also show some promise in community settings using similar but scaled down protocols. However it is not known through these programmes which aspects of the interventions are working and which are not.

The UK health care organisation (NHS) continues to change in line with a series of policies for planning and implementing optimal programmes for chronic disease. These include the development of public health guidance, which I was involved with through my work with NICE. Prior to this the NSF (DH 2001) and the NHS Plan (DH 2000) were influential in the development of current programmes.

Redesigning delivery systems can enhance access to diabetes care and efficiency, but needs to take into account the shifts in roles and responsibilities that are impacted by such change. These changes require adequate practitioner training and integration of support systems in order to foster successful collaboration. My work has shown that these aims are in place though in practice they remain work in progress.

Glasgow *et al* (2001) provided a rationale for combining the aims of care management and prevention of chronic illness, albeit with the acknowledgement that there are differences as well as similarities. In the case of type 2 diabetes, I found that prevention and care not only require the same interventions and changes to lifestyle behaviour, there is a continuum of risk from pre-diabetes to diabetes that poses some uncertainty for patients and providers alike. Similarly, behaviour change for the prevention of

diabetes and its complications is hampered by a range of barriers that may be better understood by attending to the 'life-world' of patients and providers (Kelly 2006) and differences in their perspectives.

Efforts to reduce health inequalities in diabetes include links to community resources, which may be empowering for at risk groups, but need to be developed by those communities. Similarly, in terms of empowering individual patients, the Expert Patient initiative has encouraged enhanced knowledge and skills, though within a specific agenda that may or may not be compatible with the lifestyle and beliefs of the patient. Finally, concordance may offer a structure through which patients and providers can develop shared understanding, but again there needs to be a true awareness of the life-worlds from which these understandings arise (Kelly 2006). The five publications presented here have had an impact on public health policy making as well as on clinical practice, and have been cited in the continuing literature on diabetes and qualitative research methods.

6.1 Limitations

The content of this thesis is dependent upon the information provided within my five included publications. Whilst the content also borrows from the broader literature this is only applicable to the themes already discussed. However it was the aim in writing this thesis that the whole should become more than the sum of its parts, providing a coherent narrative as well as new insights.

The qualitative methods used within the included publications (primary and secondary) can only go so far in identifying the impact of care management and prevention interventions given the complexities that providers and patients face in their interactions with health services.

Evidence synthesis methods were agreed with our funders for two of the included publications, often creating a tension in carrying out the original reviews as well as in the peer review process for publication. Similarly, timescales for carrying out the reviews constrained to some extent the development of methods and analysis.

7. Reflexivity

In this section I reflect on the processes of carrying out the research and writing the papers that are presented within this thesis. I also reflect upon how I came to write my thesis and the implications of submitting a PhD by publication.

7.1 Studies and papers

I have included papers in my thesis that represent four studies from my research career. Two of the studies utilise primary qualitative methods and two utilise review methods to synthesise evidence from published papers.

At the start of my research career in 2003 I worked as a contract researcher, beginning in the field of type 2 diabetes, which provided experience in designing primary research studies as well as in data collection and analysis. Type 2 diabetes was a condition that I had encountered during my clinical career though I did not specialise in that area. My professional nursing background helped in terms of familiarity with the health service as well as feeling reasonably comfortable speaking to members of staff. It was interesting (and an honour) to speak with service users in their home environment; this provided context for the issues that were being discussed.

My role as non-clinical researcher was not always fully understood by service users who, because of my interest in diabetes, would query aspects of their medication, often following the interview. As a former nurse I would find this situation difficult, as in the past I was so used to being able to help patients in a clinical role. I was at this time in a transition stage between clinical and researcher roles. I had not continued to practice as a nurse and was instead still learning the processes of researching. I found that the major barrier to carrying out primary research was recruitment; I was usually over-optimistic about the number of people that would agree to participate. However, I was well supported and assisted by our NHS collaborators.

The vignette approach that was used for one of the primary studies highlighted some interesting issues around ownership of narratives. Since vignettes access reactions to a story, data was a combination of beliefs about the character's behaviour as well as actual experiences related by patients and professionals. As all narratives are to some extent constructed and dynamic, it cannot be maintained that related experiences were

'true', rather they were how participants felt about what happened to them whilst looking back over time.

Eventually, funding opportunities meant that I worked on other topics as well as methods other than primary qualitative research. However my main interest was in qualitative methods and my involvement in evidence synthesis projects reflects this. Much of the research that I carried out was bound by timescales imposed by funders, which meant that some data collected in primary studies was not accessed for use in publications. Moving on to other studies prohibited the opportunity to fully explore information beyond the scope of the research questions and requirements of policy makers.

In terms of evidence synthesis I would particularly have valued time to develop methods along with my colleagues, as this is a relatively new area. Timescales for reviewing and synthesising evidence were limited at times to a few weeks, which included developing a search strategy that was agreeable to funders. During this time there were also negotiations taking place about how much evidence of what type is available. The funders were understandably concerned that included evidence be comprehensive as well as relevant.

I have since reflected on the process of evidence synthesis and its relationship with systematic reviewing. The evidence that could be included in evidence synthesis has a much looser boundary than the traditional systematic review of RCTs both in terms of study type and content. This makes for challenging decisions regarding what is and what is not considered relevant to the question.

I found this ambiguity both frustrating and interesting; frustrating because public health interventions are complex and therefore a narrow focus on search terms that are directly related to terms within the research question can exclude all manner of interesting data about how the theoretical basis for interventions and what might work in different contexts. The interesting aspect relates to how methods can be developed in the future to create reviews that resonate with practice.

Writing papers for publication has been a learning experience in terms of how to choose and approach relevant journals, as well as how to structure and present relatively concise information.

7.2 Thesis

The route of PhD by published works was introduced in the University of Sheffield at the end of 2012. This gave me an opportunity to revisit my work in a new light, looking at how it developed over time and how, combined, it might inform practice and future research.

This was the first thesis to be submitted by the route of publication at the University, therefore the lack of precedents was a challenge; regulations are unique to each university (although they may share some common elements). I was lucky to have ongoing support from people who had been involved in carrying out a PhD by this route elsewhere, or who were setting up support facilities for University of Sheffield (ScHARR) staff wanting to submit a thesis based on their publications.

The process was more of a challenge than I had anticipated, particularly given that I had publications on a range of topics. The timescale for submission was set at eight years which meant that my initial diabetes publications would be too old after 2013. In addition, I was continuing to publish in the field of diabetes, this time on prevention. There was an uncomfortable time waiting for the final publication to be accepted whilst I was writing my thesis.

I decided to only include my diabetes publications as they provided a more coherent picture of my work; the more I thought about it, I felt that they did add up to more than the sum of their parts. It was challenging remembering back to the early studies and revisiting the methods that were used, as well as combining these with more recent publications. I felt that I had learned a lot over the years about theorising and about writing, and revisiting one's work brings this to the fore.

8. Implications for practice and research

8.1 Implications for practice

Supporting the National Diabetes Audit 2011-2012 as well as work carried out by Wagner in the US to evaluate the CCM, this thesis highlights gaps in regard to the routine care of patients with type 2 diabetes. The data from my work shows that such gaps are related to the following:

- Lack of integrated IT systems for the implementation of care management and prevention programme communication.
- Variable levels of knowledge, skills and confidence for both care and prevention in primary care.
- Variable experiences of patients in terms of routine monitoring, education and information.
- Lack of shared understanding regarding the integration of preventive behaviours into daily life.

These gaps might be addressed by attending to:

- Attention to communication systems and shared information across settings.
- Increased training and education for primary care professionals involved in the care of diabetes.
- Support in primary care from specialists and leaders in the field of diabetes.
- Provision of equitable access for patients to health information and services.
- Increased involvement of communities to develop care and prevention strategies that are culturally sensitive and empowering.
- Increased involvement of patients in the design and implementation of individually tailored interventions and care planning.
- The attention to patient narratives to gain an understanding of how diabetes and its precursors impact on and are impacted by the life-world.

8.2 Implications for research

Synthesis of evidence around the prevention of type 2 diabetes showed a particular dearth of evaluations in hard to reach groups who are also at increased risk. Available

evidence also suggested that prevention strategies need to be tailored for greater access and acceptability. These issues could be addressed by:

- Local (UK) evaluations of 'real world' diabetes prevention programmes.
- Assessing social as well as individual components and impacts of interventions.
- The involvement of community members in the design of research to ensure that the agenda meets the needs of those most at risk.
- Assessment of patient narratives to identify need and acceptability of interventions in the context of their life-world.

8.3. Conclusion

This thesis has discussed five peer reviewed publications using a mixed methodology that were originally products of four separate projects. Combining the findings in the context of the Chronic Care Model highlights how the prevention and care management of type 2 diabetes could be improved utilising an integrated system and adapting prevention strategies into primary care.

Gaps in terms of delivery are mainly concerned with inadequate communication systems, insufficient training and accessing hard to reach groups. Collaboration with specialists and leadership qualities are positive aspects of primary care delivery. Addressing gaps and building on positive elements may facilitate the development of 'resourced and expert' practitioners.

For patients there are a range of barriers to optimum care and prevention that need to be addressed within interventions as well as consultations. To obtain narratives regarding the patient's life-world is a starting point to allowing understanding how diabetes care and prevention strategies can be integrated into daily life. Such support may enable patients to become 'informed and active' in their own care in a way that is congruent with their beliefs and lifestyles.

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10. Appendices

Appendix 1: List of publications

The following is a list of the publications presented in this thesis:

Johnson M., Goyder E. Changing roles, changing responsibilities and changing relationships: an exploration of the impact of a new model for delivering integrated diabetes care in general practice. *Quality in Primary Care* 2005 13: 85-90

Johnson M., Newton P., Jiwa M., Goyder E. Meeting the educational needs of people at risk of diabetes-related amputation: a vignette study with patients and professionals. *Health Expectations* 2005 8: 324-333

Johnson M., Newton P., Goyder E. Patient and professional perspectives on prescribed therapeutic footwear for people with diabetes: A vignette study. *Patient Education and Counseling* 2006; 64: 167- 172

Maxine Johnson, Emma Everson-Hock, Roy Jones, Helen Buckley Woods, Nick Payne, Elizabeth Goyder. What are the barriers to primary prevention of type 2 diabetes in black and minority ethnic groups in the UK? A qualitative evidence synthesis. *Diabetes Research and Clinical Practice* 2011; 93: 150-158

Maxine Johnson, Roy Jones, Crystal Freeman, Helen Buckley Woods, Michael Gillett, Elizabeth Goyder, Nick Payne. Can diabetes prevention programmes be translated effectively into real world settings and still deliver improved outcomes? A synthesis of evidence. *Diabetic Medicine* 2013; 30: 1 DOI: 10.1111/dme.12018

Appendix 2: Requests and permissions

i. Student request to publishers

The following request was made to editorial staff regarding the five included publications:

“I wish to include the following published material in my thesis, and am contacting you as the rights-holder:

[Full citation of article]

I wish to include this work as part of my submission for a PhD by Publication. I am also required to submit an electronic version of my thesis, which I am required to deposit in White Rose eTheses Online repository (<http://etheses.whiterose.ac.uk/>).

The repository is non-commercial and openly available to all.

I would be grateful if you could advise if this will be acceptable.

Kind Regards,

Maxine Johnson

ii. Journal responses / policies

The responses and / or statements within the author guidelines are listed for each included publication below:

Publication 1

Journal: Quality in Primary Care

Hi Maxine

“...I am happy to grant the permission you require”.

Good luck with your PhD!

with best wishes

gillian

Gillian Nineham
Publishing Director
Radcliffe Publishing
Unit C5 Sunningdale House
43 Caldecotte Lake Drive
Milton Keynes
MK7 8LF

Publication 2

Journal: Health Expectations

Hello Maxine. Thank you for your email.

Please can I direct you to our website
[http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1369-7625](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1369-7625)

From there, please locate our 'Permissions' section under 'About This Journal'.

Hope this helps. Thank you.

Kind regards,
Robert Huston
Editorial Office

At the time of writing (13.12.12) Wiley-Blackwell state that:
“Contributors may use the articles in teaching duties and in other works such as theses”.

Publication 3

Journal: Patient Education and Counseling

Specific permission was requested from the Editor with the following response dated 10.07.12:

“Inclusion of the paper in a doctoral dissertation is permitted as long as a specific reference is made to Patient Education and Counseling”.

Sincerely,
Arnstein Finset, PhD
Editor-in-Chief
Patient Education and Counseling

Publication 4

Journal: Diabetes Research and Clinical Practice

Publisher: Elsevier state that:

Dear Maxine Johnson

Thank you for your email.

As author of the requested article, you do not need to seek Elsevier's permission to include it in your thesis as it is part of the rights you retain as an Elsevier journal author.

If your thesis is being hosted online by your university, then the version you should include in your thesis should not be Elsevier's PDF version but the Accepted Author

Manuscript (“AAM”), it is the author’s version of the manuscript of an article that has been accepted for publication and which may include any author-incorporated changes suggested through the processes of submission processing, peer review, and editor-author communications. AAMs do not include other publisher value added contributions such as copy-editing, formatting, technical enhancements and (if relevant) pagination.

Yours sincerely
Jennifer Jones
Rights Associate
Global Rights Department

Elsevier Ltd
PO Box 800
Oxford OX5 1GB
UK

Publication 5

Journal: Diabetic Medicine

Publisher: Wiley

Correspondence: 23.08.12

Re Can Diabetes programmes be translated effectively into real world settings and still deliver improved outcomes? A synthesis of evidence.

The archiving policy for Diabetic Medicine is

“Can archive pre-print (ie pre-refereeing)”

iii. Responses from co-authors

I declare that I have received permission from all co-authors to include the articles in this thesis.

Appendix 3: Pre-published full text versions of included papers

Publication 1: Johnson M., Goyder E. Changing roles, changing responsibilities and changing relationships: an exploration of the impact of a new model for delivering integrated diabetes care in general practice. *Quality in Primary Care* 2005 13: 85-90

Changing roles, changing responsibilities and changing relationships: an exploration of the impact of a new model for delivering integrated diabetes care in general practice

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Abstract

Aims To explore the views and concerns of professionals after the introduction of a new and more integrated model of diabetes care. Teams consisting of a specialist physician and a diabetes specialist nurse were assigned to individual general practices to support them in delivering diabetes care to an increasing proportion of their patients with diabetes.

Methods Semi-structured interviews were conducted with 17 health care professionals including general practitioners, hospital-based medical specialists, practice nurses and diabetes specialist nurses involved in the pilot scheme to provide specialist support to primary care teams. The interviews were transcribed and analysed using a “Framework” approach to identify the key issues for professionals involved in changes in organisation and delivery of diabetes care.

Results All professional groups supported the overall aims of the initiative but expressed a range of concerns about the impact on workload and job satisfaction. Major themes identified included time, training and workload; collaboration, relationships and sharing information across organisational boundaries; and the impact of changing professional roles. Differences between professional groups emerged with nurses much more concerned about the impact of change in terms of the practical implications for their role and workload. Doctors identified the major impact as improving relationships and communication between specialists and generalists.

Conclusion Development of integrated models of diabetes care which involve professionals increasingly working across organisational boundaries have significant implications for all the professional groups involved. Understanding these implications can help ensure new service developments have positive outcomes for both patients and professionals.

Introduction

Organisation of diabetes care in the UK has evolved significantly over the last forty years. Developments in primary care have encouraged an increasing emphasis on structured chronic disease management programmes based in general practices. A range of different models for providing diabetes care – generally known as “shared care” schemes - has led to the development of closer links between practitioners in specialist diabetes services and primary care practitioners.¹

Recent national policy emphasis on the importance of integrated services for people with diabetes² and in providing more specialist care within the community has led to further shifts in the provision of diabetes care towards an increasingly community-based service. In practice, this involves health care professionals working across the traditional boundaries of primary and secondary care, to provide an integrated service.

In the city of Sheffield, much routine care for people with Type 2 diabetes has traditionally been provided in primary care. However, referrals to specialist hospital-based clinics have included patients who are newly diagnosed, patients with complications, and patients requiring insulin. In response to national policy changes and local service development needs, a pilot project was set up in six volunteer practices to develop general practice-based diabetes care for such patients. The practices are all group practices, and are based across the four Sheffield primary care trusts (PCTs), serving a diverse range of socio-economic and ethnic populations. General practices involved in the scheme are expected to deliver diabetes services in accordance with locally developed evidence-based guidelines, and are supported by members of the specialist hospital teams in terms of sharing knowledge, skills, and advice. The key features of this model are given in Box 1.

The aim was that more patients would have access to systematic care in their own general practice, whilst supported by specialist expertise. There were also expected to be benefits for both primary care teams, who would have more support from specialists, and for specialist teams who would spend less time providing routine care, such as annual review, in hospital clinics.

Previous qualitative work has examined the impact of changing organisation of care on patients with diabetes.^{3,4} Despite the key importance of health care professionals in implementing these policy-driven changes in the provision of diabetes care, there has been less interest in the impact on the clinicians involved. We were commissioned to

evaluate the pilot project at a relatively early stage of implementation in order to capture the initial impact of change and identify potential barriers and difficulties, so these could be addressed before the pilot was rolled out to additional practices. This also provided an opportunity to identify the wider issues for professionals involved in delivering more integrated diabetes care.

This paper highlights the key issues for health professionals and explores the changes in professional attitudes and practice that are needed to successfully develop innovative ways of providing diabetes care.

Methods

In June and July, 2003, all the health professionals involved in the six pilot teams were contacted by letter or e-mail and invited to discuss their experience of the pilot scheme. Six consultants with a specialist interest in diabetes, and six general practitioners (GPs), one from each of the pilot practices, agreed to be interviewed. Three Diabetes Specialist Nurses (DSNs), and two practice nurses (PNs) involved in diabetes care agreed to be interviewed. Each nurse was involved in a different pilot practice, so that nurses involved with five out of the six practices were interviewed.

Face to face interviews lasting 20-45 minutes were conducted by one of the researchers (MJ). A summary of the topic guide for the interviews is given in Box 2. The interviews were audio-taped with permission from the participants, and then transcribed. Analysis was carried out according to the framework method.⁵⁻⁷ To increase the reliability of the findings, the transcripts were read by two researchers (MJ and EG) and the themes identified were compared and discussed. Using an iterative process, transcripts were then re-read and searched for data that might challenge or change the analyses, to ensure that the findings were robust.

Results

Major themes identified in professionals' experience of the pilot were: time, training and workload; collaboration and relationships across organisational boundaries, including the sharing of knowledge and information; and the impact of changing professional roles.

Time, Training and Workload

Delivery of routine diabetes care by primary care teams was strongly supported by all the health professionals, provided that adequate resources, personnel and training were in place. These requirements were seen as a significant issue, particularly if the pilot was to be extended to more practices in the future. Both secondary and primary care professionals expected an increase in their caseloads in the future, as primary care teams take over routine assessments and screening that may have been previously carried out in hospital clinics. Consultants felt that they would be seeing the more complicated cases, which could have implications for the role and job satisfaction of clinicians in the hospital setting. There could be extra referrals from primary care due to the increased knowledge and vigilance of GP's and practice nurses, and so a two-way movement of patients was envisaged.

"We know if you give health professionals ability to deliver health care in any particular subject, whether it be diabetes, or asthma, or whatever, they will find more problems, and refer more problems to the hospital." (Consultant 2)

GPs, on the whole, were not concerned about their caseload increasing. They were, however concerned about the extra workload that would be expected of practice nurses, who provide most of the actual care, and this view was shared by the practice nurses themselves.

Practice nurses have continuously extended their roles, to include the care, and education, of patients with chronic conditions. Starting patients with Type 2 diabetes on insulin was accepted as a challenge, but with an opportunity cost as less time could be spent with other patients. Time is also needed to carry out training to provide the necessary care, and because there is a need to assess patients individually, training requirements could be substantial. Practices had varying views and experiences of this new challenge, some were already starting patients on insulin at the time of interview, while others were not yet considering making this change to practice. Training for this skill was delivered by the DSNs, who already have busy schedules. They could foresee problems if the pilot extended, in that they would not be able to give as much support to a large number of practices. One way of dealing with this was suggested:

"I know it's intended to respond to a practice's individual needs, but whether we should be doing this with a group of practices together instead of just one, which would be a more efficient use of our time rather than to do all this work with one practice" (DSN 3)

Collaboration across organisational boundaries

Implementation of the pilot required new ways of working together that included the sharing of information. Specialist nurses were passing on their knowledge of diabetes care to practice nurses, and patient information was being shared across primary and secondary care. Traditional channels of communication between teams were problematic for all professional groups, particularly in terms of information exchange about patients. This was partly because of inadequate completion of correspondence, but also because computer systems were not consistent across settings. Primary care teams were equipped with more sophisticated technology with which to implement patient recall, and audit. They also accumulated more contextual knowledge of patients and their lifestyles, because of their position within the community.

“So we have more information than they have, and don’t necessarily know what to do with it, and they know what to do but they don’t have the information” (GP 5)

In contrast, specialists were seen as the holders of clinical knowledge, and experts in diabetes care. Within the aims of the pilot, specialists were a resource and source of support for primary care practitioners, as well as patients. Some respondents pointed out that historically, collaboration had been lacking between primary and secondary care, and this could lead to misconceptions, and a ‘them and us’ situation. In order to overcome this, it was necessary for a change to take place in terms of how the professionals perceived their own roles, and the roles of others.

Collaboration within the pilot was chiefly operationalised as regular meetings held at the practice between consultant, specialist nurse, GP and practice nurse. Generally, the meetings were seen as a good way of developing relationships, as well as a forum for discussing patient care and management issues. In addition, participants found that face-to-face discussions were helping to improve communication. Building relationships was a key issue for GPs:

“because of the discussions, it has been interesting to talk about the roles of starting people on insulin, and glitazones and various other strategies for people who are having difficulties; it has been valuable – the educational input, and certainly, very much closer communication.”(GP 3)

There was concern that, because the pilot model assigns a specialist team to a particular practice, this could limit choice for referrals. There is also the potential for confusion because patients within one practice were previously under the care of several consultants, who may differ in their approaches to care.

Changing Roles

The aims of the pilot demanded that all practitioners adapted their professional roles. Consultants and specialist nurses were now providing support and education to primary care teams, and this meant visiting community settings, as well as being available for telephone advice. There was concern that if more practices were to be supported in the future, their role would alter significantly:

“if we are going to do it with more practices, then we would get into perhaps every other week involvement with primary care, which would probably mean changing our job description” (Consultant 5)

GPs and practice nurses were extending their skills to include areas of diabetes management that had previously been carried out in hospital clinics. Views about these changes varied between practices and professionals; some practices were more experienced in diabetes care, and were positive about new challenges, while others were less confident. However, GPs on the whole were positive about having more control in the care of patients, particularly as some patients had previously been difficult to follow up once they had entered the secondary care system.

Practice nurse roles were extending their role to include administrative tasks, as well as clinical, and although they were keen to learn new skills, there was concern about the effect on other areas of their work. Some respondents saw their roles as evolving over time, perhaps to include the facilitation of specialist clinics within the community, or to provide specialist services for other practices within the same area.

“let’s have a clinic somewhere in the community, say, practice-based, for newly diagnosed patients, so you may have one GP with an expertise who would provide GTT, other GP’s could refer patients that they were wondering if they were definitely diagnosed, then they are referred back “(GP 5)

However, this ideal was not shared by everyone, and there was expression of the conflict between the concept of GPs with a specialist interest in a specific disease and their traditional role in providing holistic care.

Discussion

We used a qualitative approach to explore the views of health care professionals affected by changes in the provision of diabetes care. The findings highlight some practical barriers to change such as provision of adequate training and workload. For

practice nurses, there is also an issue of confidence in extending their role, although this has been shown to increase with adequate support and education¹, and the challenge is often balanced with a sense of increased job satisfaction.⁸

In order to provide 'seamless' care, close collaboration is necessary between traditionally distant professionals, who can contribute their own area of expertise.⁹ Successful collaboration involves breaking down traditional barriers and developing relationships and trust. In this pilot, this is being achieved by acknowledging the need for better communication, and the two-way flow of information and knowledge.¹⁰ It has been recognised that communication issues across organisational boundaries may also adversely influence patient satisfaction.³

Some of these findings are supported by previous evaluations of "shared care" schemes. Greenhalgh¹ highlighted the importance of communication and trust that could be enhanced by effective computer systems and regular meetings. Professional groups often have misconceptions about each other's roles¹¹, and making time to meet in person has the potential to break down barriers, by allowing professionals to understand each other's roles better.¹²

Although a range of professionals were interviewed, ideally we would have interviewed more nurses and other professionals affected by service changes, such as community nurses and general practitioner colleagues of those involved in the pilot. Time restrictions prevented exhaustive follow-up of potential participants, and not all professionals involved in the pilot were willing or able to take part. This could reflect workload and lack of time, particularly as most practice nurses and some specialist nurses were working part-time.

This is a relatively under-investigated area and there is a need for further work to explore some of the issues raised in this pilot study in greater depth and in a much wider range of settings.

Conclusion

Development of integrated models of diabetes care which involve professionals increasingly working across organisational boundaries have significant implications for all the professional groups involved. Understanding these implications can help ensure new service developments have positive outcomes for both patients and professionals.

Our findings are particularly relevant to the organisation of diabetes care: the large number of different professionals involved presents particular challenges in establishing an integrated service. However these key themes are relevant to other situations where health professionals collaborate across organisational and professional boundaries.

Acknowledgements

The model for the pilot programme was developed and implemented by the Sheffield Diabetes Local Implementation Team and the pilot project steering group. The authors are particularly grateful to all the individuals involved who gave up their time to be interviewed for this study.

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Box 1: Main elements of specialist-supported diabetes care based in general practice

- **Joint meetings:** Regular meetings for at least two hours every three months. These meetings involve the practice diabetes team, hospital consultant, diabetes specialist nurse (DSN) and community nurse. The meetings take place on the practice premises. All those attending are expected to contribute to setting the agenda which can include all aspects of diabetes care, but usually focuses on the key elements of the intervention identified below. Both organisational and clinical issues are discussed.
- **Shared clinical responsibility:** Explicit agreement on which patients will be seen in the hospital clinic, which by the practice team. Patients are involved in any decision to discharge them from follow-up in the hospital clinic.
- **Improving access:** An agreed policy is developed for contacting individuals that do not attend routine review appointments in either primary care or hospital clinics, a patient group that is recognised as being potentially at high risk of poorer control and long-term complications.
- **Identification of education needs:** The needs for further educational provision or support for practice teams are jointly identified by the practice and specialist team members. These may include refresher courses or learning new skills such as insulin initiation.
- **Identification of organisational needs:** Similarly the potential for changes in the organisation of care at the practice is discussed, in order to develop an appropriate development plan. This may include changes in the contribution to diabetes care of different team members or changes in arrangement for information exchange to improve communication about patient care.
- **Development of practice plans:** An explicit systematic plan to meet organisational and professional educational needs is developed. Plans need to be realistic and take into account the availability of time and resources in determining the pace of change. Educational needs may be met in a variety of ways, ranging from attending courses to one to one teaching and support in the practice setting.

**Box 2. Summary of the topic guide for interviews with healthcare professionals
in pilot practices**

- Individual's role in provision of diabetes care
- Their role in the pilot
- Their experience of the pilot
- Impact of the pilot on their own work, on other professionals and on provision of care to patients
- Any specific changes to ways of working
- Related changes in resource and training requirements
- Strengths of the pilot model of diabetes care provision
- Weaknesses of the pilot model of diabetes care provision
- Obstacles or barriers to implementation of the pilot
- Changes needed before 'rolling out' to other practices
- Any other issues they wished to raise about the pilot

Publication 2: Johnson M., Newton P., Jiwa M., Goyder E. Meeting the educational needs of people at risk of diabetes-related amputation: a vignette study with patients and professionals. *Health Expectations* 2005 8: 324-333

Meeting the educational needs of people at risk of diabetes-related amputation: a vignette study with patients and professionals

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Elizabeth Goyder MRCGP MFPH Senior Clinical Lecturer in Public Health, School of Health and Related Research (SchARR), University of Sheffield, Sheffield, UK

Abstract**Objective**

To investigate how patients and professionals view the role of advice in diabetes foot care, in order to inform educational practice.

Design

A qualitative study based upon one-to-one interviews using a vignette technique with patients and professionals.

Setting and participants

Interviews with 15 patients with diabetes related foot complications attending diabetes foot clinics, and 15 health professionals across two hospital sites and two primary care trusts.

Results

There were similarities between issues raised by patients and professionals, with differences in emphasis. An important factor was patient understanding and acceptance of the implications of diabetes from diagnosis. Many patients reported a lack of early understanding that may reflect inadequate provision or acceptance of advice. Development of positive relationships with health professionals was important for patients and encouraged shared understanding. Use of the vignette technique highlighted the gap between patient knowledge and action, with patients and professionals emphasizing their own responsibilities in relation to reduction of risk through education and action. Responses suggest that early positive interactions with appropriately trained professionals are needed to help patients assimilate advice into everyday routines.

Conclusions

For effective preventive care, patients need to understand how diabetes impacts on their health. Foot care education should begin early, be patient-centred and delivered with empathy by professionals whom the patients trust. The findings reflect patient and professional expectations in educational practice, and therefore have relevance for other chronic conditions for which much education and advice is related to self-care.

Keywords: diabetes, education, foot complications, patient-centred, qualitative, vignette

Introduction

Lower limb amputation remains a major cause of morbidity in people with diabetes, with an incidence of 2–3 per 1000 of the diabetic population.¹ A much higher proportion are at risk of foot problems,² of which the main risk factors are peripheral vascular disease (PVD), and neuropathy, which have estimated prevalence rates of 11% and 41.6% respectively.³ This is despite efforts to prevent ischaemic, traumatic and infective damage, such as the provision of guidelines aimed at encouraging increased monitoring of, and information for, patients with diabetes-related foot problems.^{4,5} Foot complications are costly for service providers,⁶ and have a marked impact upon quality of life for the individuals concerned, but they are not inevitable, and risk reduction through high quality preventive care has recently been advocated in the National Service Framework for Diabetes.⁷

Patient education plays an important role in the care of patients with diabetes; appropriate information helps to empower patients by providing the knowledge base to perform self management skills.⁴ Education in optimum glycaemic control^{8,9} and appropriate foot care^{8,10–12} in particular is thought to be a major factor in prevention of lower extremity amputations and ulceration. However, a systematic review by Valk et al.¹³ concluded that most trials that examined educational programmes for prevention of foot complications have poor design or conflicting results. Approaches to patient education and information-exchange in practice vary from opportunistic sessions at GP or clinic visits, to structured management programmes that follow a set curriculum. The latter has been shown to be more effective than ad hoc delivery of information in terms of retained knowledge.¹⁴

Educational interventions for people with diabetes have been extensively studied, but are fragmented in design and delivery, often lacking a theoretical base, and mainly focussing on outcomes such as amount of knowledge attained, and objective glycaemic control.¹⁵ This approach tends towards a professional-oriented perspective and does not take into account the expectations and capabilities of patients, or the communication skills and knowledge base of professionals. Two recent reviews show that knowledge acquisition is not the only important factor in self-management training; patients also need to be motivated¹⁶ to learn, and the effect upon quality of life should be taken into account.¹⁷ A study by Cooper et al.,¹⁸ addresses this issue with an educational intervention that includes humanistic, cognitive and behaviourist elements.

Qualitative data show that patients appreciated the learner-centred approach and empathy towards their real experiences, but some health professionals were reluctant to commit to a shared learning model. The patient centred approach to education has been explored using qualitative methods in other areas, such as low back pain, in order to improve available information¹⁹ and reduce barriers to provision.²⁰ These studies allowed respondents to openly discuss their own needs to help improve the quality of and access to information.

The aims of this paper are to explore factors that prevent people with diabetes receiving optimal advice or information to help reduce their risk of foot complications. The views of patients and professionals who deliver care and education to people with diabetes were obtained using a structured vignette.

Method

Ethical approval was granted by North Sheffield Local Research Ethics Committee (LREC). Health professionals and patients gave informed consent to take part in the study, and to having their interviews recorded by audiotape. The interviews took place between September 2003 and April 2004; health-care professionals were interviewed at their place of work (at one of two hospital sites, or in primary care). The interviews took place either at their home, or, if preferred by the patient, in the hospital-based diabetes foot clinics.

Participants

Purposive sampling was used to identify participants for the study, patients with type 1 and type 2 diabetes, and with a long history of foot complications were invited to participate because of their potential wealth of experience in relation to diabetes foot care services. We provided the Diabetes Foot Clinics at two teaching hospitals with 20 information packs each to distribute to suitable patients (a total of 40 packs). Fifteen patients, whose characteristics are summarized in Box 1, agreed to be interviewed.

Sheffield has a diverse population in terms of socio-economic circumstances, with its 10 most deprived wards being within the 10% most deprived, and the two most affluent being within the 5% most affluent in England and Wales.²¹ The patients reflected this diversity, being drawn from postcode areas ranging from relatively deprived, to relatively affluent. Seventeen health-care professionals were contacted by letter, or by other health professionals, and 15 agreed to be interviewed; three consultants (one in

vascular surgery, two diabetologists), two general practitioners, three nurses, three orthotists, three podiatrists, and a dietician.

The vignette

We used a structured, large-print vignette (Box 2), relating to a patient with diabetes-related foot complications. The use of vignettes allows patients to express their views without a direct reference to themselves. This method facilitates the expression of knowledge, opinions, beliefs, values and attitudes²² but is also less intrusive than focusing the patient on their own history, and for health professionals is less judgmental than asking direct questions about the participants own values or behaviour.^{23,24} A single, continuous vignette was used rather than several short scenarios. This method has been used successfully in other areas of health research, such as HIV/AIDS, to explore patient's attitudes and experiences. It allows a story to build up, maintaining the interest of the respondents, and prevents the repeated introduction of new characters, which could be tiresome for the audience.²⁵

Interviews were chosen in preference to focus groups because we were particularly interested in individual views rather than interaction between participants. In addition, problems may have been encountered in attempting to assemble patients at an appropriate site, particularly given the limited mobility of this population. Focus groups can also inhibit the expression of views where there is a power differential between various health-care professionals. The vignette was developed with reference to the relevant literature and following discussions with an expert panel²⁶ before being piloted. The items within the vignette were chosen to depict a plausible patient care trajectory, so that any barriers to such care could be identified from responses to the prompts. Development of the vignette was an iterative process and modification took place several times before a final version was agreed. Patients and professionals were presented visually and verbally with the vignette in stages, with open-ended prompts to encourage discussion (Box 2). Relevant related issues were explored as volunteered during the interviews. The interviews were audiotaped and transcribed verbatim. Data was analysed using framework analysis.²⁷ This method involves becoming familiar with the data prior to developing a thematic framework which is then used to classify or code the data. Two researchers (MJ,PN) carried out this process using a small number of transcripts to develop a set of categories, which were then applied to the larger data set, as in the constant comparative method.²⁸ In this way the categories were further refined, and main themes charted into a matrix with the numbered subcategories in

columns and respondents in rows. There is transparency with this method, which allows other members of the team to easily follow the process.

Findings

Understanding diabetes and its implications was seen as crucial for patients to cope and effectively manage their disease and their life. Patients understanding had three elements: the factors that prevent initial understanding, the circumstances that reinforce understanding over time, and the relationship between understanding information and acting upon it. For health professionals, these themes were presented in terms of both ideal and challenging situations, for themselves, and for patients. Professionals provided a second-hand account of patient experiences that came from their clinical encounters, but also provided their views of the ideal situation compared with the reality of dealing with limited resources and the varied perspectives of patients.

For patients, the themes were based mainly on personal experience, with some idealistic views being vicariously offered through the vignette. There was also a sense of passing time in accounts, as patients related events from the time of their diagnosis through to the present, and this is reflected in the themes.

Barriers to early understanding

Lack of information

Many of the participants stressed the importance of understanding diabetes and its implications from diagnosis. Professionals pointed out potential barriers to understanding in terms of the timing, content and delivery of information:

“if he’s given leaflets with little, sort of, explanation, he could easily put them to one side and not look at them”. (Cons 1)

“I think the GP’s have got to be able to reiterate to the patients exactly what the long term effects of diabetes are, the need is to push those things, rather than it all come to the hospital”. (Orth 10)

A common report from patients was an early misunderstanding that type 2 diabetes was not serious; this could result from inappropriate framing of information by professionals, and/or inadequate lay knowledge. Patients often came to realize the potential effects of diabetes as complications were taking effect:

“When I first got it, I was er, Oh, it’s only diabetes I didn’t know anything about it, and I just thought it were another illness, I didn’t realise at the end of the day, I’d to have become like this, I didn’t realise it’ll not happen to me, but it has, everything’s happened.... I know when I were younger, I neglected myself, I really did, and now I’m paying for it”. (female patient G)

“I mean, I was never told about the importance of looking after my feet, it’s only in the last six, seven years, if that, that I’ve been told”. (female patient F)

Patients often felt let down, reporting that they had not received foot care advice, or adequate referral during the initial years of having diabetes. Possible explanations for this could be differences over time in attitudes towards patient education, or variations in the skills and knowledge of the professionals involved. Some patients did not feel confident about the specialized knowledge levels in primary care compared with those at the diabetes foot clinic:

“He’s alright, he’s alright [GP], but I take more notice of them, and I know he’s good, and they reckon he’s good in his field, and he’s a good doctor and that, but I listen more to them [clinic team]... because I think they’re more expert....” (female patient B)

“They are, very good, diabetic nurses, very good...diabetic nurses in my opinion are far better than doctors...” (male patient N)

“I’d got ulcers on my legs as well as on my feet through my working boots. My doctor, my personal GP never did anything for them, never”. (male patient K)

Previous experiences, such as receiving inadequate information and advice, or suspecting that practitioners are not well-informed, can have an effect on the level of trust that patients with implications for the patient–practitioner relationship, and future health-care seeking behaviour.

Lack of accessibility

Professionals were concerned about the inconsistency of relevant education, lack of time to provide adequate information, and the poor accessibility of podiatry and dietetic advice in primary care. Dietary advice was seen as an important factor in early education, so that appropriate blood glucose levels and tailored diets can be established before complications arise. However, in practice, by the time patients are seen by a dietician or a podiatrist, it is often too late for routines to be established:

“The value of professional dietetic advice [in primary care] is really underestimated ... and I think that dieticians really have a very crucial role, providing that people with diabetes can adjust their diet and lifestyle. (Cons 2)

“I’m not always sure that we pick people up soon enough, I think probably we pick them up when they’ve got a problem, and maybe prevention is better than cure...I think the patients need to understand the implications...and what can happen on a long term basis”. (Orth 11)

Inconsistent access to relevant advice might have been affected by the socio-economic background of patients, as well as inequitable provision across the city.

Lack of acceptability

Although health professionals and patients stressed the importance of specific advice and explanations early in the course of diabetes, professionals suggested that too much information at once can be overwhelming, and that patients often appear to forget advice, or deny having received it. This is particularly likely when advice includes lifestyle changes such as smoking cessation, or dietary restriction. The initial shock of diagnosis may restrict the absorption of information, so there is a need for continual assessment of appropriate educational strategies.

Shared understanding

Interviews with professionals and patients highlighted the importance of shared understanding of the patient situation in providing both support and advocacy. Health professionals had gained a wealth of insight from their clinical interactions and professional knowledge that was used to build relationships with patients. Patients were particularly positive about Diabetes Specialist Nurses in terms of their expertise, empathy and accessibility; allocation to a particular nurse provided continuous access to advice and support:

“I just think they know more, more than what the doctors know, and they know every crook and cranny, whereas your doctors, working on a general principle, whereas they are working, specialising... and they’re friendly, more like a family basis...” (male patient N)

Understanding and acceptance of foot care information was encouraged by the constant sharing of knowledge, the reinforcement of knowledge, and provision of new pieces of information, which patients perceived as supportive.

“You pick up lots of different advice from lots of different people, you know....(podiatrist) may well tell you about your socks being, you know wear your socks inside out..., I’ve been diabetic for ten years, going to foot clinic for two years and I’ve not heard that one before, so, you know, you do, it does, it does increase your knowledge base attending a specialist foot clinic, rather than just going to see your GP”. (female patient M)

This shared understanding between the professionals and patients appears to have created a sense of security for patients, which encourages participation in self-care while also providing a safety net when problems arise.

Acting on information

While professionals provided insights into the patient experience from their professional interactions, there was some evidence of a different worldview in terms of acting upon knowledge.

Knowing vs. Doing

Professionals are provided with evidence-based guidance on specific practice, such as foot care for people with diabetes, the essence of which is passed on to patients in consultations. While guidelines aim to standardize care, patients have different needs and circumstances that cannot be accounted for in standard advice. In addition, some patients find that professional expectations conflict with social expectations. Advice may therefore interfere with activities of daily living, and appear unreasonable or impossible to carry out.

“When I’m in the house and I’m resting...obviously I do, but as long as there’s things to do, you know, I can’t neglect everything else ‘cos of that, ‘cos it’s not going to rule my life, that’s not what it’s all about is it?” (male patient L)

This was verified by one of the nurses:

“They never rest it to the full effect, because they’ve got to make a cup of tea if they’re on their own, or they’ve got to sort themselves out, or go to the shops”. (nurse 15)

Some patients might have difficulty accepting their diagnosis, and disregard preventive advice. Particularly in the early years, patients with type 2 diabetes generally have no serious symptoms to remind them of the need for action:

“Not having any problems, you feel alright, I mean, I felt alright, for a long time I felt fine...and I think, when you feel alright, you start thinking, oh, it’s not serious, so you just carry on your own life... but as soon as you start getting some problems, you look into things more”.(female patient B)

However, when discussing the fictitious character in the vignette, some of the patients referred to rules or instructions that he should follow in order to avoid complications. There was therefore a conflict between knowing what needs to be done, and actually carrying the actions out. The character was chastised for non-adherence, or non-attendance:

“All I can say is, he didn’t do what he was told to do...and what’s the point of going to clinics if you don’t do what they tell you to do?” (female patient K)

“I always keep my appointments, but like I say, if he thinks Oh, it looks alright, and he gets infection in it, it’s his fault, it’s his problem”. (male patient L)

Health professionals also found that encouraging some patients to act upon their advice could be a challenge. Possible reasons reported for this were lack of cognitive ability to assimilate or remember the necessary information, cultural barriers that limit understanding of medical language, and cultural differences in the perception of health:

“[People from Glasgow] just have more of a carefree, c’est la vie...approach to life. I’ve worked in Cambridge... the approach there is different, the people there tend to get very concerned about their health, they’ll try their very best, and I guess there are socioeconomic factors that come into it as well, and what different background you come from”. (Orth. 9)

These views highlight the problems in delivering and evaluating educational programmes without taking into account the variations in acceptability to patients of the information being given. They also show that acceptability can change over time, and with circumstances. With hindsight, patients with complications realised that they either did not receive or accept appropriate information at a time when it was crucial. They now felt a strong desire to share their experiences, or warn newly diagnosed patients of potential risks.

“Show them in a class, what happens when you don’t look after yourself, show them that; in the end, it is the end, it’s death, and that’s your fault....” (Male patient N)

Shared responsibility

While most patients focussed on the (real or fictional) patient's responsibility to follow advice, professionals were also concerned with their own, and the organizational responsibilities in providing and maintaining effective communication with patients.

"There's a greater duty of care because the staff know...which factors they haven't compensated accordingly, so he's missed appointments, carried on smoking, surely that's more the reason for chasing him up". (Pod 7)

Professionals were concerned that patients should receive enough advice to be able to carry out self-management, and this was a challenge if patients did not attend appointments, or if organizational barriers prevented access to optimal information.

Discussion

In this paper we have examined the issues around education and information exchange that affect people with diabetes-related foot complications. We found that patients reported a lack of early understanding of diabetes that may contribute to suboptimal self-care, and delayed health-care seeking. Reasons for this include inadequate or inconsistent information, a possible variation in cognitive ability, and difficulties in absorption of uncomfortable information in excessive amounts. Inequitable access to health education across the city could also be a factor at the time of diagnosis. For people with type 2 diabetes, in particular, there is also a paradox between understanding prevention and the lack of symptoms in early years. Early education was, however, seen as important, with regular, full explanations to ensure that patients fully understand the implications of diabetes, and misunderstandings are dealt with. The varied knowledge base of professionals may have influenced referral behaviours, leading to delay of treatment, and some patient experiences have fostered ongoing mistrust of certain professionals. However, mistrust could have arisen from professional training issues, or patient-professional relationships. The latter was the most striking feature of perceived support in self care, along with expertise and empathy. It therefore seems important that professionals develop an understanding of the patient in order to empower them in their self care activities, and this shared responsibility was acknowledged by some of the practitioners in this study.

The use of vignettes was helpful in allowing patients to discuss a range of issues without necessarily having to remember their own history, or disclose personal

information. It also allowed comparison of patient and professional data as the same vignette was used in all interviews. While the vignette focussed on the patient situation, prompts were used to encourage respondents to consider any issues that might affect the patient experience, for example, patient behaviour, or service delivery. To ensure that responses were not restricted by the vignette items, respondents were also encouraged to raise issues of their own interest at the end of the interview. Care has to be taken to separate potential behaviour of the fictitious character from actual experiences of the patient or professional. These were clearly identifiable in that respondents tended to signpost when they shifted focus from one to the other. Previous work has commented on the validity of the information obtained using vignettes.²² In this study the vignette was thoroughly tested with an expert panel and piloted to obtain internal validity.

Patients with longstanding foot complications and experience with health-care services were chosen for the study in order to access the potential barriers that lead to amputation. The findings cannot therefore be directly generalized to all people with diabetes, who may have experience of different local service provision. Previous studies and reviews that have examined patient education have usually evaluated prospective educational interventions^{15,18} in terms of their outcomes. Interventions tend to vary in style, content, delivery and theoretical base, and include only a selected group of participants, and the studies rarely include patient views of the intervention. One study¹⁸ that did include qualitative information supported our findings in that patients had often not received adequate information following diagnosis. They also found that education programmes are generally poorly attended, possibly not only because of misconceptions about the seriousness of type 2 diabetes, but also because there was often a perceived mismatch between educational recommendations and the reality of living with diabetes.

A qualitative study that assessed female patient attitudes to type 2 diabetes²⁹ also found that practitioners had tended to underplay its seriousness, which led to a lack of incentive for patients to make recommended changes to their lifestyle. Campbell et al.³⁰ suggested in their meta-ethnography of qualitative studies that in order to cope with diabetes, patients need to realize the seriousness of their disease, and that time is required to allow patients to become familiar with the effects of diabetes on the individual. A review by Krichbaum et al.³¹ supports the need to tailor educational packages to meet the needs of individuals, and their varied coping styles. A contradiction in diabetes education, evident in our study, is that patients realize with

hindsight the importance of early education, and that they want to share their experiences with those who are newly diagnosed. However, when patients are newly diagnosed, they may not receive or accept this information; furthermore, because there are no symptoms, the importance of changing their lifestyle is not immediately apparent. The results highlight the need for a thorough evaluation to determine the gaps that need to be closed to fulfil the expectations and requirements of individual patients, as well as the patient population. This could involve assessment of professional training, patient–professional relationships, and the barriers that patients may experience in accepting information that may seem irrelevant at the time of delivery.

Acknowledgements

We thank all the health professionals and patients who took part in the interviews, and the Consultants and nurses who identified and contacted patients on our behalf.

Funding for this study was provided by a Department of Health Public Health Scientist Career Award, and the Sheffield Health and Social Research Consortium.

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Box 1: Demographic details of patient sample

Patients:

15 patients (including three in pilot) from two teaching hospitals (9/6)

Sex: 9 male, 6 female

All were of white ethnic group, and English-speaking

Age: No of participants:

30–39	1
40–49	2
50–59	5
60–69	4
70 or more	3

Diabetes diagnosed (years)

0–2	0
3–5	1
6–10	2
11–20	4
21 or more	8

Treatment

Type1	7
Type 2 on insulin	6
Type 2 on oral medication	2

Health professionals:

Total of 15 based in two teaching hospitals, and primary care.

Consultant diabetologists	2
Vascular surgeons	1
General practitioners	2
Nurses	3
Podiatrists	3
Orthotists	3
Dieticians	1

Box 2: Vignette and prompts used for interviews

Mr Smith is 61 years old, and a retired storekeeper. In 1992 he was told that he had diabetes, which needed to be controlled by taking tablets and adjusting his diet. His doctor advised him to stop smoking, and look after his feet.

Mr. Smith visited his GP for check-ups. On some visits his blood sugars were higher than they should have been. He continued to smoke.

Why do you think his blood sugars were sometimes high?

Why do you think he was still smoking?

Gradually, Mr. Smith's eyesight began to deteriorate, and he lost some of the sensation in his feet. One day, he caught his big toe on a piece of torn lino. He didn't feel anything, but it started to bleed. He put a plaster on it, and left it for a few days, after which the cut began to discharge, and he showed it to his GP.

Why do you think he waited before seeing his GP?

What might influence this decision?

The GP referred Mr. Smith to the hospital foot clinic, where the ulcer was dressed, antibiotics were prescribed, and a district nurse was arranged. It took a long time to heal.

Why might this be?

After some time, the ulcer healed, and Mr. Smith was discharged from clinic and given special shoes. One year later, the ulcer reappeared.

Why do you think the ulcer might have reappeared?

Mr Smith has a hospital foot clinic appointment every 2 weeks; he doesn't always make it.

Why might he not attend?

The staff in the foot clinic arranged for Mr. Smith to see a vascular surgeon. He didn't

arrive for the appointment.

Why do you think he didn't turn up?

This is a study looking at services for people with diabetes, and in particular, with diabetes related foot problems. The interview consists of a short story that is about a person with diabetes, and will be presented in stages so that you can discuss any issues you think relate to the story.

There are no right or wrong answers, we are not attempting to find out how much you know about diabetes; we are trying to find your views about services available to patients.

The information is recorded on tape with your permission, and will remain confidential. No names will be attached to the data, either on tapes, transcriptions, or in any report that is produced. Tapes will be erased after writing up, and you will be able to read any report that is written, and give feedback, before it is circulated generally.

You can stop the interview at any time, or contact me later if you decide you no longer wish to take part in the study, or if you want to add to, or change anything you have said during the interview.

Prompts for patient information

1. *Who is regarded as important in diabetes care*
2. *Mode of travel to and from GP/clinic*
3. *Working/retired. Occupation if working*
4. *Housing*
5. *Marital status*
6. *How access could be improved.*

Publication 3: Johnson M., Newton P., Goyder E. Patient and professional perspectives on prescribed therapeutic footwear for people with diabetes: A vignette study. *Patient Education and Counseling* 2006; 64: 167- 172

Patient and professional perspectives on prescribed therapeutic

footwear for people with diabetes: A vignette study.

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Abstract

Objective

This article draws on a qualitative study to identify and discuss patient and health professional views of the use of therapeutic footwear for people with diabetes-related foot complications.

Methods

Semi-structured interviews were conducted with 15 patients and 15 health professionals using a 'vignette' technique. The interviews were audio-taped, and Framework analysis was used to identify main themes and categories.

Results

The prescription of therapeutic footwear was an important issue for patients, and health professionals were aware of this. The main issues were the differing perspectives between patients and professionals in terms of the expectations and reality of preventive behaviour, and difficulties in fitting shoes when feet are constantly changing shape.

Conclusions

Patients often have difficulty changing their shoe-wearing behaviour in line with guidelines, particularly within the limits of available therapeutic shoes. The choice of available shoes may not meet the varied and specific needs of patients. Patient perspectives therefore need to be taken into account in shoe provision.

Practice Implications

The concept of concordance would appear to be useful in allowing patient needs to be identified before designing and prescribing therapeutic shoes. More choice in styles, and involving patients in footwear design and selection, might encourage the use of appropriate footwear.

1. Introduction

Diabetes-related foot complications present a growing burden for health services [1] and affect the quality of life for patients. Recent literature and guidelines suggest that many foot ulcers and amputations could be prevented using optimum care and monitoring. [2,3] In addition, the regular use of inadequate or inappropriate footwear contributes to the risk of ulceration and amputation [4,5], therefore specially designed therapeutic footwear or 'special shoes' have been recommended as a preventive measure. Issues around footwear for people with diabetes have received little research attention; what exists highlights the complexity of special shoe provision and wear. Similarly, studies of the diabetes experience and self-care behaviours have not tended to include issues arising from the prescription of footwear.

Randomised controlled trials and systematic reviews have not provided support for widespread preventive use of therapeutic footwear or insoles.[5-7] . Dahmen et al [8] acknowledged the limited evidence base and practical difficulties of providing accurate assessments and measurements of various complications, such as Charcot foot. They compiled an algorithm based mainly on experience, in order to simplify the decisions required in prescribing, although it is uncertain whether using the algorithm improves outcomes. Davies et al [9] found that quality of life for patients with diabetes receiving orthotic care was most affected by role reduction caused by physical problems, and concluded that shoes should be prescribed for at risk feet. However, Litzelman et al [10] reported that recommendations for therapeutic footwear were not being taken up, and that hardly any of their participants actually wore the shoes.

Because effectiveness of footwear is dependent upon optimal use, some research has been undertaken in this area. One questionnaire study found that only 28% of respondents reported full compliance with instructions for wearing their shoes, despite reporting that they understood their importance, and liked the shoes. [11] An audit of special shoe wear was more encouraging, showing up to 83.5% compliance provided that regular reviews are carried out by appropriate professionals, and that patients are well-informed and feel involved in the prescribing process. [12] Reasons for non-compliance have also been investigated. A study examining the beliefs and behaviour of patients with neuropathic feet proposed that fear of the consequences of diabetes, anger towards practitioners, and depression are potential factors in inhibiting adherence to foot-care. [13]

Previous work on therapeutic footwear has included guidelines and recommendations for prevention of foot complications, based on available evidence. Compliance studies focus on patient behaviour, but from the perspective of the professional. There is, however, a lack of research that explores the experiences and views of people involved in prescribing and wearing footwear designed to reduce diabetes-related complications. As part of a larger qualitative study that aimed to discover why foot complications and amputations persist despite the availability of preventive interventions, this paper explores issues identified by clinicians and patients that impact upon the prescription and use of therapeutic footwear.

2. Methods

The study was carried out following ethical approval from North Sheffield Local Research Ethics Committee (LREC). A more detailed account of the methods used in this study can be found in previous work [14]

2.1 Participants

Purposive sampling was used to identify a broad range of health care professionals with experience in delivering care to people with diabetes-related foot complications. Three consultants (one in vascular surgery, two diabetologists), two general practitioners, three nurses (including two diabetes nurse specialists), three orthotists, three podiatrists, and a dietician (a total of fifteen professionals) agreed to be interviewed.

In addition, health care professionals identified a purposive sample of patients from the two diabetes foot clinics. Patients with type 1 and type 2 diabetes, and long-term experience of foot care services, were invited to participate. Fifteen patients from diverse areas of the city in terms of socio-economic circumstances agreed to be interviewed. It was expected that this range of social and clinical experiences might be reflected in responses, providing a broad spectrum of beliefs and attitudes. All 15 patients had been attending the foot clinic for some time, with foot complications that varied from ulceration to amputation. Twelve patients stated that they had used prescribed footwear. Other participant characteristics are summarised in Box 1.

2.2 The Vignette

A structured, large-print vignette (Box 2), was used for all the interviews. The vignette depicts the experiences of a fictitious patient with diabetes-related foot complications. Vignettes facilitate the expression of knowledge, opinions, beliefs, and attitudes [15-17] without necessarily referring to the patient's own history, or the professionals' behaviour. The use of single vignettes maintains interest by building up a continuous story, and has been successfully utilised in other areas of health research. [18] The vignette was piloted following reference to relevant literature and discussions with an expert panel. [19] It was then presented visually, with each section of the vignette being shown in large-print on A4 paper, whilst being read out loud by the interviewer. Open-ended prompts (Box 2) encouraged discussion in both patient and professional interviews.

2.3 Interviews

Interviews with health professionals and patients were carried out between September 2003 and April 2004, and were audiotaped with consent. Vignettes have been used with focus groups but we used individual interviews in order to obtain individual accounts rather than group interaction, and because focus groups might be problematic in terms of access for patients with limited mobility. They can also create difficulties for professionals in terms of openly discussing sensitive issues among colleagues and senior staff.

Health care professionals were interviewed at one of two hospital sites, or in primary care, and patients were interviewed at their home, or at one of the hospital-based diabetes foot clinics. Prompts (Box 2) were used after each vignette section to explore participant views about the development of the storyline. This was to elicit potential personal or service delivery issues that might affect patient outcomes. Responses were then followed up as necessary to increase clarity and depth of information; actual experiences were not asked for, but were often volunteered by the participants.

2.4 Analysis

The audiotapes were transcribed verbatim prior to analysis using the framework approach. [20] This method involves familiarisation with the data and the consequent

development of a thematic framework from which to classify or 'code' the data. Two researchers (MJ, PN) carried out this process with a sample of transcripts before applying the framework to the remaining data. Care was taken to distinguish between responses that reflect beliefs about the storyline, and those that relate to an actual experience, though both were regarded as indicators of potential issues in care delivery.

Categories and subcategories were charted into a numbered matrix, which was then used for further analysis. There were a total of nine subcategories relating to the association between foot complications and therapeutic footwear. The data within these categories was analysed for commonalities, links and differences, resulting in the themes described in section 3, which summarise the important issues for patients and professionals.

3. Results

For prevention or healing of foot ulceration, continuous use of therapeutic footwear is advised. This poses challenges to patients and professionals, whose different viewpoints are highlighted in the interviews. The main issues were the incongruence difference between professional guidance and patient behaviour, which highlights the balance between risk and choice, and the problem of providing or using footwear to cope with inevitable changes in the size or shape of user's feet. These issues became the themes and sub-themes that are discussed below.

3.1 Prescribed Behaviour vs. Routine Behaviour

3.1.1 Minimising risk

Specific concerns were raised that reflected the different perspectives of the two groups. The main difference was the professional emphasis on health promotion, and the patient focus on accommodation of health promoting behaviour into daily life. From a health promotion perspective, routine activities can become a hazard:

“people do some strange things with footwear...a lot of people go on holiday... and they don't want to wear protective footwear, they wear open heeled sandals, flip-flops, they're walking round swimming pools, where there's danger of stones and things round the pool, on the beach, and places like that” (Pod 14)

For patients, there appear to be risks involved whether or not advice is taken. Carrying out advice that does not fit in with usual behaviour or that of others may result in feeling 'different', particularly in social situations. However, to ignore advice may be seen as deviant, as well as being potentially detrimental to health. Patients can differ in their approach to minimising these risks, and differences are apparent in the patient and professional accounts.

3.1.2 Maximising choice

Four out of the twelve respondents who had experienced wearing special shoes did not report any problems associated with them. For these patients and most professionals, wearing special shoes was a common-sense behaviour that promoted health. However, for the other eight, the reality of wearing prescribed footwear conflicted with usual assumptions around the wearing of shoes:

“when I looked at the shoes in the catalogue, they were horrendous, and there’s no way, even for me own health, that I’d wear them. Because, how can you walk out in t’summer, with a nice dress on, or shorts, and wear them bloody things?” (female pt 5)

Social occasions present a particular dilemma, as being seen in functional shoes not only conflicts with one’s style in clothes, but also draws attention to health status:

“there were ever so many in Church that didn’t know I was a diabetic, until I started wearing this big shoe; you don’t want to broadcast it!” (female pt K)

One male patient reported that shoe styles have improved in recent years. Even so, the style of shoe prescribed might differ from that normally worn:

“I used to wear casuals, and he said “stop wearing casuals... I’d just bought a pair actually, twenty-four hours before he told me I’d just bought a pair.....But er. I haven’t worn casuals since, so, only lace-ups” (male pt E)

Nine out of 15 professional responses indicated that patients might not always wear prescribed shoes, and the role of the practitioner in educating the patient in order to promote health was emphasised:

“often, they don’t think they’re fashionable; we’ve got one or two people who are still wearing winkle pickers...and again, all you can do is keep reiterating the importance of why you have to continue with them” (nurse 17)

One nurse however recognised that limited choice of footwear across settings might be problematic for patients:

“it’s getting this information across, that this specialist footwear should be worn at all times, and being able to provide people with more than one pair of shoes, and more than one style of shoe, ones that they can wear in summer, and others they can wear when it’s cold in the winter” (DSN 8)

These comments highlight the importance of identifying the patient’s social context when prescribing health promoting behaviour.

3.2 Stable shoe vs. instable foot

Patients and professionals had concerns about the fit of the shoe, which, whilst essential to effectiveness, was not always optimum. Problems arise because, despite shoes being made to measure, the foot shape, size and structure can alter. For patients this often means giving up on the shoe, or adapting it to suit the foot:

“I wear special shoes at the moment, I’ve got some, but I can’t wear them because I’m having a lot of pain in my bone, and I think the soles have been made of...they fit my foot perfect, but they put pressure on in places that I’ve never had pressure on before, so they’re hurting me, so I’ve stopped wearing them for a while, but I do wear ‘em, I don’t like ‘em, but I wear ‘em” (Male pt 1)

The complexities of fitting therapeutic shoes were expressed by over half of the professionals; the tendency of patients’ feet to alter, and have a unique shape and size creates a risk even when special shoes are worn:

“there’s something like thirty-one considerations in the fitting of the shoe; you only tend to get length measurements and width measurements, all the other things, aren’t things that are measured for, and catered for in the shoe. Now, if that shoe fits perfectly in the morning, if all of these thirty-one considerations just happen to perfectly match, it’s not going to fit in the afternoon because the foot will swell ...somewhat during the day, so those thirty-one things won’t match later in the day. So, at best, you’re hoping for a reasonable compromise, with the footwear” (Pod 10)

The complexities of fit are taken on board by patients as well as professionals; patients attempt to modify the prescribed footwear to accommodate their changing physiology,

or changes in sock thickness. Modifications may or may not be beneficial in the long term, and might be viewed either as resourceful self-care behaviour, or a deviation from the advised behaviour.

In summary, the prescribing of one or two pairs of therapeutic shoes for patients with at risk feet to wear at all times could be at the root of the low level of take-up, as the shoe is not sensitive to the varying contexts in which it is to be used, or the varying shape of the patients' foot. The concept of risk is used to highlight the differing perspectives of patients and professionals in relation to the wearing and non-wearing of the shoes.

4. Discussion and Conclusion

4.1 Discussion

The findings in this study highlight difficulties faced by patients and professionals in provision and wearing of special shoes. Some of these difficulties are practical issues, such as measuring and fitting, and coping with the changing shape and structure of patients' feet. Although patients receive recommendations in the continual use of therapeutic footwear, this requires potentially unacceptable changes in behaviour and can also cause discomfort.

Whilst there is some commonality between patient and professional reports in this study, there is a difference in perspective. Professionals are advocating preventive measures in order to limit morbidity, though they seem to be aware of how difficult this could be for patients. Patients, on the other hand, are receiving advice in the context of their lived experiences, and this is often unacceptable in terms of personal and social norms. The difficulty in achieving ideal health promoting behaviour therefore poses a challenge for both patients and professionals.

Knowles and Boulton [21] also found that prescribed footwear can be unacceptable to users; women in particular were less satisfied with the available styles, and, as in this study, there were problems associated with comfort and fit of the shoes. The unacceptability of therapeutic footwear may be linked to aspects of self-identity. According to Giddens [22], regimes of dress signify particular aspects of the individual,

such as self-image. In this study, lack of choice may interfere with the ability to project one's identity in a satisfactory way, limiting the acceptability of wearing the shoes.

These findings highlight the way that health promotion requires that people adapt and modify their everyday lives in accordance with advice. This trade-off has been shown to influence decision-making in terms of accepting prescribed treatments, such as antidepressants [23], and the differentiation between visible and invisible health promotion activities in people with type 1 diabetes was highlighted by Thorne and Paterson [24]. Wearing therapeutic shoes can be regarded as a highly visible activity, with associated stigma and embarrassment.

Some of the issues raised in this study challenge the concepts of compliance and adherence as professional centred [25]. In contrast, concordance involves input from the patient in terms of feasible and desirable methods of treatment, and can be seen as a partnership between patient and professionals in order to achieve well-being [26]. From a concordance perspective, the focus for change would include the feasibility, accessibility, and affordability of options open to patients, as well as patient's own values and beliefs. If patient behaviour is seen in the context of risk minimisation, for example, rather than compliance, this might help our understanding of different responses to health promotion advice.

This article has outlined how a particular prescribed behaviour may be viewed by professionals and patients, and the need for more thorough exploration of patients' requirements prior to prescription. The small sample involved in the study prevents generalisation to a larger population of people with foot complications, but the issues raised are transferable to similar settings.

4.2. Conclusion

From the findings in this study, it would appear that changes in professional practice are needed if patient requirements and values are to be taken into account at all stages of the preventive process. For therapeutic footwear to be effective, it needs to be used optimally, and this will not occur if optimal use is unacceptable to patients.

4.3. Practice Implications

Negotiating the extent of use, provision of varied styles for different contexts, and evaluation of the fit of shoes might improve the feasibility and acceptance of this particular form of preventive behaviour. Patients might also be encouraged to assist in footwear design, and their views obtained in more detail about the acceptability of recommendations. This input could help to provide more realistic aims in prevention that can be carried out within the patient's, rather than the professionals', terms of reference. The issues raised in this study might be used as part of research with larger samples to identify the issues involved for patients with diabetes receiving self-care advice.

Acknowledgements

We thank all the Consultants, GPs, nurses and patients who took part in the interviews, and the Consultants and nurses who identified and contacted patients on our behalf. We also thank Paul Ward, Lecturer in Public Health Medicine, Public Health, ScHARR, University of Sheffield, for his helpful comments on an earlier draft. Funding for this study was provided by a Department of Health Public Health Scientist Career Award, and the Sheffield Health and Social Research Consortium.

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Box 1. Demographic details of patient sample

Patients:

15 patients (including 3 from pilot) from 2 teaching hospitals

Sex: Patients: 9 male, 6 female

All were of white ethnic group and English-speaking

Age: No. of participants:

30-39 1

40-49 2

50-59 5

60-69 4

70 or more 3

Diabetes diagnosed (yrs):

2. 0

5. 1

10. 2

20. 4

21 or more 8

Treatment:

Type 1 7

Type 2 on insulin 6

Type 2 on oral medication 2

Health Professionals:

Total of 15 based in 2 teaching hospitals and primary care.

Consultant Diabetologists 2

Vascular surgeons 1

General Practitioners 2

Nurses 3

Podiatrists 3

Orthotists 3

Dieticians 1

Box 2. Vignette used for interviews

Mr Smith is 61 years old, and a retired storekeeper. In 1992 he was told that he had diabetes, which needed to be controlled by taking tablets and adjusting his diet. His doctor advised him to stop smoking, and look after his feet.

Mr. Smith visited his GP for check-ups. On some visits his blood sugars were higher than they should have been. He continued to smoke.

Gradually, Mr. Smith's eyesight began to deteriorate, and he lost some of the sensation in his feet. One day, he caught his big toe on a piece of torn lino. He didn't feel anything, but it started to bleed. He put a plaster on it, and left it for a few days, after which the cut began to discharge, and he showed it to his GP.

The GP referred Mr. Smith to the hospital foot clinic, where the ulcer was dressed, antibiotics were prescribed, and a district nurse was arranged. It took a long time to heal.

After some time, the ulcer healed, and Mr. Smith was discharged from clinic and given special shoes. One year later, the ulcer reappeared.

Mr Smith has a hospital foot clinic appointment every two weeks; he doesn't always make it.

The staff in the foot clinic arranged for Mr. Smith to see a vascular surgeon. He didn't arrive for the appointment.

Publication 4: Maxine Johnson, Emma Everson-Hock, Roy Jones, Helen Buckley Woods, Nick Payne, Elizabeth Goyder. What are the barriers to primary prevention of type 2 diabetes in black and minority ethnic groups in the UK? A qualitative evidence synthesis. *Diabetes Research and Clinical Practice* 2011; 93: 150-158

What are the barriers to primary prevention of type 2 diabetes in black and minority ethnic groups in the UK? A qualitative evidence synthesis.

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Abstract

Background:

This review aimed to synthesise available qualitative evidence on barriers and facilitators to the implementation of community based lifestyle behaviour interventions to reduce the risk of diabetes in black and minority ethnic (BME) groups in the UK.

Methods:

A search of medical and social science databases was carried out and augmented by hand-searching of reference lists and contents of key journals. Qualitative evidence was synthesised thematically.

Results:

A total of 13 papers varying in design and of mainly good quality were included in the review. A limited number of intervention evaluations highlighted a lack of resources and communication between sites. A lack of understanding by providers of cultural and religious requirements, and issues relating to access to interventions for users was reported. Behaviour change was impeded by cultural and social norms, and resistance to change. There were variations in the way dietary change and physical activity was approached by different groups and contrasting practices between generations.

Conclusions:

Qualitative data provided insight into the ways that providers might improve or better design future interventions. Acknowledgement of the way that different groups approach lifestyle behaviours may assist acceptability of interventions.

Introduction

In the UK 100,000 people are diagnosed with type 2 diabetes every year and many more may have the condition (Diabetes UK 2006). Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT) are risk factors for type 2 diabetes which together are often described as hyperglycaemia, or Impaired Glucose Regulation (IGR). Between 33% and 66% of people with such risk factors will go on to develop type 2 diabetes over a period of 3–6 years (Diabetes Prevention Programme Research Group 2002; Lindstrom *et al.* 2003; Pan *et al.* 1997; Ramachandran *et al.* 2006). Therefore, identifying and intervening with those at risk could reduce the prevalence of T2DM in

the long term (US DPP 2002; Tuomilehto *et al* 2001). Whilst major international trials have focussed on prevention in populations that already have impaired glucose levels, groups at higher risk due to ethnicity, and / or low socio-economic circumstances may also benefit from targeted intervention.

A systematic review of UK literature was carried out to identify available evidence on community promotion of healthy lifestyle behaviours among adults aged 18-74 from black and minority ethnic (BME) groups in the UK. Data for this review was limited to that produced within the UK to increase feasibility in terms of resources, as well as applicability to UK practice. A review of reviews that assesses non-UK evidence on interventions for high-risk groups (low socio-economic groups and BME) is available online (O'Mara *et al* 2010).

This paper reports on the synthesis of this evidence, focussing on barriers and facilitators to the implementation of interventions and behaviour change relating to preventing diabetes and pre-diabetes. A range of study designs was considered including evaluations, surveys, interviews and focus groups.

Methods

Search strategy

Searching for relevant literature was carried out in 2009 by an information specialist. An emergent, rather than exhaustive search strategy (Booth 2008) was utilised. This method was developed in order to achieve maximum specificity in the context of complex review questions such as those addressing public health topics. The method entailed close working between the information specialist and reviewer, with the reviewer identifying relevant terms that were further explored by the information specialist. Initial mapping searches were carried out to identify the range of available literature relating to the review question (Grant & Booth 2009). This literature was then used to expand searches in order to focus on the strategies and terms that were fruitful, as well as those that might fill the gaps in retrieved literature.

The following electronic databases were searched: Medline via OVID SP; Embase via Ovid SP; CINAHL via EBSCO; British Nursing Index via OVID SP; PsycInfo via OVID SP; The Cochrane Library via Wiley; Science Citation Index via Thomson ISI; Social Science Citation Index via Thomson ISI, EPPI Centre Databases – Bibliomap, DoPHER, TRoPHI, The database on Obesity and Sedentary behaviour studies. These

databases were selected in order to cover both medical, health and social science topics.

Additional websites searched for the initial mapping review include Diabetes UK; NHS Evidence specialist collection for Diabetes; NHS Evidence specialist collection for Ethnicity and Health. From sourced articles, further searches were carried out using key phrases, words, and authors. Details of the full search strategy are available upon request.

Inclusion / exclusion criteria

Papers that were included in the review addressed the prevention of pre-diabetes and other related conditions (e.g. cardiovascular disease (CVD), obesity) with adults (over the age of 18 years). Although inclusion of evidence was not restricted by study type, though there was a focus on study designs that elicited the views of professionals and users, or that included relevant process evaluation information. Retrieved papers were restricted to those published in the English language after 1990.

Findings

Identification of retrieved papers

In order to identify the barriers and facilitators to the effective implementation of an intervention, data were derived from studies evaluating interventions as well as from qualitative studies that focussed on the views of target groups in relation to behaviour change. A range of study designs including action research, questionnaires, interviews and focus groups were used to obtain the views of patients and professionals on interventions and behaviour change aimed at preventing pre-diabetes and other related conditions.

Quantity of available evidence

Initial mapping searches yielded a total of 3416 abstracts for screening, after de-duplication. Of these, 90 were deemed relevant to this review, with 82 being rejected on further scrutiny of full texts. Focussed searches yielded 237 abstracts after de-duplication, with 235 being rejected on further scrutiny. Web searches yielded 3 relevant papers. On examination of full texts, 13 papers were found for inclusion in the review of barriers and facilitators to intervention implementation and behaviour change.

Data Extraction and analysis

Qualitative data relevant to the research question was extracted from all 13 included papers. A data extraction tool developed for qualitative studies was piloted on two papers and adjusted to ensure the optimum extraction of relevant material to address the review question. Data was extracted and the papers assessed for quality by two reviewers (MJ; EEH) who double-checked each other's extractions and assessments. Thematic analysis was carried out with the qualitative data extracted from each included paper, taking into account different settings and sub-groups.

Quality

The quality of included studies was assessed by one of two reviewers (MJ, EEH); all quality assessments were double checked by a reviewer not involved in the initial assessment. Quality criteria and ratings were based on those developed for the methods guide for development of NICE public health guidance (2009a). Quality ratings from – (poor) through + (good) to ++ (very good) were designated to papers in relation to transparency of reporting, validity of the conclusions given the data provided, as well as relevance to the research question. The general quality of the thirteen included studies was good. Two qualitative studies were rated as ++ and eleven qualitative studies were rated +. The quality ratings are shown for each study in Table 1.

Settings

This review was limited to UK evidence. Four studies were carried out in the North of England, 3 in London, 3 in Scotland and the remaining 3 in a range of UK locations.

Populations

Nine studies focussed specifically on South Asian populations, with a further 2 studies including South Asian groups. One of these two studies also included Caribbean and African communities, whilst the other study included African (Somali and Zimbabwean) women. One study focussed on a Somali community and another on a Gypsy Traveller site. Whilst it is likely that a degree of acculturation into UK society, or exchange of cultural norms would take place within groups participating in the included studies, this issue was not explicitly discussed by the authors.

Two studies included health professionals and leaders as well as target groups for interventions. Five studies focussed on female users, two of which explored the views of overweight or obese women. Details of included studies are set out in Table 1.

Main themes from included studies

Barriers and facilitators to intervention implementation

One included study explored health professional, co-ordinator and organiser views on intervention provision (Carroll *et al.* 2002). From the findings of the survey part of a study evaluating 'Exercise on Prescription' (EoP) for South Asian Muslim women, a lack of financial resources was reported, as well as a lack of communication between different teams that were organising the intervention in different parts of the country.

Views of users and providers highlighted lack of understanding of black and ethnic minority groups by health professionals, organisers and other users as a barrier to successful implementation. There were particular gaps in understanding reported in relation to religious beliefs, male-female dynamics in Islamic culture and perceived body image in the way they impact on health and health promoting activities. For example, South Asian Muslim women commented on a non-Muslim perception that the practice of Islam and physical activity are incongruent (Carroll *et al.* 2002), a belief that was refuted by both lay members of the community and religious leaders (Grace *et al.* 2008).

"I think it is really bad for women like me who can't speak English. I can understand it most of the time but I can't reply or read or write it. Sometimes I think that white people don't understand our needs. They just think we don't want to be healthy and exercise – but we do" (Carroll et al. 2002).

A lack of understanding of how males and females interact within Islam was a barrier to provision of physical activity classes that respect the needs of Muslim men and women (Carroll *et al.* 2002). Health professionals in one study expressed the belief that Bangladeshi people associate obesity with good health and fertility, creating a perception that Bangladeshi communities are unwilling to manage their weight (Grace *et al.* 2008). In contrast, one evaluation showed that an understanding of the importance of timing interventions around religious events meant that attendance was optimised (Netto *et al.* 2007). These examples highlight the importance of cultural understanding and its impact on the motivation to organise facilities that are appealing and acceptable to specific groups.

Barriers and facilitators to acceptability of interventions

Advice, information and encouragement

In one evaluation small changes to dietary practices such as cutting down the amount of fat, red meat, salt and sweetmeats consumed were attributed to appropriate support to change. This included adequate advice and encouragement from organisers. Similarly, one participant reported that staff had given support in how to exercise 'properly', that is, advising on the optimum speed, frequency and duration necessary to have an impact on health. (Netto *et al.* 2007).

Access to facilities

For South Asian Muslim women interviewed in the evaluation of EoP (Carroll *et al.* 2002), a barrier to attendance was lack of access to exercise facilities, which often required the use of public transport to the nearest venue. Four further studies provided evidence for the reluctance of South Asian women to travel unaccompanied during the evening (Darr *et al.* 2008; Grace *et al.* 2008; Khanam & Costerelli 2008; Williams & Sultan 1999). Close access to classes was a particular facilitator for a Gypsy traveller community, where attendance at physical activity sessions increased at events that were facilitated on-site (Kopp 2009). For all these groups, travelling away from home presented issues of safety.

For South Asian women, language was a barrier to travel for older members of the community, who found it difficult to read signs or ask for directions. There was also a reluctance to walk to venues in winter months (Williams & Sultan 1999). Issues of access were also raised by South Asian women in relation to potential cooking classes (Lawrence *et al.* 2007), with local schools being suggested as potential venues.

Family and work commitments

Lack of time for carrying out prescribed physical activity was cited by South Asian women due to childcare and other home care commitments (Carroll *et al.* 2002; Khanam & Costerelli 2008; Netto *et al.* 2007; Williams & Sultan 1999). There was a cultural expectation of Bangladeshi women in one study to remain within the home (Grace *et al.* 2008). For South Asian men in one study, working long hours limited access to organised physical activity (Netto *et al.* 2007).

A lack of childcare facilities within some Exercise on Prescription (EoP) establishments meant that women needed to be accompanied by a relative who would mind the children outside the venue during participation. Facilities were not consistent across schemes or across classes, with some women-only classes not being serviced by a crèche (Carroll *et al.* 2002). Lack of child care facilities also limited participation in non-prescription physical activity sessions (Grace *et al.* 2008; Kopp 2009).

Costs

Whilst EoP schemes are low-cost, they were still seen as too much of a financial burden for some South Asian Muslim women, particularly if transport was required. Women prioritised spending money on their children rather than on themselves (Carroll *et al.* 2002). Similarly, activities organised away from a Gypsy Traveller site were seen as too expensive (Kopp 2009).

Organisation of sessions

For South Asian women, physical activity classes in one evaluation were not long or frequent enough to make the effort associated with attendance (Williams & Sultan 1999). A lack of women-only sessions was a common problem in physical activity interventions for Muslim women. Where women-only sessions were available, these were often at difficult times of the day or week for women with families, or sessions were still visible to male members of staff, which conflicted with cultural and religious norms (Carroll *et al.* 2002). Some South Asian men also found attendance at mixed gender sessions uncomfortable (Farooqi *et al.* 2000; Grace *et al.* 2008).

There was a reported dislike of the gym environment by first generation Muslim women (Khanam & Costerelli 2008; Rai & Finch 1997); in particular, the use of loud music, inappropriate television scenes and the need to dress in a culturally inappropriate way were cited as deterrents.

Language

For many South Asian study participants, language was a barrier to accessing and understanding information as well as communicating needs to those delivering services (Carroll *et al.* 2002; Grace *et al.* 2008; Khanam & Costerelli 2008; Rai & Finch 1997). Relatives were often recruited to accompany women and act as translators (Carroll *et al.* 2002).

Identified barriers and facilitators to behaviour change

Religious influences

Religious customs were reported as barriers or facilitators to lifestyle change in six studies. Change was more likely where participants believed they had some degree of free will despite for example, the presence of a family history of diabetes (Darr *et al.* 2008), though there were ambivalent reports regarding fatalistic attitudes. A perception that change might be impeded by fatalism (Grace *et al.* 2008) was countered by reports that health conditions could be the will of God and the responsibility to attempt to prevent ill health lies with the individual (Darr *et al.* 2008). However, health promotion activities must not conflict with religious teachings (Grace *et al.* 2008; Khanam & Costarelli 2008; Farooqi *et al.* 2000; Rai & Finch 1997; Carroll *et al.* 2002).

Cultural and social influences and differences

Both dietary and physical activity practices were influenced by cultural identity in a number of studies. Food is symbolic of generosity and economic status as well as representing traditional health beliefs passed down through generations (Rai & Finch 1997; Grace *et al.* 2008; Lawrence *et al.* 2007; Netto *et al.* 2007). The use of fat in south Asian cooking, especially for guests, represents good hospitality. Traditionally, reducing the amount of ghee or oil renders the food unattractive as well as being shameful (Grace *et al.* 2008; Netto *et al.* 2007). For Somalis in one study (McEwen *et al.* 2009) meat consumption was associated with wealth while fruit and vegetables were valued less because of their relative cheapness back in the homeland. Conversely, fruit and vegetables were more readily eaten by Gypsy Travellers (Kopp 2009) precisely because they were relatively cheap.

Medicinal properties, including prevention or management of diabetes were associated with certain fruit and vegetables in a study of South Asian dietary practices (Pieroni *et al.* 2007). Foods could be 'good' or 'bad' for a healthy body. Second generation South Asians and Somalian males were reported to be consuming more take-away food as a change from their traditional fare (Grace *et al.* 2008; McEwen *et al.* 2009). Traditional dietary practices were differentiated from Western eating habits ('our' food; 'your' sorts of food) by women whose choices were informed by both cultures (Bradby 1997).

However, some South Asian women are beginning to cook traditional meals in more healthy ways, such as reducing the amount of fat (Netto *et al.* 2007). Women from

Zimbabwe were not used to cooking for themselves as in Africa maids had done the cooking; having to cook in the UK was seen as time consuming (Lawrence et al. 2007).

Just as dietary behaviours were reported as having different associations and practices in the homeland compared with the UK, physical activity also had a different purpose and association 'back home', where every-day activity such as housework or river bathing was the norm and vigorous exercise was seen as unnecessary, or unacceptable (Darr et al. 2008; Rai & Finch 1997; Grace et al. 2008; Farooqi et al. 2000; Khanam & Costarelli 2008; Carroll et al. 2002).

Swimming and slow walking were preferred ways to remain active (Rai & Finch 1997; Khanam & Costarelli 2008). In the UK, organised activities such as attendance at swimming or dance classes or membership of a gym are the typical method of exercise (Khanam & Costarelli 2008; Rai & Finch 1997; Kopp 2009; Carroll et al. 2002). Authors used the terms 'separate' and 'integral' to describe these two approaches to physical activity (Rai & Finch 1997), with 'separate' activity typically incurring travel and attendance costs as well as having further potential barriers regarding access to venues, lack of childcare facilities and cultural insensitivity in the organisation of classes and facilities (Darr et al. 2008; Rai & Finch 1997; Farooqi et al. 2000; Grace et al. 2008; Khanam & Costarelli 2008; Netto et al. 2007; Carroll et al. 2002). "Facilities are provided, but there are very few sessions per week only for women. In Bangladesh it was possible to go swimming at any time of the day, as it was close by and the males were aware of us being in the river." (Khanam & Costarelli 2008)

In addition, the South Asian belief that sweating is beneficial to well-being is less likely to be achieved in a cold climate (Rai & Finch 1997). In a similar way to dietary behaviours, some young people were adopting Western practices by going to the gym. However this was not so much associated with the aim of achieving greater levels of physical fitness, rather it was a means of filling time, escaping from social conditions and keeping up with fashion trends (Rai & Finch 1997).

Understanding and carrying out health related behaviour change

Limited access to information in the home language was reported as a barrier to obtaining information regarding healthy lifestyle behaviours (Netto et al. 2007; Grace et al. 2008; Khanam & Costarelli 2008; Carroll et al. 2002), as well as accessing activities and shopping facilities outside the neighbourhood (Grace et al. 2008).

Knowledge of risk factors in maintaining health was reported as a high in South Asian communities (Grace *et al.* 2008; Lawrence *et al.* 2007; Netto *et al.* 2007) and low in male Somali participants (McEwen *et al.* 2009). As is well documented, however, knowledge alone does not always translate to change in practice (Lawrence *et al.* 2007; Netto *et al.* 2007), though education can be a first step in resisting restrictive practices (Grace *et al.* 2008).

In addition to accessible information, there was evidence that advice and encouragement were appreciated and were instrumental in motivating behaviour change (Netto *et al.* 2007). Sources of encouragement to increase physical activity included the media, where role models such as successful sporting personalities could be inspirational, particularly when they represented a minority culture. Family and friends were also major sources of encouragement (Rai & Finch 1997), though in some cases family members could pose limitations to behaviour change when such change was perceived as conflicting with social norms (Netto *et al.* 2007; Carroll *et al.* 2002).

I think that some husbands believe that women dress disrespectfully when they exercise, so they [the husbands] have to be told that it is not like that.” (Carroll *et al.* 2002). Medical personnel were also reported to be sources of advice and motivation to change (Rai & Finch 1997). Barriers to adopting healthier lifestyles were also reported in regard to access and affordability. First generation migrants in particular were more likely to use traditional foods for cooking which were not always available locally and were reported to be expensive (Grace *et al.* 2008; Lawrence *et al.* 2007; McEwen *et al.* 2008). Yet travelling to shops, or indeed to physical activity classes, created problems in respect of navigating the public transport system with a limited use of the English language. There were also fears regarding safety when travelling out of the neighbourhood (Grace *et al.* 2008).

Five included studies reported body image issues as potential barriers or facilitators to healthy lifestyle behaviours. Differences were reported between expectations and associations of body image in the UK and in other cultures (Darr *et al.* 2008; Grace *et al.* 2008; Lawrence *et al.* 2007; Khanam & Costarelli 2008; Netto *et al.* 2007). Aspiring to a culturally ideal body size was reported as an important factor in attracting a partner (Rai & Finch 1997), in motivating healthy behaviour change (Lawrence *et al.* 2007), and in giving an impression of prosperity (Netto *et al.* 2007).

The extent to which importance was attached to an ideal body size differed by gender, age and culture (Darr *et al.* 2008; Rai & Finch 1997; Netto *et al.* 2007); it was not

always women that were keen on managing weight (Darr *et al.* 2008), though for older people such change was seen as potentially weakening (Netto *et al.* 2007).

Discussion

Qualitative data from 13 studies of generally good quality using a range of methods provided data on the barriers and facilitators to implementing population level lifestyle interventions for prevention of type 2 diabetes in BME groups. Evaluations provided information about positive and negative aspects of interventions from the perspective of users and providers. Interviews and focus groups gave an insight into the cultural and social norms that might facilitate or impede healthy behaviour change in order to prevent blood glucose disorders.

From searching the evidence for this review, and from other sources (e.g. Kumanyika 2008) it is clear that knowledge relating to BME groups in respect of how to prevent diabetes is sparse. Certainly, the evidence base is lacking in trial and evaluative research that could inform future decisions on provision. O'Mara *et al.* (2010) assessed the effectiveness and cost-effectiveness of population- and community-level interventions to improve modifiable risk factors associated with pre-diabetes among BME and low-income / low-SES groups. Their review of review-level evidence was not limited to UK data yet concluded that there was scarce good quality evidence in this field and most evidence focussed on the African American population. There was a suggestion of positive outcomes for dietary and physical activity outcomes, particularly in interventions that included both components. A systematic review of obesity prevention in US multi-ethnic adults (Seo & Sa 2008) concluded that multi-component interventions (both individual and group) that focus on favourable health related changes based on daily routines and with the support of family members showed the greatest effect.

Whilst our review could not examine the effectiveness of components, it is clear from qualitative evidence that health changes need to be favourable to those targeted, and that daily routines and family support would be facilitative to behaviour change. Our review also provides possible reasons for these conclusions, by assessing the views of people involved in providing and using lifestyle interventions. For the interventions that have published evaluations, resource and organisational issues were impediments to successful implementation, whilst acknowledging and acting upon the specific religious and cultural needs of users was crucial to acceptability. For example, provision of single-sex classes with child-care facilities in accessible locations would appear to

facilitate attendance. Providers need to be aware of the specific requirements of particular groups and provide appropriate advice, information and encouragement.

Conclusion

This review has examined factors that impact on people from BME groups who are attempting to make behavioural changes. Cultural and religious factors were most likely to influence first generation migrants, with language barriers and access issues preventing full engagement with activities and changes at home. Younger people were adopting UK behaviours to some extent but not necessarily the more healthy options. Traditional beliefs around foods and physical activity were contrasted with UK practices. Some UK practices, such as attending the gym were seen as separate to daily life, expensive and in some cases inaccessible compared to the traditional way of being active as part of everyday living.

Whilst attendance at gyms might be beneficial to weight management, it might be prudent to re-think the approach that Western populations have taken regarding physical activity. In the same way, traditional South Asian cooking, adapted to use less fat, could be a healthy option for the general population. There was evidence of perceived shame associated with choosing healthier options such as low fat cooking and particular physical activities that involve certain dress codes. Traditional resistances to such change are required however, and this may need to start with education to prevent the 'complex value hierarchy' (Grace *et al.* 2008).

There is therefore a need for providers to take into account the varied needs of particular groups. For example, assessing the language needs of BME groups in terms of accessing information, whether this is related to dietary and physical activities or for example finding one's way around the city. In addition, provision of single-sex classes and crèche facilities at the gym, and dietary classes that include the use of familiar traditional foods, is likely to increase the acceptability and therefore the attendance of those interventions.

Acknowledgements

This review was funded by the National Institute for Health and Clinical Excellence (NICE) as part of their programme of public health guidance development. This paper represents the authors' views and not the views of NICE.

The authors have no conflicts of interests to declare.

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Table 1: Summary of study characteristics

Study	Area of research	Design	Participants	Intervention / Control
Bradby 1997 + Glasgow, UK.	Understandings of the way food and health are related.	Interviews Participant observation.	n = 47 Punjabi 20-30 years All females.	None
Carroll 2002 + UK	The extent of provision of Exercise referral schemes for South Asian Muslim women.	Evaluation using questionnaires and interviews.	137 practices. 58 Leisure Centres. 5 EoP organisers. 10 GPs. 8 leisure centre staff 35 South Asian Muslim women on the EoP schemes.	None
Darr 2008 + West Yorkshire, UK	Illness beliefs of South Asian and European patients with CHD about causal attributions and lifestyle change.	Interviews.	n=65 BME groups (Pakistani Muslim, Indian Sikh, Indian Hindu): 40-82 years 26 males 19 females European groups: 40-83 years 10 males 10 females	None
Farooqi 2000 + Leicester, UK	Knowledge of and attitudes to lifestyle risk factors for CHD among South Asians.	Focus groups	n=111 South Asian (Muslim, Hindu and Sikh) 40-72 years 24 male	None

			20 female	
Grace 2008 ++ Tower Hamlets, London, UK	Lay beliefs and attitudes, religious teachings and professional perceptions in relation to diabetes prevention in the Bangladeshi community.	Focus groups	n=137 29 Islamic scholars/ religious leaders 28 health professionals 80 lay people 54 males 83 females	None
Khanam 2008 + Tower Hamlets, London, UK	Attitudes and beliefs held by overweight and obese UK Bangladeshi women on health and physical activity.	Interview-guided questionnaire	n=25 Bangladeshi 30-60 years All female All overweight / obese	GP PA referral 40-minute 3 sessions p/week, by professionally supervised.
Kopp 2009 + Wakefield UK	Health and health care needs of a Gypsy and Traveller population.	Needs Assessment	38 plots 31% Irish Travellers 69% English Gypsies 18-24 years 26% 25-34 years 26% 35-44 years 23% >45 years 25% Female 89%	None
Lawrence 2007 ++ Dundee, Scotland and South England / Hampshire	Food choices of girls and young women of African and South Asian descent	Focus groups	n=20 African South Asian (Pakistani and Bangladeshi) 10-35 years (only those > 18 years included in review) All female	None
McEwen 2009 + North London, UK	Dietary beliefs and eating behaviours of Somalis in the UK	Focus groups	n=62 Somali 18% aged <30,	None

			52% aged 30-39 17% aged 40-49 13% aged >50 years 58 male 12 female	
Netto 2007 + Edinburgh, UK	Service user perspectives on culturally focused CHD prevention interventions for South Asian groups	Action research –focus groups	n=91 Indian 32 Pakistani, 27 Bangladeshi 32 >16 years 39 men, 52 women	Khush Dil ('happy heart') Access to CHD prevention services for South Asian communities. Nurse-led CHD risk clinic; nutrition workshops; voluntary healthy lifestyles initiatives.
Pieroni 2007 + Bradford, UK	Traditional culinary use of and health perceptions of vegetables	Semi-structured interviews Questionnaires	n=150 19 interviews 93 aged > 60 years 10 males 140 females	None
Rai & Finch 1997 + A range of locations in England	Attitudes towards and barriers to physical activity among South Asian and black communities in England.	Focus groups	n=175 18-50 years 87 men, 88 women	None
Williams & Sultan 1999 + Trafford, Manchester, UK.	Follow-up of women who participated in a pilot group of the Asian women's healthy eating and physical activity group.	Semi-structured interviews.	n = 15 South Asian All female All overweight or obese.	Healthy eating and physical activity group. 14 weeks

Publication 5: Maxine Johnson, Roy Jones, Crystal Freeman, Helen Buckley Woods, Michael Gillett, Elizabeth Goyder, Nick Payne. Can diabetes prevention programmes be translated effectively into real world settings and still deliver improved outcomes? A synthesis of evidence. *Diabetic Medicine* 2013; 30: 1

Can diabetes prevention programmes be translated effectively into real world settings and still deliver improved outcomes? A synthesis of evidence.

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Abstract

Objective

Randomised trials provide evidence that intensive lifestyle interventions leading to dietary and physical activity change can delay or prevent type 2 diabetes. Translational studies have assessed the impact of interventions based on, but less intensive than trial protocols, delivered in community settings with high risk populations. The aim of this review was to synthesise evidence from translational studies of any design to assess the impact of interventions delivered outside large randomised trials.

Research Design and Methods

Medical and scientific databases were searched using specified inclusion and exclusion criteria. Studies were included that used a tested diabetes preventive study protocol with an adult population at risk from type 2 diabetes. Included papers were quality assessed and data extracted using recommended methods.

Results

From an initial 793 papers, 19 papers reporting 17 studies were included. Translational studies from a range of settings utilised a variety of methods. All were based on the US Diabetes Prevention Programme (DPP) protocol, or the Finnish Diabetes Prevention Study (DPS), with modifications that increased feasibility and access. The main outcome which was reported in all studies was weight change. Weight loss, which occurred in all but one study, was greater in intervention arms than in controls. No consistent differences were found in blood glucose or waist circumference.

Conclusions

Translational studies based on the intensive diabetes prevention programmes showed that there is potential for less intensive interventions both to be feasible, and to have an impact on future progression to diabetes in at risk individuals.

Keywords: Type 2 diabetes; prevention programmes; evidence synthesis.

Abbreviations:

BMI: Body Mass Index

DPP: US Diabetes Prevention Programme

DPS: Finnish Diabetes Prevention Study

NICE: National Institute for Health and Clinical Excellence

n-RCT: Non-Randomised Controlled Trial

RCT: Randomised Controlled Trial

YMCA: Young Men's Christian Association

Introduction

Prevention of type 2 diabetes is a major global public health objective, with 366 million people estimated to have the condition worldwide, and the anticipation that this will increase to 522 million by 2030 [1]. Individuals that have raised blood glucose levels, yet below the threshold for type 2 diabetes, are estimated to have between 5% and 15% greater absolute risk for progressing to diabetes than those with normal glucose levels [2]. Since it is known that modifiable risk factors such as obesity can be prevented or reversed by changing lifestyle behaviours (in particular, dietary and physical activity), there is an opportunity to intervene to prevent or delay diabetes onset.

A number of randomised controlled trials of intensive lifestyle change have shown that changes in both dietary and physical activity behaviours can achieve positive results [3, 4, 5, 6, 7]. Both the Diabetes Prevention Program (DPP) based in the US [3, 8], and the smaller Diabetes Prevention Study (DPS) in Finland [4,9] achieved a reduction of diabetes incidence compared to the control groups.

The proven effectiveness of these two trials has given urgency to the question of whether such effects might be replicated in community settings including primary care. 'Translational research' has been described as the assessment of smaller programmes in 'real world' settings where resources are more limited and samples less selective than in the trial environment [10].

Ali and colleagues examined and meta-analysed 28 translational studies based on the DPP, including studies where the sample included no more than 50% of people with type 2 diabetes. The authors reported a 4 percent weight loss across a range of interventions at 12 months follow-up [11].

Our review differs in that we provide a narrative synthesis of 'translational' studies based on both the DPP and the DPS diabetes prevention protocols. We excluded studies that had knowingly recruited individuals with a diagnosis of type 2 diabetes. Our aim was to assess 'real world' lifestyle intervention programmes of any design to prevent type 2 diabetes and / or reduce BMI and weight in high risk adults. We aimed to compare reported effectiveness to that of larger trials and assess the modification of components and design.

Methods

Methods were agreed with the funders and were carried out in line with their methods manual [12]. Documents relating to the scope of the review are available online at <http://guidance.nice.org.uk/PHG/45>.

Inclusion criteria

Studies of any design with any length of follow up were included. The population assessed were adults at risk from type 2 diabetes, and with raised blood glucose levels. Only lifestyle interventions based on protocols that were replicable and that had been shown to have some success in preventing or delaying type 2 diabetes were included. Any comparator was considered for inclusion, and the primary outcomes were diabetes incidence, as well as changes in weight, BMI and waist circumference.

Exclusion criteria

Studies were excluded if they did not state the protocol on which the intervention was based, or if they included individuals that were under the age of 18 years, or were known to have a diagnosis of type 1 or type 2 diabetes.

Searching

Searches were undertaken by a qualified Information Specialist. The electronic databases Medline, Medline in Process, Embase, CINAHL, British Nursing Index and Archive, The Cochrane Library, Science Citation Index, Social Science Citation Index, PsycINFO and selected EPPI Centre Databases were searched.

An initial overarching search was undertaken at the outset of the programme of reviews. This search was generated by identifying concepts from the programme scope and from studies identified from key known literature as being relevant to the review questions; free text and MeSH terms were then devised.

The searches were limited to English language publications due to lack of resources for translation. Diabetes prevention translational studies are a relatively recent development (during the last two decades), following on from the larger trials. Therefore the search was limited to articles published between 1990 and 2011.

We searched the reference lists of included papers as well as reviews that were identified in the searches. Topic experts, including members of the NICE Programme Development Group, were asked to identify relevant articles and studies.

Assessment for inclusion

Search results were transferred to a reference management database and three reviewers (MJ, RJ, CF) each sifted one third of the titles (and, if necessary, abstracts) for relevance to the review question. The sifting of each third of the results was double-checked by a different reviewer (MJ, RJ, CF). Full texts were retrieved of papers that were assessed as relevant and these were discussed in meetings between the three reviewers to finalise the set of included papers. Disagreements were resolved by further reading of the full text to ensure relevance to the question.

Quality assessment and data extraction

Quality of retrieved papers was assessed using a 27-item tool for the assessment of quantitative studies recommended in the National Institute for Health and Clinical Excellence (NICE) methods manual [12] (see Appendix 1). A single checklist was recommended for all studies with quantitative outcomes rather than a range of critical appraisal tools for each study design [12, p. 202].

A data extraction form recommended for quantitative studies in the methods manual [12] was adapted for use with a range of study types. The structure of the adapted extraction form was agreed with funders prior to use. We extracted details of the article such as author, date and journal. Study details that were extracted included study type, population characteristics, sample size, funding, ethical considerations and intervention

characteristics. For this review we extracted data that specifically related to differences between the study and the DPP or DPS. Finally, results were extracted in terms of included outcome measures and follow up. Incidence of type 2 diabetes, changes in blood glucose measures, and changes in weight, BMI and waist circumference were recorded. Quality assessment and data extraction was carried out by reviewers (MJ; RJ; CF), who each double checked a proportion of another reviewer's assessments.

Results

The initial searching following de-duplication produced a total of 793 database citations, including 4 papers suggested by topic experts [13,14, 15,16]. Of these, 723 were rejected at title / abstract level and 70 were considered at full text. Fifty one studies were rejected at full text level, with a total of seventeen studies reported in nineteen primary level papers assessed as appropriate for inclusion (see Figure 1 and Table 1). One included study reported findings in two papers at 16 week and 10 month time points [13,17]. Another study reported findings in two papers at one year and three year follow up [18,19].

Characteristics and quality

Generally the quality of the included studies was moderate to good (see Appendix 2). No included study complied with all of the 27 quality criteria in the assessment tool [12], though this was mainly due to the range of study types included and the complexity of the intervention. For example, concealment of treatment type is unlikely to be feasible for lifestyle interventions.

We included all relevant studies, particularly as they provided results from a range of settings, with the caution that results from non-RCTs and observational studies are more likely to be impacted by bias. Whilst the individually randomised trials generally had very good internal validity, inevitably the more pragmatic and non-randomised studies were at greater risk of both selection and information biases and therefore had weaker internal validity (with potentially greater external validity) as discussed in the following section.

The studies varied in terms of sample size, length of follow up and the presence of a comparator (see Table 1). All the included studies based their protocol on either the Diabetes Prevention Programme [3], or the Finnish Diabetes Prevention Study [4]. One

study based the interventions on both these protocols. No study was based on any of the other major diabetes prevention studies such as the Da Qing [5] or the Indian Diabetes Prevention Programme [6].

Fourteen studies were carried out in the US in a range of settings with protocols based on the DPP. Three studies were based on the DPS only; two carried out in Finland [18, 19, 20] and one in Australia [21]. A further German study [14] was based on both the DPP and the DPS. Four studies [14, 15, 22, 23] were randomised controlled trials, though of these, two [22, 23] were pilot studies with small samples, and one had only a 6 month follow up [23]. Four non-randomised studies compared findings between groups. One non-randomised study compared an intervention implemented in church settings with a control [16].

The Almeida study [24] compared matched pairs from a health care organisation and one study compared outcomes from those that had not enrolled onto a programme with those that had enrolled [25]. Vadheim et al [26] compared outcomes from two groups that received the same intervention in different settings. The remaining studies [13,17, 19, 20, 21,27,28,29,31] used a pre-test / post-test single group design. Follow-up ranged from 16 weeks to 3 years, with 12 studies providing results from a follow up of at least 12 months. Settings were mainly health care related, typically an outpatient clinic. Three studies [16, 27, 28] delivered the intervention through US churches, and one [22] used YMCA facilities compared to a health care setting. Two studies [26, 29] used available technology to deliver the interventions, one via the internet and one through video-conferencing (tele-health).

All the studies targeted 'at risk' populations, with one or more risk factors for type 2 diabetes, such as having a BMI of $\geq 25 \text{ kg/m}^2$, having raised blood glucose levels, and / or a raised diabetes risk score. The programmes included a dietary as well as a physical activity component to the intervention, as with the DPP and DPS protocols. As in the original trials, trained personnel such as nurses, dieticians and physical fitness experts were recruited to deliver the interventions in all but one study, where community members were trained to carry out a church-based intervention [16]. The included studies typically did not describe intervention content in detail, since they were based on the two protocols. There was generally an emphasis on goal-setting as well as self-monitoring dietary and physical activity achievements in order to achieve weight loss goals of between 5 and 7%.

Specific modifications to the original trial protocols were described. To allow feasibility in community settings in terms of resources, the most common modification was a decreased number of sessions. In addition, the tendency for individual-based visits and sessions in the DPP and DPS was altered to group sessions. Interventions were also modified to increase accessibility to the venue and to the intervention in terms of cultural sensitivity for the target audience. For example, three interventions utilised church premises from which the African American congregation were invited to be screened or to receive the intervention. However one of these studies reported that blood testing was not allowed on church premises [16].

Church based strategies have been used in other screening programmes; as well as having the potential to increase uptake, original protocol materials are modified to increase cultural sensitivity for diverse groups. Another study used well established networks developed through the YMCA to access a wider population as well as to sustain interest through membership. Two studies harnessed tele-health technology (video-conferencing and the internet) as methods of delivering lifestyle interventions to a wider population.

Studies varied in terms of sample characteristics, such as sex and ethnicity (see Table 2). Three studies targeted African-American populations. Ethnicity of the sample was not reported in any of the three DPS based studies, nor in five of the DPP based studies. Of the remaining DPP based studies, all but one [29] included more than 25% non-white participants. The majority of participants in all but one study [14] were female.

Reported Outcomes

The primary outcome of the DPP and DPS was cumulative diabetes incidence at follow up. This outcome was not typically measured in translational studies that included a comparator, probably because there was not sufficient statistical power to do so. Therefore it is difficult to make direct inferences about the effectiveness of the intervention in reducing diabetes. All studies reported changes in body weight, and some also reported blood glucose levels, and waist circumference.

Findings – weight change

All the included studies assessed changes in weight at baseline and follow up (see Table 2). Included randomised controlled trials [14, 15, 22] reported greater weight loss (at least 4.0%) in the intervention arm than in the control groups (no greater than 2.0%). Whittemore *et al* [23] reported $\geq 5\%$ weight loss in 25% of the intervention group compared to 11% of the control group at 6 months.

Non-randomised studies also reported weight loss. The largest study [24] reported a loss of $>5\%$ body weight that was 1.5 times more likely in the intervention arm. In the WiLLoW study, 27% of enrollees achieved more than 7% weight loss compared to 6% of non-enrollees [25]. Motivation may however be higher in those that enrolled to the interventions. At 16 weeks, 48% of a tele-health intervention group and 50% of the comparator group achieved at least 7% weight loss, with the mean weight loss in both groups more than 6.4kg [26]. In this study, the same intervention was being tested in two different settings.

In three studies that did not include comparators, the goal to lose at least 7% body weight was achieved by between 18% and 45% of participants at between 10 and 12 months [13, 29, 30]. Two church-based interventions achieved weight losses of 3.6% and 4.6% respectively [27, 28].

The three DPS based studies achieved smaller weight losses at 12 months than did the DPP based studies. The Australian study [21] achieved the greatest weight loss (2.7%). Absetz and colleagues [18,19] reported differences in weight loss for males and females (1.5% and 0.6% respectively) whilst Saaristo [20] reported the same reduction in both men and women (1.3%). The latter study reported sustained weight reduction at 3 years.

Only one non-randomised study reported no weight loss [16], with a mean gain in weight of 0.2% in the intervention arm and 0.4% in controls. However, there were reported significant differences in baseline characteristics of intervention and control groups.

Findings – changes in waist circumference

Changes in waist circumference were reported in seven studies. In two randomised controlled trials, reductions of at least 4cm were reported in the intervention arm compared to less than 0.6cm in the controls after 12 months [14, 15]. Single group studies based on both the DPP and DPS also reported reductions of between 1.6 and 4.3 cm at 12 months [14,19, 21, 31], though in one study this was not sustained at 3 years [20]. Authors of one study [21] calculated that their reported 4.0% reduction in waist circumference equated with a 40% reduction in diabetes risk.

Findings – changes in blood glucose and HbA1c levels

Reported changes in blood glucose following DPP or DPS based interventions were minimal. However, caution needs to be taken in interpreting these figures since measuring average changes in blood glucose can mask some instances of significant reduction.

Two randomised controlled trials [14, 15] each reported mean decreases in blood glucose of 0.24 mmol/l in the intervention groups at 12 months follow up compared to 0.02 mmol/l and 0.09 mmol/l respectively in the control groups ($p < 0.001$).

The Kulzer study [19] found no mean change in HbA1c at baseline and 12 months in the intervention group, and a rise of 22 mmol/l (approximately 2.0%) in the control group ($p = 0.165$). Ackermann and colleagues [20] reported a reduction in mean HbA1c of 22 mmol/l (approximately 2.0%) compared to no change in the controls ($p = 0.28$) at 12 months.

No other included studies that measured blood glucose levels provided a comparative measure. The largest mean reduction in fasting blood glucose at 12 months was 0.5 mmol/l. This was achieved following a US church-based intervention [28]. A reduction of 0.26 mmol/l was reported in primary care settings [17].

Similarly, interventions based on the DPS reported minimal mean change in fasting plasma glucose at 12 months (+0.1 mmol/l and -0.14 mmol/l) [18, 21], and at 3 years 0.0 mmol/l [19]. These limited results could be due to a regression to the mean over time.

Seidal and colleagues [31] reported an increase in the number of participants from low socio-economic groups that had fasting blood glucose levels equal to or above 5.5 mmol/l at 3 and 6 month follow up.

Reported associations between outcomes

Weight change and programme delivery

One church based study [16] attributed their negative weight change results to a lack of fidelity to the DPP protocol; community members were trained to deliver the intervention rather than utilising qualified health professionals and experts. The trained advisors were encouraged to be creative regarding the content and mode of delivery of the intervention, tailoring to each individual participant's preferences.

Weight change and programme attendance

The Saaristo study [20] reported that those who lost more than 5% of their body weight made on average the most intervention visits (3.5) whilst those that maintained their weight made an average of 2.9 visits, and those that gained weight 2.5 visits. However, this result could be confounded by the higher baseline weight of those that made the most visits (BMI 32.6 ± 5.6 compared to 31.3 ± 5.1 kg / m² for those making two visits, 30.7 ± 4.8 kg / m² for those making one visit and 30.9 ± 5.0 kg / m² for those making no visits). In addition, Ackermann and colleagues reported a 6.0% reduction in weight despite 57% overall attendance [22].

Weight change and diabetes incidence

Saaristo et al [20] analysed weight change and diabetes incidence in their DPS based study, reporting a step-wise association. Incidence in those that lost more than 5% of body weight over 12 months was 2% compared to those that gained weight (almost 8%), and those that maintained a stable weight (7%). Incidence was also more likely at 12 month follow up in those that already had IFG or IGT at baseline, with a 6-9 fold increase in likelihood of developing diabetes than those with normal glucose levels at baseline.

Waist circumference and diabetes incidence

One Australian study [21] used results from the DPS sample as a reference to equate their reported 4.0% reduction in waist circumference with a 40% reduction in diabetes risk.

Loss to follow up

The majority of studies lost between 9% and 15% of the original sample during follow up. However there were cases of very high and low attrition rates. All the DPS based studies reported at least 23% attrition over one or three years and one church based study lost a third of the small sample over 12 months [16]. By contrast, one sizeable and diversely populated RCT reported loss to follow up of 2% or less in both arms [15]. This would suggest that findings from this study could be considered as relatively robust.

Discussion

This review aimed to assess the impact of adapting diabetes prevention protocols to 'real world' settings on key outcomes. We included 19 studies (reported in seventeen papers) based on either or both the DPP and the DPS protocols in terms of aims and content. Interventions were adapted to a range of settings and modified for feasibility.

The main modifications were number of sessions and mode of delivery (i.e. group-based rather than one-to-one) to reduce the resources required and also to increase accessibility to diverse populations. Some of the sample sizes were very small and some follow ups were short; only one study provided results beyond 12 months follow up. Seven studies included a comparator; four were randomised controlled trials, of which two were pilot studies.

Populations in the DPP based studies were more diverse, including up to 100% of non-white participants. However there was no particular distinction made in outcomes between ethnic groups. Most of the interventions attracted predominantly female samples, highlighting the need to address ways of increasing the accessibility and acceptability of lifestyle intervention for men.

Reporting of weight loss outcomes differed between studies and included mean weight reduction, percentage weight reduction, or the percentage achieving a specified weight loss. Much of the detail regarding delivery of interventions was not reported. This degree of heterogeneity was deemed not appropriate for a meta-analysis.

Whilst the findings varied widely in terms of effect size, there was a strong trend toward weight loss following all but one of the interventions. In one study, over 45% of participants who had completed the intervention achieved the goal of at least 7% weight reduction [13]. This figure may however be inflated compared to those derived from an intention-to-treat analysis such as that carried out in the DPP. Studies that included a comparator reported greater effects in the intervention arm than in the controls. One study reported no weight reduction [16] though the intervention arm gained less weight than the control. This could be due to significant differences in baseline characteristics as well as lack of protocol fidelity.

Changes in waist circumference were not reported in all studies, though in the seven studies that did, this outcome was favourable and was associated (through imputation) in one study with a reduction in diabetes risk [21]. A minority of studies measured mean fasting blood glucose or HbA1c changes, with reported reductions mirrored by the DPP where 1% change was detected at 12 months.

Reduction in diabetes incidence was not measured in any controlled study. This may reflect the difficulty assessing incidence within the short duration of the included studies. One study however, provided evidence of a step-wise incidence associated with weight gain [20]. This suggests that type 2 diabetes can be prevented in 'real world' settings providing there is sustained weight management. The main challenge is how best to deliver and achieve engagement with interventions and how to sustain lifestyle change. Attrition rates varied across the studies from very low to around a third of participants. This has to be taken into account in terms of assessing the robustness of findings as well as reasons for participant drop-out and whether these can be addressed in future programmes.

Large RCTs have shown that the onset of type 2 diabetes can be prevented or delayed to a large extent, particularly in those that achieve lifestyle targets [8]. One review of behavioural strategies [32] highlighted individualised delivery as a factor in the success of large RCTs. One-to-one intervention delivery however is unlikely to be feasible in clinical practice due to resource and financial restraints. This review demonstrates that

group-based interventions can yield significant weight loss (with the expectation of reductions in the risk of type 2 diabetes), provided that changes are sustained over a number of years. Even in the intensive DPP [3] and DPS trials [4], there was partial regain of weight in the intensive arm. It is clear from reviews of behavioural strategies that effectiveness reflects intensity of the intervention, as well as proven behavioural strategies, and that interventions comprising modified versions of most of the core modules of the original DPP are the most effective [7, 32].

The feasibility of implementing nationwide diabetes prevention programs is dependent on identifying the most economic modes of delivery. Findings from this review suggest that significant weight loss may be achievable with larger groups than are currently adopted in clinical practice, with some DPP translation studies using classes of fifteen [24] and seventeen participants [17]. Equally important is the skill of the educators [34]. There was a variety of professional backgrounds amongst the educators in the studies in this review, with associated variation in costs. Further research is needed to identify the most cost-effective mode of delivery. From the findings of the included papers, one option may be a highly qualified diet and physical activity professional supported by a less qualified individual.

Other reviews have assessed the translation of diabetes prevention studies into real world settings. One review identified 12 studies that were all carried out in clinical settings. Not all the included studies stated that they were based on a particular protocol such as the DPP or the DPS. Results from four studies that were meta-analysed showed a positive effect on weight and waist circumference at one year [35]. Our review supports the findings that significant effects from translational lifestyle interventions on clinical parameters such as blood glucose and diabetes risk may be difficult to demonstrate, and that decreases in weight following adapted interventions are a more promising finding [36]. Another review assessed studies based on the DPP and translated into community settings such as churches [36]. The review included seven papers, though four of these did not exclude individuals with known type 2 diabetes at baseline. The authors conclude that significant weight loss was achieved in three studies at 12 months following intensive interventions [36].

This review has assessed only those studies that applied a specified, known protocol that has previously been associated with a reduction in the incidence of type 2 diabetes as well as weight loss. Given the relatively short follow-up and smaller sample size, translational studies were more likely to have sufficient statistical power to measure

change in weight than in diabetes incidence. However, weight loss is associated with a reduction in diabetes incidence. In the DPP for example, weight loss was reported to be the dominant factor in diabetes incidence reduction in a high risk population to the extent that 5kg lost was estimated to result in a 55% reduction in incidence over 3 years follow up [37].

Some of the interventions may be regarded as country or health system specific. However, the general principles of lifestyle change to reduce weight and diabetes incidence are generalisable to any high risk population. Some issues to consider in translating diabetes prevention trials into community settings include the extent of available resources, differences between health care delivery organisations and cultural variations between settings. For example, whilst the YMCA network might provide a useful gateway from which to access at risk populations in the US, this might not be the case elsewhere. In addition, church based interventions were specific to the African-American population. To increase applicability to a specific setting the intervention would need to be tailored to meet the needs of local faith groups. Future research needs to assess whether translating prevention protocols is feasible in terms of acceptability and cost.

Conclusions

Translational studies based on the DPP and the DPS, but with modifications to increase feasibility, reported mean and percentage weight loss (as well as reductions in waist circumference) in a range of settings. Weight loss is associated with diabetes prevention and so can be regarded as a marker for potential prevention over the longer term, though current evidence for sustainability beyond three years is limited. There is therefore potential, given that the lower costs of group-based interventions lessens financial barriers to implementation, for interventions to have an impact on future progression to diabetes in at risk individuals in 'real world' settings. More long-term research is required to assess the sustainability and long-term outcomes of translational interventions.

Contributions

MJ contributed to the literature review, data extraction, quality assessment and manuscript drafting. MJ had access to the data used in the study and takes responsibility for the decision to submit this paper. RJ and CF contributed to the data

extraction, quality assessment, reviewing and editing of the manuscript. HBW contributed to the development and implementation of the search methods and to editing the manuscript. MG contributed to the discussion and to the editing of the manuscript. EG and NP contributed to the discussion and to the writing and editing of the manuscript.

All authors significantly contributed to the work and approved the manuscript for submission.

Acknowledgements

This review was funded by the National Institute for Health and Clinical Excellence [NICE] as part of their programme of public health guidance development. This paper represents the authors' views and not the views of NICE.

Conflicts of interest

The authors have no conflicts of interests to declare.

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Table 1. Characteristics of intervention studies based on the DPP and DPS.

Author; country; setting	Study design	Population	Intervention	Comparator(s)	Length of follow up
DPP ^{3,8} US	Randomised controlled trial 3 groups	Adults with FPG 5.3 – 6.9 mmol/l; IGT; BMI ≥ 24kg/m² (22 in S.Asian population).	16 core sessions 30-60 minutes. Maintenance: Phone or in person 1-2 times monthly.	Standard 20-30 minute session and written materials.	3.2 years and 10 years.
Ackermann 2008 ²² US YMCA	Pilot cluster-randomized trial (DEPLOY) Two groups	Semi-urban. ADA risk score ≥ 10 BMI ≥ 24kg/m ²	16 group sessions (n=8-12) of 60 -90 minutes duration. Maintenance: Twice weekly individual or group for 4 weeks. Monthly YMCA sessions open to family members.	Brief counselling alone.	12 months
Almeida 2010 ²⁴ US Integrated health care	Non-randomised Longitudinal. Two groups (matched pairs)	Newly diagnosed pre-diabetes. IFG (100-125 mg/dl).	Two 4-6 monthly group sessions (n=10-20). 90-minute duration.	Usual care.	12 months
Amundsen 2009 ¹⁷ Vanderwood 2010 ¹³ US Primary Care	Evaluation. One group.	BMI ≥ 25kg/m ² One or more: IFG / IGT Hypertension Hyperlipidaemia History of GDM Birth to baby of >9 pounds.	16 group sessions (n=8-34) of 60 minute duration. Maintenance: Monthly sessions over 6-12 months.	N/A	12 months
Boltri 2008 ²⁷ US African American Baptist church	Pilot pre-test post-test. One group.	Pre-diabetes (FG = 100-125 mg / dl).	16 sessions over 4 months. Modified for church Implementation. Culturally sensitive.	N/A	12 months
Davis-Smith 2007 ²⁸ US Rural African American church	Evaluation. One group.	Church congregation. ADA risk score ≥ 10 FBG 100-125 mg/dl	6 sessions over 7 weeks.	N/A	12 months

Faridi 2010 ¹⁶ US African American Church	Evaluation. Two groups.	African American church congregations. One or more: BMI >25kg/m ² Parent / sibling with diabetes. History of GDM.	Number of sessions not standardised. Flexible content and mode of delivery (either group or individual).	Intervention compared in two geographical settings.	12 months
Katula 2011 ¹⁵ US	Randomised controlled trial (HELP-PD). Two groups.	BMI between 25–40 kg/m ² Fasting blood glucose 95-125mg/dl*	24 group sessions (weekly for 6 months). Maintenance: Monthly sessions for 18 months.	Two individual sessions with nutritionist over 3 months.	24 months
Kramer 2009 ³⁰ US	Nonrandomized prospective One-group.	25–74 years BMI ≥25 kg/m ² FG 100-125 mg/dl	12 group sessions of 1-hour duration delivered over 12–15 weeks.	N/A	12 months
Kulzer 2009 ¹⁴ Germany	Randomised controlled trial. (PREDIAS) Two groups.	Age 20-70 years BMI ≥26 kg/m ² , IGT or IFG. Diabetes Risk Score > 10	12 group sessions of ~ 90 minutes. Eight core sessions over 8 weeks then every two weeks.	Written information and materials.	12 months
Mc Tighe 2009a ²⁵ US	Controlled cohort study (WiLLoW). Two groups.	BMI ≥ 25 kg / m ²	12 group sessions. Maintenance: Monthly sessions for eight months.	Individuals that did not enrol on the programme.	12 months
Mc Tighe 2009b ²⁹ US Primary Care	Cohort study. One group.	Age 18–80 Access to internet. BMI ≥ 25 kg / m ² History of CVD risk factors (including pre-diabetes).	16 weekly 30–45 minute online sessions. Maintenance: 8 monthly lessons.	N/A	12 months
Seidal 2008 ³¹ US Medically underserved communities.	Non-randomised prospective. One-group.	BMI ≥ 25 kg / m ² ≥ 3 components of metabolic syndrome.	12 group sessions (n=5-13) over 12-14 weeks. 90minute duration.	N/A	6 months

Vadheim 2010 ²⁶ US Hospital clinic and on-line.	Non-randomised controlled trial. Two groups.	Age > 21 years BMI ≥ 25 kg / m ² At least 1 diabetes / CVD risk factor or History of GDM Birth to baby of >9 pounds.	16 weekly tele-health sessions.60 Minutes in duration. Maintenance: 6x monthly sessions.	Hospital site: 2 to 4 weekly supervised physical activity sessions.	16 weeks
Whittemore 2009 ²³ US Nurse practitioner clinics.	Pilot randomised controlled trial. Two groups.	Age ≥ 21 years BMI ≥ 25 kg / m ² If < 65 years: Family history of T2DM History of GDM Birth to baby of >9 pounds Ethnic group at high risk	6 in-person 20 minute sessions and 5 phone sessions over 6 months.	One nurse practitioner and one nutrition session.	6 months
DPS ^{4;9} Finland	Randomised controlled trial. Two groups.	IGT and BMI ≥ 25 kg/m² N=523 randomised N=212 at 12 months.	7 sessions with Nutritionist during first 12 months followed by visits every 3 months.	General information at start of trial.	3 years
Absetz 2007 / 2009 ^{18; 19} Finland Primary Care	Pre-test post-test (GOAL). One group.	Diabetes Risk score ≥ 10.	6 group counselling sessions (n=12) over 8 months. 2 hours duration. Follow-up measurements: years 1&3.	N/A	1 and 3 years
Laatikainen 2007 ²¹ Australia Primary Care	Pre-test post-test Greater Green Triangle). Two groups.	Diabetes Risk score ≥ 12.	6 group sessions over 8 months. 90 minute duration. 5 sessions in first three months; final session at eight months.	N/A	12 months
Saaristo 2010 ²⁰ Finland Primary Care and Occupational Health.	Pre-test post-test (FIN-D2D). One group.	FINDRISC ≥ 15	4-9 group weekly or bi-weekly sessions and some individual sessions. Follow-up session one month after intervention.	N/A	12 months

Table 2. Findings from intervention studies based on the DPP and DPS.

Author; country; setting; follow up	Sample	Changes in mean Blood Glucose at follow up	Mean weight loss at follow up	Change in mean waist circumference at follow up	Lost to Follow up
DPP ^{3,8} US	Lifestyle intervention n=589 (Female 68%; non-white 53%) Control n=582	Intervention: HbA1c 5.9% to 5.8%. Control: HbA1c 5.9% to 6.0% at 12 months.	7 kg over 12 months, then a gradual regain to 2 kg at 10 years.	NR	Not seen in 18 months: 65 (11%) in lifestyle intervention arm 69 (11.9%) in control arm.
Ackermann 2008 ²² US YMCA 12 months	N = 92 (46 Intervention; 46 Control) Non-white 29% Female 61%	Intervention: HbA1c -0.1% Control: No change (p=0.28).	Intervention: 6.0 kg Control: 1.8 kg (p=0.008)	NR	15% Intervention 17% Control
Almeida 2010 ²⁴ US Integrated health Care 12 months	N = 1,520 760 matched pairs. Ethnicity NR Female 53%	NR	Intervention: 1.4 kg (95% CI 1.6 kg to 1.1 kg). Control: 0.6 kg, 95% CI, 0.9 kg (2.0 lbs) to 0.4 kg (0.8 lbs) (p < 0.001).	NR	60 from each arm (total 15.8%) at 12 months.
Amundsen 2009 ¹⁷ Vanderwood 2010 ¹³ US Primary Care 12 months	N = 355 Ethnicity NR Female 65%	NR FBG: - 0.26 mmol/l (SD 0.39) at 10 months.	6.7 kg (SD 4.0) no other details reported. 9.5kg (SD 19.3) at 10 months	NR NR	17.5% at 4 months
Boltri 2008 ²⁷	N = 26	-0.22 mmol/l	0.45kg at 12 months.	NR	None reported.

US African American Baptist church	All African American Female 58%		(2.52kg at 6 months).		
Davis-Smith 2007 ²⁸ US Rural African American church	N=11 All African American Female = 64%	Fasting Serum Glucose - 0.5 mmol/l.	4.0, 3.0 and 4.8 kg immediately after the intervention, and at six- and 12-month follow-up, respectively. No other details reported.	NR	N=1 (9%)
Faridi 2010 ¹⁶ US African American Church	13 Congregations Intervention: N=121 Comparator: N=125 100% African- American Female: 85% intervention 72% control	NR	Intervention: +0.32lbs (0.15 kg) (SD 25.92) Control : +0.82 lbs (SD 19.30) (0.37kg)	NR	Intervention n=31% Comparator n=37.6% At 12 months No reasons
Katula 2011 ¹⁵ US 12 months	N=301 Intervention: N=151 Control: N=150 25% African- American Female 58%	-0.21mmol/l (SD0.02)	Intervention group lost 5.73kg (SD 0.42) compared to control group*	-5.05cm (SD 0.38)	Attrition at 6 months: Intervention: 1% Control: 2% Attrition at 12 months: Intervention: 1% Control: 2%
Kramer 2009 ³⁰ US 12 months	N =51 phase 1 27% non-white Female 82% N=42 phase 2 0% non-white	-0.08mmol/l or -1.4% (p=0.52)	Phase 2: -4.5 kg [p<0.001].	Phase 2: -4.3 cm (- 1.7 ins) (-4.2%), (p<0.001).	Phase 1: 18 (35%) did not attend post-assessment visit. Phase 2: 2 (4.8%) did not attend post-assessment

	Female 79%				visit; 12 (28.6%) did not attend 12 month visit.
Kulzer 2009 ¹⁴ Germany 12 months	N=182 Ethnicity NR Female 43%	FBG – 4.3 SD 6.0) (p=0.001). HbA1c 0.0% OGTT -7.3 (SD 30.8)	-3.8 kg (SD 5.2) (p<0.001)	-4.1 cm (SD 6.0)	17 lost to follow up (9%).
Mc Tighe 2009a ²⁵ US	N = 155 Enrolees N=72 Non-enrolees N=82 Ethnicity NR Female 84%	NR	Intervention: 5.19 kg (CI, -7.71 to -2.68) Control: +0.21 kg (CI, -1.50 to 1.93) (p < .001).	NR	Follow up data unavailable for 7% of sample. (attrition n= 5 (6.9%) in enrolees; n=16 (19.5%) in non-enrolees)
Mc Tighe 2009b ²⁹ US Primary Care	N = 50 8% African-American 4% Asian Female 76%	NR	4.79 kg (95% CI: -7.36 to -2.22)	NR	Attrition: n=5 (10%)
Seidal 2008 ³¹ US Medically underserved communities. 6 months	N = 77 36% Non-white Female 74%	Proportion with \geq 5.5mmol/l increased over time (baseline 42%; 3 months 51%; 6 months 61% p=0.06; adjusted p = 0.001).	46% lost \geq 5% body weight. 26% lost \geq 7% after 3 months. At 6 months this was sustained by 87% and 67% respectively.	Abdominal obesity decreased: baseline 90%; 3 months 82%; 6 months 68% (p=0.006).	10.4% attrition at 3 months; 35% at 6 months
Vadheim 2010 ²⁶ US Hospital clinic and on-line. 16 weeks	N= 13 on-site N= 16 telehealth Ethnicity NR Female 69%	NR	Intervention: 6.7kg (SD 3.7) Control: 6.5kg (SD 3.1) (p=0.85)	NR	On-site: 0% Telehealth: 12.5% at 16 weeks
Whittemore 2009 ²³	N = 58	Intervention:	Intervention:	NR	12% attrition at 6 months.

US Nurse practitioner clinics. 6 months	Intervention: N=31 Control: N=27 Non-white 55% Female 93%	Trend in OGTT 0.01 mmol/l per month Control: 0.83 mmol/l per month	1.5% (p=0.8), Control: 0.0% (p=0.45).		
DPS ^{4,9} Finland 12 months	N=522 Female 66% Ethnicity NR	Fasting plasma Glucose. Intervention: -0.2 mmol/l (SD 0.31) (95% CI -6 to-2) Control: +0.05 mmol/l (SD 0.001) (95% CI 0- 2) (p< 0.001)	Intervention: -4.2 kg (SD 5.1) Control: -0.8 kg (SD 3.7) (p< 0.001)	Intervention: -4.4cm (SD 5.2) (95% CI 5.1-3.9) Control: -1.3 cm (SD4.8) (95% CI 1.9-0.7) (p< 0.001)	59% attrition at 12 months
Absetz 2007 / 2009 ^{18,19} Finland Primary Care 12 months and 3 years.	N = 352 Ethnicity NR Female 77%	Fasting plasma glucose: +0.1 mmol/l (SD 0.6) (p<0.001) OGGT: +0.1 mmol/l (SD 1.7) (not significant) At 3 years: 0.0 1 mmol/l (SD 0.8) (NS) OGGT: +0.1 (SD 1.9) (NS)	-0.8 kg (SD 4.5) (p=0.002) At 3 years: -1.0 kg (SD 5.6) (p<0.003)	-1.6 cm (SD 4.8) (p=0.001) At 3 years: +0.1 cm (SD 6.4) (NS)	23% attrition at 3 years
Laatikainen 2007 ²¹ Australia Primary Care 12months	N = 311 Ethnicity NR Female 55%	Fasting Plasma Glucose: -0.14 mmol/l (95% CI -0.20 to -0.07) (- 2.5%) OGTT: -0.58 (95% CI -0.79	-2.36 (95% CI -3.19 to -1.85)	-4.17 cm (95% CI - 4.87 to - 3.48) (-4.0%). Some reduction in 75% of sample.	74 (23.8%) non-completers.

		to -0.36) (-8.6%).			
Saaristo 2010 ²⁰ Finland Primary Care and Occupational Health. 12 months	N = 2,798 Ethnicity NR Female 67%	NR	Males: -1.2 kg (SD 5.3) (p<0.0001) Females: -1.1 kg (SD 5.8) (p<0.0001)	Males: - 1.3 cm (SD 4.9) (p<0.0001) Females: - 1.3 cm (SD 5.9) (p<0.0001)	32% attrition.

*Corrections included in final on-line version.