Patient Reported Outcome Measures for Mental Health: Development and Pragmatic Evaluation in the NHS

Paul Blenkiron

BM BCh Hons (Oxon), MA (Cantab), MMedSci, FRCPsych

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The University of Hull and The University of York

Hull York Medical School

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ABSTRACT

Background: Patient-reported outcome measures (PROMs) are standardised questionnaires or interviews that elicit subjective reports of health. They have growing potential for improving patient-centred care and decision making. The National Institute for Health and Care Excellence (NICE) recommends considering their use at regular points in the treatment pathway for common mental health conditions and physical problems such as cancer.

Aims: To assess the feasibility, acceptability and usefulness of implementing four established PROMS: the Patient Health Questionnaire-9 (PHQ-9) for depression, Generalised Anxiety Disorder-7 scale (GAD-7), Short Warwick & Edinburgh Mental Wellbeing Scale (SWEMWBS) and Distress Thermometer (DT), and to pilot two novel 'developed for purpose' satisfaction tools: Carers' & Users' Expectations of Service (CUES) and Recovering Quality of Life (ReQoL).

Setting: Mental health multidisciplinary teams within the UK National Health Service.

Methods: Outcomes evaluated were mental/physical symptoms, emotional distress, life/service satisfaction and global quality of life. Designs were pragmatic, including quantitative and mixed methods, cross sectional and prospective before and after studies.

Results: The thesis comprises five original research publications and three academic linked papers. Where assessed, PROM acceptability and completion rates were high (76-98%), leading to changes in care in 49% cases. Following therapeutic interventions, a large clinical effect size was observed: within community mental health teams PHQ-9, GAD-7 scores and functioning all improved (Cohen's d = 0.52-0.77). In cancer psychology services, median distress (DT) scores decreased significantly (Wilcoxon's $z = -4.83$, $p<0.001$, Cohen's $d = 1.22$). Sensitivity to change was greater for ReQoL, PHQ-9, GAD-7 and DT than for SWEMWBS.

Conclusions: This body of research provides cumulative evidence that validated mental health PROMS can reliably assess meaningful changes at key stages in a patient's journey, with apparent absence of significant harms. PROMS should be more widely integrated into frontline care, to inform individual treatment planning and contribute to service improvements.

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Paul Blenkiron

Consultant Psychiatrist, York

CBT Tutor, Tees Esk and Wear Valleys NHS Foundation Trust

Honorary Professor, Hull York Medical School

President, York Medical Society, 2025-2026

AUTHOR'S DECLARATION

I confirm that this work is original and any passages or diagrams that have been copied from academic papers, books, the internet or any other sources are clearly identified by the use of quotation marks with the reference fully cited.

I certify that, other than where indicated, this is my own work and does not breach the regulations of HYMS, the University of Hull or the University of York regarding plagiarism or academic conduct in examinations.

I have read the HYMS Code of Practice on Academic Misconduct, and state that this piece of work is my own and does not contain any unacknowledged work from any other sources.

I also confirm that any patient information obtained to produce this piece of work has been appropriately anonymised.

The **WORD COUNT** for this thesis (excluding references) is 9426

CHAPTER 1: INTRODUCTION AND OVERVIEW

Introduction

Health outcomes matter - to all of us - more than ever before. The 21st Century National Health Service (NHS) quality agenda promotes three central themes: effective services, safety and a positive patient experience[1]. Arguably, it is the users of those services who are best placed to judge how they feel[2].This may be especially true within mental health, where care is individualised, personalised and unique - but where there is often an apparent absence of a fixed concrete output. Measurement and judgement are therefore key parameters of interest to everyone - from patients, carers and clinicians to research institutions and health economists, from local managers and national commissioners to politicians, the media and the wider public. Tools, rating scales and questionnaires help not only to quantify the end result of health care - but also actively contribute to the quality of its content.

This doctoral thesis summarises the rationale and practical experience of creating, implementing and evaluating patient rated outcome measures (PROMs) at the frontline of NHS psychiatric care. The body of work comprises five key original research publications and three academic linked papers. It draws together common themes and pragmatic lessons learned on a journey of NHS and societal development over a 20-year period of increasing service user involvement.

History and Policy Context

Since the 1990s, mental health focus groups have believed that relying on psychiatric symptoms alone is too narrow a concept to measure improvement and service satisfaction[3]. ‘Patient and carer experience’ has been a key area for determining performance within the Government’s National Service Frameworks for Mental Health from 1999 onwards[4]. The Mental Health Policy

Implementation Guide[5] further envisaged 'increased meaningful service user and carer involvement and inclusion in service planning'.

2011 saw the publication of 'No Health without Mental Health: A Cross-Government Mental Health Outcomes Strategy for People of All Ages'[6]. It emphasised the importance of using outcome measures to evaluate services. The 'Five year Forward View for Mental Health'[7] followed in 2016, highlighting the benefits of outcome use to individual patients and the wider system. NHS England introduced the Mental Health 'Clustering' tool in 2016 within a proposed National Tariff Payment System The widespread use of 'Payment by Results' (PbR - actually payment by activity) was advocated to deliver the Five Year Forward View for Mental Health[8]. Since 2020, outcome measures have been reported as 'Key performance indicators' (KPIs) both locally and nationally via NHS England's specialist commissioning dashboards[9].

Types of Outcome Measure

Patient-reported outcome measures (PROMs) are standardised questionnaires or interviews that elicit subjective reports of health and illness. They aim to assess the personal effects of symptoms, functioning, problems, risks and general well-being on an individual's quality of life (QoL)[10].

Other types of outcome measure often used alongside PROMS[11] are clinician reported outcome measures (CROMS) such as The Health of the Nation Outcome Scale (HoNoS) and the Mental Health Clustering Tool, and patient reported experience measures (PREMS)[6], sometimes known as patient satisfaction questionnaires[7].

The dictionary definition of an outcome is 'the result or effect of an action' (ie an output). Examples within healthcare include a reduction in symptoms or an improvement in social functioning. This should be clearly distinguished from the processes (inputs) that drive these improvements1[2]. These can be assessed internally eg using KPIs[9], or externally via PREMS such as the NHS 'Friends and Family test'[13].

PROMS used in mental health may be generic (eg the EQ-5D measure of general health[14,15]), condition-specific eg the PHQ-9 (Patient Health Questionnaire) for depression or patient-generated (where individuals decide their own personalised outcomes and goals, typically within a clinical consultation).

Furthermore, PROMS data can be collected in a variety of ways: cross-sectional (at a single time point) eg sample and population questionnaires, or cohort surveys (across two or more points in time) eg before and after a care intervention. Traditional methods of collection (face to face, paper, post) are increasingly being replaced by electronic responses via smart phone and other electronic devices. Digitalisation of data can facilitate real time monitoring of symptoms and more systematic data gathering[16].

What makes a good PROM?

The Royal College of Psychiatrists (RCPsych) has published ten key principles for good practice in the use of mental health outcome measures[17] (box 1). When designing a new PROM, the United States Food and Drug Administration (FDA) recommends that services users are involved at all stages, including design, content, data collection and analysis[18]. Ideally, both qualitative and quantitative methods should be used in development[19,20]. Several methodological and statistical properties define a well-designed PROM[21]. The Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) group emphasises the importance of content validity (ensuring that the concept of interest is truly being measured) and its reliability (test-retest repeatability) [22]. In addition, as many PROMS are completed without assistance, they should be clearly set out, easy to use and understand[23].

Box 1: Principles for Good Outcome Measurement[17]

- The focus should be on what is important to patients and carers
- Measures should be relevant to patients and carers
- Measures should be clear and unambiguous
- Measures should allow comparisons between teams and services
- Measures should be validated for the purpose for which they used
- IT support should simplify data collection and analysis, and ensure maximum use of data already collected
- Data should be checked for reliability
- Data should be used at the clinical, team and organisational level
- Ideally, there should be immediate feedback of the data to patients, carers and clinicians so that it can influence the treatment process

Uses of PROMS

PROMs have great potential for improving care and decision making across the NHS. Drawn from recent reviews,[9, 11,17] table 1 lists a wide range of possible applications. Outcome measures can be useful because they allow patient progress to be monitored individually as well as tracking performance between local teams and the rest of the country[24]. It is now essential for clinical teams to report outcomes in order to evaluate their work, demonstrate effectiveness and support future commissioning decisions[25,26].

Table 1: Uses for PROMS

Area	Purpose and Application
Across Healthcare	Evaluate work, clinical and cost effectiveness at all levels
	Drive up quality of care for individuals, populations & systems
Across Clinical Practice	Assist with screening, diagnosis and assessment
	Feedback to clinicians, leading to changes in treatment
	Improve clinical communication: focus on what is important
	Standardise approach - capture wider area of need
	Facilitate shared decision-making: plan personalised care
	Memory prompt in consultation: avoid key omissions
	Motivate and incentivise: observer (Hawthorne) effect – awareness of being measured changes behaviour
	Measure effectiveness: before & after clinical intervention
	Facilitate referral to other NHS services & external providers
Across Wider Mental Health Systems	Monitor variations in health needs and outcomes between different populations/ areas
	Clinical audit – better understand patient needs
	Service evaluation - quality improvement
Within Research Settings	Study recruitment: screen for eligibility, baseline measure
	Measure outcomes in control and intervention groups
	Evaluation of the PROM itself: properties, uses, acceptability
For Providers and Commissioners	Inform procurement and contracting of health services
	Use as a key performance indicator to justify/ inform funding

	Service development: show unmet need Justify continuing need for existing service (prevent cutbacks)
	Demonstrate value for money: managers, politicians, public

The National Institute for Health and Care Excellence (NICE) recommends 'considering' the use of validated PROMS at regular points in a patient's treatment pathway for both physical problems (eg cancer)[27] and mental health conditions (eg depression)[28]. The aim is to 'inform and evaluate care' ie assess severity, functioning and response to treatment. A 2016 Cochrane review[29] of 17 studies (8787 participants) reported insufficient evidence that using PROMS for common mental health problems leads to improved recovery from symptoms or to significant changes in care. Within NHS England's Talking Therapies Programme (formerly known as Improving Access to Psychological Therapies - IAPT), PROMS for anxiety, depression and social functioning are routinely administered at every treatment session. Evidence is accumulating that this is of potential benefit[30]. Patients who complete PROMS believe they have been assessed more thoroughly, feel better able to follow their own progress and report being more involved in their own care[31].

Drawbacks and Misuses

There are several important challenges to the effective implementation of PROMS (table 2). First, no single PROM has evidence of validity across all areas of mental health[10]. A PROM may not be valid for the purpose and population in which it is used, may not measure what it purports to measure, or assess areas that are most important to users of mental health services[32]. Not all PROMS purporting to focus on 'recovery' include key quality of life components such as Connectedness, Hope, Identity, Meaning and Empowerment (CHIME).[33]

Second, there is a risk that selective sampling could lead to marginalisation of the broad range of patients who have difficulties completing measures. These include individuals with literacy difficulties (intellectual disability, dyslexia), cognitive impairment (dementia) and those unable or unwilling to participate

due to the mental health problem itself (anxiety, depression, autism, psychosis). Access to, and competence in using, information technology (including online and Smart phone data collection) remains another key issue.

Third, the consequences of outcome measurement may affect how those providing - and collecting - the measurement behave[21]. Examples of sampling bias include asking someone to complete a PROM just after receiving good news (to get a more positive score), or ‘cherry picking’ patients whom the clinician thinks will be more likely to do well. Conversely, some patients may give responses they feel are more likely to elicit care eg a high score on the PHQ-9 scale as a marker of subjective distress rather than objective evidence of severe clinical depression.

Fourth, at a service level, the impact of outcome measurement should be assessed across all three dimensions of health care delivery: structure, process and outcome. Although PROMS can inform service commissioners and providers, long periods may elapse before improvements are apparent[34]. In addition, measurement may provide limited insight into why any improvement has occurred. Patient outcomes depend on a variety of factors outside the direct control of health services, including poverty, social circumstances, stigma and discrimination[12, 21]. Hence if ‘recovery’ is too narrowly defined, PROMS can mislead as indicators of service quality[34]. These drawbacks have been summarised by ‘Goodhart’s law’: when a measure becomes a target then it ceases to be a good measure[35].

Table 2: Potential Drawbacks in using PROMS

Area	Challenge
Health Service	Time and resources needed for systematic data collection
	Financial cost, copyright & intellectual property issues
	Collecting data without a purpose (eg because of a directive or to appear consultative)
	Measurement overload – staff burnout, distress to patients
Clinical Practice	Selective sampling or timing by clinicians
	Selective use to justify a decision Eg rejecting a referral as not 'severe enough' or risk scale to discharge after self harm
	Unintentional exclusion or marginalisation of patients
	Patient concerns about confidentiality and use of their data
	Patient bias towards 'expected' or 'desirable' responses
Methodological	Lack of face /content validity
	Arbitrary categories eg strict cut off on a continuous data scale
	Snapshot picture: data gathering at only one time point
	Conflation: grouping together disparate conditions
	Ceiling effect eg patient satisfaction questionnaires
	Regression to the mean: natural improvement over time
	False positives/negatives leading to interventions or omissions

Summary and Future Trends

Over the past two decades, an increasing role has been advocated for outcome measurement in both funding and in evaluating mental health services. Consequently, PROMS have evolved in both content and purpose. Box 2 summarises key themes and drivers behind changes in the approach to what is measured. However, in practice, few pragmatic studies exist to inform the delivery of mental health outcomes programmes[36,37]. Chapter two describes the methodology and findings of the publications in this thesis and summarises their contribution to our understanding of PROMS implementation across NHS mental health services.

Box 2: Mental Health PROMS: Evolving Themes over 20 Years[12,21]

- Collaboration: increasing service user involvement and empowerment
- Content: a broadening of what is considered important - from symptoms to quality of life measures (eg well-being, functioning, social inclusion, recovery)
- Accountability: greater need for professionals to demonstrate effectiveness for care interventions
- Financial: attempts to link outcome measures to funding and resource allocation eg clustering, payment by results
- Data collection: moving from local/ ad hoc/ paper-based approaches towards national/ systematic/ electronic methods
- Maintaining quality of care: changing focus away from clinical audit and government targets towards outcome measures

CHAPTER 2: PUBLISHED WORKS, LINKED THEMES AND METHODOLOGY

Overview

The papers in this thesis comprise five core publications (from four original research studies) and three additional works: one clinical review, one NICE learning tool and one HYMS Scholarship & Special Interest Programme (SSIP) project. Box 3 lists these studies and includes weblinks to the corresponding paper. The uniting themes across this body of research may be summarised as:

- **Aims**: Evaluation of key PROMs that assess the wellbeing of people receiving care from mental health services, and effectiveness of those interventions.

- **Approach**: pragmatic application: 'real-world' study integration within existing clinical services. Collaborative emphasis upon patient involvement in own care.

- **Setting**: front line NHS services providing specialist mental health care, in the community or general hospital, principally in North Yorkshire, UK.

- **Participation**: multidisciplinary, team-based approach across professions, with psychiatrists, nurses, psychologists, social workers, occupational therapists and other staff contributing to care delivery and data collection.

- **Study Design**: quantitative or mixed methods: cross sectional (single time point across comparator measures) or prospective, longitudinal (before and after interventions).

- **Measures**: use of structured, evidence-based questionnaires designed for completion by patients supported by carers. These comprise:
  a) four established rating scales: the Patient Health Questionnaire-9 (PHQ-9), Generalised Anxiety Disorder-7 scale (GAD-7), Short Warwick & Edinburgh Mental Wellbeing Scale (SWEMWBS) and Distress Thermometer & Problem list (DT), plus
  b) two 'developed for purpose' tools:

The Carers & Users Expectations of Service Tool (CUES) created by the Royal College of Psychiatrists (RCPsych) Research Unit and
Recovering Quality of Life, developed by Sheffield University colleagues for the Department of Health.

- **Outcomes evaluated**: symptoms (mental/physical), functioning, distress, quality of life, satisfaction with life/services.

Why These Studies Were Undertaken

The rise of patient involvement and evidence-based practice were two important drivers for undertaking this research. Service user empowerment and the concept of recovery[38] necessitates a greater role for people to contribute to their own care and receive systematic feedback on key outcomes. This includes piloting and implementing new PROMs which evaluate the broader range of quality of life measures valued by patients[39].

For over 15 years, professional guidelines (eg from NICE) have consistently recommended using structured measures to improve care and assess response to treatment – across physical (eg cancer[33]) and mental health services[25]. In NHS services delivering cognitive behaviour therapy - the psychotherapy with the most evidence of benefit[15] - the use of personalised (eg problems and targets) and standardised (eg PHQ-9) rating scales is well established[36].

However, reported voluntary usage – and perceived value - of using PROMS in generic mental health settings, is low (15% of psychiatrists in Study H). If evidence showed that validated measures can be usefully integrated into daily practice, this could help overcome apparent professional aversion to their implementation and improve the quality of holistic care for patients.

Box 3: List of Papers comprising this Thesis

A. Blenkiron P, Mo KH, Cuzen J and Hammill AC. Involving service users in their care: the CUES Project. *Psychiatric Bulletin (The Journal of Psychiatric Practice),* Oct 2003; 27(9): 334-338 (Print). Published online by Cambridge University Press 2Jan 2018 https://doi.org/10.1192/pb.27.9.334

B. Blenkiron P, Hammill CA. What determines patients' satisfaction with their mental health care and quality of life? *Postgraduate Medical Journal,* 2003; 79(932): 337-340. http://dx.doi.org/10.1136/pmj.79.932.337

C. Blenkiron, P, Brooks A, Dearden R & McVey J. Use of the Distress Thermometer to Evaluate Symptoms, Outcome and Satisfaction in a Specialist Psycho-oncology Service. *General Hospital Psychiatry* 2014; 36(6): 607-612 https://doi.org/10.1016/j.genhosppsych.2014.06.003

D. Keetharuth AD, Brazier J, Connell J, et al, on behalf of the ReQoL Scientific Group: Recovering Quality of Life (ReQoL): a new generic self-reported outcome measure for use with people experiencing mental health difficulties. *British Journal of Psychiatry*, 2018; 212(1):42-49. https://doi.org/10.1192/bjp.2017.10

E. Blenkiron P & Goldsmith L. Patient Reported Outcomes Measures in Community Mental Health Teams: Pragmatic Evaluation of PHQ-9, GAD-7 and SWEMWBS. *BJPsych Bulletin* Oct 2019; 43(5): 221-227 http://dx.doi.org/10.1192/bjb.2019.20

F. Lynch S, Clarkson P, Blenkiron P, Fraser J. Scale based protocols for the detection and management of depression. *Primary Care Psychiatry* 2002; 8(3): 77-84. https://doi.org/10.1185/135525702125001506

G. Blenkiron P, Byng R, Chew-Graham C, Goldberg D, Ivbijaro G, Nipah R, D, Rathod S, Shafran R. NICE: Common Mental Health Problems: Clinical Case Scenarios for Primary Care. A learning & development resource to support the NICE guideline CG123 (Common Mental Health Disorders: Identification & Pathways to Care). Ch7: Active Monitoring & Psychoeducation. *National Institute for Health and Clinical Excellence*, 2012. https://www.nice.org.uk/guidance/cg123/resources/clinical-case-scenarios-pdf-version-pdf-181726381

H. Ransom S & Blenkiron P: Mental Health Outcome Measures: A clinical review and descriptive survey of psychiatrists' current practices. Scholarship & Special Interest Programme (SSIP) Project & Poster, Hull York Medical School *(Unpublished).*

Author Involvement

The prima facie case submission thesis materials provide details of author contributions and peer validation of evidence. For papers A, B, C and E, Paul Blenkiron (PB) conceived each study design, led the clinical implementation and data collection, analysed the data, led the writing of the published paper as first author and disseminated results to peers.

For paper D (ReQoL 2014-2019) PB was a core member of the ReQoL Scientific Group that developed the PROM for this National Institute of Health Research (NIHR) multicentre study. Acting as Principal Investigator (PI) and Associate Director of Research, PB also led regional recruitment for ReQoL piloting, data collection and implementation across two large NHS Trusts.

For paper F (review and discussion), PB acted as co-author.

For publication G, PB was co-author in his capacity as a 'NICE Fellow' (one of ten nationally appointed ambassadors for evidence-based guideline implementation 2011-2014). PB contributed to this educational resource as a core member of NICE's

Common Mental Health Disorder Advisory Group, including writing Chapter 7: Psychoeducation and Active Monitoring which focussed on PROMS use in practice, linked to a case study.

In study H, PB acted as SSIP mentor and supervisor to SR, a year 3 medical student, facilitating project design and data collection for the paper and poster presentation.

Methodology, Data Handling and Statistical Analysis

Tables 3 and 4 describe key features of the six PROMS that were evaluated. The methodology is detailed within each paper accompanying this thesis. For publications A, B, C and E, data was anonymised and analysed using the latest IBM version of the Statistical Package for Social Sciences for Windows (SPSS)[40]. Dichotomous variables were examined using the Chi-squared test. Non-parametric tests were applied to ordinal and continuous variables: Wilcoxon's signed rank (z) test for paired data (eg initial versus final measures), and Mann-Whitney U and Spearman's correlation coefficient for independent samples[41]. Free text responses (eg to life and service satisfaction questions) were categorised by qualitative thematic analysis. Paper C used multivariate regression modelling (ANOVA) to examine predictors of Distress Thermometer score at discharge. Paper E used the Kruskal–Wallis H-test for PROM differences between superclusters, and clinical effect sizes (Cohen's d) were calculated for reported changes in measures[42].

In paper D, qualitative methods were used to develop ReQoL questionnaire items and test them[43]. Quantitative methods were then applied to reduce the number of items and construct the scale. Confirmatory factor analysis was carried out[44] using Mplus 7.4. Specific tests examined reliability (eg Cronbach's alpha), construct validity (eg Pearson's correlation coefficient - with Clinical Outcomes in Routine Evaluation - CORE-10 and SWEMWBS as comparator measures) and responsiveness (eg the standardised response mean).

In papers A and B, individual responses for quality of life and service delivery were added to obtain four global CUES-U scores. For paper E, self harm risk, functional impairment and problem-solving ability scale items were analysed as additional factors. Missing scale response data were managed by imputing the mean value of

missing items, or (for paper E) by using syntax coding to adjust participants' scores in proportion to the number of questions answered.

Research Governance, Ethical Approval and Funding

Informed consent was obtained from all participants, following provision of written information about each study. All electronic and paper-based data were stored securely and confidentially in accordance with approved information governance policies. For publications A, B, C and E, statistical advice on data analysis was obtained from a senior statistician at York University Department of Health Sciences (VA). Papers were improved following independent academic peer review by the journals in which they were published. Details of study registration and type (service evaluation or research), ethical and research governance approval, competing interests and acknowledgments, are described in each paper. Funding for ReQoL (Paper D) was provided by the Department of Health (DOH) Policy Research Programme and National Institute for Health Research (NIHR) Collaboration in Yorkshire and Humber. For other studies, external sources of funding were not required.

PROMS Evaluated

Tables 3 and 4 list the PROMS evaluated in this thesis. **Appendix 1** (e-folder) contains all six questionnaires used in papers A to E, accompanied by scoring, notes and any additional questions for service users and professionals.

Treatment of References

References A to H that comprise the main body of works of this MD are marked within the text with the corresponding superscript letter for each paper [A-H]. References cited in this thesis are then numbered using the Vancouver System[1-115] and cited at the end of the final chapter. Those preceded by an *****asterisk are new. They were added during the literature research and writing of this thesis and additional to those cited at the end of each original published paper.

Table 3: PROMS Evaluated: a) Existing measures

PROM	Description	Comments
Patient Health Questionnaire[45] (PHQ-9)	Nine-item measure of depressive symptoms based on International Classification of Diseases Volume 10 (ICD-10) criteria. Each is rated using four ordinal response options (0, not at all; 3, nearly every day), giving a severity score between 0 and 27. Also rates difficulty in functioning. Over 9 = clinically significant depression	Well validated against standard criteria. Demonstrates sensitivity to change. Used in a variety of clinical settings [46,47].
Generalised Anxiety Disorder Scale[48] (GAD-7)	Seven-item measure of anxiety and worry symptoms. Each is rated on the same four ordinal responses as the PHQ-9, giving a severity score between 0 and 21. A score above 7 is recommended to identify a likely anxiety disorder. Change sensitivity not previously demonstrated	PHQ-9 and GAD-7 form part of the UK Department of Health's National Minimum Data Set.[36] Use supported by NICE for assessing clinical progress in mental health services[25]
Distress Thermometer and Problem Checklist Tool (DT & PC) [49]	Patients circle a number on a visual analogue scale from zero (no distress) to ten (extreme distress) that best describes how much distress they felt in past week, then on a checklist of 33 problems (practical, family, emotional, spiritual/religious, physical, other), tick any that have caused distress. Originally devised as a screening tool in USA/UK[50]. Validated against structured clinical outpatient interviews, acceptable to patients[51,52]. Recommended by several UK cancer research networks.	The most widely used rapid screening tool in UK cancer services[51]. Similar sensitivity (77-100%) & specificity (49-67%) to PHQ-9 & HAD (Hospital Anxiety & Depression) scales[53,54]. Not previously used to monitor clinical outcome, yet can detect changes in distress over time[55].
Short Warwick & Edinburgh Mental Wellbeing Scale (SWEMBS)[56]	Seven items, each with five response categories (1 = none of the time up to 5 = all of the time). Score range 7–35: higher scores = greater well-being. Short version of a measure originally developed to monitor well-being in general population and evaluate policies addressing it[57]. Developers recommended demonstrating sensitivity to change before using it clinically.	Adequate internal consistency & reliability reported[58]. Not previously systematically evaluated in mental health populations. Adopted by local NHS at time of study to help implement Mental Health PbR.

Table 4: PROMS Evaluated: b) Newly developed measures

PROM	Description	Comments
Carers' and Users' Expectations of Service, User Version (CUES-U)[59]	16-item booklet assessing 7 quality of life areas (Where you live, Money, Help with Finances, How you spend your day, Family & friends, Social life, Stigma & discrimination) and 9 areas of mental healthcare delivery (Information & advice, Access to mental health services, Choice of mental health services, Relationships with mental health workers, Consultation & control, Advocacy, Medication, Access to physical health services, Relationship with physical health workers). Each area has 2 questions. Part A (comparison) gives a normative statement describing the ideal situation if there was no problem (eg Money – 'You should have enough money to pay bills…'). Patients rate how their situation compares (good, worse or very much worse). Part B (satisfaction) asks if they are satisfied in that area (yes, unsure or no).	Quality of life is a strong predictor of psychological well-being[60]. People with mental illness have lower life satisfaction than the general the population[61]. Arose from Department of Health (DoH) Outcomes of Social Care for Adults initiative[62]. Developed by RCPsych Research Unit in collaboration with the National Schizophrenia Fellowship, Royal College of Nursing Institute, University of East Anglia School of Social Work Covers issues of quality of life & satisfaction with mental health services that users (rather than professionals) have identified as their priorities.
Recovering Quality of Life (ReQoL-10 & ReQoL-20)[63] www.reqol.org.uk	For each of 10 items (20 items in longer research version), individuals tick one box that best describes their thoughts, feelings and activities over the last week, (from 'none of the time' to 'most/all of the time', score 0 to 4, positively & negatively worded items). One extra question rates physical health problems (pain, mobility, self- care, feeling unwell). Covers seven key themes that service users value as most important: activity, hope, belonging & relationships, self-perception, well-being, autonomy, and physical health. ReQoL-10 score below 25 (max=44) is within the clinical range. Minimum clinically important difference is a 5-point total score change.	Specifically developed by DoH for use in mental health populations with user input and testing (>6K participants). Free for use after registration. Users should review individual items to facilitate care, not solely look at total score. Both versions have acceptable internal consistency, test–retest reliability (>0.85), and are responsive over time (standardised response mean > 0.4). Performs marginally better than SWEMWBS and markedly better than EQ-5D^{E}.

CHAPTER 3: RESULTS AND DISCUSSION OF SIGNIFICANT FINDINGS

This chapter presents key results from each of five core research papers (A to E), in turn critically evaluating strengths and limitations – of the research design and the main outcomes. The discussion compares significant findings with previous and subsequent research, highlighting original contributions to knowledge and clinical practice. Impact of results, their importance and dissemination (via conference presentations, posters, awards, press releases, linked articles and citations) is then described.

Appendix 2 summarises each publication, the journal abstract and provides an electronic link to the full study. It tabulates the PROM(s) evaluated, participants and setting, author involvement, how findings were disseminated and their impact after publication. English language citations (available via PubMed & Google Scholar) are also listed. These include other peer reviewed research papers, books, academic or governmental reports and key website links (eg NHS Evidence, NICE) that reference or highlight the works.

The content, findings and impact from the three additional linked papers (F,G and H) is discussed in chapter 4, where their relevance is contextualised within the practical implementation of PROMS in NHS practice.

Papers A and B: The CUES Project

Community mental health teams (CMHTs) are a key component of specialist mental healthcare, yet front-line systematic use of PROMs has not previously been evaluated in this setting[E]. In this study, 120 adults receiving CMHT care were invited to complete CUES-U (Carers' and Users' Expectations of Service, User Version), a 16-item booklet covering the issues of quality of life and satisfaction with services that patients (rather than professionals) identify as being their priorities[62]. Documentation from the Royal College of Psychiatrists (RCPsych) Research Unit was adapted for local use. This study was also the largest participating data contributor to the CUES national scheme.

Paper A demonstrated the feasibility and practical use of the CUES tool in daily practice: the PROM (parts A and B) was fully completed by 86 (76%) of respondents across a range of severe and enduring mental health diagnoses and 72% also provided free text responses (part C). Patients' subsequent discussion with their care coordinator resulted in the identification of one or more areas for action (eg 'where you live', 'money' or 'medication') for 49% of individuals. Front line professionals rated CUES as a good use of their time in 64% cases. This tool also allowed benchmarking and comparison with similar services nationally (tables 1 & 2), with life and service satisfaction ratings ranging from 49% (for 'social life') to 88% (for 'relationships with physical health workers').

Paper B examined individual determinants of satisfaction within the same population. Satisfaction with psychiatric services correlated significantly with patients' age (Spearman's $r = 0.444$, $p<0.001$) and their satisfaction in other areas of their lives such as housing, money, and relationships ($r = 0.575$, $p<0.001$). Importantly, these areas are not under the direct control of clinicians. Gender and duration of disorder were unrelated to service satisfaction. Interestingly, those with psychotic disorders rated their quality of life as higher than other respondents (median total satisfaction score 12 *v* 9, Mann-Whitney U = 377, p = 0.001).

These findings have been supported by subsequent research, including that in paper E. In large UK population surveys, scores for life satisfaction and happiness rise throughout middle and older age in both men and women up to age 80[64.] Adult psychiatric morbidity survey data (n=7000) confirm[65] that wellbeing scores are not significantly altered by adjustment for mental disorder: moderately high levels of wellbeing can be achieved despite severe mental illness. We may conclude that mental wellbeing and mental distress are correlated but independent variables.

There are limitations to the findings reported in these two CUES papers. For example, the respondent population lacked ethnic diversity or a control group, blinding was not possible and changes over time were not assessed.

Measuring quality of care using patient satisfaction is in part tautological[66], and there is no simple relationship between them[67]. In one study[68], only 4.6% of the

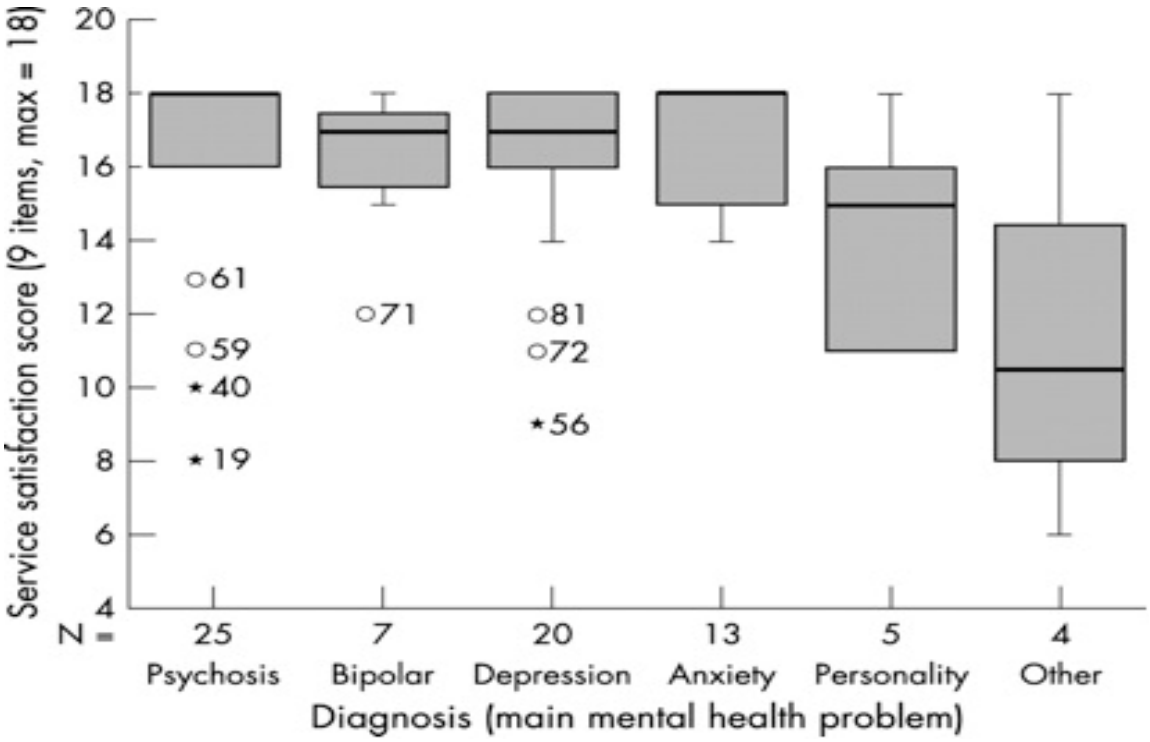
variance was attributable to differences between services – individual patient perception of experience remaining the most important factor. Other research confirms a 'ceiling effect' is likely[69]. High satisfaction ratings may therefore suggest that care is adequate, not that it is necessarily superior in quality to other comparable services. Arguably, it may be better to report the proportion of patients expressing low satisfaction rather than give mean satisfaction ratings.

Importance and Dissemination

Papers A and B were awarded the Douglas Bennett Prize by the RCPsych for the best original research presented in the field of rehabilitation psychiatry to promote the recovery of people with severe mental illness (Joint Conference of Rehabilitation & Social Psychiatry, Bristol, 2003). It formed the basis of a press release 'Carers' & Users' self-rating questionnaire supports clinical care: Its use led to improvements in care for nearly half of patients'. Key findings were also reported via RCPsych Division Newsletters. It is cited by NHS evidence (2023), highlighted as an example of innovative good practice by the National Centre for Mental Health www.nimhe.org.uk, Northern Centre of Mental Health www.ncmh.org.uk & Rethink: http://www.rethink.org/research/rethinkres/cues.htm.

York and Selby CUES project was the largest single contributor to the linked national dataset that led to additional publications with the RCPsych Research Unit[59]. Paper B data, including results and box whisker plots (figure 1), have since 2015 been used as the basis for questions for the critical appraisal section of The Membership Examination of the Royal College of Psychiatrists (MRCPsych). This twice yearly internationally recognised qualification determines progression to higher training. In March 2022 alone, 987 candidates sat the exam. See **Appendix 3** for sample questions that include the CUES paper content. CUES boxplot data also appear on two popular revision sites: SPMM (the MRCPsych revision platform) and Psychmentor (https://spmmcourse.com).

Figure 1: CUES Diagnosis: MRCPsych Boxplot Question



This research has subsequently informed wider PROM development - including DIALOG, a satisfaction measure increasingly used locally and nationally (see chapter 4). It also had a significant impact upon the creation of a PROM using a similar format - the Carer Wellbeing and Support questionnaire (AQ, Personal communication, 2022, Research and Audit RCPsych). A 2018 systematic review rated the CWS as the 'best available tool for measuring quality of life of carers of people with dementia[70].

Publication A was reissued electronically by the British Journal of Psychiatry Bulletin in 2018. The CUES PROM remains unique in two aspects. First, having a comparator normative statement of what a service user's 'ideal' life and health service received could potentially look like, allowing self-ratings with depth and texture beyond a single descriptor sentence. Second, it includes both PROMS and PREMS domains ie a combination of life satisfaction and service experience ratings in the same format. A central conclusion from the study is that a person's satisfaction with the care received is positively correlated with

their satisfaction with their general quality of life outside of the NHS. This has continued relevance in highlighting that there are limits to what a heath service can achieve on its own - without wider changes also occurring to more social and interpersonal determinants of health.

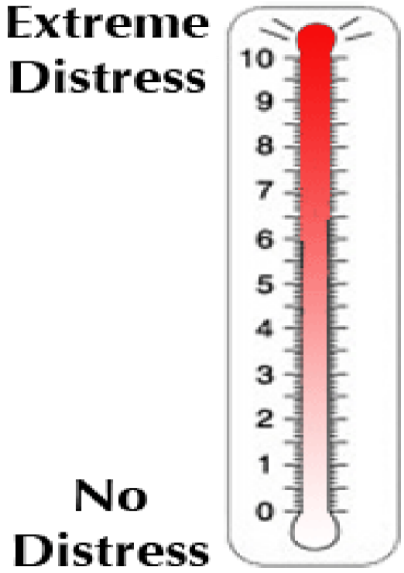
Paper C: The Distress Thermometer

The diagnosis and treatment of cancer can lead to high levels of psychological distress and significantly impair a person's quality of life[71]. NICE recommends the use of structured tools to improve holistic care for patients with cancer. Paper C pioneered the use of the Distress Thermometer and Problem Checklist (DT) as a PROM integrated within specialist psycho-oncology services, rather than simply as a screening tool for referral to those services. 111 adult outpatients completed the DT at their first appointment. After receiving psycho-oncology care, they re-rated emotional distress, problems and service satisfaction on the DT at discharge. Number of emotional problems was observed to fall by 15-24% and median distress scores decreased from 6 to 4 (Wilcoxon's $z = -4.83$, $p<0.001$, Cohen's $d = 1.22$). These improvements occurred despite no significant change in cancer patients' physical health or practical problems. The study concluded that the DT is a useful tool for enhancing the delivery of structured care and provided new evidence suggesting psychological and psychiatric interventions are effective in this population. Subsequent reviews have confirmed the findings - notably the benefit of the DT in facilitating communication as part of a holistic therapeutic conversation[50,72].

Strengths of this research include use of a simple visual analogue scale, the high response rate across a diverse population and the mixed methodology design. Analysis of free text comments, grouped according to the most commonly cited themes, showed patients particularly value supportive listening and advice on coping strategies from a professional independent of their physical care. Interestingly, satisfaction was linked to lower distress scores at discharge but not to the number of appointments attended – suggesting that quality rather than quantity of care is what matters most to patients.

There remain important limitations to the findings in paper C. First, further work is still required to determine the validity and test-retest reliability of the DT as an outcome measure. Second, this was a prospective service evaluation, not a controlled intervention study. However, other randomised controlled evidence suggests these improvements are unlikely to be simply due to the passage of time[73]. Third, the high level of patient satisfaction may be masking important difference between patients. This 'ceiling' effect is consistent with research in other areas of health care[B,74].

Figure 2: Distress Thermometer



Importance and Dissemination

Paper C was presented at the 2013 RCPsych International Congress in Edinburgh and the 2014 RCPsych Faculty of Addictions Psychiatry and Faculty of Liaison Psychiatry Joint Annual Conference in Leeds. http://www.rcpsych.ac.uk/pdf/Poster_presentationsAL2014.pdf . It generated significant international interest after publication, with 427 views/downloads in first 12 months across the USA, UK, Australia & China. It was a regional poster prize winner at the regional Trust Research Forum in 2013 and was also published as a short report https://www.leedsandyorkpft.nhs.uk/research/wp-content/uploads/sites/6/2017/04/innovation-issue15-oct13 The key findings have been cited by several peer reviewed publications, notably the 2015 joint

report on Cancer PROMS produced by Macmillan Cancer and Oxford University[75].

Paper D: Recovering Quality of Life

Recovering Quality of Life (ReQoL) is a short self-report questionnaire specifically commissioned and funded by the UK Department of Health (DoH). Over 6000 service users aged over 16 were involved in its design and testing. Paper D describes the validation and field testing of this unique new PROM. The main stages (figure 1) in its development were:

a) qualitative interviews and systematic review leading to the generation of seven common themes across 1597 candidate items: activity, belonging & relationships, choice autonomy & control, hope, self-perception, well-being and physical health

b) face and content validity testing of 61 initially shortlisted items, which were then re-assessed by the ReQol Scientific Core Group and shortened without loss of predictive ability to 10 and 20 item versions

c) psychometric evaluation of the final scales – including comparison with four existing PROMS: the Short Edinburgh and Warwick Mental Wellbeing Scale (SWEMWBS), EuroQoL Dimension 5 (EQ-5D), Patient Health Questionnaire (PHQ-9) and Generalised Anxiety Disorder 7 (GAD-7) scales, and comparison with two CROMS - the Clinical Outcomes in Routine Evaluation 10 (CORE-10) and the Health of the Nation Outcome Scale (HoNoS).

Table 4 in Chapter 2 summarises the format and psychometric properties of ReQoL. Both the 10 and 20 item versions achieve excellent face and content validity, acceptable internal consistency, test retest reliability and responsivity over time (standardised mean difference >0.4). ReQoL strongly correlates with other PROMS ($r>0.8$) across all diagnostic groups (depression, anxiety, schizophrenia, bipolar disorder and personality disorders. Importantly, ReQoL is slightly (versus SWEMWBS) or markedly (versus EQ-5D) more responsive over time – ie better at detecting changes where a change in mental health was reported.

This was a large, multicentre study with a number of strengths. ReQoL remains the first wellbeing PROM specifically designed for clinical and research use in mental health populations. It can be incorporated into electronic patient systems and used across the whole spectrum of mental disorders from common to very severe. By focussing not only on symptoms but also on wellbeing, functioning and quality of life, ReQoL aims to address the areas that patients with lived experience (rather than professionals) feel are most central to their recovery. As with CUES, it has the potential to be used as a clinical tool for regular monitoring within clinical appointments and help individuals feel in control of their treatment and recovery.

The ReQoL measure has some limitations. First, there is no gold standard in mental wellbeing research, so indirect comparisons with other PROMS were used to assess validity and responsiveness, in a potentially circular fashion. Second, including both positive and negatively worded items increases precision and relevance to patients but adds some complexity to its scoring. Third, both ReQoL 20 and 10 perform similarly – in fact almost all items correlated significantly with each other in the extended factor analysis. It could be argued that a two-question PROM (one positive, one negative item) would be almost as predictive, albeit with loss of significant clinical detail. Fourth, further research using ReQoL is needed to validate it within different ethnic groups and languages.

It is envisaged that ReQoL, like CUES and the DT, will be integrated into care planning, enabling service users to participate in decisions and evaluate their own progress in real time clinical appointments. This use in real world settings is discussed in chapter 5.

Importance and Dissemination

ReQoL was launched in Parliament at the Palace of Westminster in October 2016. This implementation event was attended by members of the ReQoL Scientific Group, NHS England, Paul Boating MP and stakeholder organisations.

ReQoL is freely available for use by NHS Staff and for publicly funded research via the Oxford University Innovation website: http://innovation.ox.ac.uk/outcome-measures/recovering-quality-life-reqol-questionnaire/ . Over 170 licenses have been issued without charge, including 66 to UK mental health trusts, 27 to academic institutions and 24 to voluntary organisations (Keetharuth, personal communication, 2022). It has now been translated into several other languages, including Chinese, Punjabi and German.

The interpretation of ReQoL-10 scores has since been further defined using study data (Appendix 1): a rise or fall of at least 5 points denotes clinically reliable change (improvement or deterioration). A score of 25 or above lies within the 'general population' range and 0-24 in the 'clinical' range for impaired quality of life.

Paper D was cited by at least 82 other papers on outcome measurement in the first 3 years after publication. Additional papers linked to the development of ReQoL have been published, describing the integration of qualitative and qualitative measures[76], exploration of item sets using factor analysis[77] and wider lessons learned from service users[78] and the public[79].

In November 2018, a ReQoL in Practice event hosted by the University of Sheffield, brought together clinicians and service users with NHS England, commissioners and managers to share learning about ReQoL in frontline clinical practice. This 'World Café' process was successfully used to set priorities for implementation and quality improvement across the wider NHS[80].

Leeds and York Partnership Foundation Trust (LYPFT), a key field testing site, was the first UK health organisation to use ReQoL in 2016. ReQol has since been adopted by other NHS mental health trusts, notably another author contributing site: Tees, Esk & Wear Valleys (TEWV) NHS Foundation Trust (see chapter 5).

Paper E: PROMS in CMHTs

Paper E describes the first UK study to examine the pragmatic integration of PROMS within adult community mental health teams (CMHTs). Three widely

used measures were evaluated: PHQ-9, GAD-7 and SWEMWBS. Routine use, acceptability and response rates were recorded at initial contact and questionnaires were repeated three months later. Professionals recorded the setting, refusal rates and cluster diagnosis.

In total, 245 patients completed 674 measures. The results confirmed good initial return rates (81%), excellent scale completion (98-99%) and infrequent refusal/unsuitability (11%). Significant improvements occurred in functioning ($p=0.01$), PHQ-9 ($p=0.02$) and GAD-7 ($p=0.003$) scores (a large clinical effect, Cohen's d = 0.52-0.77) but not in SWEMWBS ($p=0.91$). Individuals in supercluster A (non-psychotic disorders, including anxiety and depression) had higher initial PHQ-9 & GAD-7 ($p<0.001$) and lower SWEMWBS scores ($p=0.003$) than people in supercluster B (psychotic disorders including schizophrenia). Supercluster C (organic disorders, mainly dementia) showed the greatest functional impairment ($p=0.003$).

It is important that outcomes are validated for the population in which they are used. This study provided new evidence that the GAD-7 is responsive to change in a community mental health population[81,82]. The total mean initial GAD-7 score of 12.9 improved to 8.1 at follow up – a large clinical effect size. There was a similar decrease in PHQ-9 scores (eight points within Cluster A). This significant and reliable improvement[79] is comparable to that found in large, randomised treatment trials for depression[80]. A central conclusion from this research is that PHQ-9 and GAD-7 seem acceptable as patient reported outcome measures when used in CMHT settings.

Strengths of this research included its 'real world' NHS application in daily practice, the broad study population across all main psychiatric diagnostic categories in the International Classification of Diseases (ICD-10)[83] and the involvement of a wide range (n=25) of mental health professional groups in its implementation. In addition, SPSS Syntax coding was used to correct for potential bias from patients omitting responses to some questions[85].

Possible study limitations include a lack of information on possible harms and costs from collecting PROMS data. It also remains uncertain whether professionals used the responses in their meetings with patients to improve

quality of care (rather than solely to measure that care). Moreover, as this was necessarily a non-controlled study, it remains uncertain whether the improvements observed can be directly attributed to clinical interventions (eg medication, psychotherapy, practical support) rather than the passage of time or regression to the mean.

In this population, SWEMWBS appeared insensitive to change. Possible explanations for this finding include a lower internal reliability of the measure, or a lag in subjective wellbeing behind improvements in symptoms in this secondary care cohort with more severe mental disorders. SWEMWBS change over time has been observed in other settings, including the ReQoL validation field study[D]. Future research in CMHTs could usefully examine the of SWEMWBS responsiveness using methods such as the standardised response mean.

An important finding was the low collection rate (n=32, 13%) for follow up measures in everyday practice. This figure is similar to local audit study data at the time using a psychiatric inpatient sample (n=104). This showed a collection rate of 10% for SWEMWBS and other follow up data (R Smith, Personal communication). Other mental health outcome studies have recorded follow up rates as low as 10-25%, even after prompting of professionals[85,86] as in this study. However, no evidence was found within this sample for attrition bias, and no differences were observed in scale scores between completers and non-completers. This suggests the outcome changes observed may be generalisable to the wider clinical population. In the future, a good response rate will remain central to the success of PROMS[2,8,36]. This could be improved by implementing robust electronic collection systems[12,17] within national outcomes programmes - for example as used by NHS Talking Therapies services.

Importance and Dissemination

Paper E was presented (orally and as a poster) at the RCPsych International Congress in London (2016), LYPFT NHS Trust Research Forum (2016), Durham University (2017), and at the Annual Conference for the British Association for Behavioural and Cognitive Psychotherapies (BABCP) in

Glasgow (2018). Two linked NHS articles publicising the main findings were also published in 2016 (Innovation, LYPFT R&D, 2016, 7(15) and TEWV NHSFT e-bulletin, April 2019).

Paper E formed the basis for strategic links and discussions within TEWV NHS Foundation Trust that led to the adoption of ReQoL rather than SWEMWBS as the preferred global wellbeing measure in 2022 (chapter 5).

International citations of Paper E (see Appendix 2) highlight the validity and change sensitivity of both GAD-7 and PHQ-9 as PROMS. They include a systematic review of screening for depression in 2000 older adults[85] and CBT as an intervention for psychological distress linked to hand surgery[86] (pre and post measures). Paper E was also cited by three studies conducted during the Covid-19 Pandemic: the prevalence of anxiety amongst 2000 Chinese students[87], the effects of Covid on population distress in Myanmar[88], and a factor analysis of 6000 individuals across four European countries[89]. This research confirmed the reliable, unidimensional nature of PHQ-9 and GAD-7 as clinically useful PROMS.

CHAPTER 4: PROMS Into Practice

This chapter discusses the findings and implications of the three linked papers within this thesis: a review of the evidence for using patient rated scales in the management of depression (Paper F), a NICE educational tool including patient vignettes that enables clinicians to integrate PROMS within their evidence based practice (Paper G), and a descriptive survey of psychiatrists' current reported use of common measures in specialist mental health settings (Paper H).

Paper F: Scale based Protocols for Depression

Publication F reviews the research base and clinical use of patient rated scales in the screening, detection and management of depression across primary and secondary care. It examines the strengths and limitations of combining PROMS such as the Beck Depression Inventory (BDI) and Hospital Anxiety and Depression Scale (HADS) with management protocols to guide the clinician into appropriate treatment pathways (depending on the scale score). The paper also describes the development by the authors of a new 10-item PROM – the Brief Depression Scale (BDS) - specifically created for this purpose. Like the PHQ-9, BDS items were derived from the ten key ICD-10 symptoms of depression (table 2 in paper F). Research demonstrates good convergence of the BDS with the HADS depression subscale ($r=0.89$, $p<0.0001$), with a sensitivity of 87% and specificity of 90% for a cut off score of 19 and satisfactory internal consistency (Cronbach's alpha = 0.86). Sensitivity to clinical change was validated in studies with 325 patients in primary care, psychiatric outpatient and inpatient populations[90,91]. Paper F is cited in academic reviews of the clinical management of depression[92,93].

One limitation when using PROMS is that patients may not perceive the scores are important if their clinician does not discuss them or act upon their responses. A metanalysis at the time Paper F was published[94] found that routine administration of questionnaires for screening did not consistently improve detection or clinical outcomes, even when results were fed back to clinicians. This finding has been confirmed by subsequent evidence including an updated Cochrane review of 17 studies involving 8787 participant[29].

The GP Quality and Outcomes framework (QoF) financially incentivised follow up of depression at 5-12 weeks with PROMS (eg PHQ-9) between 2009 and 2013. One study examining primary care records that had used the PHQ-9 (n=604) found that treatment interventions (eg antidepressant changes or specialist referral) occurred five times more often in patients who showed an inadequate response at initial follow up[31]. However, final outcomes for patients after treatment were not reported. In conclusion, for primary care, there is currently only limited low quality evidence that routine screening and monitoring improves depression or anxiety symptoms[28,29].

However, in secondary mental health services and in psychological therapy settings (eg NHS Talking Therapies) more recent metanalytic research has shown benefit on outcomes, especially patients who responded poorly to initial treatments[95,96]. In addition, patients report feeling more understood and more involved in their own care when measures are used[31.]

Paper G: NICE Common Mental Health Clinical Case Scenarios

The National Institute for Health and Care Excellence (NICE) encourages GPs to be 'alert' to depression and anxiety, selectively using brief screening measures to support assessment, rather than screening all patients routinely[28]. NICE additionally recommends all primary and secondary care practitioners 'consider' using a validated PROM for actively monitoring treatment response to psychological or drug interventions.

Given these recommendations, the NICE Common Mental Health Disorder Advisory Group (of which author PB was a member) developed an online practical educational resource (publication G). This aims to help clinicians improve their evidence based identification, assessment and management of anxiety and depressive disorders. It is designed to support implementation of NICE clinical guideline 123 (Common Mental Health Disorders: Identification & Pathways to Care).

There are eight fictional clinical case vignettes incorporating the use of one or more of the following validated PROMS: PHQ-9, GAD-7, HAD scale and the Distress Thermometer. Decisions about diagnosis and management are examined using a question and answer approach, with hyperlinks to the relevant NICE

recommendation. Following peer reviewed dissemination[97], the pdf guide has been incorporated within NICE Pathways and 'Into Practice' webpages. Into practice | What we do | About | NICE

Publication G recommends that assessing clinicians consider using a very brief verbal scale – the PHQ-2 tool[98] or GAD-2 tool[99]. These two-question case finding measures of core symptoms are sensitive but not specific and so may generate false positives. If a person answers 'yes' to at least one PHQ-2 question, or scores 3 or more on GAD-2, the patient is encouraged to complete the longer PHQ-9 scale (for suspected depressive disorder) or GAD-7 (for a suspected clinical anxiety problem). This baseline measure of severity can be repeated after intervention or referral, within a stepped ('matched') care model.

Trials of collaborative care show cost effectiveness for depression, especially with coexisting physical health problems, although less evidence exists for anxiety disorders[97].

A particular strength of this NICE resource is its emphasis upon inclusivity and cultural awareness. Case vignettes illustrate a diverse range of ethnic backgrounds. Access to PROMS and information about services is promoted in a variety of languages, settings and formats (visual, verbal and aural). In addition, where language or communication difficulties are suspected, the guide advises clinicians that they can go through the PROMS questions in real time, involve a family member or instead facilitate completion of the Distress Thermometer[51] visual scale (with a score over 4/10 rated as significant).

Professionals are encouraged to develop local care pathways for groups vulnerable to exclusion (eg black and ethnic minorities, older people, ex-service personnel and those within the criminal justice system). However, because little evidence exists to support significant changes to validated PROMS, the resource advises users 'not to significantly vary the content or structure' of the tool to address specific cultural or ethnic factors, other than translation into another language.

Paper H: Outcome Measures in Psychiatric Practice: Review & Descriptive Survey

This literature review and cross-sectional survey examined the frequency of use and perceived clinical utility of commonly used mental health measures amongst 210 UK psychiatrists. A seven-item Qualtrics e-questionnaire comprising Likert quantitative and qualitative themes (**Appendix 4**) was designed then used to evaluate the following tools:

- PROMS (PHQ-9, GAD-7, SWEMWBS, ReQoL-10),
- PREMS (Family & Friends Question)
- CROMS for dementia cognitive screening (Mini Mental State Examination - MMSE and Montreal Cognitive Assessment - MoCA), alcohol dependence (CAGE questions, Alcohol Use Identification Disorders – AUDIT test) and
- Mandated NHS service measures: HoNOS, Mental Health Clustering Tool.

Results were presented orally and by poster at HYMS 2018 Scholarship & Special Interest Programme (SSIP) conference.

The study found that clustering tools and cognitive screens were used most frequently (at least once a month by 44%) whereas PHQ-9 (16%) and ReQol (4%) were used least often. Cognitive screens were rated very useful by 69% and clustering tools least useful (with 60% rating them not at all useful). There was high agreement (Spearman's r = 0.83-0.88) across junior and senior doctors, gender and psychiatric subspecialities regarding the utility of individual measures.

The most common factors affecting use of outcome measures were perceived clinical usefulness, properties of the tool itself (eg short, easy to use) and whether use was mandatory (eg clustering). The most frequent concerns were time needed to complete measures (24%) and a belief they should not be used as an alternative to clinical judgement (14%).

These findings are comparable to those of a survey of UK consultant psychiatrists conducted over 20 years ago[94], which found most psychiatrists did not voluntarily use outcomes measures in daily practice because they saw little

benefit to themselves or their patients' care. Even for conditions where measures were used most often (anxiety, depression and assessment of cognitive function), only half used them routinely. At the time, only 13.5% of clinicians reported being required routinely to collect outcome measures. In contrast, the responses in Paper H suggest that mandated use of PROMS has increased significantly in recent years. The types of PROMS used have evolved too – with clinicians switching from HADS and BDI to shorter copyright-free tools (eg PHQ-9 and GAD-7). Paper H also indicates a greater use of new broader well-being measures that evaluate functioning and quality of life as well as symptoms (eg SWEMWBS and ReQoL).

CHAPTER 5: FUTHER RESEARCH AND CONCLUSIONS

This final chapter discusses the current and future implementation of PROMS within front-line mental health practice. Potential benefits and challenges of moving towards a more patient-centred, outcomes based clinical service are then described. Lastly, areas of continued uncertainty and questions for future research are critically addressed.

NHS Community Transformation Project

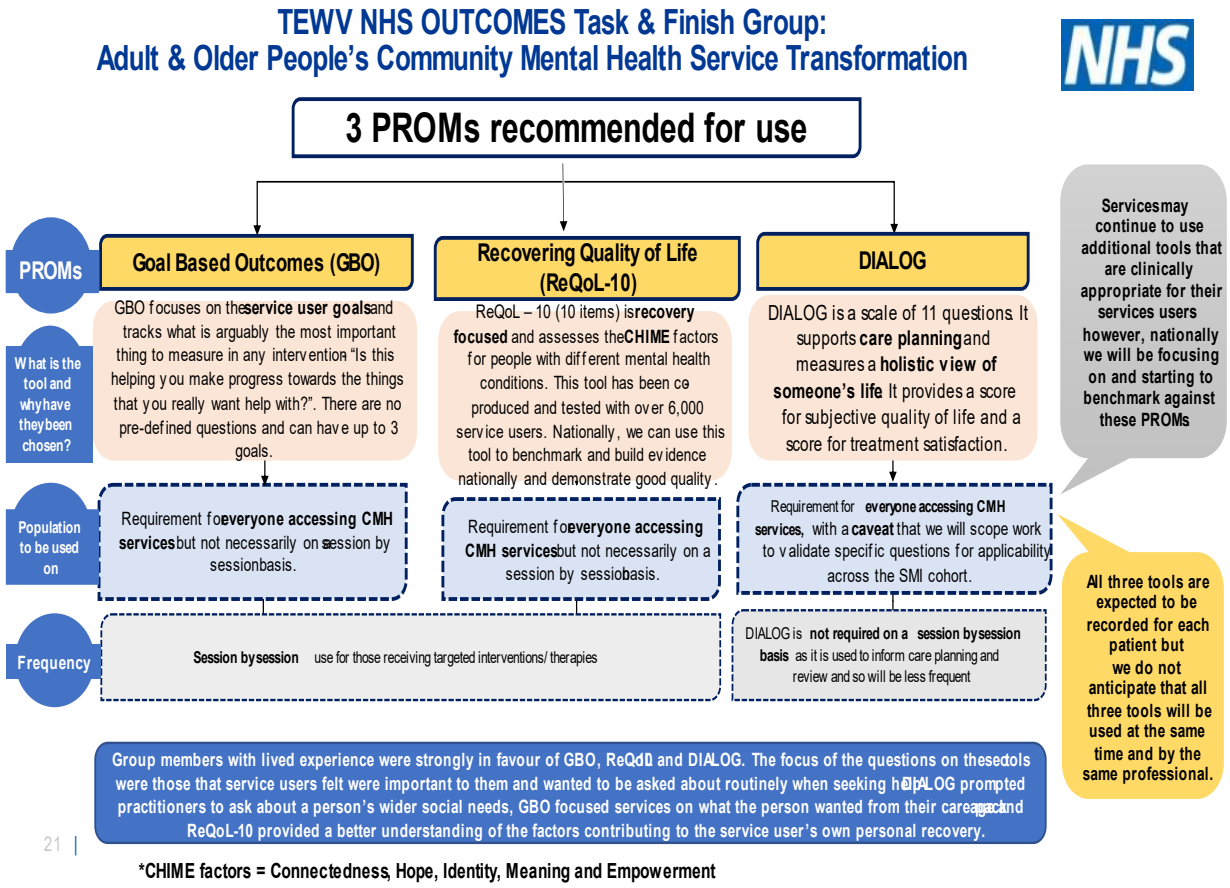
NHS England's community mental health transformation programme (2022-2027) has introduced mandated PROMS for the first time[100]. Building on the NHS Long term plan, the strategy was designed during the Covid-19 pandemic by the National Centre for Mental Health in collaboration with users and carers. Both the Mental Health Clustering Tool and the Care Programme Approach have been discontinued. The stated aim of transformation is to enable people to get the care they need by reducing boundaries and increasing joint working between primary and secondary care, social services and the voluntary sector (figure 3). NHS areas are mapped on to Primary Care Networks[101] each serving a population of 30,000 to 50,000. Each area designs its own model, so there is no 'blueprint' to follow. Mental health services have been asked to measure outcomes that are important to patients and their families.

Figure 3: The Community Mental Health Transformation Project[101] (RCPsych, 2022)

An Innovative Approach: TEWV NHS Foundation Trust

As an exemplar of 'Putting PROMS into Practice', the community transformation project of one large mental health trust is highlighted below[102]. This locality (TEWV NHS Foundation Trust) is where most of the research within papers A to E was conducted. From 2024, TEWV has directly implemented PROMS recording across three levels: a service user's individual priorities (via Goal Based Outcomes, GBOs), their quality of life (using ReQoL-10) and their satisfaction with life and services (using DIALOG, informed by CUES). These measures (figure 4) are built into CITO, a new patient centred electronic records system.

Figure 4: PROMS Adopted by TEWV Mental Health NHS Foundation Trust



ReQoL into Practice

TEWV NHS Foundation Trust has replaced SWEMBS with ReQol-10 as its main new global wellbeing measure. ReQoL[D] has several potential advantages over SWEMWBS:

1. Content co-created with active mental health service user input
2. Piloted and field tested across a range of UK mental health settings – primary care, NHS talking therapies and secondary mental health services
3. Use validated for anyone age 16 and over who does not have an intellectual disability or significant cognitive impairment such as dementia
4. Greater sensitivity to clinical change[D,E].
5. Includes an additional eleventh question about physical health. This is important because of the close links between physical and mental health outcomes, including the reversible lifestyle risks (eg exercise, smoking and

diet) that contribute to a reduced lifespan of up to 20 years for those with severe mental illness[53].

In one of the Trust's new integrated hubs[103], early paired ReQoL data showed that after 5 months, 11/13 (85%) service users sustained a reliable and significant clinical improvement (defined as a minimum 5-point score increase).

CUES into Practice: DIALOG Satisfaction Outcomes

DIALOG is an 11 item scale[104] (figure 5) that may be regarded as an evolution of the CUES-User tool that was field tested in papers A and B. Both DIALOG and CUES combine assessment of subjective quality of life (a PROM) with treatment satisfaction (a PREM) which evaluates process and quality of mental healthcare[105]. Both tools assess life and service satisfaction, with six overlapping question items covering similar content.

Field studies of DIALOG reference MD Paper B and its findings. For example, NHS research using routinely collected DIALOG data from one London mental health Trust[106] found patients were 'fairly satisfied' overall. Treatment (PREM) items received higher scores than life items (PROM) at all time points. Both PROM and PREM scores increased over time.

Comparing DIALOG with CUES (table 5), there are interesting differences in research studies that have evaluated them. Compared to those with depression and anxiety, individuals with a diagnosis of psychosis completing DIALOG rated health *services* more highly, whereas in CUES^{B} field studies, patients with psychosis rated their quality of *life* more highly. This might be due to question wording variations, or geographical population sampling differences (London versus North of England).

TEWV NHS has adopted an easy to use pictorial version of DIALOG+ within its updated electronic patient records system as part of the Community transformation (figure 6).

Figure 5: DIALOG Scale

1. How satisfied are you with your mental health? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

2. How satisfied are you with your physical health? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

3. How satisfied are you with your job situation? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

4. How satisfied are you with your accommodation? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

5. How satisfied are you with your leisure activities? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

6. How satisfied are you with your relationship with your partner/family? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

7. How satisfied are you with your friendships? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

8. How satisfied are you with your personal safety? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

9. How satisfied are you with your medication? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

10. How satisfied are you with the practical help you receive? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

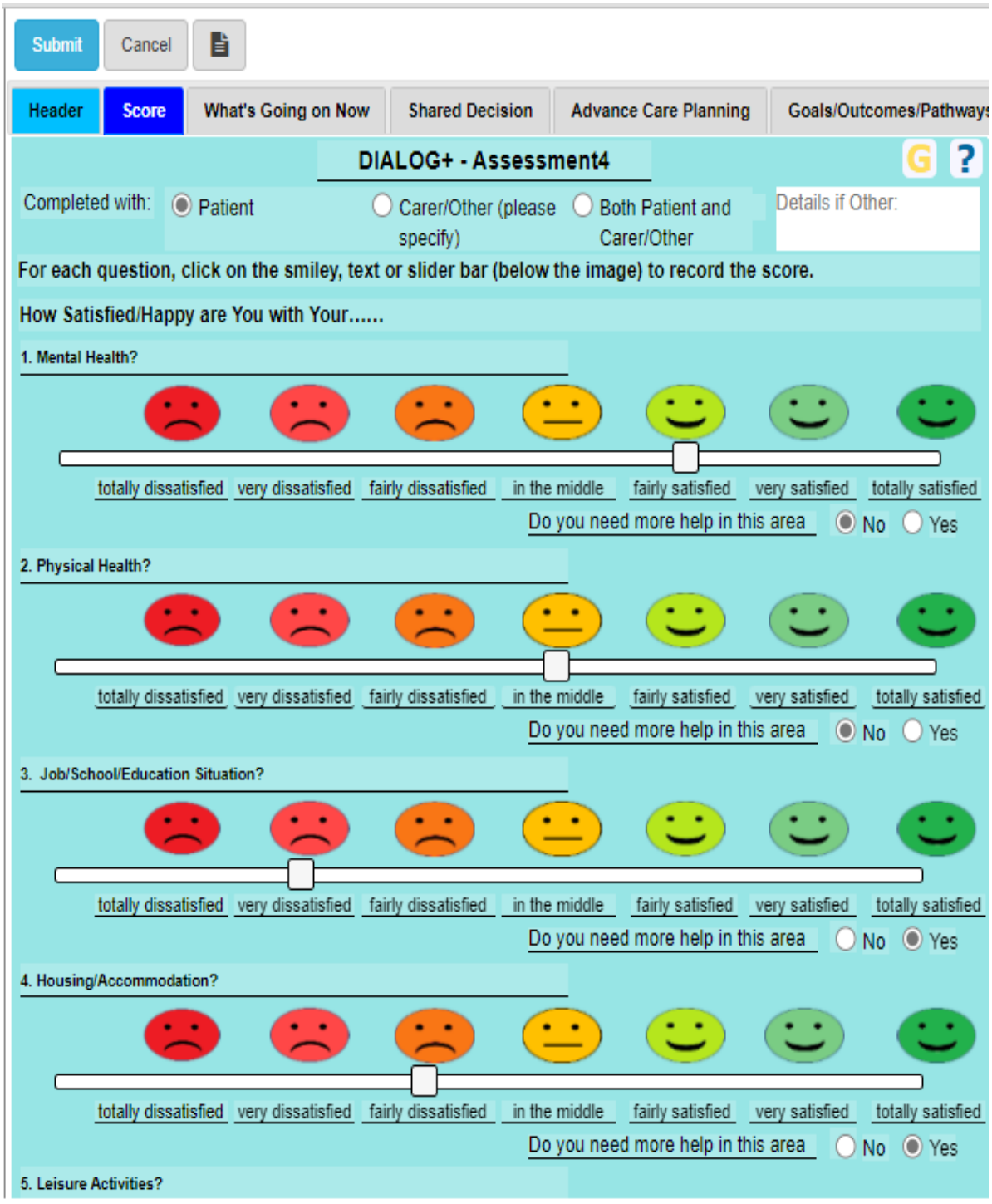
11. How satisfied are you with your meetings with mental health professionals? Do you need additional help in this area? Y/N

1	2	3	4	5	6
Totally dissatisfied	Very dissatisfied	Fairly dissatisfied	In the middle	Fairly satisfied	Very satisfied

Table 5: Development of Satisfaction Measures in UK Mental Health Services: CUES v DIALOG

	CUES – RCPsych User Version Blenkiron 2003[13b, A, B]	**DIALOG – TEWV CITO Version Mosler, 2020**
Description	Patient rated Outcome *and* Experience Measure: POEM = PROM + PREM	
Evaluation	Satisfaction in the areas that service users and carers value as important – within services and their life	
Completion	At initial meeting, key review points, discharge, not every meeting	
Purpose	Informs individualised planning and review of a person's mental health care	
Content	16-item booklet	11-item paper /electronic scale
Areas Assessed	7 quality of life and 9 mental health service	6 quality of life and 5 mental health service
Format	3 point Likert scale (Are you satisfied? yes, unsure, no) plus 3 point 'ideal description' Likert rating (as good, worse, very much worse than this)	7-point Likert Scale (1= totally dissatisfied to 7 = totally satisfied) with 'smiley face' pictorial and 'sliding scale ruler' options
Item areas - in common	Mental health, leisure, job, accommodation, relationships with friends and family, medication	
Item areas - unique to each POEM	Money, help with finances, access to services, stigma, control, advocacy, information	Physical health, personal safety, meetings with professionals
Free Text option	Yes, for every question	No
Help option included	No	Yes, asks 'do you need help in this area?' for every question

Figure 6: DIALOG+ : Electronic Patient Record Version (CITO TEWV)



PROMS: Recommendations for Future Research

Continued research is still needed into the evidence base for the use of mental health PROMS, including – crucially - whether their use leads to consistently improved outcomes for patients. Five key areas of study are described below:

a) Outcomes Methodology

Important methodological issues to address in outcome studies include selection bias[C], attrition[29] and the ceiling effect[B] (eg high mean satisfaction scores could mask important differences between respondents). More randomised controlled trials (RCTs) rather than longitudinal[C] or cohort studies could evaluate the impact of focussed interventions: for example, comparing use of a PROMS with and without feedback of results to clinician and patient. Follow up should ideally be for longer than 6 months to assess for sustained benefit[31]. In addition, a statistically significant score difference may not be clinically meaningful. Both ReQol-10[D], and the PHQ-9[107] define an improvement of least 5 points as a minimum clinical important difference (MCID), and this difference should be established for other widely used PROMS. Finally, more cost-utility analyses[D] (currently underway for ReQoL) are needed.

b) Reach and Inclusivity

It will be useful to investigate the use of PROMS in defined patient settings (eg to enable self-recognition of a mental disorder) and populations (such as those who find it difficult to articulate specific symptoms when asked open questions). Validation is needed in potentially marginalised groups – autism spectrum disorders, intellectual disability and those with visual impairment. Are visual analogue scales like the DT and DIALOG+ best for certain groups, or for everyone? Categorical dataset choices can also limit some responses (eg ethnicity and gender). Future research could use existing measures to evaluate new health problems – or develop new condition-specific PROMS such as complex post-traumatic stress disorder (PTSD) and ‘long’ Covid[58].

Technology and Artificial Intelligence

Developing robust electronic data collection systems[E2,3] will greatly enhance the future use of PROMS. This includes enabling access via 'real time digitised capture' eg a patient smartphone app linked to a clinician web portal[108] and implementing outcome feedback technology. One large RCT (n=2233) within IAPT services found that feedback of repeated PHQ-9 and GAD-7 measures to clinicians in real time improved symptom recovery in those at risk of a poor treatment response[30]. There is also a growing need to make data available to those that wish to examine it and to prevent data distortion and misuse. Given the rise of Artificial Intelligence (AI) systems (eg Chat Generative Pre-Trained Transformer – Chat GPT), it is increasingly important to secure the providence and accuracy of collated outcomes data, based on a verifiable original source.

c) Benefits v Harms

PROMS can potentially free up time in clinical consultations by a) focussing attention on the most important symptoms and concerns and b) providing a negative response to some areas that are being screened[102]. However, current evidence suggests routine screening in primary care for anxiety and depression leads to a large number (80%) of false positives without improving mental health symptoms[109]. If adoption is to be sustained[80], PROMS should reduce the workload of front line clinicians and enhance the care experience of patients - not expose them to survey and questionnaire overload. More research is also needed into possible harmful effects of outcomes monitoring[29] and the costs.

d) Implementation

Important practical questions remain. How can PROMS best be used within personalised care plans?[11] How may clinicians be assured of the utility of outcome measures[H]? Do NICE guidelines and implementation tools[G] increase uptake of PROMS? Diagnostic coding is poor in community mental health settings. Research shows that using broad NICE categories rather than specific ICD-11 codes when collecting outcome data has demonstrable validity and reliability[110]. Front line mental health professionals may argue that PROMS should not replace clinical wisdom: 'You do not make a pig fatter by weighing it'.

Summary: Benefits and Challenges

The key healthcare themes driving the evolution of PROMS over the past 20 years were described in chapter 1 (see box 2). NHS Talking Therapies, which treats over one million patients annually, is successfully using PROMS for the dual purpose of individual clinical care and collated data to assess service performance[111]. However, it is important that the focus of a mental health consultation remains the whole patient, not any one individual measure. PHQ-9 scores may not always match an individual's global rating of how they feel[112]. Emerging research suggests that assessing global life satisfaction with measures such as ReQoL & DIALOG (rather than narrower measures such as Quality adjusted life years) is one of the best predictors of life expectancy[113].

A systematic review of reviews[114] found that health services which successfully implement PROMS invest time and resources into three key areas:

1) The 'preparing' stage - getting an organisation and its staff ready to use PROMs, in particular persuading clinicians of their validity and usefulness, delivering training and developing electronic systems.
2) The 'designing' stage - planning which PROMs to use, how to administer them, and deciding how the data would be used for clinical purposes.
3) Having an implementation lead to oversee and develop the process based on feedback

Focusing on these earlier stages may prevent problems arising, as well as organised sharing of experience via community of practices networks eg the modified World Café Process used for ReQoL dissemination.[80]

Conclusions

Data and process are important - but it is outcomes that matter most to patients and to clinicians. They will need to be reassured that the time spent completing PROMS will be rewarded with better care.[110]

The collated body of papers in this thesis provides cumulative evidence that mental health PROMS can:

1) be successfully integrated into front line NHS care
2) assess the range of areas that are important to service users and clinicians – from symptoms to functioning, life and service satisfaction to global distress and wellbeing and from problem solving to everyday functioning.
3) reliably assess meaningful changes at key points in the patient journey
4) show absence of significant harms
5) inform care planning in real time at an individual level, and
6) potentially contribute to service and organisational improvements

A central aspiration of the NHS Plan - integrated mental health services with a focus on coproduction, early intervention and equality of access – has yet to be fully realised. However, the TEWV NHS community project contextualises the forward impact of the summated research in this thesis.

In 2024, NHS England issued important guidance[115] on psychological therapies for severe mental health problems to NHS managers and clinicians https://www.england.nhs.uk/publication/psychological-therapies-for-people-with-severe-mental-health-problems/ The central aim is ‘to understand and measure service users’ needs, personal goals, and level of recovery’. A key recommendation is that the three PROMS selected by TEWV NHS – GBOs, ReQol-10 and DIALOG - are adopted nationally within adult and older adult community mental health services. The guidance aspires to near 100% collection levels pre and post interventions but advises that the exact frequency of PROMS use can vary according to need and an individual’s protected characteristics where appropriate.

Time, effort and resources will need to be invested to secure the successful implementation of PROMS. It is probable that different measures will be needed for different NHS settings, with no one size fits all. Excellent holistic care in the 21st century is likely to be defined by a judicious combination of clinical wisdom, expert user experience and service coherence. All of these areas may benefit from the appropriate use of PROMS that are shown to be reliable, practicable and evidence based.

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GLOSSARY

ABBREVIATIONS

AI	Artificial Intelligence
BABCP	British Association for Behavioural & Cognitive Psychotherapies
CBT	Cognitive Behaviour Therapy
ChatGPT	Chat Generator Pre-trained Transformer
CHIME	Connectedness, Hope, Identity, Meaning and Empowerment
CMHT	Community Mental Health Team
COSMIN	Consensus-based standards for the Selection of health Measurement instruments
CPA	Care Programme Approach
CROM	Clinician Rated Outcome Measure
DoH	Department of Health
FDA	Food and Drug Administration
GP	General Practice
HoNoS	Health of the Nation Outcome Scales
HYMS	Hull York Medical School
IAPT	Improving Access to Psychological Therapies
ICD-10	International Classification of Diseases volume 10
KPIs	Key Performance Indicators
LYPFT	Leeds and York Partnership NHS Foundation Trust
MRCPsych	Member of the Royal College of Psychiatrists
NHS	National Health Service

NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PbR	Payment by Results
POEM	Patient Rated Outcome and Experience Measure
PREM	Patient Rated Experience Measure
PROM	Patient Rated Outcome Measure
PTSD	Post Traumatic Stress Disorder
QoF	Quality and Outcomes Framework
QoL	Quality of Life
RCPsych	Royal College of Psychiatrists
RCT	Randomised Controlled Trial
SPSS	Statistical Package for Social Sciences
SSIP	Scholarship and Special Interest Programme
TEWV	Tees, Esk & Wear Valleys NHS Foundation Trust
UK	United Kingdom
USA	United States of America

OUTCOME MEASURES cited in this thesis

AUDIT	Alcohol Use Disorders Identification Test
BDI	Beck Depression Inventory
BDS	Brief Depression Scale
CORE-10	Clinical Outcomes in Practice Evaluation-10
CUES-U	Carers' and Users' Expectations of Service User version
CWS	Carer Wellbeing and Support questionnaire
DT & PL	Distress Thermometer and Problem List
EQ-SD	EuroQoL Standardised Dimensions
GAD-7	Generalised Anxiety Disorder-7 questionnaire
GBO	Goal Based Outcome
HADS	Hospital Anxiety and Depression Scale
MMSE	Mini Mental State Examination
MoCA	Montreal Cognitive Assessment
PHQ-9	Patient Health Questionaire-9
ReQoL	Recovering Quality of Life
SWEMWBS	Short Edinburgh & Warwick Mental Wellbeing Scale