Functionality and feedback: A realist synthesis of the collation, interpretation and utilisation of PROMs data to improve patient care

Summary of Research

Since April 2009, patient reported outcome measures (PROMs) have been collected by all providers of NHS funded elective surgery for varicose vein and hernia repair and hip and knee replacements in England. This constitutes one of the largest bespoke datasets in the country. PROMs were devised with the aim of measuring patients' perceptions of the impact of disease and its treatment on their health. These perceptions are now taken to be a key indicator of the quality of care patients receive and the feedback and public reporting of these data aims to improve the quality of care provided to patients. The purpose of this project is to take stock of the evidence to understand by what means and in what circumstances the feedback of PROMs data leads to the intended service improvements. For any application of PROMs feedback, its impact on the quality of patient care depends on a long, complex chain of inputs and outputs and is greatly affected by where and how it is implemented. This complexity has made it difficult for existing systematic reviews to provide a definitive answer regarding whether PROMs feedback leads to improvements in patient care at either the individual patient level [1-5] or the level of health care organisations [6]. In this project we will use a different review method, Realist Synthesis (RS) [7], to clarify how the different applications of PROMs feedback are intended to work and identify the circumstances under which PROMs feedback works best and why in order to inform its future implementation within the NHS.

Realist synthesis involves (Stage 1) identifying the ideas, assumptions or 'programme theories' which explain how PROMs feedback is supposed to work and in what circumstances and then (Stage 2) reviewing the evidence to determine the extent to which these expectations are met in practice. For Stage 1, we have provisionally identified six potential 'functions' of PROMs feedback to structure our review. At the individual level, PROMs data are utilised to improve patient care by (i) screening for undetected problems; (ii) monitoring patients' problems over time and (iii) involving the patient in decisions about their care. At the group level, PROMs data may improve patient care by (iv) improving the appropriateness of the use of interventions; (v) stimulating quality improvement activities through benchmarking provider performance or (vi) through informing decision making about choice of provider [6]. For each function, we will identify the different programme theories that underlie these different goals through searches of the grey literature, journal commentaries, letters, editorials and critical pieces. To express each programme theory, we will develop a logic map of the respective implementation process, showing how the collation, interpretation and utilisation of PROMs data is intended to improve patient care for each function of PROMs data. Our specific objective is to identify the potential blockages, obstacles and unintended consequences of PROMs feedback which may prevent or limit the achievement of its intended outcome of improving patient care. This will provide a framework for the review.

In Stage 2, we will identify studies that will provide empirical tests of each component of the programme theories to evaluate the circumstances in which the potential blockages or obstacles can be overcome (or not) and whether and how the unintended consequences of PROMs feedback arise. This literature will include existing systematic reviews of PROMs feedback and their constituent studies [1, 2, 5] (to test components of the theory relating to the impact of PROMs on patient care across different contexts) and qualitative studies investigating providers' experiences and views of PROMs feedback [8, 9] (to test components of the theory relating to stakeholders different reactions to PROMs feedback). For some of the more recent ambitions of PROMs feedback at the group level, there may be relatively little direct evidence. To interrogate these ideas we will also include literature with a similar programme theory, for example, studies evaluating feedback and public reporting of mortality report cards and other performance reporting initiatives in the US, which are also intended to stimulate quality improvement activities and improve patient choice [6]. We will synthesise this evidence to (i) identify the implementation processes which support or constrain the successful

collation, interpretation and utilisation of PROMs data; (ii) identify the implementation processes through which the unintended consequences of PROMs data arise and those where they can be avoided. Through developing and then testing and refining programme theories about how PROMs feedback is supposed to work against existing evidence of how it works in practice, we will identify what support is needed to optimise the impact of PROMs feedback and distinguish the conditions (eg settings, patient populations, nature and format of feedback) where feedback might work best. We will produce guidance to enable NHS decision makers to tailor the collection and utilisation of PROMs data to local circumstances and maximise its impact on the quality of patient care.

Background and rationale

Definitions and policy context

Patient reported outcome measures (PROMs) are questionnaires that measure patients' perceptions of the impact of a condition and its treatment on their health [10]. Many of these measures were originally designed for use in research to ensure that the patient's perspective was integrated into assessments of the effectiveness and cost effectiveness of care and treatment [11]. Over the last five years the routine collection of PROMs data has played an increasing role in health policy in England with the introduction of the National PROMs programme in the NHS. The original challenge which led the Department of Health to pilot the routine collection of PROMs data in 2007 was a demand management issue - to assess whether surgery for certain conditions was over utilised [12]. However, more recent findings showing the gradient in use of these interventions by social class and ethnicity have led to calls for PROMs to be used to improve the equity of care [13]. In 2008, the Darzi report [14] called for the routine collection of PROMs data to benchmark provider performance, assess the appropriateness of referrals, support the payment of providers by results (PbR) and support patient choice of provider. The public reporting of PROMs data to support the patient choice agenda was given further impetus in the 2010 government White paper [15] which set out that 'Success will be measured..against results that really matter to patients" and that "Patients …. will have more choice and control, helped by easy access to the information they need about the best GPs and hospitals". Most recently, in light of the Francis report [16], it is planned to introduce single aggregated ratings and develop ratings of hospital performance at department level to support public accountability and patient choice [17].

Alongside the use of PROMs data at an aggregate level, the routine collection and use of PROMs data at the individual patient level has also become more widespread but in a less co-ordinated way, with individual clinicians using them on an ad-hoc basis, often with little guidance [18-20] . At the individual level, the intention of PROMs feedback is to improve the detection of patient problems, support clinical decision making about treatment through ongoing monitoring and to empower patients to become more involved in their care [21, 22].

Despite the fact that the ambitions for the usage of PROMs data have multiplied, PROMs research has focused on form rather than function. There is a substantial body of evidence on the psychometric properties of PROMs but less attention has focused on clarifying the subsequent decisions and actions that the measures are intended to support [22]. For example, careful deliberation went into selecting the instruments for the UK PROMs programme and piloting the feasibility of their collection [23] but the precise mechanisms through which PROMs data will improve the quality of patient care for each of their intended functions have been less well articulated [22]. Furthermore, there are inherent tensions between the different uses of PROMs data that may influence how it is collated and interpreted and thus its success. For example, individualised measures, where the patient specifies the domains to be measured, may be more relevant to patients and thus may better support patient involvement in their care than standardised measures [24]. However, such personalised measures may lose their meaning when used at the group level and may not be adequate reflections of the quality of patient care. Accordingly, there is a significant need for

research that clarifies the different functions of PROMs feedback and delineates more clearly the processes through which they are expected to achieve their intended outcomes.

Despite their relatively recent introduction to the NHS, the underlying reasoning about how PROMs data will be mobilised is familiar and has a long and somewhat chequered history. For example, the use of aggregated PROM data to benchmark provider performance and the public reporting of these data to inform consumer choice shares many of the assumptions and some of the drawbacks of other 'feedback' or 'public disclosure' interventions (eg, hospital star ratings in the UK [25] and surgical mortality report cards in the US [6]). These interventions may improve patient care through a 'change' pathway (whereby providers initiate quality improvement activities to improve the quality of patient care) or a 'selection' pathway (whereby patients choose a high quality hospital) [26]. Evidence across a range of different forms of this intervention suggests that public reporting of performance data results in improvements in performance in situations where the named party is motivated to maintain their market share, the reporting occurs alongside other market sanctions (eg financial incentives), the public reporting caries intensive but controllable media interest, the disclosed data are unambiguous in classifying poor and high performers and the reporting authority is trusted by those who receive the data [27]. The evaluation and implementation of public reporting and feedback of PROMs data will benefit from a careful review of the extent to which equivalent conditions apply to the impact of public dissemination of these data on the quality of patient care. At the individual level, PROMs feedback for detection and monitoring of patients problems can be seen as an attempt to modify clinical judgement with encoded, standardised knowledge as part of the move toward scientific-bureaucratic medicine [28]. Their intention of increasing patient involvement in the consultation replicates the hallmarks of other collaborative care interventions [29] and much can be learned by reviewing common underlying mechanisms. As PROMs feedback is rolled out to other services and settings, it is vital that such cumulative evidence on parallel interventions informs future implementation.

Existing evidence

Evaluating and reviewing the evidence of PROMs feedback is a challenge for several reasons, all of which arise from the complexity of the intervention. Firstly, PROMs feedback is unavoidably heterogeneous and varies by PROM used, purpose of feedback, patient population, setting, format and timing of feedback, recipients of the information and level of aggregation of the data [22]. Systematic reviews using traditional methodologies based on aggregating results from different studies found it difficult to draw overall conclusions about the effectiveness of PROMs feedback or to isolate the precise combination of factors that make for its success [3, 6]. There is some evidence to suggest that the purpose or function of PROMs feedback may influence its impact, with greater impact on patient outcomes when PROMs are used to monitor patient progress over time in specific disease populations, rather than as a screening tool [5]. Thus, there is a need for review methods which explicitly take account of the heterogeneity of the intervention and seek to understand how this shapes the success of the intervention.

Secondly, the implementation chain from feedback to improvement has many intermediate steps and may only be as strong as its weakest link [30]. At an individual level, PROMs feedback may improve communication and detection of patient problems, but may have less impact on the patient management or health status ([1, 30]. However, its impact on communication within the consultation is not uniform and depends the nature of the patients problems. In oncology, where there is most evidence that PROMs influence communication, clinicians were more likely to discuss symptoms with their patients in response to PROMs feedback but not psychosocial issues [31, 32]. We are confronted with the cautionary hypothesis that PROMs feedback may not result in further discussion or the offer of symptomatic treatment because high PROMs scores (suggesting high disease impact) do not always represent a problem for the patient or a problem that clinicians perceive as falling within their remit to address [33].

At an aggregate level, there are many organisational, methodological and logistical challenges to the collation, interpretation and then utilisation of PROMs data [34]. These include reducing the risk of selection bias as older, sicker patients are less likely to complete PROMs [35], reducing the variation in recruitment rates in PROMs data collection across NHS trusts [36], ensuring that procedures are in place to adequately adjust for casemix [37, 38], collecting the data at the right point in the patient's pathway and summarising this information in a way that is interpretable to different audiences [39]. In summary, a number of potential obstacles may prevent or lead to partial success in PROMs feedback achieving its intended outcome of improving patient care. There is a need to pinpoint these obstacles or blockages more systematically in terms of their location in the implementation chain and identify the circumstances in which they occur and those in which the can be overcome.

Thirdly, the success of PROMs feedback is context dependent and these contextual differences influence the precise mechanisms through which it works and its impact on patient care. For example, using PROMs data as an indicator of service quality for surgical interventions in acute care is very different from its use as a quality indicator of general practitioners' management of long term conditions within primary care. The impact of surgery on disease specific PROMs and knowledge of the natural variability of scores has been well documented [40] but this knowledge is lacking regarding the impact of primary care on EQ-5D scores [41]. At an individual level, surgeons are specialised and need only interpret the generic and disease specific PROMs data in their specialty. In contrast, general practitioners manage patients with different long term conditions, and need to make sense of data from different disease specific PROMs or to disentangle the impact of different conditions on scores from generic PROMs. Interpretation of the meaning of changes is therefore very different in each context.

Furthermore, differences in context can result in the intervention not working through the intended mechanisms, leading to unintended consequences [42]. For example, the feedback and public release of performance data may stimulate improvement activity at hospital level through increased involvement of leadership or a refocusing of organisational priorities [43] but has also been shown to lower morale and may focus attention on what is measured to the exclusion of other areas [44]. Others have cautioned that it may also lead to surgeons refusing to treat the sickest patients to avoid poor outcomes and lower publicly reported ratings [42]. Data from the national PROMs programme has been misinterpreted by some as indicating that a significant proportion of varicose vein, hernia and hip and knee replacement should not take place [45]. Public reporting of performance data may not improve patient care, as intended, through informing patient choice [6, 46]. Rather, patients are often ambivalent about performance data and rely on their GP's opinion when choosing a hospital [47, 48]. Thus, there is need to highlight the potential unintended consequences of PROMs feedback and distinguish the circumstances in which they arise.

Fourthly, PROMs have been implemented against a backdrop of other initiatives designed to drive up the quality of patient care which can potentially either support or derail the intended impact of PROMs feedback. For example, QOF payments are dependent on the use of a standardised questionnaire for depression screening, resulting in GPs sometimes avoiding coding a person as suffering from depression in order to circumvent completion of questionnaire viewed as unnecessary by many GPs [8, 49].

Finally, despite PROMs feedback having many functions and aspirations, research coverage of them is uneven, with more studies (trials and qualitative case studies) examining PROMs feedback at an individual level and few studies examining their use as a performance indicator at a group level.

In summary, we have identified a number of gaps in our knowledge that this review seeks to address:
- How can the tensions between the different purposes of PROMs data collection and their use by different stakeholders be resolved?
- Through what processes or mechanisms are the different applications of PROMs feedback supposed to work?

- For each application of PROMs data, what are the potential obstacles or unintended consequences of PROMs feedback that may prevent, limit of constrain the intervention improving patient care?
- For each application of PROMs data, what are the implementation processes that enable, facilitate or support PROMs feedback to improve patient care?

Why this research is needed now

It is likely that the routine collection and feedback of PROMs data will be rolled out to other settings and services (eg primary care, coronary revascularisation and rheumatology) in the future. From 2013 PROMs will be used in the NHS Outcomes Framework to performance manage commissioning. As the King's Fund highlight, these are functions "far removed from the initial intentions" of instrument developers and "the wide array of methodological challenges facing researchers are only just starting to be addressed" [50]. The impact of PROMs data on patient care crucially depends on whether "decision makers are prepared to act on the basis of this data" [50]. Furthermore, in light of the Francis report [16], it is planned to introduce single aggregated ratings and develop ratings of hospital performance at department level [17]. It is critical at this point in time to consolidate our understanding of how and in what circumstances PROMs data are effectively collated, interpreted and utilised to improve patient care to inform their future implementation.

The ideas and principles that underlie the feedback of PROMs data, such as quality improvement [51] and the public disclosure of performance data [27] have met with mixed fortunes. Programmes may work in a different way and produce an entirely different set of outcomes when implemented in a different context. The feasibility, interpretation and utilisation of PROMs data as an indicator of the quality of GP management of long term conditions is very different to its use as a quality indicator of elective surgery [41]. It is therefore essential that learning from the successes and failures of these programmes are applied to guide the effective implementation of PROMs feedback. Through using realist synthesis, we can apply what we know about how performance feedback works from previous research to better understand the inner workings of their present incarnation as PROMs feedback. This assimilation of both positive and negative scenarios is important now as the ambitions for PROMs feedback continue to proliferate and their usage is rolled out to other areas.

Aims and objectives

As the applications of PROMs data continue to multiply, our first aim is to identify and classify the various ambitions of PROMs feedback. These are currently directed at quality improvement and clinical decision making and perhaps more controversially, performance management and patient choice. Our objectives are to (a) produce a comprehensive taxonomy of the 'programme theories' underlying these different functions, capture their subtle differences and the tensions that may lie between them and (b) produce logic models of the organisational logistics, social processes and decision making sequences that underlie the collation, interpretation and utilisation of PROMs data. We will use these models identify the potential blockages and unintended consequences of PROMs feedback which may prevent the intervention achieving its intended outcome of improving patient care. This will provide a framework for the review.

To inform the future implementation of PROMs feedback, our second aim is to test and refine these programme theories about how PROMs feedback is supposed to work against existing evidence of how it works in practice. We will synthesise existing evidence on each application of PROMs feedback including, where necessary, evidence from other quality reporting initiatives. The specific objectives of this synthesis are to (a) identify the implementation processes that support or constrain the successful collation, interpretation and utilisation of PROMs data and (b) identify the mechanisms and circumstances through which the unintended consequences of PROMs data arise and those where they can be avoided. Our third aim is to use the findings from this synthesis to identify what

support is needed to optimise the impact of PROMs feedback and distinguish the conditions (eg settings, patient populations, nature and format of feedback) where PROMs feedback might work best. We will produce guidance to enable NHS decision makers to tailor the collection and utilisation of PROMs data to local circumstances and maximise its impact on the quality of patient care.

Research plan

Design and theoretical/conceptual framework

We have chosen to use Realist Synthesis (RS) as methodology for this review because it is specifically designed to manage the uneven body of evidence such as is available on PROMs feedback. RS is designed to disentangle the heterogeneity and complexity of the intervention and to make sense of the various contingencies, blockages and unintended consequences that may influence its success. The methodology was developed by one of the co-applicants on this proposal (RP) [7, 52]. It is an approach which is finding increasing use in the healthcare field [53] and a number of current and recently completed HS&DR projects are making use of the approach (for example project 11/1022/04 led by Pawson with Greenhalgh as co-applicant, project 10/1012/03 led by Chambers and project 10/1012/07 led by Anderson). Pawson was also a team member of another key HS&DR project 10/101/51, 'Realist and meta-narrative evidence synthesis: evolving standards – RAMESES' which led to the development of reporting standards for realist synthesis [54].
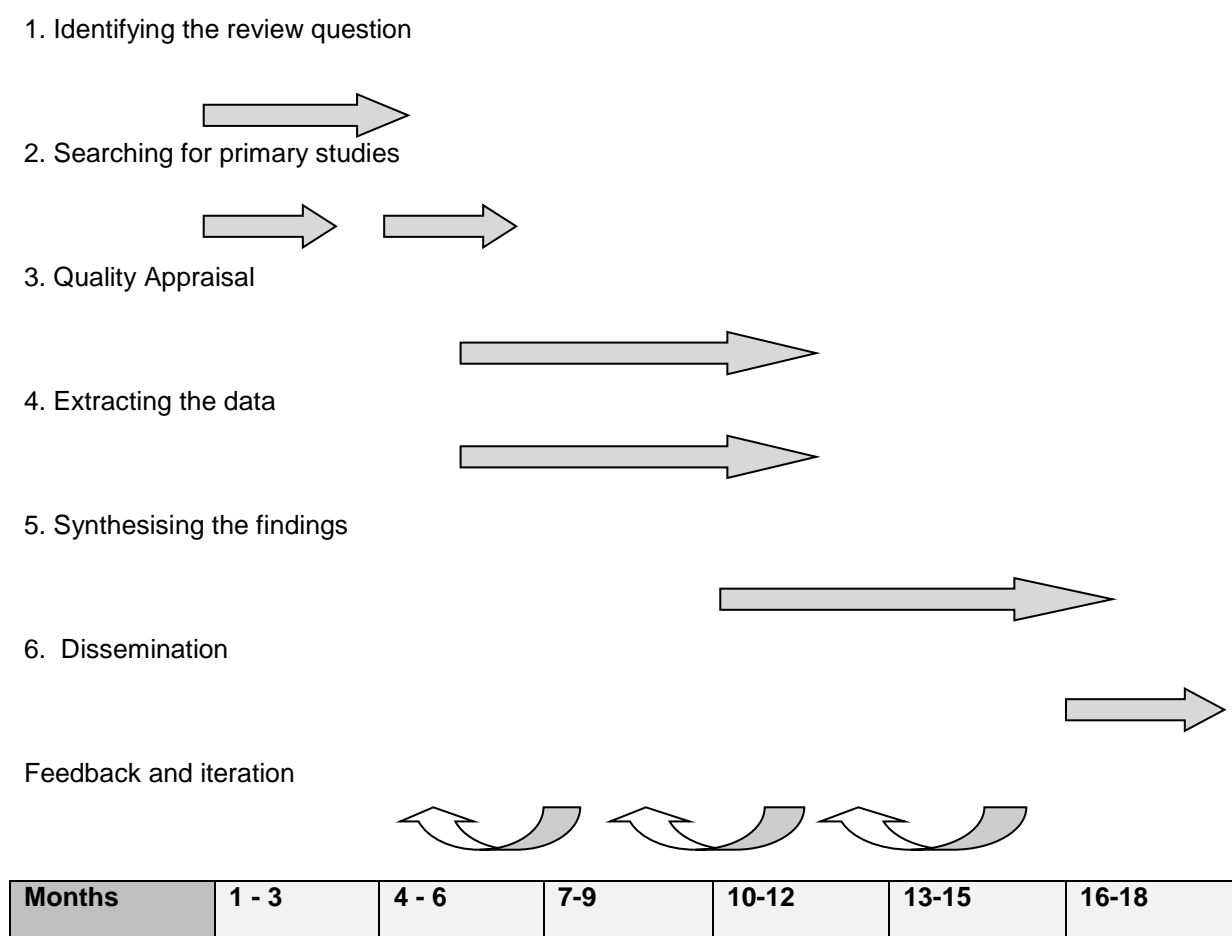
RS rests on an iterative process of theory development, testing and refinement that will enable us to build explanations about how and in what circumstances the feedback of PROMs data improves the quality of patient care. Realist synthesis is premised on the basis that it is not the PROMs feedback in and of itself that gives rise to its outcomes, rather, PROMs feedback offers resources to people and it is people choosing or not to act on these resources (known as *mechanisms*) that will determine its impact on patient care. Furthermore, a complex intervention such as PROMs feedback is never universally successful as people differ in their response to the intervention and their responses are supported or constrained by the social, organisational and political circumstances in which PROMs feedback is implemented (*context*). What realist synthesis aims to do is *explain why* PROMs feedback works in some circumstances and not others and it does this through a process of developing, testing and refining theories about how the intervention works.

Initially, these theories focus on practitioner, policy maker and participants' ideas and assumptions about how the intervention is intended to work (or not). These ideas can then be formulated into programme theories to specify hypotheses that certain *outcomes* (O) (intended or unintended) will occur as a result of particular *mechanisms* (M) being fired in particular *contexts* (C). As synthesis progresses and these theories are tested across a range of contexts through a review of the empirical literature, these theories are refined to develop explanations at a level of abstraction that can allow generalisation beyond a single setting. The 'end product' of realist synthesis is explanation through the formulation of 'middle-range' theories which are limited in scope, conceptual range, and claims, rather than offering general laws about behaviour and structure at a societal level [55] . Middle-range theories are identified by drawing across the literature to explain why regularities in the patterns of contexts, mechanisms, and outcomes occur. Thus, they provide the basis for guidance to help policy makers to target PROMs feedback interventions to local circumstances and highlight what support they may need to put in place in order to maximise its impact on patient care.

Realist synthesis methodology (including review strategy and search strategy)

Explanation building through theory development, testing and refinement is an iterative process that occurs throughout the review. This can be broken down into six-stages as outlined in figure 1, which also locates each phase of inquiry on the 18-month timeline required for this study. Each stage is annotated below, both with an explanation of the various techniques and with examples of how they will be applied in this study.

Figure1: Flow diagram for Realist Synthesis

1. Identifying the review question

2. Searching for primary studies

3. Quality Appraisal

4. Extracting the data

5. Synthesising the findings

6. Dissemination

Feedback and iteration

Months	1 - 3	4 - 6	7-9	10-12	13-15	16-18

1: Identifying the review question

The basic unit of analysis in realist synthesis is not the intervention but the ideas and assumptions or *programme theories* that underpin it. Thus, the starting point of RS is to catalogue and build logic models of the different ideas and assumptions about how interventions are supposed to work. Initially, these models focus on practitioner, policy maker and participants' ideas and assumptions about how the intervention is intended to work (or not). These may specify the sequences of steps required to deliver the intervention and the organisational and social processes required in order for the intervention to achieve its intermediate and final outcomes. They may also identify potential blockages within this process and potential unintended consequences. They often contain ideas about the different reactions or responses that participants may have to an intervention (*mechanisms*) that will determine whether the intervention is successful or not (*outcome*). They may also include ideas about the circumstances (or *context*) that determine the kind of reactions participants may have to an intervention and the blockages that may occur which thus influence the impact of the intervention.

In developing the proposal, we have already begun to engage with this process and have identified 6 functions of PROMs data that will provide an initial structure for the review: At the individual level, PROMs data are utilised to improve patient care by (i) screening for undetected problems; (ii) monitoring patients' problems over time and (iii) involving the patient in decisions about their care. At the group level, PROMs data may improve patient care by (iv) improving the appropriateness of the use of interventions; stimulating quality improvement activities through (v) benchmarking provider

performance or (vi) through informing decision making about choice of provider [5]. These are provisional and will be supplemented and refined during the first phase of the review.

We will provide detailed elaboration of the different programme theories that underlie these different functions of PROMs data through (1) electronic searching and (2) discussion with the NHS stakeholders and topic experts on our team and a patient group. The search strategies for the theories and evidence searches will be collaboratively and iteratively developed by the Information Specialist (JW) and reviewers (JG and RF). The main searching activity will happen in two distinct phases though it is anticipated the reviewers may identify relevant papers through citation tracking, snowballing and ad-hoc searches throughout the project. All searches will aim to be purposive rather than exhaustive.

We will conduct electronic searches of the grey literature to identify guidance documentation and policy documents and electronic searches of the peer reviewed literature to identify position pieces, comments, letters, editorials and critical pieces which explain how the different applications of PROMs feedback are intended to work. The search strategy for electronic databases will comprise three search concepts as illustrated in Appendix 1. Concept 1 identifies studies involving PROMs and includes subject headings (e.g. "Outcome Assessment (Health Care)"/, patient satisfaction/), text words and phrases (e.g. publically reported measures, patient outcome measures). Concept 2 aims to identify studies on improvements and impact resulting from PROMs feedback. This includes subject headings (e.g. Feedback/, Quality Improvement), textwords and phrases (e.g. improve* or impact* or implement*). Terms and synonyms for the 6 recognised theories of the impact and function of PROMs feedback will also be included in this concept (e.g. Decision Making/, Benchmarking/). Concept 3 is a search filter limiting the search result to commentaries, editorials and opinion pieces. These types of publication are particularly valuable in eliciting 'theories' at the early stages of a realist synthesis review. The three concepts will be combined using 'AND'.

Scoping searches have identified approximately 60 references to commentaries/opinion pieces in MEDLINE (see Appendix 2 for examples). It is estimated the final electronic searches will identify 100-250 references when conducted on Medline, Embase, HMIC (all Ovid), Health Business Elite (NHS HDAS). Further searches of Google will explore citations of key references found in the electronic database searches, and grey literature. We will also conduct electronic hand searches of Pulse, the Health Service Journal and the British Medical Journal as our current synthesis on Demand Management has found them to be particularly useful sources of programme theory.

The aim of this first phase of RS is to capture in detail the reasoning that underlies an intervention. To strengthen this process and ensure these theories reflect the views of NHS stakeholders, we will discuss this process and our findings with the topic experts and NHS stakeholders in our project team and with a patient group. LW will use his extensive contacts to establish and manage a patient group who will work with us throughout the review. Our first meeting with them will focus on identifying how PROMs are supposed to work.

To express each programme theory, we will develop a logic model of how the mobilisation of PROMs data is intended to improve patient care for each function of PROMs data. For each application, we will identify the potential blockages and unintended consequences of PROMs feedback which may prevent or limit the achievement of its intended outcome of improving patient care.

It is likely that we will unearth many different ideas about how each function of PROMs data is supposed to work, their potential blockages and unintended consequences. It will not be possible to review them all and the next stage of realist synthesis involves a process of (1) identifying common mechanisms or issues across the different programme theories and (2) prioritising which set of program theories to review. We will do this in a two step process. First, we will present and discuss our logic models and theories with two existing stakeholder networks, The Yorkshire and Humber PROMs network and the PROMs conference attendees. The Yorkshire and Humber PROMs network

was developed by CW and colleagues and consists of clinicians and NHS managers throughout the Yorkshire and Humber Region whose role includes the collection, interpretation or utilisation of PROMs data. The PROMs conference attendees are a network of academics, policy makers, NHS managers and clinicians who attended the PROMs research conference in November 2012 held by the London School of Hygiene and Tropic Medicine and the Kings Fund. We will hold two events, one in London and one in Leeds, where we will present and discuss our initial programme theories and ask participants to prioritise the theories in terms of their potential to provide the most valuable learning for the NHS and thus inform the implementation of PROMs collection. We will then discuss the insights learned through these events with our patient group and our project advisory group to agree the programme theories that will provide the focus for the reviews.

2. Searching for evidence/primary studies

It is these programme theories or hypotheses that provide the backbone of the review and determine the search strategy and decisions about study inclusion into the review in order to test and refine these theories. The next stage of the review thus involves an evidence search to identify primary studies that will provide empirical tests of each component of the theory. This literature will include, for example, existing systematic reviews of PROMs feedback and their constituent studies [1] (to test components of the theory relating to the intended and unintended impact of PROMs on patient care across different contexts) and qualitative studies investigating providers experiences, views and use of PROMs feedback [8, 9, 33, 56] (to test components of the theory relating to stakeholders different reactions to PROMs feedback and potential blockages in the system). We will also draw on the literature relating to stakeholder interpretation of PROMs and performance data [39, 57-61] and studies investigating the logistics of PROMs data collection [62-64] to test components of theory relating to the methodological, technological and social and organisational processes that may form blockages to the collection, interpretation and utilisation of PROMs data. For some components of our theories, especially those relating to group level data, there may be relatively little existing evidence on how they work in practice. To test these components, we will also include literature with a similar programme theory, for example, studies evaluating feedback and public reporting of mortality report cards and other performance reporting initiatives in the US [6], which are also intended to stimulate quality improvement activities and improve patient choice.

A starting point for our evidence searches will be existing systematic reviews of PROMs feedback, performance reporting and clinician and patient interpretation of performance data described above. Additional studies will be identified through searching electronic databases. We will search the Cochrane Library, Medline, Embase and the researcher's own personal libraries for existing reviews with a focussed PROMS search (Concept 1 in PROMs phase 1 'theories' search) limited to review publication type. Scoping searches indicate 100-200 review abstracts would be retrieved. Initial searching indicates that reviews alone will not provide current evidence that covers known (and unknown) theories. Where relevant reviews are out-dated or do not adequately cover our theories we will search electronic databases for relevant studies.

Databases for the evidence search will include Medline, Embase, HMIC (all Ovid), Health Business Elite (NHS HDAS) : PsycINFO (Ovid), Science Citation Index, Science Conference Proceedings Citation Index (both Thomson Reuters) and Dissertation and Theses (ProQuest). All searches will consist of three concepts but some may include a fourth to limit the results to particular empirical evidence publication types or study designs. Searches will include subject headings and text words. Concepts 1 and 2 will be consistent across all 'evidence' searches. Concept 1 will comprise terms relating to PROMs, public reporting, performance status and self reported outcomes and health related quality of life instruments. Concept 2 will comprise terms relating to the impact of PROMs feedback i.e. changes in clinical decision making, physician behaviour and patient behaviour. The concept 3 searches will be constructed individually and will each relate to a function and/or impact of PROMs at identified at various points along the logic models developed in Phase 1. For example, one

concept 3 search will comprise terms for the function of PROMs feedback as a method of screening for undetected feedback using subject headings and text words such as; Mass Screening/ , "undetected problem", "undiscovered condition". Searches for the concepts 1, 2 and 3 will be combined using 'AND' and may be further limited to a study design or publication type. The example search in Appendix 3 illustrates the construction of this search. Appendix 4 provides an example search for PROMs used to monitor patients over time. Initial scoping searches indicate each theory search will identify 200-800 references depending on the extent of evidence for the theory (concept 3), however since the theories search and reviews search will inform and determine these further evidence searches it is difficult to estimate at this stage. We anticipate developing at least 6 'evidence' searches to search for evidence on each theory identified in phase 1. Further relevant material will be sought from targeted searches of websites eg PROQOLID, Google. We will also make extensive use of citation and reference tracking to identify relevant papers [65].

The results of electronic searches and references found via citation tracking/snowballing will be kept in EndNote library. Details of all search activities (databases, websites, date of search, number of records found, search strategies) will be recorded in the form of a Working Paper to provide transparent search methods in the final report. Titles and abstracts will be screened after each searching phase by JG and the RF.

3/4. Data extraction and quality appraisal

These are combined in RS. Different programme theories require substantiation in divergent bodies of evidence. Hypotheses about the optimal contexts for the utilisation of PROMs data are tested by comparing the outcomes of experimental studies in different settings; claims about the reactions of different recipients of PROMs data are tested using qualitative data etc. Studies (or parts thereof) are included in the study depending on their relevance to the programme theory being tested.

Quality appraisal will be conducted throughout the review process and go beyond the traditional approach that only focuses on the methodological quality of studies [66]. In RS, assessment of study rigour occurs alongside an assessment of the relevance of the study and occurs throughout the process of synthesis. Quality appraisal is done on a case-by-case basis, as appropriate to the method utilised in the original study. Where appropriate, we will use relevant methodological checklists (eg CASP) to assess the methodological quality of included studies. We will also make early use of the standards and guidelines emerging from the RAMESES project [54].

Different fragments of evidence are thus sought and utilised from each study. There is no common 'data extraction form'. Both qualitative and quantitative data are compiled as well as the inferences and conclusions drawn from them. Each fragment of evidence needs to be appraised, as it is extracted, for its relevance to theory testing and the rigour with which it has been produced [66]. Data extraction requires active engagement with each document through note taking and text annotation. Evidence will be compiled, stored and annotated using *NVivo*.

5. *Synthesis/Review strategy*

The goal of realist synthesis is to refine our understanding of how the programme works and the conditions and caveats that influence its success, rather than offering a verdict, descriptive summary or mean effect calculation on a family of programmes. Specifically, our synthesis is concerned with understanding the conditions in which blockages or unintended consequences occur (which may prevent or limit the impact of PROMs on patient care) and those in which these blockages can be overcome. Synthesis takes several forms. At its most basic realist synthesis is a form of 'triangulation', bringing together information from different primary studies and different study types to explain why a pattern of outcomes may occur. For example, systematic reviews of PROMs feedback at the individual level demonstrate a pattern of outcomes such that PROMs feedback influences communication within the consultation and increases the detection of problems but has much less

impact on patient management or outcomes [1, 2]. This suggests there is a 'blockage' or 'obstacle' in the implementation chain between discussing PROMs findings in the consultation and subsequent action on these findings by clinicians. We can then explore potential explanations for these findings. For example, qualitative studies suggest that clinicians may discuss symptoms but not psychosocial issues [31] and may close down discussion or not offer treatment if the problem identified is not a problem for the patient or perceived as outside of their remit [33, 67]. One possible option to address this blockage it to provide training to doctors to enable them to make explicit reference to PROMs data and discuss difficult issues [33]. In this way, different studies can be brought together to understand progress (or otherwise) along the implementation chain. In general we will explore proximal, intermediate and distal in PROMs feedback and explain why disruption may occur and identify the circumstances in which it may be overcome.

Another form of synthesis, particularly useful when there is disagreement on the merits of an intervention is to 'adjudicate' between the contending positions. This is not a matter of providing evidence to declare a certain standpoint correct and another one invalid. Rather adjudication assists in understanding the respects in which a particular programme theory holds and those where it does not. For example, some studies assessing the feedback of performance data argue that poor performing hospitals are more likely to engage in quality improvement activities following such feedback [68], suggesting the feedback works through motivating hospitals to improve care. However, other studies have found that poor performing hospitals may experience lowered morale and respond by focusing on what is measured to the exclusion of other aspects of care [25]. Our review would seek to identify explanations for these contrasting findings to identify the circumstances in which the intended mechanism (motivation to improve) and intended outcomes occur (improved care) and those in which unintended mechanisms (lowered morale, tunnel vision) occur. Thus, it seeks to provide an explanation for the whole pattern of outcomes across studies rather than seek out an average effect. This will enable NHS managers to target PROMs feedback to local conditions more effectively, to identify the ways in which the intervention could be implemented to maximise its impact on patient care and the resources need to support this.

Finally, the main form of synthesis is known as 'contingency building'. All PROMs feedback programmes make assumptions that they will work under implementation conditions A, B, C and applied in contexts P, Q, R. . The purpose of the review is to refine many such hypotheses, enabling us to say that, more probably, A, C, D, E and P, Q, S are the vital ingredients. For example, at an aggregate level there is debate about whether the public reporting of performance data (which PROMs data are a form of) is a necessary ingredient to stimulate quality improvement activities [68], or whether such improvement would occur with private feedback to hospitals alone [69]. Others have argued that the public reporting *and* pay for performance can result in greater improvements than public reporting alone [70]. Our review would seek to identify the necessary conditions under which the feedback of performance data results in improvements to the quality of care. Similarly, there is also a hypothesis that the feedback of PROMs data at an individual level is more likely to improve patient outcomes if it is accompanied by management guidelines [71, 72]. Our review will test and refine these hypotheses against the empirical literature to identify the conditions that optimise the impact of PROMs feedback on patient care.

6. Dissemination

The purpose of RS is to improve the implementation and targeting of interventions. Accordingly, dissemination will focus on NHS decision makers responsible for the design and implementation of PROMs feedback initiatives and these stakeholders will be involved from the outset of the review. These are discussed in more detail in the next section.

Dissemination and project outputs

Our review will produce the following knowledge: (1) classification of the various functions of PROMs feedback; (2) a comprehensive taxonomy of the 'programme theories' underlying these different functions; (3) identification of the potential blockages and unintended consequences of PROMs feedback; (4) identification of the implementation processes that support or constrain the impact of PROMs feedback on patient care; (5) guidance to enable NHS decision makers to target PROMs feedback to local conditions more effectively, to identify the ways in which the intervention could be implemented to maximise its impact on patient care and the resources need to support this. The findings from our review will be used to produce a number of different outputs and disseminated through a number of different mechanisms including:

(1) A final report to NIHR

(2) A briefing document containing guidance to NHS managers specifying the implementation processes needed to support the successful collation, interpretation and utilisation of PROMs data to improve the quality of patient care.

(3) Showcasing our findings through local, national and international networks and conferences – eg the Yorkshire and Humber PROMs network, the Annual National PROMs Summit (for NHS staff), the Annual PROMs Research Conference (held by LSHTM and the King's Fund) and the International Society for Quality of Life Research (ISOQOL).

(4) Work with ISOQOL, LSHTM and the King's Fund to host a webinar on the review and its findings.

(5) Highlighting our project and its findings on the University, NHS and ISOQOL websites

(6) Using social networks such as Twitter to highlight our findings to a wide range of audiences

(7) A specific dissemination event to present our guidance to NHS decision makers

(8) Peer reviewed publications in academic journals (eg BMJ, The Millbank Quarterly) and articles in practitioner and management journals and newsletters (eg the Health Services Journal, Pulse)

(9) Presenting our findings to the local HealthWatch network

The specific objectives of our impact plan are: a) To raise awareness of the project among practitioners, policy makers and members of the public b) To secure the commitment of stakeholders to the project aims c) To influence future guidance on the implementation of PROMs. We will engage with the networks discussed above to ensure that our findings are communicated to NHS decision makers. We expect our guidance will assist NHS decision makers in the following ways:

1. Influence future policy on the roll out of PROMs data collection in different settings and for different purposes by highlighting the implementation processes that support or constrain their impact on patient care.

2. Help commissioners identify how PROMs data can be used to inform commissioning decisions, monitor service quality and inform referral guidelines and the resources needed to support this.

3. Support clinicians in interpreting and utilising PROMs data and identify the pathways through which they might use PROMs data to improve the quality of patient care.

4. Support clinicians who wish to use PROMs data to assess and monitor individual patients and identify what factors support or constrain their use in different settings.

5. Provide guidance on the presentation of PROMs data to patients to inform their choices about the care they receive.

6. Inform future evaluation work. For example, it will inform CV's NIHR programme of work to develop and evaluate a complex intervention for the feedback of PROMs data in primary care. It will also inform future evaluations of the impact of PROMs feedback so that these evaluations can be theory driven and inform our understanding of what PROMs feedback intervention works for whom and in what circumstances.

Plan of investigation and timetable

Realist Synthesis operates with an iterative and flexible study design illustrated in Figure 1. The timetable below provides details of the activities and milestones at each stage. Key programme theories will be explored simultaneously throughout the review, though our design is adaptive and new lines of inquiry will emerge during the course of the review. The review will be managed to ensure that any modifications will be consistent with delivering outputs to an agreed schedule.

Our review will be carried out in collaboration with different stakeholders who are defined below for clarification but explained in more detail in subsequent sections:
1. **Project team**: co-applicants of the proposal who will carry out the review (JG, RP, CV, EG, LW, JW, CW, DM, CM, NB)
2. **Patient group**: a group of 5 service users who will assist in theory development, shaping the focus of the review and interpretation of findings
3. **Advisory Group**: group of NHS stakeholders and academics with expertise in PROMs, realist synthesis and NIHR project management who will advise the project team.

Months 1-3
• Initial meeting of project team to establish ways of working and discuss and elaborate upon candidate programme theories outlined in our proposal
• Test and finalise theory search strategies with JW
• Set up Endnote database and establish Working Paper 1 to record search strategies and results
• Run 'theory' searches to identify range of programme theories for each function of PROMs feedback
• Review results of searches and select and obtain sources of theories for each function of PROMs feedback
• Hold theory development workshop with the patient group to introduce the project and identify patient theories of PROMs feedback and potential blockages and unintended consequences
• Produce a catalogue of the range of theories for different function of PROMs feedback in the form of a Working Paper 2

Key milestones (by month 3)
• Initial overview of the range of theories for each function of PROMs feedback to establish the boundary of our review
• Production of a catalogue of programme theories for each function of PROMs feedback
• Mapping the range of evidence relevant to the programme theories
• Establishment of working relationships with the project team and patient group

Months 4-6
• For each function of PROMs feedback, develop logic models to represent the different programme theories, formalise the theories in terms of context-mechanism-outcome configurations and identify the potential blockages and unintended consequences of PROMs feedback in the form of Working Paper 3

- Present these logic models to the Yorkshire and Humber PROMs network, the PROMs Research Conference Network and the Patient Group to identify commonalities and prioritise models that will form the focus of the review
- Project group meeting to revise logic models in light of stakeholder events
- Hold first advisory group to review progress to date and agree on which programme theories and logic models will form the focus of the review.

Key milestones (by month 6):
- Consolidation of the logic models for each function of PROMs feedback and identification of blockages and unintended consequences along each chain in form of Working Paper 3
- Identification of commonalities across logic models and agreement about the focus of the review

Months 7-9
- Test and refine evidence searches to identify evidence underlying the programme theories
- Running 'evidence' search strategies and carrying out other search methods to identify sources of evidence underlying each programme theory
- Reviewing results of searches, selecting and obtaining sources of evidence depending on the relevance to each component of the logic model (s)
- Sorting sources of evidence in terms of their location within on the implementation chain logic model
- Annotation, quality appraisal and develop emerging synthesis to identify circumstances in which blockages and unintended consequences occur or are overcome
- Contact and discussion with project team topic experts as required
- Conducting further searches as necessary

Key milestones (by month 9):
- Identifying and classifying the volume and scope of the evidence relating to the logic models for each function of PROMs feedback
- Completion of initial cycle of synthesis to test programme theories for each function of PROMs feedback

Months 10-12
- Provisional synthesis through further testing of hypotheses regarding the contexts in which unintended consequences and blockages occur or are overcome in form of Working Paper 4
- Develop initial outline of the review and draft guidance for review by project team, patient group and advisory group in form of Working Paper 5
- Hold patient group meeting to discuss provisional synthesis, guidance and methods dissemination
- Second advisory group meeting to discuss progress

Key milestones (by month 12):
- Develop provisional synthesis of posited logic models for each function of PROMs feedback (Working Paper 4)
- Develop draft guidance for NHS decision makers (Working Paper 5)
- Review of synthesis and guidance by key stakeholders

Months 13-15
- Meeting of project team to review advisory group meeting, identify areas for theory refinement and development and discuss dissemination plans
- Develop initial dissemination plan and begin organisation of dissemination event

- Revisit existing sources of evidence, conduct further searches, annotation and quality appraisal if necessary to refine and further test the logic models
- Draft final review and guidance for NHS decision makers for review by project team and Advisory Group

Key milestones (Months 13-15):
- Draft final synthesis/review of programme theories and guidance for review by NHS decision makers

Months 16-18
- Final advisory group meeting
- Final patient group meeting to finalise draft guidance for patients
- Final project team meeting to finalise review, guidance and dissemination event
- Completion of final review and submission to HS&DR based on previous Working Papers
- Production of final guidance for NHS decision makers
- Dissemination event
- Begin to draft manuscript of review for publication in peer reviewed journal

Key milestones (months 16-18)
- Production of final synthesis/review integrating theory with empirical evidence for our programme theories
- Production and dissemination of guidance for NHS decision makers
- Completion and submission of final HS&DR report

Project management

JG will be responsible for the design, co-ordination and quality assurance of the review and the management of the research fellow. She is currently project managing a realist synthesis of demand management for planned care under the guidance of RP, which follows a similar timetable to the review proposed here. The review itself will be carried out by the research fellow under the supervision of and with assistance from JG and with regular methodological support from RP. Our NHS stakeholder and topic experts, NB, CV, EG, DM, LW, CW and CM will provide ongoing topic support throughout the review but specifically in relation to (1) informing the focus of the review; (2) interpreting the findings of the review and (3) advising and planning the dissemination of the review. JW will be responsible for testing, refining and running the searches and setting up and managing the Endnote database. To provide a forum for and co-ordinate this input and discussion, the whole project team (JG, RP, NB, CV, EG, CW, LW, DM, CM, JW) will meet at four points during the review – at the outset (month 1), prior to the first advisory group meeting (month 5), after the second advisory group meeting (month 13) and at the dissemination stage (month 17). Two of these meetings will be held at the University of Leeds and two at the LSHTM. These meetings will also have a project management function and the achievement of key milestones will be monitored and future tasks reviewed and discussed. Support to organise and minute these meetings, assist in organising the stakeholder, patient group and disseminate events and manage the expenses of the patient group will be provided by Gill Sayers within the Department of Sociology and Social Policy. In the interim, our project team will also be contacted on an ad-hoc basis to advise on emerging issues relevant to their expertise. Co-ordination of this input will be managed by JG.

Laurence Wood will be responsible for recruiting members to our patient group and chairing the patient group meetings. He has already established a successful patient group for our realist synthesis for planned care ((11/1022/04) and we expect some members of this group will wish to continue working with us. LW will be responsible for identifying and approaching additional members to join this group. Support to organise and minute these meetings will be provided by Gill Sayers.

A particular challenge in carrying out this form of review is to ensure the emerging synthesis is recorded and shared amongst all team members. We will address this challenge though adopting a practice that has proved fruitful in our current realist synthesis of demand management for planned care; that of writing a series of Working Papers (see project timetable) to summarise key processes within the review – for example, documenting search strategies, scope of the evidence and volume of included studies (Working Paper 1) a catalogue of the programme theories underlying the different functions of PROMs feedback (Working Paper 2), production of logic models for each theory (Working Paper 3), provisional synthesis (working Paper 4) and draft guidance (Working Paper 5). These represent work in progress and can be shared at key points amongst the project team for comment, edit and refinement. Co-ordination of the comments will be provided by JG. The working papers will form the basis of briefing papers for our patient group and advisory group and will also provide material for the final report to HS&DR.

JG will also be responsible for co-ordinating the day to day management of the review itself. JG and the research fellow will meet weekly to discuss progress, trouble shoot and plan the next steps of the review. JG and the research fellow will also meeting monthly with RP to discuss progress and refine strategy in the review.

To oversee the management and strategic direction of the review, a project advisory group of NHS stakeholders, clinicians and academics with substantive topic and methodological expertise will be set up. They will meet three times during the review to inform and oversee key decision making processes in the review. If the project is successful we will also utilise LW's extensive networks to identify a PPI representative to sit on the advisory group and will also seek to identify an academic or NHS stakeholder with expertise in patient choice.

Approval by ethics committee

As we are engaging with patients and NHS staff as collaborators in conducting the research, rather than as participants in the research, the INVOLVE statement and IRAS guidance issued in 2011 indicates that we do not need NHS Research ethics approval. However, our sponsor, the University of Leeds, has advised us to seek approval from the University's Research Ethics Committee prior to the project commencing.

Patient and public involvement

Laurence Wood (LW) is a Leeds LINk member and sits on the Healthy Leeds Joint Strategic Commissioning Board. He has extensive experience of representing the patient's voice in the governance of NHS services and is currently working with us to provide a patient perspective in HS&DR funded realist synthesis of demand management for planned care. He also has a wide network of contacts within the local CCGs and Leeds Teaching Hospitals Trust. LW will be a member of our project team and contribute to the defining the focus of the review, reviewing our preliminary synthesis and advising on dissemination plans. LW has been actively involved in preparing the proposal and has reviewed and commented on the draft proposal.

To ensure the review is based on patient theories of how PROMs feedback works, that the focus of the review reflects the priorities of patients and our dissemination plans are tailored to the needs of patients, LW will assemble at patient group who will provide regular advice and guidance at key points during the review. LW has already established such a group and we expect that some members of this group will wish to continue working with us. This has significant advantages as we have established good working relationships and the group have become familiar with the process of conducting a realist synthesis. LW will identify and approach additional service users to join this group who have particular experience of the PROMs programme within the NHS.

We will meet this group four times at key points during the review. There is some flexibility regarding the timing and precise of focus of the meetings, depending on what emerges from the review and the feedback from the group. However, a rough timetable is as follows: The initial meeting (month 3) will focus on inducting new members into their role, introducing the methodology and topic area and undertaking a theory brainstorming exercise. The second meeting (month 5) will focus on prioritising theories for review. The third meeting (Month 11) will focus on reviewing and refining the provisional synthesis and discussing guidance and dissemination plans). The fourth meeting (month 17) will focus on finalising the draft guidance to ensure it meets the needs of patients.

Expertise and justification of support required

Chief Investigator, methodological expert, topic expert, project design and management and reviewer: Dr Joanne Greenhalgh, University of Leeds
Reviewer: Research Fellow (to be recruited)
Methodological expert and project design: Professor Ray Pawson, University of Leeds
Academic GP and PROMs in individual patient care topic expert: Dr. Chema Valderas, Department of Primary Care Health Sciences, University of Oxford
PROMs programme in primary care and nursing topic expert: Dr. Elizabeth Gibbons, Department of Public Health, University of Oxford
PROMs programme in secondary care topic expert: Professor Nick Black, London School of Hygiene and Tropic Medicine
PROMs implementation and data collection/interpretation topic expert: Ms. Charlotte Wood, Yorkshire and Humber Quality Observatory (soon to be part of Public Health England)
Patient choice and heath economics topic expert: Mr. David Meads, Academic Unit of Health Economics, University of Leeds
Patient advocate: Laurence Wood (Leeds Healthwatch member, previously chairman of Leeds West Clinical Commissioning Group patient panel)
GP and NHS Commissioner: Dr Chris Mills, Lead for planned care, Leeds West Clinical Commissioning Group
Information Specialist: Judy Wright, Senior Information Specialist
Admin support:

Joanne Greenhalgh (JG) has previously conducted a systematic review and a theory driven review of PROMs feedback at the individual level as well as numerous qualitative studies of clinicians' use of PROMs and other standardised outcome measures in clinical practice. She is currently project managing an HS&DR funded realist synthesis of demand management for planned care (11/1022/04). She will be responsible for the design, co-ordination and quality assurance of the review. JG will receive regular support, direction and methodological advice from Ray Pawson (RP). RP developed the methods of realist synthesis and has undertaken number syntheses across a range of policy areas. He will act as a methodological advisor to the review. The review will be carried out by a research fellow (RF) with assistance from JG.

Our project team also includes seven key stakeholders who will provide topic advice and expertise throughout the review as discussed in the project management section. Chema Valderas is an academic General Practitioner and currently holds an NIHR clinician scientist award and has a 5 year programme of work to develop and evaluate a complex intervention of PROMs feedback to manage long term conditions in primary care. Nick Black is Professor of Health Services Research, runs an extensive programme of research to evaluate the National PROMs Programme in elective surgery, and advises the DH (and in future NHS Commissioning Board) about PROMs policy. Elizabeth Gibbons trained as a nurse and has worked alongside Professor Ray Fitzpatrick to evaluate the collection of PROMs data in primary care for long term conditions. Chris Mills is a GP and the lead for planned care at Leeds West CCG and is currently incorporating PROMs measurement into care pathways for MSK referrals. Charlotte Wood is a Health Intelligence Specialist and manages the

Yorkshire and Humber PROMs network and supports clinicians and managers to interpret and utilise PROMs data in practice. David Meads is a health economist with expertise in PROMs and patient choice. Laurence Wood is Leeds LINk member and was previously the chair of the Leeds West Clinical Commissioning Group Public Patient Advisory Group. Laurence has extensive experience of representing the patient's voice in the governance of NHS services and sits on the Healthy Leeds Joint Strategic Commissioning Board. He is currently working with JG and RP on an HS&DR funded realist synthesis of demand management for planned care (11/1022/04). Judy Wright (JW) is a Senior Information Specialist and has extensive experience of supporting literature searching and database management for systematic reviews, qualitative synthesis and recently realist synthesis. JW is also working with JG and RP on an HS&DR funded realist synthesis of demand management for planned care (11/1022/04).

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59.   Hibbard, J.H., et al., *Consumer competencies and the use of comparative quality information: it isn't just about literacy.* Medical Care Research & Review, 2007. **64**(4): p. 379-94.
60.   Hildon, Z., D. Allwood, and N. Black, *Impact of format and content of visual display of data on comprehension, choice and preference: systematic review.* International Journal for Quality in Health Care, 2012. **24**(1): p. 55-64.
61.   Faber, M., et al., *Public reporting in health care: how do consumers use quality-of-care information? A systematic review.* Medical Care, 2009. **47**(1): p. 1-8.
62.   Rogausch, A., et al., *Feasibility and acceptance of electronic quality of life assessment in general practice: an implementation study.* Health & Quality of Life Outcomes, 2009. **7**: p. 51.
63.   Gutteling, J.J., et al., *Logistic feasibility of health related quality of life measurement in clinical practice: results of a prospective study in a large population of chronic liver patients.* Health & Quality of Life Outcomes, 2008. **6**: p. 97.
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68.   Hibbard, J.H., J. Stockard, and M. Tusler, *Does publicizing hospital performance stimulate quality improvement efforts?* Health Affairs, 2003. **22**: p. 84-94.
69.   Guru, V., et al., *Public versus private institutional performance reporting: what is mandatory for quality improvement?* American Heart Journal, 2006. **152**: p. 573-578.
70.   Lindenauer, P.K., et al., *Public reporting and pay for performance in hospital quality improvement.* The New England Journal of Medicine, 2007. **356**: p. 486-496.
71.   Rubenstein, L.V., et al., *Improving patient quality of life with feedback to physicians about functional status.* Journal of General Internal Medicine, 1995. **10**(11): p. 607-614.
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Appendix 1: Example 'Theory' Search strategy for first phase of the review

Database: Ovid MEDLINE(R) <1946 to March Week 2 2013> Search Strategy:
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1   Comment/ (490699)
2   Letter/ (763678)
3   Editorial/ (310957)
4   news/ or newspaper article/ (159692)
5   "Comment on".ti. (10877)
6   (letter* adj3 editor*).ti. (2388)
7   opinion*.ti. (9371)
8   (view or views).ti. (36369)
9   or/1-8 [Commentary and Opinion Pieces] (1356191)
10   ("patient report*" adj3 outcome*).tw. (2405)
11   proms.tw. (102)
12   ("public* report*" adj3 outcome*).tw. (69)
13   *"Quality of Life"/ and exp Health Status Indicators/ and (*patient satisfaction/ or *patient preference/ or *Patient-Centered Care/) (203)
14   exp Health Status Indicators/ and (*patient satisfaction/ or *patient preference/ or *Patient-Centered Care/) (791)
15   exp *Health Status Indicators/ and (*patient satisfaction/ or *patient preference/ or *Patient-Centered Care/) (164)
16   *"Outcome Assessment (Health Care)"/ and (*patient satisfaction/ or *patient preference/ or *Patient-Centered Care/) (663)
17   10 or 11 or 12 or 15 or 16 (3192)
18   Mass Screening/ (76652)
19   Quality Improvement/ (2930)
20   exp diagnostic errors/ (88938)
21   incidental findings/ (4845)
22   exp Longitudinal Studies/ (804827)
23   Patient Participation/ (16484)
24   exp Decision Making/ (110357)
25   Health Services Accessibility/ (46429)
26   (access* adj2 (care or healthcare or service*)).tw. (11936)
27   Benchmarking/ (9482)
28   quality indicators, health care/ or "standard of care"/ (9597)
29   ("performance measure*" adj4 quality).tw. (272)
30   Quality Improvement/ (2930)
31   ((choice* or choose) adj3 provider*).tw. (525)
32   ((choice* or choose or select* or decide*) adj3 (service* or supplier* or provider*)).tw. (2205)
33   exp treatment outcome/ (579666)
34   (improve* or impact* or implement*).ti. (239915)
35   exp Feedback/ (39103)
36   (feedback or fedback or "fed back").tw. (67688)
37   or/18-36 (1833886)
38   17 and 37 (1717)
39   limit 38 to "reviews (maximizes specificity)" (101)
40   9 and 38 (59)

Appendix 2: Examples of papers retrieved from the Theories Search from Appendix 1

(2011). "Public reporting of surgical outcomes." Lancet **377**(9772): 1126.

Atherton, P. J. and J. A. Sloan (2006). "Rising importance of patient-reported outcomes." Lancet Oncology **7**(11): 883-884.

Basch, E., A. Bennett, et al. (2011). "Use of patient-reported outcomes to improve the predictive accuracy of clinician-reported adverse events." Journal of the National Cancer Institute **103**(24): 1808-1810.

Bierman, A. S. (2011). "The PROMise of quality improvement in healthcare: will Canada choose the right road?" Healthcarepapers **11**(3): 55-60; discussion 79-83.

Bottomley, A., C. Quinten, et al. (2009). "Making better use of existing cancer data: Patient Reported Outcomes and Behavioural Evidence: a new international initiative." European Journal of Cancer Care **18**(2): 105-107.

Daveson, B. A., S. T. Simon, et al. (2012). "Are we heading in the same direction? European and African doctors' and nurses' views and experiences regarding outcome measurement in palliative care." Palliative Medicine **26**(3): 242-249.

Dawson, J., H. Doll, et al. (2009). "Re: Patient-reported outcomes after total hip and knee arthroplasty: comparison of midterm results." Journal of Arthroplasty **24**(5): 827-828; author reply 828-829.

Fischer, D., A. L. Stewart, et al. (1999). "Capturing the patient's view of change as a clinical outcome measure." JAMA **282**(12): 1157-1162.

Gray, D. R. and I. Rongve (2011). "Role for PROMs data to support quality improvement across the healthcare system: an informed exchange with senior health system leaders." Healthcarepapers **11**(4): 34-41; discussion 55-38.

Groene, O. (2012). "Patient and public involvement in developing patient-reported outcome measures: indispensable, desirable, challenging." The Patient: Patient-Centered Outcomes Research **5**(2): 75-77.

Guex, J.-J. (2008). "Patient-reported outcome or physician-reported outcome?" Phlebology **23**(6): 251.

Hildon, Z., D. Allwood, et al. (2012). "Making data more meaningful: patients' views of the format and content of quality indicators comparing health care providers." Patient Education & Counseling **88**(2): 298-304.

Hildon, Z., J. Neuburger, et al. (2012). "Clinicians' and patients' views of metrics of change derived from patient reported outcome measures (PROMs) for comparing providers' performance of surgery." BMC Health Services Research **12**: 171.

Hinds, P. S. (2008). "Patient-reported outcomes: a desirable specialty standard for oncology or an incomplete measurement approach?" Cancer Nursing **31**(4): 259-260.

Howell, D. and G. Liu (2011). "Can routine collection of patient reported outcome data actually improve person-centered health?" Healthcarepapers **11**(4): 42-47; discussion 55-48.

Johansson, B., S. Borjeson, et al. (2010). "Editorial comment on "Disregarding clinical trial-based patient-reported outcomes is unwarranted: Five advances to substantiate the scientific stringency of quality-of-life measurement"." Acta Oncologica **49**(2): 163-165.

Lenderking, W. (2003). "Task Force report of the Patient-Reported Outcomes Harmonization Group: too much harmony, not enough melody?" Value in Health **6**(5): 503-504.

Marcellin, F., M. P. Carrieri, et al. (2012). "Choice of therapeutic strategies in the context of HIV infection: key role of patient-reported outcomes." Expert Review of Antiinfective Therapy **10**(4): 403-406.

Mazur, D. J., D. H. Hickam, et al. (2005). "The role of doctor's opinion in shared decision making: what does shared decision making really mean when considering invasive medical procedures?" Health Expectations **8**(2): 97-102.

Nieuwkerk, P. T. and M. A. G. Sprangers (2009). "Each measure of patient-reported change provides useful information and is susceptible to bias: the need to combine methods to assess their relative validity." Arthritis & Rheumatism **61**(12): 1623-1625.

Otuki, M. F., R. C. Reis, et al. (2011). "Patient-reported outcomes in psoriasis research and practice." British Journal of Dermatology **165**(6): 1361-1362.

Pegram, R. (1999). "Patient feedback surveys. Experience of the Patient Feedback Instrument Advisory Committee (PFIAC)." <u>Australian Family Physician</u> **28**(4): 308-309.

Pelaez-Ballestas, I. (2012). "Patient reported outcome measures: what is their importance?" <u>Reumatologia Clinica</u> **8**(3): 105-106.

Pouwer, F. (2008). "Omissions impact measurements of patient-reported outcomes." <u>Quality of Life Research</u> **17**(6): 963-964; author reply 965-966.

Richards, T. (2012). "Payment for medical care should be linked to outcomes that patients value, meeting concludes." <u>BMJ</u> **345**: e6104.

Sanderson, T. and J. Kirwan (2009). "Patient-reported outcomes for arthritis: time to focus on personal life impact measures?" <u>Arthritis & Rheumatism</u> **61**(1): 1-3.

Snyder, C. and M. Brundage (2010). "Integrating patient-reported outcomes in healthcare policy, research and practice." <u>Expert Review of Pharmacoeconomics & Outcomes Research</u> **10**(4): 351-353.

Soljak, M. A. and A. Majeed (2010). "Access to artificial hips. Using PROMs to improve equity." <u>BMJ</u> **341**: c5014.

Strand, C. V. and B. Crawford (2007). "Longterm treatment benefits are best reflected by patient reported outcomes." <u>Journal of Rheumatology</u> **34**(12): 2317-2319.

Sullivan, M. (2003). "The new subjective medicine: taking the patient's point of view on health care and health." <u>Social Science & Medicine</u> **56**(7): 1595-1604.

Vallance-Owen, A. J. (2008). "Measuring patient care: PROMs promote health gain and patient involvement." <u>BMJ</u> **336**(7640): 344.

Zimmermann, C. (2010). "Ultra-short PROMs: clever or not?" <u>British Journal of Cancer</u> **103**(10): 1477-1478.

Appendix 3: Example of Evidence Search' using 'screening for undetected feedback'.

1   ("patient report*" adj3 outcome*).tw. (2405)
2   proms.tw. (102)
3   ("public* report*" adj3 outcome*).tw. (69)
4   or/1-3 [PROMs] (2498)
5   exp *"Outcome Assessment (Health Care)"/ (23387)
6   exp *health status/ (46186)
7   *"Quality of Life"/ (46868)
8   performance status.ti. (347)
9   (outcome? adj2 assessment).ti. (968)
10   outcome? measure?.ti. (1933)
11   health status.ti. (6847)
12   quality of life.ti. (32998)
13   (QL or QoL or HRQL or HRQoL).ti. (744)
14   (function* adj2 (status or psychological or mental or physical or social)).ti. (6436)
15   disabilit*.ti. (25744)
16   exp "Activities of Daily Living"/ (47464)
17   activities of daily living.ti. (1004)
18   (wellbeing or well being).ti. (6233)
19   exp happiness/ (2386)
20   (happi* or happy).ti. (2080)
21   or/5-20 [Outcome Measures] (189120)
22   (assessment or index or indicies or instrument? or measure? or rating? or profile? or report? or
     scale? or schedul* or scor* or survey?).ti. (801080)
23   exp *Health Surveys/ (99244)
24   Self-Assessment/ (9852)
25   self-assessment.ti. (1308)
26   *questionnaires/ or *self report/ (27137)
27   (questionnaire? or "self report*").ti. (26009)
28   patient report*.ti. (1739)
29   patient related*.ti. (210)
30   patient satisfaction/ (53869)
31   patient preference/ (1885)
32   Patient-Centered Care/ (9211)
33   or/22-32 [Self Reporting Format] (966912)
34   21 and 33 [outcome measures terms AND self-reporting format] (42636)
35   4 or 34 [PROMs or self-reported outcomes] (44187)
36   Physician-Patient Relations/ (57066)
37   Clinical Competence/ (59888)
38   Physician's Practice Patterns/st [Standards] (3600)
39   "Attitude of Health Personnel"/ (85846)
40   (behavio* adj2 (clinician* or physician* or doctor or "health* professional*")).tw. (2197)
41   (attitude* adj2 (clinician* or physician* or doctor or "health* professional*")).tw. (2693)
42   exp Decision Making/ (110357)
43   (clinical* adj3 decision*).tw. (14614)
44   (decision* adj2 (clinician* or physician* or doctor or "health* professional*")).tw. (2255)
45   ((choice* or choose or select* or decide*) adj3 (service* or supplier* or provider*)).tw. (2205)
46   or/36-45 [Clinical attitudes behaviour and decisions] (303924)
47   35 and 46 [PROMS AND DECISIONS OR BEHAVIOUR] (1948)
48   exp *"Diagnostic Techniques and Procedures"/ (1799303)
49   *Mass Screening/ (39601)
50   (undetect* adj5 (diagnosis or problem? or condition?)).tw. (525)
51   (undiscovered adj5 (diagnosis or problem? or condition?)).tw. (13)
52   (("not found" or "not detected" or "not discovered") adj5 (diagnosis or problem? or
     condition?)).tw. (835)
53   incidental findings/ (4845)
54   (screen or screening or screened).ti. (97821)
55   or/48-54 [Screening function or Undetected problems] (1851689)
56   47 and 55 [PROMS Decisions Behaviours Screening] (192)

Appendix 4: Example of evidence search for monitoring

Database: Ovid MEDLINE(R) <1946 to March Week 2 2013>
Search Strategy:
----
1   ("patient report*" adj3 outcome*).tw. (2405)
2   proms.tw. (102)
3   ("public* report*" adj3 outcome*).tw. (69)
4   or/1-3 [PROMs] (2498)
5   exp *"Outcome Assessment (Health Care)"/ (23387)
6   exp *health status/ (46186)
7   *"Quality of Life"/ (46868)
8   performance status.ti. (347)
9   (outcome? adj2 assessment).ti. (968)
10   outcome? measure?.ti. (1933)
11   health status.ti. (6847)
12   quality of life.ti. (32998)
13   (QL or QoL or HRQL or HRQoL).ti. (744)
14   (function* adj2 (status or psychological or mental or physical or social)).ti. (6436)
15   disabilit*.ti. (25744)
16   exp "Activities of Daily Living"/ (47464)
17   activities of daily living.ti. (1004)
18   (wellbeing or well being).ti. (6233)
19   exp happiness/ (2386)
20   (happi* or happy).ti. (2080)
21   or/5-20 [Outcome Measures] (189120)
22   (assessment or index or indicies or instrument? or measure? or rating? or profile? or report? or scale? or schedul* or scor* or survey?).ti. (801080)
23   exp *Health Surveys/ (99244)
24   Self-Assessment/ (9852)
25   self-assessment.ti. (1308)
26   *questionnaires/ or *self report/ (27137)
27   (questionnaire? or "self report*").ti. (26009)
28   patient report*.ti. (1739)
29   patient related*.ti. (210)
30   patient satisfaction/ (53869)
31   patient preference/ (1885)
32   Patient-Centered Care/ (9211)
33   or/22-32 [Self Reporting Format] (966912)
34   21 and 33 [outcome measures terms AND self-reporting format] (42636)
35   4 or 34 [PROMs or self-reported outcomes] (44187)
36   Physician-Patient Relations/ (57066)
37   Clinical Competence/ (59888)
38   Physician's Practice Patterns/st [Standards] (3600)
39   "Attitude of Health Personnel"/ (85846)
40   (behavio* adj2 (clinician* or physician* or doctor or "health* professional*")).tw. (2197)
41   (attitude* adj2 (clinician* or physician* or doctor or "health* professional*")).tw. (2693)
42   exp Decision Making/ (110357)
43   (clinical* adj3 decision*).tw. (14614)
44   (decision* adj2 (clinician* or physician* or doctor or "health* professional*")).tw. (2255)
45   ((choice* or choose or select* or decide*) adj3 (service* or supplier* or provider*)).tw. (2205)
46   or/36-45 [Clinical attitudes behaviour and decisions] (303924)
47   35 and 46 [PROMS AND DECISIONS OR BEHAVIOUR] (1948)

57   (monitor* adj5 patient*).tw. (38642)
58   Time Factors/ (949476)
59   exp Longitudinal Studies/ (804827)
60   or/57-59 [Monitoring function] (1680118)
61   47 and 60 [PROMS Decisions Behaviours Monitoring] (291)