

## **INVITATION TO TENDER**

### **EVALUATION OF A PILOT FOR ROUTINE COLLECTION OF PATIENT REPORTED OUTCOME MEASURES (PROMs) IN MANAGEMENT OF LONG-TERM CONDITIONS**

#### **RESEARCH BRIEF**

##### Background

1. In his report, *High Quality Care for All. The Final Report of the Next Stage Review*, Professor Lord Darzi, Parliamentary Under Secretary of State for Health, identified an important role for measuring outcomes as assessed by patients themselves in securing the delivery of more effective care. *HQCFA* proposes to make these patient-reported outcome measures (PROMs) a key mechanism in the strategy to secure improvement in the quality of care in the NHS. In a companion document, *NHS Next Stage Review. Our vision for primary and community care*, the direction of travel is clearly stated: 'We will explore the use of patient reported outcome measures (PROMs) to enhance overall indicators of quality'.

2. PROMs involve standardised research instruments designed to capture self-assessed health states or health-related quality of life using items validated as being of importance to patients themselves. This method of measuring outcomes clearly differs from clinician ratings or administrative data (such as mortality rate). It also differs from self-reported patient experience data, which focus on aspects of the process of care delivery. All of these indicators may be used in complementary ways to build a picture of care quality.

3. PROMs address a number of important considerations in health policy and delivery. Information from systematically collected PROMs data can inform

- Patient choice of provider
- Commissioning of services by PCTs and practice based commissioners
- Clinical quality improvement
- Patient self-care
- Implementation of personal care plans
- Strategies to reduce health inequalities
- Assessment of health gain from public expenditure on the NHS.

4. The value of routine collection of PROMs in the NHS has also been recognised in a recent report published by the Office for Health Economics [<http://www.ohe.org/page/commission.cfm>].

5. The DH has already been active in PROMs implementation. Guidance has recently been published on routine collection of PROMs in line with the *NHS Operating Framework 2009/10*, which states (para 26) that PROMs will be introduced under the standard NHS contract for acute services. From April 2009 they will cover patients undergoing elective hip and knee replacements, and varicose vein and groin hernia surgery. The guidance is intended to support providers and PCT commissioners in implementing the requirement to collect PROMs contained in the standard NHS contract for acute services.

6. The Department of Health is keen to take forward the PROMs agenda and this research brief signals a major development in our PROMs programme. **Research proposals are now invited** for evaluation of pilot implementation of a system for routine collection of PROMs in the management of long-term conditions (the LTC PROMs pilot). It is anticipated that the evaluation will run over an 18-month period, with interim reporting at key stages during the project.

Existing DH PROMs research programme

6. The evidence base supporting the PROMs initiatives in elective surgery derives from research commissioned by the DH on the feasibility of routine administration of PROMs in elective surgery and undertaken by the London School of Hygiene and Tropical Medicine (LSHTM) [<http://www.lshtm.ac.uk/hsru/research/PROMs-Report-12-Dec-07.pdf>].

7. In addition to PROMs for elective procedures, the DH has also been developing plans for implementing LTC PROMs. A programme of DH-commissioned reviews of research literature on PROMs is underway at the University of Oxford (National Centre for Health Outcomes Development), led by Professor Ray Fitzpatrick. The aim of the reviews programme is to identify the best candidate instruments for use in routine PROMs collection by assessing the evidence regarding psychometric and other relevant properties of existing instruments. Initially six LTCs were covered and in November 2006 NCHOD published *A Structured Review of Patient-Reported Measures in Relation to Selected Chronic Conditions, Perceptions of Quality of Care and Carer Impact* (<http://www.nchod.nhs.uk/>). The Oxford PROMs review team programme is close to completing an exercise to bring the review of the literature on PROMs in these six LTCs up-to-date. In a further stage, the Oxford team will consult with clinicians and other stakeholders regarding recommendations they make on the basis of the reviews to help refine the final recommendations for instruments suitable for routine use in the NHS.

8. A final report from this phase of the Oxford review work will be available shortly, at which time the table below will be updated. However, the provisional recommendations are summarised here:

TABLE 1.

<i>Asthma</i>	The AQLQ, mini AQLQ and MAQLQ are shortlisted as promising condition specific PROMs
<i>Chronic obstructive pulmonary disease (COPD)</i>	The CRQ, SF-CRQ, SGRQ and SGRQ-C are shortlisted as promising condition specific PROMs
<i>Diabetes</i>	The ADQoL, DHP and DQOL are shortlisted as promising condition specific PROMs
<i>Epilepsy</i>	The QOLIE-89, QUOLIE-31, and ESI-55 are shortlisted as promising condition specific PROMs

<i>Heart failure</i>	The MLHFQ is shortlisted as the most appropriate condition specific PROM
<i>Stroke</i>	No single measure can be recommended without qualification. The SIS needs validation in UK context. At this stage a generic measure coupled with some disability index may be appropriate.

9. In addition to condition-specific instruments, the Oxford programme will also assess the evidence regarding preference-based generic measures in LTCs (such as EQ-5D). The LTC PROMs pilot will include an examination of the value of including such instruments alongside condition-specific measures.

10. The forthcoming report from the Oxford team will be available to inform the detailed plans for the evaluation project described in this research brief. Those submitting a proposal in response to this call should be guided by the table above but remain uncommitted to specific instruments pending on delivery of the final Oxford report on these LTCs. The emphasis in the proposal should be on design and methods for the evaluation that would be applicable whichever instruments are eventually selected for inclusion.

The LTC PROMs pilot

11. The purpose of the pilot is to determine the feasibility of a system for routine collection of LTC PROMs in a primary care setting. The model underlying such a system is the potential for PROMs to reflect over time the (variation in) quality of care for patients with these conditions, thus providing actionable information for all concerned with quality improvement.

12. Long-term conditions require effective management regimes, including supported self-management. This will aim to reduce exacerbations, avoid admissions and minimise impact of the condition on quality of life. It is the impact on quality of life that is measured in the PROM. However, in important respects, the establishment of an LTC PROMs system is more challenging than for elective procedures. Care for long-term conditions is provided on an ongoing basis. There is not a focus for data collection around a specific intervention such as a hip replacement procedure, with a clear-cut ‘before and after’ basis for assessment of benefits. Many people with LTCs may have difficulty completing PROMs because of frailty or incapacity. Deciding on the appropriate time interval over which to assess change through repeated administration of PROMs is not straightforward. The meaning of observed changes in PROMs scores over time in LTCs will need to be considered in relation to an expected trajectory given the natural history of a condition as well as the quality of care. Of particular significance in the context of the LTC PROMs feasibility study is the fact that people with LTCs commonly receive care from multiple providers and it is thus less apparent how to attribute PROMs results to the effects of particular patterns of care.

13. The DH will facilitate the evaluation by identifying PCT partners willing to host the pilot and by providing analytical and logistical support to the evaluation team. These PCTs will work with the research team to implement agreed plans for the

project. The design the DH has in mind for a routine PROMs system for LTCs is that it can most feasibly be rooted in general practice clinical data systems. The Quality and Outcomes Framework (QOF) rules provides a ready vehicle for identification and selection of LTC patients. The six conditions to be covered – see Table I above – are all included in the QOF indicators. A number of PCTs in London and in the NW of England are offering to support the project by establishing working relationships with local general practices. These practices will be the source of patients for the pilot. Query sets will be developed for identification of patients on practice registers with defined clinical characteristics. The PCTs or practices will support a process for gaining patient consent for participation in the pilot and sharing their data with the research team. The evaluation will inform an assessment of whether a general practice based system of this kind can support routine PROMs data collection from patients with LTCs.

14. PROMs are normally used in a longitudinal context for measuring the impact of clinical interventions. For the LTC PROMs pilot, the measurement timeframe is not built around a defined intervention but is intended to capture the quality of ongoing care for a chronic condition. In this respect any time interval between repeated administration of PROMs is to some extent arbitrary. The burden of data collection and allowance of sufficient elapsed time during which measurable change could be expected must be taken into account. For piloting purposes the model proposed is a time interval of 12 months between sweeps of PROMs data collection.

Requirement for the evaluation of the PROMs LTC pilot

15. Proposals will need to address the key objectives of the pilot evaluation, which are to

- (1) assess the acceptability of the instruments and pilot administrative system to relevant stakeholders;
- (2) estimate potential response rates in a fully implemented system, identify differential response rates in different population groups – including barriers relating to language, mental capacity or disability – and consider methods for maximising participation across different groups;
- (3) develop a strategy for robust analysis and interpretation of LTC PROMs data, including measuring (clinically) significant change over time and comparative analysis at different levels of aggregation;
- (4) explore methods of communication/presentation of PROMs results to relevant stakeholders; and
- (5) estimate the costs of activities in the pilot to facilitate construction of a costing model for any future roll-out of the pilot system.

16. As indicated above, a number of aspects of the pilot arrangements are not yet finalised at this stage – e.g. the number of participating PCTs and practices, and the distribution of coverage of the LTCs in scope. We recognise, therefore, that some

elements of the proposed research plan may need to be provisional. However, the evaluation will need to include some plans for

- (1) rapid mobilisation of the project following award of contract;
- (2) handling all ethical and data protection issues;
- (3) determining target numbers of respondent, adopting a sampling or census strategy;
- (4) producing the appropriate questionnaires, combining condition-specific and generic measures with other items relevant to the analysis;
- (5) providing patients with access to the appropriate questionnaires, means of return of responses, follow-up of non-responders, and secure storage of completed questionnaires.

#### Key evaluation issues

17. The evaluation is intended to inform decisions regarding possible roll-out of the LTC PROMs pilot system. Evaluation proposals will need to consider a number of important issues in this context, for example:

- i. Whether a *cohort or cross-sectional* approach is more appropriate. The standard approach would be to follow-up the same individuals (cohort) but attrition and the changing composition of the practice population have to be considered. A cross-sectional approach, taking a fresh sample of patients each year, would better reflect the current practice population but may raise other questions regarding interpretation of the data.
- ii. Identifying optimal methods for *assessing change in PROMs scores over time*. It is envisaged that, in this pilot, 'baseline' and one-year repeated measure scores will be compared as a model for year-on-year comparison over the longer term. Consideration will need to be given to determining clinically significant change over time in these LTCs, e.g. by considering a role for the minimally important difference (MID);
- iii. The issue above has implications for determining *target numbers* for recruitment from GP lists. Observed response rates in the pilot are obviously a key factor and will clearly influence assessment of the viability of such a system. Sample size requirements for determining significant change in PROMs scores year-on-year will need to be considered.
- iv. How to *interpret PROMs in the context of performance measurement*. The LTC PROMs pilot is to some extent pushing PROMs into new territory as part of a service quality improvement framework. As indicated above, interpreting PROMs data in a context where there is not a single intervention is more complex. Care for people with long-term conditions commonly involves multiple providers and attribution of effects is more problematic.

- v. *Comparative analysis of PROMs.* A system of this kind has potential for benchmarking of performance. However, there are risks and complexities that would need to be addressed – e.g. case mix adjustment and adjustment for other contextual factors that might influence performance.
- vi. *Perceptions of the PROMS system* by patients, practitioners and commissioners. The experience and views of participants and wider stakeholders regarding the burden and the value of the system will contribute important material to the overall evaluation and considerations around roll-out. Qualitative approaches to this are likely to be required.
- vii. The potential for *adding value in the clinical relationship.* While the pilot is concerned with the role of PROMs in indicating quality of care at an aggregated patient level, there is clear potential for PROMs to inform decision-making by individual patients – including self care - and by clinicians involved in their care. Providing a framework for meaningful use of PROMs data at the individual patient level is a challenge.
- viii. *Impact on the behaviour of providers.* Awareness of the PROMs system may incentivise a focus of particular effort on the care of these groups, with reduced attention to other clinical groups.
- ix. *Presentation of results.* This will involve considering ways of summarising data in a form usable by patients, practitioners and commissioners.
- x. *Estimating the costs* of a system for routine administration of PROMs for LTCs, or options for such a system relative to different costs.

#### Phases of work

18. It is important that this study can report promptly on the initial implementation phase – the ‘baseline’ phase. The Department wishes to learn at an early point during the evaluation about the potential for establishing a routine system for collection of PROMs data in LTCs. An interim report covering the baseline phase should explore issues around, for example:

- Necessary sample sizes
- Identification of target patients
- Screening for inappropriate cases
- Patient data confidentiality
- Instrument formats
- Providing access to the instruments
- Equality impact
- Managing return and storage of completed instruments
- Follow-up of non-responders
- Response rates
- Costs
- Findings from analysis of baseline data
- Feedback of results to clinicians, commissioners and patients

The commissioning process

19. Through this tender brief, we are inviting full research proposals. As indicated above, some operational details regarding the pilot scheme are not yet finalised and we expect that proposals will offer some degree of flexibility in their approach. Proposals should, however, include sufficient detail in addressing the issues identified in the brief to enable the commissioning panel to get a clear sense of its key strengths in comparison with others. Following selection of an evaluation partner based on the strength of applications (and possible presentations), the DH will work with this team on the development of more detailed plans.

20. In assessing proposals, the DH commissioning panel will look for evidence regarding:

- Knowledge of the PROMs field
- Broad understanding of the policy context for the LTC pilot
- Experience in policy-related evaluation
- Robust design for the evaluation
- Appropriate disciplinary mix in the team or collaborators
- Credible approach to rapid mobilisation following award of contract
- Delivery milestones and clear arrangements for project leadership and management
- Well-justified costs

21. As a guide to the scale of funding the Department anticipates providing for this project, we anticipate that an evaluation of this kind may well require two (whole time equivalent) researchers, together with senior supervision, over an 18-month period. However, applicants will need to propose a credible resource requirement to deliver the project as specified here, while bearing in mind the Department's obligation to secure value for money.

22 Research leaders and their employers should ensure that they identify and plan to discharge effectively their obligations under the *Research Governance Framework for Health and Social Care*.

23. We anticipate that this project will involve considerable iteration between the Department and the research team as the evaluation progresses and we will require the team to be responsive to requests for reports on progress. In addition, key milestones are indicated below for the project as a whole:

Activity	By
Submit proposal by	5.00pm 11 May 2009
Contract awarded/project commences	June 2009
1 <sup>st</sup> interim report (covering baseline results)	December 2009
2 <sup>nd</sup> interim report	June 2010
Final report	November 2010

24. Further enquiries regarding the research brief should be directed to Alan Glanz by email ([alan.glanz@dh.gsi.gov.uk](mailto:alan.glanz@dh.gsi.gov.uk)) or by telephone (020 7972 4754). Clarification can be provided on aspects of the research brief and the commissioning process but not advice regarding the content of proposals.

25. For general enquiries regarding the application and commissioning process, call: 0208 943 7663 or 0208 943 8979

Email: [prp@nihr-ccf.org.uk](mailto:prp@nihr-ccf.org.uk)

Or visit <http://www.nihr-ccf.org.uk>

26. All applications are to be submitted electronically through the NIHR Central Commissioning Facility (NIHR-CCF), which manages the on-line application process and provides the secretariat for the commissioning process for the DH Policy Research Programme. It also provides a point of contact for queries.

27. All details of the call, including guidance notes, FAQs and the application forms can be found at [www.nihr-ccf.org.uk](http://www.nihr-ccf.org.uk). To apply, if you have not already registered, click Registration in the left hand menu and follow the instructions to register. Once registered, to access application forms, please follow the 'login to extranet' link in the left hand menu on the website and then click PRP in the left hand menu.

28. As the application system is on-line we do NOT require any hard copies of your application, except for Section 27, declaration and signatures page, which should be submitted to NIHR- CCF within one week of the closing date.

29. Applicants are expected, before submitting applications, to have discussed their proposals with their own or any other body whose co-operation will be required in the conduct of the research. The declarations and signatures form which is associated with the application form must be signed by an administrative or finance officer for the host (contracting) institution to confirm that the financial details of the application are correct and that the host institution will agree to administer the award if made. This form should be printed, signed by the relevant authority and returned **within one week of the closing date for applications**. Please send signed declaration forms to:

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NIHR-CCF  
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