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**NHS**60

# Guidance on the routine collection of Patient Reported Outcome Measures (PROMs)

For the NHS in England 2009/10

## DH INFORMATION READER BOX

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# 1 Introduction

- 1.1 The purpose of this document is to provide guidance on the national standards for routine collection of Patient Reported Outcome Measures (“PROMs”). The national standards will cover the PROMs questionnaires and the methods of administration.
- 1.2 This guidance supersedes the *Guidance on the Routine Collection of Patient Reported Outcome Measures* document<sup>1</sup>, published in December 2007. Where there are differences between that document and this, the guidance set out here takes precedence.

## A requirement to collect PROMs

- 1.3 The new Standard NHS Contract for Acute Services, introduced in April 2008, includes a requirement in Schedule 5 for providers to report from April 2009 on PROMs.
- 1.4 In practice, this means that all licensed providers of NHS-funded Unilateral Hip replacements, Unilateral Knee replacements, Groin Hernia Surgery or Varicose Vein Surgery (“Providers”) are expected to invite patients undergoing one of these procedures to complete a pre-operative PROMs questionnaires from April 2009 in accordance with this guidance.
- 1.5 An outline of the administration methodology for Providers is set out in **Chapter 5**, below.
- 1.6 For non-Foundation Trust NHS Acute Trusts, the PROMs data collection has been given mandatory collection status by the Review

of Central Returns (ROCR) Secretariat. The ROCR reference number for this data collection is **ROCR/OR/0237**. Further details can be seen on the NHS Information Centre for Health and Social Care’s Information Catalogue<sup>2</sup>.

## Who is this guidance aimed at?

- 1.7 This guidance is intended to support:
  - Service providers who are required to collect PROMs data under the terms of the Contract. The Contract will, in due course, apply to all NHS Acute Trusts, Foundation Trusts, independent sector Health Services Providers commissioned by Primary Care Trust (“PCT”) Commissioners and those Independent Sector Providers on the Extended Choice Network (“ECN”)<sup>3</sup>.
  - Service providers to understand how the collected data will be used,
  - PCT Commissioners to understand how the collected data will be of use.
- 1.8 This guidance sets out in detail:
  - The procedures for which PROMs data should be collected,
  - Details of the national standard PROMs questionnaires,
  - Roles and responsibilities of the different organisations involved in the delivery of the PROMs programme,
  - A step-by-step guide to the administration of PROMs questionnaires.

1 See: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_081100](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081100)

2 See: <http://www.icapp.nhs.uk/infocat/>

3 See paras 1.8 and 1.9 of the Guidance on the Standard NHS Contract for Acute Hospital Services: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_081100](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081100)

## 2 Aims and Objectives

### What are PROMs?

- 2.1 PROMs are measures of a patient's health status or health-related quality of life. They are typically short, self-completed questionnaires, which measure the patients' health status or health related quality of life at a single point in time.
- 2.2 For the purposes of this guidance document, the term "Patient Reported Outcome Measures" or "PROMs" refers to **self-completed questionnaires** administered to Patients to assess their self-reported health status before and after certain **elective** healthcare interventions funded by the NHS.
- 2.3 The Health status information collected from patients by way of PROMs questionnaires **before** and **after** an intervention provides an indication of the outcomes or quality of care delivered to NHS Patients. Changes in health status as measured by PROMs, controlling for variation in patient characteristics and the influence of other factors, are attributed to the healthcare delivered to the patient by the Provider and the wider healthcare system. This outcomes data can be used in a variety of ways to assess the quality of care delivered to NHS patients by Providers.
- 2.4 PROMs questionnaires and the administration methodology described in this guidance document are based on methodologies, which have been extensively piloted. A **pre-operative PROMs questionnaire** is administered to

patients before an intervention takes place and a follow-up **post-operative PROMs questionnaire** is administered to patient by post after an appropriate time interval.

- 2.5 **Chapter 4** of this guidance provides further details of the national standard PROMs questionnaires.

### Why PROMs?

- 2.6 *High Quality Care for All*, the NHS Next Stage Review Final Report envisages putting quality at the heart of everything the NHS does. Particularly important is quality as assessed by patients themselves and the report highlights PROMs as a means of assessing effectiveness of care from the patient's perspective: *"Effectiveness of care. This means understanding success rates from different treatments for different conditions. Assessing this will include clinical measures such as mortality or survival rates and measures of clinical improvement. Just as important is the effectiveness of care from the patient's own perspective which will be measured through patient-reported outcomes measures (PROMs)..."*<sup>4</sup>
- 2.7 PROMs are a means of collecting information on the clinical quality of care delivered to NHS patients as perceived by the patients themselves. The collection of these data will fill a gap in the set of information available on the care delivered to NHS-funded patients and will complement existing information.

- 2.8 The improvement of clinical quality and outcomes for patients is at the heart of recent NHS reforms. For example, the Patient Choice reforms envisage patients making informed decisions over their healthcare based on quality information.
- 2.9 Data collected routinely by way of PROMs will improve the available information on clinical quality. A Hip replacement questionnaire, for example, compares patients' own assessments of their mobility and pain before and after a hip operation, creating a measure of clinical success.

### Potential applications of PROMs data

- 2.10 There are a range of potential applications to which PROMs data collected routinely from patients undergoing elective interventions can be put. PROMs data can be used to:
- Evaluate the relative clinical quality of Providers of elective procedures. PROMs data can be used by clinicians, managers, regulators and PCT Commissioners to benchmark Providers' performance. It can be used for clinical audit and it can be used by patients and GPs exercising choice,
  - Research what works. Efficacy and cost-effectiveness of different technical approaches to care can be evaluated using PROMs in association with other measures,
  - Assess the appropriateness of referrals to secondary care. PROMs data can be used to establish whether referrals for elective

procedures are appropriate by examining variation in baseline PROMs scores across the country,

- Support the reduction of inequalities,
- Empower commissioners. PCT Commissioners can use the data to establish the quality of services, which they are contracting with Providers for.

- 2.11 Furthermore, the Next Stage Review Final Report indicated the intention to link payments to PROMs data: *"First, we will make payments to hospitals conditional on the quality of care given to patients as well as the volume. A range of quality measures covering safety (including cleanliness and infection rates), clinical outcomes, Patient experience and patient's views about the success of their treatment (known as Patient reported outcome measures or PROMs) will be used."*

### The research base

- 2.12 The PROMs data collection methodology described in this document draws heavily on reported research commissioned by the Department of Health from the London School of Hygiene and Tropical Medicine (LSHTM). The LSHTM piloted candidate measures for a small number of elective procedures with 2,400 Patients at 24 sites, and demonstrated the feasibility of routine outcomes measurement. Further details of the work to identify candidate measures<sup>5</sup> and to pilot the data collection methodology<sup>6</sup> can be found on the LSHTM website.

5 <http://www.lshtm.ac.uk/php/documents/PROMs%20Final%20Report%20Dec%2005.pdf>

6 <http://www.lshtm.ac.uk/hsru/research/PROMs-Report-12-Dec-07.pdf>

## 3 Roles and responsibilities

3.1 A number of organisations will be involved in the collection, processing and analysis and reporting of PROMs data, including Providers, PCT Commissioners, The NHS Information Centre for Health and Social Care (“NHS IC”) and contractors. In this Chapter, the roles and responsibilities of each of the organisations involved in delivering the PROMs programme are set out:

### Providers

3.2 The main role for Providers in the collection of PROMs data is to administer pre-operative PROMs questionnaires to patients. Once questionnaires have been completed these will be collated and returned to the PROMs Administration contractor.

3.3 Providers are expected to be a key audience for the resulting record-level PROMs data (see **Chapter 7**, below).

3.4 There are four main responsibilities for Providers:

- To nominate a member of staff to act as a contact point between the Provider and the PROMs contractor(s),
- To administer pre-operative PROMs questionnaires to patients ensuring that the collected data is as representative of their patient populations as possible. To this end, Providers are expected to request minority language versions of PROMs questionnaires from the PROMs Administration contractor and use them where appropriate (see **Chapter 4**, below),

- To detach and retain for a period of up to 12 months patient consent forms,
- To work with the PROMs Administration contractor to ensure that patients who require translations are sign-posted to local translation services offered by Providers or PCT Commissioners.

3.5 Providers are required to nominate a member of staff who will act as a contact point between the Provider and the PROMs Administration contractor (see **Chapter 4**, below). Details will be provided to the PROMs Administration contractor, and the onus is on Providers to ensure that contact details are up to date and the contractor is notified of any changes. The Provider’s contact person will be:

- the conduit through which Providers agree local arrangements with the PROMs Administration contractor for taking delivery of sufficient numbers of PROMs questionnaires,
- responsible for administering the pre-operative PROMs questionnaires to patients, and
- responsible for the collection and return of completed questionnaires (see **Chapter 5**, below).

3.6 It is the responsibility of Providers to administer pre-operative PROMs questionnaires to patients undergoing one of the relevant procedures. National piloting suggested that administration of the pre-operative PROMs questionnaires on the day of admission was the preferred strategy. However, such an approach will

not work for all Providers. Therefore, it is for Providers to determine how and when the pre-operative PROMs questionnaire should be administered to patients in order to fit in best with local processes. Local administration methodologies should be agreed with the PROMs Administration contractor in order to maximise response rates and to ensure that the process is as efficient as possible.

- 3.7 It is also the responsibility of Providers to ensure that their reported PROMs data are as representative of their local populations as possible. Low rates of completion of pre-operative PROMs (as a proportion of eligible patients) may result in PROMs data being unrepresentative of patient populations as certain patient groups may be excluded (see **Chapter 6**, below).
- 3.8 It is the responsibility of the Provider to detach and retain completed consent forms. Patients completing the pre-operative PROMs questionnaire are expected to give their consent for their personal details to be stored and used within the PROMs programme. They do so by signing a consent form within the pre-operative PROMs questionnaire before completing the rest of the questionnaire. Before completed PROMs questionnaires are returned to the PROMs Administration contractor, the Provider should ensure that consent forms have been completed, that they have been detached, and that they are securely stored (either with medical notes or under an alternative arrangement) for a period of up to 12 months.

- 3.9 Where patients have completed the pre-operative PROMs questionnaire, but have failed to complete the consent form, the patient should either be invited to complete the consent form **or** the questionnaire should be destroyed in a secure manner, as the data cannot be used without explicit consent being given by the patient.
- 3.10 Providers should not apply undue pressure on patients to complete the PROMs questionnaires at any time. Completion of the questionnaires is voluntary for patients.
- 3.11 Providers will liaise with the PROMs Administration contractor to identify local arrangements for translations (see **Chapter 4**, below).

### PCT commissioners

- 3.12 The main role of PCT commissioners in the collection of PROMs data is to work with Providers to establish appropriate thresholds for the participation rate – the proportion of patients completing the pre-operative PROM questionnaire – and to hold them to account where performance does not meet the agreed levels (see **Chapter 6**, below).
- 3.13 It is expected that PCT commissioners will be a key audience for aggregated average outcomes data.

### PROMs Administration contractor

- 3.14 The PROMs Administration contractor is mainly responsible for the collection of questionnaire data and the conversion of these data into an electronic record for onward transmission to the NHS IC.



3.15 The main responsibilities of the PROMs Administration contractor are to:

- Work with Providers' nominated contact person to develop and establish local processes for the administration and collection of pre-operative PROMs questionnaires,
- Ensure that Providers have timely access to adequate numbers of pre-operative PROMs questionnaires, including appropriate minority language versions where available, so that all patients may be given a questionnaire prior to a procedure taking place,
- Supply any materials that are considered necessary for the return of completed pre-operative PROMs questionnaires,
- Supply patient information materials considered necessary for the collection of PROMs data, including materials translated into minority languages,
- Handle patient enquiries and sign-post patients to local translation services where necessary,
- Administer by post, post-operative PROMs questionnaires to patients who have completed and returned a pre-operative PROMs questionnaire,
- Transmit record-level PROMs data to the NHS IC in a secure and timely manner.

### The NHS Information Centre for Health and Social Care

3.16 The NHS IC will play a central role in delivering the PROMs programme. It will have responsibility for linking the

identifiable, record-level PROMs data to existing routinely collected administrative data including Hospital Episode Statistics (HES).

3.17 The NHS IC will be responsible for:

- Converting the collected PROMs questionnaire responses into health status measurements,
- Linking the PROMs data to other routinely collected administrative data held about the patient, in a secure environment,
- Removing patient details from the data once it has been linked to preserve the anonymity of the patient in any subsequent analysis,
- Distributing the non-identifiable record-level data to the PROMs Data aggregation & Analysis contractors,
- Distributing the non-identifiable record-level data to Providers, PCT Commissioners and other healthcare stakeholders subject to a standard set of terms and conditions,
- Keeping a record of the data collected and processed each month.

### PROMs Data Aggregation contractor

3.18 The key function that will be carried out by the PROMs Data aggregation contractor is the aggregation of the monthly batch of non-identifiable record-level data from the NHS IC into Provider-, commissioner- and national- level data.

- 3.19 In order to produce comparable aggregated data across units of interest, the PROMs Data aggregation contractor will develop a robust, evidence-based case-mix and risk adjustment methodology, that will be applicable to the data, as the linked, record-level data becomes available.
- 3.20 It is anticipated that the PROMs Data aggregation contractor will review the case-mix adjustment methodology at appropriate intervals and/or in light of new evidence on appropriate adjustment methodologies as it becomes available.

- Adding value to the aggregated data extracts produced by the PROMs Data aggregation contractor,
- Adding value to the non-identifiable record-level PROMs data extracts available from the NHS IC.

- 3.22 A standard set of reports are expected to be delivered to the Department of Health, which will be of significant benefit to the NHS as a whole.

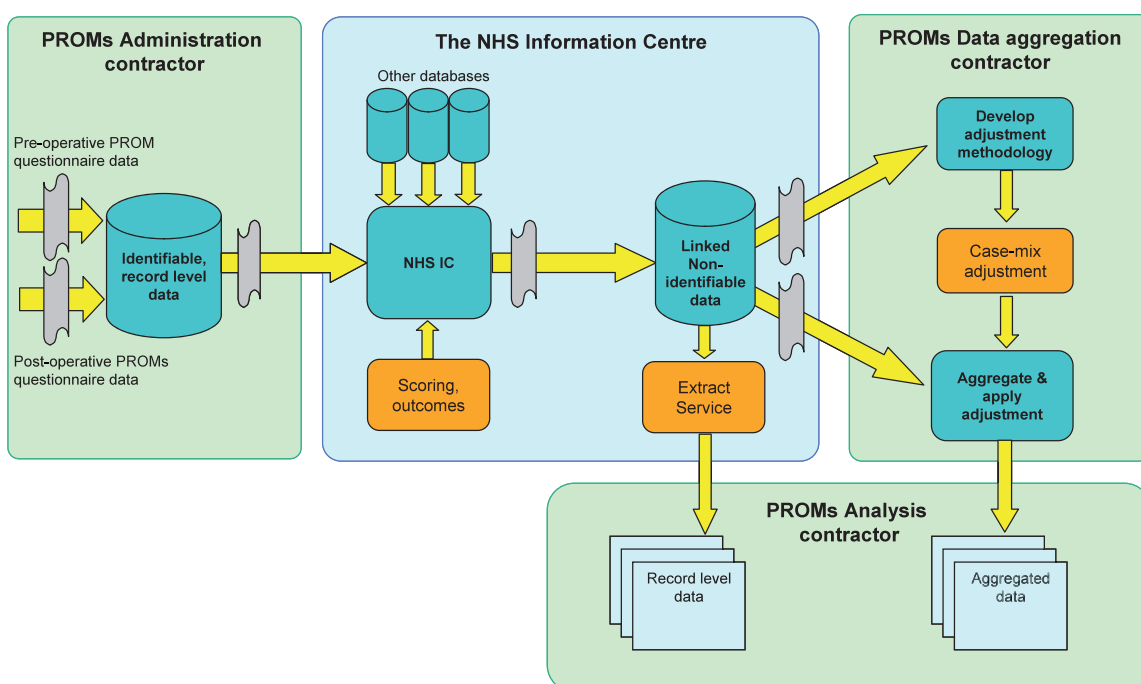
### The PROMs data collection model

- 3.23 Figure 3.1, below, demonstrates how each of the organisations interact to collect, process and analyse the collected PROMs data.

### PROMs Analysis contractor

- 3.21 The PROMs Analysis contractor is chiefly responsible for:

**Figure 3.1 – The PROMs data collection model**



## 4 Scope

### Which procedures?

- 4.1 There are four sets of procedures for which PROMs will be collected (“Procedures”). These are:
- Unilateral Hip Replacements (Primary and Revisions),
  - Unilateral Knee Replacements (Primary and Revisions),
  - Groin Hernia Surgery,
  - Varicose Vein Surgery.
- 4.2 All patients undergoing one of these Procedures will be invited to complete PROMs questionnaires (see **paragraphs 4.10–4.17**, below).
- 4.3 Technical definitions of the Procedures in terms of the relevant clinical codes are set out at **Annex A**.

### The PROMs questionnaires

- 4.4 Both the pre-operative and post-operative PROMs questionnaires comprise a number of elements which include:

- A generic measure of health status which is common to questionnaires for all of the relevant Procedures permitting comparison both within and between Procedures,
  - Condition-specific measures of health status, specific to a single Procedure. Condition-specific measures are more sensitive to changes in health status within a given Procedure but can only be compared within that Procedure.
  - A question about the patient’s living arrangements, which is used to understand differences in reported health status between patients,
  - Questions about whether patients were helped to complete the questionnaire, and whether the patients consider themselves to have a disability.
- 4.5 The relevant health status measures employed within the questionnaires are presented in **Table 4.1**.

**Table 4.1 – Health status measures used in the PROMs questionnaires**

Procedure	Condition-specific	Generic
Unilateral Hip Replacement	Oxford Hip Score	EQ-5D*
Unilateral Knee Replacement	Oxford Knee Score	EQ-5D*
Groin Hernia Surgery	None	EQ-5D*
Varicose Vein Surgery	Aberdeen Varicose Vein Questionnaire	EQ-5D*

\*: EQ-5D™ is a trademark of the EuroQol Group ([www.euroqol.org](http://www.euroqol.org))

4.6 In addition, the pre-operative PROMs questionnaire includes:

- Patient Information sheet,
- Consent form in duplicate,
- Patient details questions such as name, address and date of birth. This information is used to link the health status information to other routinely collected datasets and to send patients a post-operative PROMs questionnaire,
- Other patient questions which ask about the patient’s condition such as whether they have co-morbidities. This information is used to understand differences in health status between patients.

4.7 In addition, the post-operative PROMs questionnaire includes:

- Questions about complications, readmissions to hospital and re-operations,

- Questions about rehabilitation services, where appropriate.

4.8 Further details of the questions included in each questionnaire are provided at **Annex B**.

4.9 The national standard PROMs questionnaires can be downloaded from the Department of Health website<sup>7</sup>.

### Eligibility to participate

4.10 All patients receiving one of the relevant Procedures from an NHS-funded Provider are eligible to participate and should be invited to complete PROMs questionnaires. Although PROMs questionnaires are intended to be self-completed and patients should be encouraged to complete them unaided, some patients will have difficulties with language or concepts.

4.11 In order to be as inclusive as possible and to comply with equality legislation the Department of Health will permit assisted completion (e.g. assistance in interpreting

7 [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_091451](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_091451)

- the meaning of questions provided to patients by family and friends or Provider staff, where appropriate) and the Department of Health will make available alternative language versions of the questionnaires where there is a reasonable demand for these.
- 4.12 Where alternative minority language versions of the questionnaires are available, the PROMs Administration contractor will be required to ensure sufficient volumes of questionnaires are delivered to Providers that request them (within a maximum of 5 business days). The PROMs Administration contractor will also make available alternative language supporting materials.
- 4.13 Minority language versions of the pre- and post-operative PROMs questionnaires will be produced by the Department of Health where there is a reasonable level of demand for them. The Department of Health is working with questionnaire licensors to develop validated, robust versions of the PROMs questionnaires in a range of minority language versions. These will be made available to the PROMs Administration contractor as and when they are ready for use.
- 4.14 It is the responsibility of Providers to request minority language versions of PROMs questionnaires from the PROMs Administration contractor. It is the PROMs Administration contractor's responsibility to provide sufficient numbers of the pre-operative PROMs questionnaires to the Provider where requested minority language versions are available.
- 4.15 Where requested minority language versions of questionnaires are not available, the PROMs Administration contractor will notify the Department of Health of the level of demand for them. The PROMs Administration contractor will coordinate with the Department of Health to ensure at all times there is sufficient stock of minority language questionnaires. Where there is reasonable demand for a specific minority language version of the PROMs questionnaires, the Department of Health will consider commissioning the necessary translation and validation work.
- 4.16 The PROMs Administration Contractor will work with Providers through the Providers' nominated contact person to identify the supporting materials required for patients completing PROMs questionnaires, including materials, which make up the multi-layered consent process. It is the responsibility of the PROMs Administration contractor to make reasonable provision at their cost of appropriate supporting materials in minority languages.
- 4.17 Furthermore, the PROMs Administration contractor is responsible for sign-posting patients to local NHS translation services. Some patients require assistance to complete the questionnaire because of language difficulties. Where appropriate minority language versions of the questionnaires are unavailable, patients requiring translations services should be signposted to local translation services by the PROMs Administration contractor.

# 5 Pre-operative administration of PROMs

5.1 A step-by-step guide to the pre-operative administration of PROMs questionnaires to patients undergoing relevant Procedures is set out below. The aim of this step-by-step guide is to help Providers to develop local processes for the administration, collection and return of pre-operative PROMs questionnaires, working in conjunction with the PROMs Administration contractor.

## Preparation

5.2 The Provider and the PROMs Administration contractor establish a working relationship through the Provider's nominated contact person in order to facilitate an effective process for collecting and collating completed pre-operative PROMs questionnaires. This will include the development of clear arrangements for the supply and return of pre-operative PROMs questionnaires, including the agreement of appropriate timelines. The PROMs Administration contractor will maintain a register of contact details for nominated members of staff from all Providers and will update it when they are notified of changes.

5.3 The PROMs Administration contractor provides a reasonable level of support to Providers where the Provider requests support. Support will be provided to develop efficient and effective ways of handling the process so that pre-operative response rates are maximised with the minimum impact on staff workload. Ultimately, the Provider is responsible to the relevant PCT Commissioner for the process and the PROMs Administration contractor

has no authority to instruct the Provider in respect of their data collection processes.

5.4 Providers will be given access to sufficient numbers of the pre-operative PROMs questionnaires by the PROMs Administration contractor so that all patients may be given a pre-operative PROMs questionnaire prior to their procedure taking place. The PROMs Administration contractor will liaise with the Provider's nominated contact person to ensure that arrangements are in place for the delivery and safe receipt of pre-operative questionnaires within 5 business days receipt of a written request for them. The costs of producing and delivering materials to Providers will be borne by the PROMs Administration contractor.

5.5 Providers are expected to indicate to the PROMs Administration contractor if minority language versions of the pre-operative PROMs questionnaires are required (see **Chapter 4**, above).

5.6 The PROMs Administration contractor shall provide to Providers any materials considered necessary for the return of completed pre-operative questionnaires (e.g. pre-paid envelopes, labels or boxes); any promotional materials considered necessary to increase response rates; and other supporting materials.

5.7 The PROMs Administration contractor will liaise with Providers and NHS Commissioners to identify the local arrangements for translations. Queries and translation requests that are received

through the PROMs Administration contractor's contact points can then be appropriately re-directed.

- 5.8 Providers will agree with PCT Commissioners appropriate thresholds for the patient participation rate – the proportion of eligible patients who complete and return a pre-operative PROMs questionnaire (see **Chapter 6**, below).

### Step 1: Identification of patient

- 5.9 Prior to admission arrangements being made, the Provider confirms that a patient is in need of one of the relevant Procedures. Once the patient has been both (i) listed for surgery **and** (ii) passed fit for surgery, then they are eligible to complete a pre-operative PROMs questionnaire.

### Step 2: Administration of pre-operative questionnaire

- 5.10 Pre-operative PROMs questionnaires should be administered to patients in the interval between being passed fit for surgery and the intervention taking place. The London School of Hygiene and Tropical Medicine final report<sup>8</sup> recommended that the pre-operative questionnaire should be administered on the day of admission. However, it is acknowledged that in many facilities administration of the pre-operative questionnaire on the day of admission is not practical. Providers should, therefore, determine their own arrangements for administering the questionnaires, between
- the time at which a patient is passed fit and the time at which their intervention takes place, which best fit with local processes. Support will be offered by the PROMs Administration contractor to develop a mutually acceptable administration methodology for collecting the pre-operative PROMs data in that interval.
- 5.11 It is expected that patients will be handed and invited to complete a pre-operative PROMs questionnaire by a member of the Provider's staff. As with the time at which the pre-operative PROMs questionnaires are administered, there is flexibility for Providers to develop alternative arrangements. Variations to the preferred administration arrangements will be at the cost of the Provider.
- 5.12 Participation of patients in completing the pre-operative PROMs questionnaire is voluntary. Patients are under no obligations to complete the questionnaires and should not feel obliged to do so.
- 5.13 Patients choosing to complete the pre-operative PROMs questionnaire are expected to give their consent for their personal details to be stored and used within the PROMs programme as set out in the Patient Information Sheet on the inside cover of the questionnaire booklet. Patients give their consent for their personal details to be used as described by signing a consent form contained within the pre-operative PROMs questionnaire. Where appropriate to do so, Providers should

8 [www.lshtm.ac.uk/hsrc/research/PROMs-Report-12-Dec-07.pdf](http://www.lshtm.ac.uk/hsrc/research/PROMs-Report-12-Dec-07.pdf)

highlight to patients the requirement for the consent form to be completed although patients should not be put under pressure to complete the forms.

- 5.14 Patients are invited to return their questionnaires, completed or otherwise, to the person who administered it to them. Where alternative administration methodologies are used by the Provider, it should be clear to whom (and how) questionnaires are returned.

### Step 3: Patient returns pre-operative questionnaire

- 5.15 The patient returns the pre-operative PROMs questionnaire to the Provider. If the patient has completed the questionnaire and/or the consent form, the patient may opt to detach and retain the "Patient copy" of the consent form before they return the questionnaire to the Provider.

### Step 4: Provider collates completed questionnaires

- 5.16 The Provider collates all of the completed pre-operative PROMs questionnaires.
- 5.17 Where patients have completed the questionnaire, but have failed to complete the consent form, the patient should be invited to complete it or the questionnaire should be destroyed in a secure manner as the data within cannot be used without the explicit consent of the patient.
- 5.18 The completed "Hospital copy" of the consent form (and "Patient copy" if not retained by the patient) should be detached from the questionnaire booklets

and retained by the Provider. This should be securely stored either with the patient's medical notes or under alternative secure arrangements for a period of up to 12 months in order to verify that a patient has given their consent for their personal details to be used within the PROMs programme. It is essential that the consent forms are detached before they are sent to the PROMs Administration contractor in order to minimise the risk and consequences of data loss.

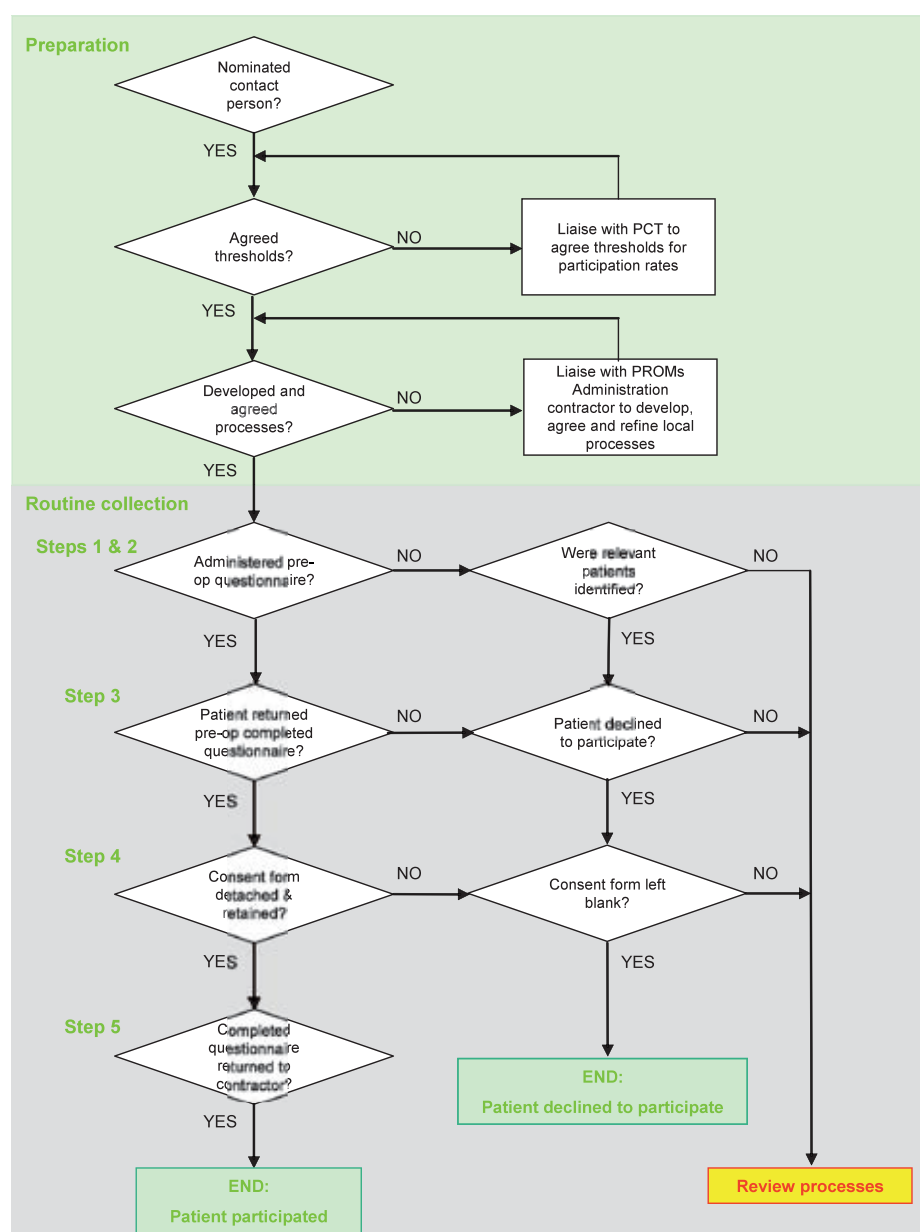
### Step 5: Completed questionnaires are returned to the PROMs Administration contractor

- 5.19 The Provider returns the completed pre-operative PROMs questionnaires to the PROMs Administration contractor, in accordance with agreed processes (see **Preparation** step, above). The costs of transporting completed questionnaires to the PROMs Administration contractor will be borne by the PROMs Administration contractor.
- 5.20 Where the PROMs Administration contractor receives pre-operative PROMs questionnaires with completed consent forms still attached, the consent form will be returned to the Provider by way of the nominated contact person. The PROMs Administration contractor will notify the Department of Health where Providers are systematically failing to detach the consent forms, if Providers are not making reasonable efforts to correct the failings of their administration processes.



5.21 The pre-operative administration process is shown as a flow diagram as **figure 5.1**, below.

**Figure 5.1 – Administration of Pre-operative PROMs questionnaires**



# 6 Contract controls

- 6.1 Providers should ensure that their reported PROMs data are as representative of their local populations as possible. Low rates of patients completing PROMs questionnaires (pre-operative and any subsequent post-operative questionnaires) may mean that the reported data exclude the responses of certain groups of patients. Consequently, the reported data will not provide an accurate picture of the effectiveness of care from the patients' perspective where participation rates are low.
- 6.2 In practice, how representative the data reported by Providers is of local populations, will be assessed by measuring the proportion of all eligible patients returning a completed pre-operative PROMs questionnaire. The rate at which patients subsequently complete and return post-operative PROMs questionnaires is considered to be outside the influence of Providers and so Providers will not be held to account for it.
- 6.3 Appropriate thresholds for data to be considered to be representative should be set locally. PCT Commissioners and Providers should agree what rate of eligible patients completing pre-operative PROMs questionnaires is appropriate in the local health economy. To support this process, the Department of Health will publish to PCT Commissioners on a monthly basis, the proportion of eligible patients completing pre-operative PROMs questionnaires by Procedure.

## Thresholds for representative data

- 6.4 Pilot research carried out by the London School of Hygiene and Tropical Medicine (LSHTM) suggests that a patient participation rate – the proportion of all eligible patients completing a pre-operative PROMs questionnaire – **of 80%** is needed to minimise the risk of data being unrepresentative. The Participation rates highlighted in **Table 6.1**, below, summarise the response rates achieved in the pilot research for each Procedure.
- 6.5 It is acknowledged that in some circumstances a patient participation rate of 80% will not be feasible. Where Providers treat large numbers of patients whose first language is not English, or where a relatively high proportion of patients require assistance to complete the questionnaires, an 80% rate may not be achievable. It should be noted, for example, that the research parameters quoted in **Table 6.1**, below, are based on stricter eligibility criteria, which excluded non-English speakers and those patients who could not complete a questionnaire unassisted. In considering what threshold is realistic, PCT Commissioners and Providers should take into account the availability of minority language versions of questionnaires and the availability or otherwise of support services.

**Table 6.1 – Pilot response rates**

Procedure	Groin Hernia (%)	Varicose veins (%)	Hip replacement (%)	Knee replacement (%)
<b>Participation rate (completion of pre-op PROM)</b>	<b>85.2</b>	<b>90.4</b>	<b>80.9</b>	<b>83.4</b>
Response rate (completion of post-op PROM)	79.4	75.3	91.6	90.2
Overall response rate (Patients completing both)	67.6	68.1	74.1	75.2

Source: Pilot research. London School of Hygiene and Tropical Medicine 2007

6.6 Ultimately, it will be for PCT Commissioners and Providers to agree what an appropriate threshold is for data to be representative of the local patient population. PCT Commissioners will monitor performance against the thresholds and hold Providers to account where performance is below the agreed level.

### Monitoring and managing performance

6.7 Under the terms of the Standard NHS Contract for Acute Services, the failure to meet required performance levels may result in nationally-mandated sanctions.

6.8 Nationally-mandated sanctions are considered to be a last resort where remedial actions have not been taken. As was set out in the *Guidance on the Standard NHS Contract for Acute Services*<sup>9</sup>, the majority of performance controls require warning and/or remedial action

before any consequences are enacted. The intention is to expose performance failures and to support improvement in the spirit of co-operation, not to sanction.

6.9 Where Providers fail to meet agreed thresholds for rates of completed pre-operative PROMs, Commissioners have recourse to two options:

- Where data is not complete, accurate or on time, to deem this a breach of clause 29 (Information) of the Standard NHS Contract for Acute Services,
- Where the number of completed and returned pre-operative PROM questionnaires as a proportion of eligible patients is lower than agreed thresholds, to deem this a Performance failure under clause 32 (Performance Management) of the Standard NHS Contract for Acute Services.

9 See: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_081100](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081100)

6.10 PCT Commissioners have discretion over the application of clauses 29 and 32 of the Standard NHS Contract for Acute Services. Before taking the relevant steps, PCT Commissioners and Providers should discuss whether there are special circumstances that have led to the reported participation rate being below the agreed threshold. In the first instance, PCT Commissioners and Providers should consider whether the agreed threshold is appropriate for the local patient population. This discussion should focus on evidence from the Provider's experience that the characteristics of the patient population differ significantly from those of the average Provider. The discussion should also consider whether there are factors outside of the control of the Provider that have resulted in low numbers of patients either being administered questionnaires or completing them, such as a failure on the part of the PROMs Administration contractor to deliver blank questionnaires on time. Problems of this nature should be documented.

## Dispute resolution

6.11 Disputes between PCT Commissioners and Providers will be resolved under the dispute resolution processes set out in Clause 28 (Dispute resolution) and Schedule 9 (Dispute resolution procedure) of the Standard NHS Contract for Acute Services<sup>10</sup>.

## Measuring participation

6.12 The participation rate is the proportion of eligible patients completing and returning pre-operative PROMs questionnaires. It is calculated for each Provider and Procedure as set out below.

6.13 For the purpose of measuring participation, returned pre-operative PROMs questionnaires are considered to be complete if:

- At least one of the health status measures contained in the questionnaire have been completed by the patient,
- The Patient consent form has been completed and signed by the patient,
- The Patient consent form has been detached and retained by the Provider,
- There are sufficiently complete patient details on the questionnaire to facilitate linkage to the patient's NHS number.

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<sup>10</sup> *ibid.*

**Table 6.2 – Calculation of the participation rate**

Participation Rate	=	Total number of completed pre-op questionnaires	÷	Total number of eligible patients
		Source: NHS IC assessment of the total volume of completed pre-op questionnaires which have been returned and can be matched to an NHS number.		Source: Extract drawn from Hospital Episode Statistics (HES) using the definitions set out in Annex A.

- 6.14 Further details of the definition of a complete questionnaire are provided at **Annex C**.
- 6.15 A monthly monitoring report will be produced by the NHS Information Centre, which sets out the participation rate by Procedure for each Provider in each of the preceding months. Where activity data are not yet available due to lags in the availability of data derived from the Hospital Episode Statistics (HES), estimates based on the previous year's activity for that month will be used. The monthly data will be updated as and when complete HES data becomes available.

# 7 Data & analysis

- 7.1 PROMs data are used to generate measures of the outcome or quality of care associated with a particular procedure. The responses to the pre- and post-operative PROMs questionnaires are converted into pre- and post-operative health status measurements by the application of scoring algorithms, where appropriate<sup>11</sup>. The difference between the pre- and post-operative health status scores is a measure of the outcome of the procedure.
- 7.2 The record-level PROMs data is stored as a supplement to the HES dataset. The output of the data collection process, described in this document, will be pre- and post-operative health status scores and a measure of outcome for each of the patients completing the PROMs questionnaires. This data is linked to the HES data relating to the patient's stay in hospital before patient-identifying information (name & address) are removed from the records. The process of removing the patient identifiers is known as *pseudonymisation*<sup>12</sup>.
- 7.3 PROMs data will be available at two levels:
- Non-identifiable (pseudonymised) record-level data on outcomes and pre- and post-operative health status scores,
  - Case-mix and risk adjusted average outcomes data.
- 7.4 The non-identifiable (pseudonymised) record-level data on outcomes and health status scores can be used for a range of applications, including:
- Clinical audit,
  - Local performance monitoring,
  - Research.
- 7.5 Case-mix and risk adjustment is applied to aggregated data in order to ensure that it can be compared across different organisations. There are a range of factors that can influence the outcomes reported by an individual patient, other than the quality of the intervention that was carried out. Some factors relate to the patient themselves including their age, the severity of their condition and whether or not they have other medical conditions such as high blood pressure. Other factors relate to the broader package of care received within the hospital and in the community such as whether the patient received rehabilitation care. The aim of a case-mix and risk adjustment is to take into account as many of these factors as possible to produce data which can be compared across Providers, PCT Commissioners or over time.

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11 Some elements of the questionnaires (such as the EQ-5D Visual Analogue Scale) will provide health status measurements directly and so scoring algorithms are not always necessary.

12 National policy on the secondary use of patient data requires that patient level records should be used in non-identifiable form, except where there are valid and justifiable reasons for using identifiable data. The process of creating de-identified data is known as pseudonymisation. This is supported by providing additional derived data items instead of items that can be used to aid identification, such as age instead of date of birth and electoral ward instead of postcode. See: <http://www.ic.nhs.uk/services/the-secondary-uses-service-sus/pseudomisation>

- 7.6 Case-mix and risk adjusted average outcomes data will be produced:
- By responsible Provider,
  - By responsible PCT Commissioner; and,
  - At the national level (all Providers and PCT Commissioners).
- 7.7 The average outcomes data can be used for a range of applications, including:
- Information to support patients making choices,
  - To support contract monitoring (for PCT Commissioners),
  - Benchmarking performance (for Providers),
  - Information for regulators,
  - National assessments of productivity.
- 7.8 Aggregated pre-operative PROMs data will further permit:
- Assessment of the appropriateness of referrals,
  - Identification of inequalities in healthcare.
- 7.9 Access to PROMs data is available to all Providers and PCT Commissioners subject to their agreement of a standard set of terms and conditions. The PROMs questionnaires comprise a number of elements, which have been licensed by the Department of Health from the owners of the Intellectual Property for non-commercial applications. Providers and PCT Commissioners wishing to access the non-identifiable record-level data will be required to agree to a set of standard terms and conditions on the re-use of the data in order to: (i) ensure compliance with the agree licenses, and (ii) ensure compliance with usual information governance arrangements.

# Annex A – Procedures

## Technical definitions

Procedure	Definition
Hip replacement	<p>(i) All unilateral Hip replacement procedures as defined by the OPCS-4.3 clinical procedure codes: Total hip replacement, primary (W37.1, W37.8, W37.9, W38.1, W38.8, W38.9, W39.1, W39.8, W39.9); Total hip replacement, revision (W37.0, W37.2, W37.3, W37.4, W38.0, W38.2, W38.3, W38.4, W39.0, W39.2, W39.3, W39.4, W39.5, W39.6); Total prosthetic replacement of the head of the femur, primary (W46.1, W46.8, W46.9, W47.1, W47.8, W47.9, W48.1, W48.8, W48.9); Total prosthetic replacement of the head of the femur, revisions (W46.0, W46.2, W46.3, W47.0, W47.2, W47.3, W48.0, W48.2, W48.3, W48.4, W48.5); Hybrid prosthetic hip replacements, primary (W93.1, W93.8, W93.9, W94.1, W94.8, W94.9, W95.1, W95.8, W95.9); Hybrid prosthetic hip replacements, revisions (W93.0, W93.2, W93.3, W94.0, W94.2, W94.3, W95.0, W95.2, W95.3, W95.4). Other Hip replacements, primary (W52.1, W52.8, W52.9, W53.1, W53.8, W53.9, W54.1, W54.8, W54.9 <u>with</u> Z76.1 or Z75.6); Other Hip replacements, revisions (W52.0, W52.2, W52.3, W53.0, W53.2, W53.3, W54.0, W54.2, W54.3, W54.4 <u>with</u> Z76.1 or Z75.6). Bilateral hip replacements defined as the above OPCS-4.3 codes accompanied by a code of Z94.1 (“bilateral operation”) or as a pair of unilateral hip replacements accompanied by both a code of Z94.2 (“Right-sided operation”) and a code of Z94.3 (“Left-sided operation”) are <u>excluded</u> from the definition of Hip replacement.</p> <p>(ii) All successor codes in updates to the OPCS-4 classification system to those identified in (i) above,</p> <p>(iii) All codes added to the OPCS-4 classification system which would be referred to as “unilateral hip replacements” in common medical terminology.</p>



Procedure	Definition
Knee replacement	<p>(i) All unilateral Knee replacement procedures as defined by the OPCS-4.3 clinical procedure codes: Total knee replacements, primary (W40.1, W40.8, W40.9, W41.1, W41.8, W41.9, W42.1, W42.8, W42.9); Total knee replacements, revisions (W40.0, W40.2, W40.3, W40.4, W41.0, W41.2, W41.3, W41.4, W42.0, W42.2, W42.3, W42.4, W42.5); Unicondylar/Unicompartmental knee operations, primary (W52.1, W52.8, W52.9, W53.1, W53.8, W53.9, W54.1, W54.8, W54.9 <u>with</u> Z76.5, Z77.1 or Z77.4); Unicondylar / Unicompartmental knee operations, revisions (W52.0, W52.2, W52.3, W53.0, W53.2, W53.3, W54.0, W54.2, W54.3, W54.4 <u>with</u> Z76.5, Z77.1 or Z77.4). Bilateral knee replacements defined as the above OPCS-4.3 codes accompanied by a code of Z94.1 (“bilateral operation”) or as a pair of unilateral hip replacements accompanied by both a code of Z94.2 (“Right-sided operation”) and a code of Z94.3 (“Left-sided operation”) are <u>excluded</u> from the definition of Hip replacement.</p> <p>(ii) All successor codes in updates to the OPCS-4 classification system to those identified in (i) above,</p> <p>(iii) All codes added to the OPCS-4 classification system which would be referred to as “unilateral knee replacements” in common medical terminology.</p>
Varicose Vein surgery	<p>(i) All Varicose Vein surgeries as defined by the OPCS-4.3 clinical procedure codes: L84, L85, L86, L87, L88 where these are accompanied by ICD-10 Diagnosis codes of I83.0, I83.1, I83.2, I83.9, O22.0; and L93 <u>with</u> Z39.5, Z39.9, Z93.9, Z98.3, Z98.4, Z98.7 or Z98.9 where this is accompanied by ICD-10 Diagnosis codes of I83.0, I83.1, I83.2, I83.9, O22.0.</p> <p>(ii) All successor codes in updates to the OPCS-4 and ICD-10 classification systems to those identified in (i) above,</p> <p>(iii) All codes added to the OPCS-4 and ICD-10 classification systems which would be referred to as “varicose vein surgeries” in common medical terminology.</p>
Groin Hernia surgery	<p>(i) All Groin Hernia surgeries as defined by the OPCS-4.3 clinical procedure codes: T19, T20, T21, T22, T23; and recurrent incisional groin hernia (T26 <u>with</u> Z49.8).</p> <p>(ii) All successor codes in updates to the OPCS-4 classification system to those identified in (i) above,</p> <p>(iii) All codes added to the OPCS-4 classification system which would be referred to as “groin hernia surgeries” in common medical terminology.</p>

## Annex B – PROMs questionnaire structure

Questionnaire component	Groin hernia surgery		Hip replacement		Knee replacement		Varicose veins surgery	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
Patient Information sheet	inside cover	n/a	inside cover	n/a	inside cover	n/a	inside cover	n/a
Consent form (in duplicate)	first two pages	n/a	first two pages	n/a	first two pages	n/a	first two pages	n/a
Patient details questions	p.1	n/a	p.1	n/a	p.1	n/a	p.1	n/a
Other Patient questions	q1-5 + q12-15	q1-10 + q17-18	q1-5 + q24-27	q1-10 + q29-31	q1-5 + q24-27	q1-10 + q29-31	q1-5 + q25-28	q1-10 + q31-32
Oxford Hip Score	n/a	n/a	q6-17	q11-22	n/a	n/a	n/a	n/a
Oxford Knee Score	n/a	n/a	n/a	n/a	q6-17	q11-22	n/a	n/a
Aberdeen Varicose Vein Questionnaire	n/a	n/a	n/a	n/a	n/a	n/a	q6-18	q11-24
Generic EQ-5D profile	q6-10	q11-15	q18-22	q23-27	q18-22	q23-27	q19-23	q25-29
Generic EQ-5D VAS	q11	q16	q23	q28	q23	q28	q24	q30
<b>Notes:</b>								
Qx: Questionnaire X								
qx: question x (where question is numbered)								
px: page x (where page is numbered)								

# Annex C – Complete questionnaires

- C.1 It is inevitable that some patients will miss out or choose not to respond to questions when completing the pre-operative and/or post-operative PROMs questionnaires. For all of the pre- and post-operative PROMs questions a missing or ambiguous response will be treated as “missing” data and coded appropriately in any electronic records.
- C.2 A degree of missing responses is tolerated. A relatively small number of missing responses can be imputed using statistical methods. On the other hand, some missing responses will render the returned questionnaire invalid as the data will not be useful for subsequent analyses.
- C.3 For the generic EQ-5D “profile” questions, responses are considered to be “complete” if no more than 20% of the questions (1 question) have missing responses. Otherwise, the responses will be considered to be “incomplete”. Further detail on the treatment of missing responses is provided in the EQ-5D user guide which can be downloaded from the EuroQol Group’s website (<http://www.euroqol.org/>).
- C.4 For the generic EQ-5D Visual Analogue Scale part of the questionnaires, the responses will be considered to be “complete” provided the response is not missing. Otherwise, responses will be considered to be “incomplete”. Further detail on the treatment of missing responses for the EQ-5D Visual Analogue Scale is provided in the EQ-5D user guide which can be downloaded from the EuroQol Group’s website (<http://www.euroqol.org/>).
- C.5 For the condition-specific elements of the questionnaires, the responses will be considered to be “complete” provided no more than 20% of the questions have missing responses. Otherwise, the responses will be considered to be “incomplete”. Further detail on the treatment of missing data from the Oxford scores is available from the University of Oxford website (see Guides to scoring, [http://phi.uhce.ox.ac.uk/ox\\_scores.php](http://phi.uhce.ox.ac.uk/ox_scores.php)).
- C.6 A pre- or post-operative PROMs questionnaire, as a whole, will be considered to be **complete** if:
- The Patient has consented to participate; **and,**
  - Patient details on the questionnaire can be matched to the patient’s NHS number; **and,**
  - The responses to **either** the EQ-5D Profile questions, the EQ-5D Visual Analogue Scale **or** the condition-specific instrument are complete; or
  - The responses to **either** the EQ-5D Profile questions or the EQ-5D Visual Analogue Scale are complete, where there is no condition-specific instrument included in the questionnaire.
- C.7 Post-operative PROMs questionnaires will be considered incomplete if the related pre-operative PROMs questionnaire was considered to be incomplete.



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