



NATIONAL PATIENT REPORTED OUTCOME MEASURES (PROMS) PROGRAMME GUIDANCE

Guidance to support the collection and reporting of data through the administration of PROMs questionnaires to patients in receipt of relevant NHS-funded care.

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This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact ENGLAND.Insight-Queries@nhs.net.

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1. The National PROMs Programme

- 1.1 Patient Reported Outcomes Measures (PROMs) are the collection of information on the clinical quality of care delivered to NHS patients as perceived by the patients themselves. PROMs comprise repeated surveying of patients and are administered pre-operatively (the "Q1" questionnaire) and post-operatively (the "Q2" questionnaire) within defined intervals and to preset standards for their administration.

Governance

- 1.2 NHS England sets the strategic direction for the National PROMs Programme, having taken over responsibility from the Department of Health in April 2013. NHS England is responsible for the decision of what conditions and procedures should be included in the national collection and what measures are used to measure the outcome following treatment.
- 1.3 NHS Digital are commissioned by NHS England to collate, process and publish the data as Official Statistics, and the data is made data available on-line via the NHS Digital website. The Head of Profession for Statistics at NHS Digital is responsible for content, timing and overall assurance of all NHS Digital publications, with each individual publication, including PROMs, also having a responsible statistician accountable for content and quality in each individual area.
- 1.4 Care providers such as NHS Trusts and independent sector hospitals (the Provider) are able to become accredited to collect and administer PROMs data themselves or to contract with an accredited PROMs supplier (the Supplier).
- 1.5 Providers or Suppliers who wish to collect and administer PROMs data must first demonstrate that they can meet the requirements of this guidance by completing the application form. These requirements include holding a current [Information Governance Toolkit](#) certificate. They will also need to pass test data submission checks with NHS Digital.

Eligible Patients

- 1.6 The patients who are eligible to be included in the National PROMs Programme are defined in terms of the procedures or interventions they are undergoing, or the diagnosis or condition that they are considered to have. These are the Eligible Procedures and a full list can be found in Annex 1 of [Patient Reported Outcome Measures \(PROMs\) in England - A guide to PROMs methodology](#).
- 1.7 All patients receiving one of the Eligible Procedures from a Provider are eligible to be included in the National PROMs Programme and should be invited to complete

the questionnaires by the Provider.

- 1.8 The Eligible Procedure operation codes included in the PROMs programme can be found in Annex 1 of NHS Digital's [Patient Reported Outcome Measures \(PROMs\) in England - A guide to PROMs methodology](#) document.

Patient Consent

- 1.9 Participation of patients in completing the Q1 questionnaire is voluntary. Patients are under no obligations to complete the questionnaires and should not feel obliged to.
- 1.10 Patients choosing to complete the Q1 questionnaire will give their consent for their personal details and other information held in other NHS databases to be used to analyse and interpret the information collected. The patient should be made aware that it is possible to withdraw consent at any time and be provided with details about how long their personal information will be held for. In summary the patient, in giving their consent, agrees to the following: (however please note, this is further detailed in Sections 1.34, 3.10 and 3.34 – 3.39).
- Their personal details and other relevant health information related to this operation will be held and used by NHS Digital, including relevant information held about them by the Personal Demographics Service, the Demographics Batch Service, the Secondary Uses Service and other NHS databases.
 - Their personal details can be used to send related follow-up questionnaires in the future.
 - Their personal details and health information can be held and used by contractors, working on behalf of NHS Digital and NHS England for this project.
 - Their responses will be used to produce statistics about the quality of healthcare services offered by different healthcare providers (hospitals) across the NHS. These statistics will be used to measure and improve the quality of healthcare services.

Q1 Questionnaires

- 1.10 There is a specific PROMs Questionnaire for use with each of the Eligible Procedures.

1.11 Copies of the existing PROMs Questionnaires can be found in Appendix A. These are currently:

- Hernia Surgery Questionnaire – Before your operation
- Hernia Surgery Questionnaire – After your operation
- Hip Surgery Questionnaire – Before your operation
- Hip Surgery Questionnaire – After your operation
- Knee Surgery Questionnaire – Before your operation
- Knee Surgery Questionnaire – After your operation
- Varicose Veins Surgery Questionnaire – Before your operation
- Varicose Veins Surgery Questionnaire – After your operation

1.12 The PROMs Questionnaires for use with specific eligible procedures may only be modified through the reissuing of this guidance.

1.13 Additional PROMs Questionnaires may be added or existing PROMs Questionnaires may be withdrawn, when appropriate, to reflect changes to the Eligible Procedures for the programme.

PROMs Methodologies

1.14 All four of the current national PROMs - groin hernia surgery, knee surgery, hip surgery and varicose veins surgery - have scores for the EQ-5D™ Index and EQ VAS. Hip surgery, knee surgery and varicose veins surgery each have their own condition-specific measure, which combine a patient's answers to a number of health questions, of particular relevance to their procedure, into a single score.

1.15 The EQ-5D™ Index collates responses given in 5 broad areas (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and combines them into a single value. The EQ-5D™ Index was developed by the [EuroQol Group](#). EQ-5D™ is a trademark of the EuroQol Group. The National PROMs Programme currently uses the 3 level (3L) version of the EQ-5D.

1.16 The EQ Visual Analogue Scale (EQ VAS) is a simple and easily understood 'thermometer'-style measure based on a patient's self-scored general health on the day that they completed their questionnaire, but which provides an indication of their health that is not necessarily associated with the condition for which they underwent surgery and which may have been influenced by factors other than healthcare. The EQ VAS was developed by the [EuroQol Group](#).

1.17 The Oxford Hip Score (OHS) contains 12 questions on activities of daily living that assess function and residual pain in patients undergoing total hip replacement surgery. The OHS was designed, developed and validated by workers within public health and at the [University of Oxford](#).

1.18 The Oxford Knee Score (OKS) contains 12 questions on activities of daily living that assess function and residual pain in patients undergoing total knee replacement surgery. The OKS was designed, developed and validated by workers within public health and at the [University of Oxford](#).

1.19 The Aberdeen Varicose Vein Questionnaire (AVVQ) allows patients to self-assess the severity of their varicose veins via a 13-item measure covering all aspects of their varicose veins including physical symptoms such as pain, ankle oedema, ulcers, the effect on daily activities, and cosmetic issues.

Assisted Patient Completion

1.20 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.

1.21 In order to be as inclusive as possible and to comply with the equalities legislation, NHS England permits some assisted completion.

1.22 Assisted completion must only be provided in order to help convey the patients' own responses. It must not comprise:

- any re-interpretation of the patients' answer so as to alter materially the patients' response,
- any assumption of what a patient's answer may have been where the patient is unable or unwilling to provide an answer. Where the patient is unable or unwilling to provide an answer, the responses must be left blank,
- any pressure, compulsion or coercion on the patient to provide responses where they are unwilling or unable to participate.

1.23 Assisted completion may comprise:

- providing help to patients to understand the text, questions, instructions or concepts,
- ad-hoc translations of text, questions or instructions into other languages,
- providing help to transcribe patients' responses onto the questionnaire.

1.24 Assistance may be provided by:

- friends accompanying the patient (pre-operatively) or at the request of the patient (post-operatively),
- family members accompanying the patient (pre-operatively) or at the request of the patient (post-operatively),
- Provider staff (pre-operative only),
- other personnel on Provider sites such as PALs staff or volunteers as

appropriate (pre-operative only).

Q2 Questionnaires

- 1.25 For each specific PROMs Questionnaire there is a defined sampling method and a defined follow-up interval as set out in Table 1, below.
- 1.26 The follow-up interval is calculated based on the operation date. This will be provided by NHS Digital from the hospital episode statistics (HES) data, where it has been possible to link questionnaire data to HES. This will be supplied using NHS Digital's Secure Electronic File Transfer (SEFT) interface.
- 1.27 The follow-up periods, sampling methods and follow-up interval may be modified from time to time, through the reissuing of this guidance. In some cases, it may not be possible to know the precise date that the Eligible Procedure took place, for example because of a failure of the linkage process meaning that a PROMs record submitted to the NHS Digital is not associated with a relevant administrative record in the Hospital Episode Statistics (HES) dataset. In these circumstances, the Supplier is required to use a "default date" for the follow-up interval. In the absence of a PROMs HES Operation Date for the patient, Q2 questionnaires should be sent to patients in line with the default send out date.
- 1.28 The default send out date for post-operative questionnaires will be 12 weeks from the questionnaire scan date, plus the duration based upon the PROMs Procedure Group type outlined below:

Table 1: Procedures and specified PROMs Questionnaires

Procedure	Specified PROMs Questionnaires	Sampling Method	Follow-up Interval (if Op date known)	Follow-up Interval (if Op date not known)
Hip replacement surgery	Hip Surgery Questionnaire Before your operation; Hip Surgery Questionnaire After your operation	Census	A minimum of 6 months post-intervention	6 months post Q1 scan date + 12 weeks
Groin hernia surgery	Hernia Surgery Questionnaire Before your operation; Hernia Surgery Questionnaire After your operation	Census	A minimum of 3 months post-intervention	3 months post Q1 scan date + 12 weeks

Knee replacement surgery	Knee Surgery Questionnaire Before your operation; Knee Surgery Questionnaire After your operation	Census	A minimum of 6 months post-intervention	6 months post Q1 scan date + 12 weeks
Varicose vein surgery	Varicose Veins Surgery Questionnaire Before your operation; Varicose Veins Surgery Questionnaire After your operation	Census	A minimum of 3 months post-intervention	3 months post Q1 scan date + 12 weeks

“Complete” PROMs Questionnaires

- 1.29 It is inevitable that some patients will miss out or fail to respond to questions when completing the Q1 and/or Q2 questionnaires. For all of Q1 and Q2 questionnaires, a missing or ambiguous response must be treated as “missing” data and coded appropriately in the submission to NHS Digital in accordance with the PROMs Technical Guidance.
- 1.30 Some degree of missing responses will be tolerated within the programme. 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. NHS Digital will apply standard imputation rules as and where appropriate.
- 1.31 For the generic set of five questions element of the questionnaires (the EQ-5D™), the responses will be considered to be “complete” provided no more than 20% of the questions (one question) have missing responses on each questionnaire. Otherwise, the responses will be considered “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](#).
- 1.32 For the generic EQ-VAS element of the questionnaires, the responses will be considered “complete”, provided the response is not missing, on each questionnaire. Otherwise, the responses will be considered “incomplete”. Further detail on the treatment of missing responses for the EQ-VAS is provided in the EQ-5D™ user guide, which can be downloaded from the [EuroQol Group's website](#).
- 1.33 For the condition-specific element of the questionnaires, the responses will be considered to be “complete” or otherwise based on bespoke rules for each condition-specific measure. For example, for the Oxford Hip and Knee scores, which are included in the Hip and Knee questionnaires respectively, provided no more than two individual questions have missing responses on each

questionnaire they will be considered to be “complete”. 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 https://innovation.ox.ac.uk/wp-content/uploads/2016/05/OHS-Scoring-System_23022016.pdf). Where the AVVQ asks patients to draw in their varicose veins, no markings constitutes a missing response for Q1 questionnaires only.

- 1.34 Q1 or Q2 questionnaires, as a whole, will be considered to be incomplete for the purposes of the PROMs programme if:
- The patient has withdrawn their consent to participate prior to submission of records to NHS Digital. Under these circumstances, the records should not be submitted to NHS Digital. Where a patient has withdrawn their consent and the record is submitted to NHS Digital, the record in question will be rejected.
 - The responses to the generic set of five questions, the EQ-VAS and the condition-specific questionnaire are all incomplete, where these have been included in the PROMs questionnaires. Incomplete questionnaires should still be submitted to NHS Digital.
 - The responses to the generic set of five questions and the EQ-VAS are both incomplete, where there is no condition-specific questionnaire included in the questionnaire, and where these components have been included in the PROMs questionnaires. Incomplete questionnaires should still be submitted to NHS Digital.
- 1.35 Furthermore, the Q2 questionnaire will be considered incomplete if the linked Q1 questionnaire was incomplete.
- 1.36 For the avoidance of doubt, a questionnaire will be considered complete if one of: (a) the generic set of five questions, or (b) the EQ-VAS, or (c) the condition-specific questionnaire are complete. Provided the patient has given their consent, and, for Q2s, that the Q1 questionnaire was also complete.
- 1.37 All questionnaires, where patient consent has not been withdrawn, should be submitted to NHS Digital irrespective of whether the Supplier considers them to be incomplete.

2. Requirements of the Provider

- 2.1 The Provider is the organisation responsible for providing NHS-funded Eligible Procedures.
- 2.2 The Provider must appoint an Accredited Supplier, or make arrangements to become an Accredited Supplier themselves, to support the collection, administration and reporting of PROMs data for all eligible patients that the Provider is responsible for, irrespective of where the relevant procedure is carried out.
- 2.3 Providers are deemed responsible for offering PROMs questionnaires to any patient receiving an NHS-funded intervention and for which the activity is recorded against them in the Hospital Episode Statistics dataset.
- 2.4 If appointing an Accredited Supplier, rather than becoming one themselves, the Provider must ensure that they undertake a competitive procurement process in line with their local Standing Financial Instructions and procurement law obligations, to ensure they are securing value for money and are appointing a Supplier who is accredited to deliver PROMs, will adhere to this PROMs Guidance and can satisfy local requirements. Providers need to ensure that the contractual arrangements they put in place require Suppliers to adhere to the PROMs Guidance.
- 2.5 The Provider shall provide and maintain a named contact person who shall give all reasonable assistance to the Supplier and to NHS England / NHS Digital in relation to the national PROMs activity.
- 2.6 Where a Provider has activity (eligible procedures) carried out at an alternative Provider site or where part of the pathway is carried out elsewhere such that Q1 questionnaire administration would be best carried out elsewhere, it must either: make arrangements for its Supplier to administer at and collect questionnaires from that site, or make arrangements with the alternative Provider for the collection of that data.
- 2.7 The Provider shall identify which patients should be surveyed and administer the appropriate Q1 questionnaire, secure the required patient Consent and then store collected questionnaires and deliver them to the Supplier, as agreed, in accordance with Information Governance requirements and in the agreed format.
- 2.8 The Provider shall offer the Q1 questionnaire to the patient at an appropriate time before the procedure takes place. This could be up to 18 weeks before the procedure at clinic/pre-assessment or on the day of admission.

- 2.9 If the Q1 questionnaire is administered more than 18 weeks before the procedure (e.g. due to a cancelled or delayed operation), the provider should administer a new questionnaire before the rescheduled procedure and notify the Supplier to cancel the original.
- 2.10 If the Q1 questionnaire is administered to a patient who does not receive the procedure (the patient no longer requires treatment or dies before treatment), the provider should notify the Supplier to cancel the original.
- 2.11 The Provider shall provide assistance to patients for the completion of questionnaires if required.
- 2.12 The Provider shall identify the questionnaire volumes, including any minority languages required, and order such in the manner agreed with the Supplier.
- 2.13 The Provider shall securely receive and store printed surveys and support materials from the Supplier for subsequent administration of PROMs questionnaires to eligible patients.
- 2.14 The Provider shall liaise with any other Provider where PROMs questionnaires are administered to eligible patients that it is responsible for, to make suitable arrangements for the administration and collection of Q1 questionnaires.

3. Requirements of the Supplier

- 3.1 The Supplier is the organisation appointed, through a competitive procurement process, by the Provider to support the collection, administration and reporting of PROMs data for all eligible patients that the Provider is responsible for.
- 3.2 The Supplier will comply with all the requirements of the National PROMs Programme. Specifically, this National PROMs Programme Guidance, the PROMs Technical Guidance and the PROMs Information Governance requirements.
- 3.3 The Supplier shall provide and maintain a named contact person who shall give all reasonable assistance to the Provider and to NHS England / NHS Digital in relation to the national PROMs activity.
- 3.4 The Supplier shall liaise with other Providers and/or Suppliers to facilitate the administration and collection of Q1 questionnaires to patients for which the Provider is responsible for, but for whom part of the pathway and/or the procedure is carried out on the other Provider's site. The Supplier will either make arrangements to collect the relevant Q1 questionnaires for onwards processing or make arrangements with another Supplier for these questionnaires to be collected and processed by them.
- 3.5 The Supplier shall ensure that any organisation which sub-contracts for the collection and reporting of PROMs data abides by the same terms and conditions that it does, including full compliance with this guidance. For the avoidance of doubt, the Supplier is responsible for actions of its sub-contractor(s). Sub-contractors may be used for example for the collection of Q1 questionnaire data by electronic means. A sub-contractor would also be required to hold a current [Information Governance Toolkit](#) certificate.
- 3.6 The Supplier may offer additional services pertaining to PROMs data to the Provider under the condition that these services comply with the stated governance restrictions placed upon the data. These services may include providing automated reporting services and/or interfaces to flow PROMs data, where appropriate, into local information systems.

Information Governance

3.7 NHS IG Toolkit Compliance

- 3.7.1 The Supplier shall comply fully with the detailed compliance requirements as set out in the this guidance, specifically:
 - Suppliers MUST submit the NHS Information Governance Toolkit (IGT)

business partner's self-assessment on an annual basis and attain and retain a minimum of level of satisfactory, or higher, compliance as assessed by NHS Digital.

- Suppliers will be expected to complete the NHS IGT on an annual basis using the latest version of the toolkit. This is released in June each year to be completed by mid-March the following year.

3.7.2 PROMs data contains patient identifiers and is considered to be very sensitive personal data. As a result, Suppliers will not be permitted to process and submit 'live' PROMs data to NHS Digital without meeting these Information Governance Requirements.

3.8 Organisational Requirements

3.8.1 If not already registered, the Supplier shall register with the Organisation Data Service <https://digital.nhs.uk/organisation-data-service> (formerly NACS) for an Organisational Code and for an Organisational Site Code for each site where the services will be delivered.

3.9 IT Requirements - the Supplier shall, at their own cost:

3.9.1 Be solely responsible for providing (or procuring the provision of) the IT requirements so as to support the delivery of the services.

3.9.2 Provide (or procure the provision of) the IT requirements so as to support interfaces with NHS Digital's Secure Electronic File Transfer (SEFT) interface for the purposes of secure data exchange, in accordance with the PROMs Technical Guidance.

3.9.3 The Supplier shall produce Disaster Recovery (DR) and Business Continuity (BC) plans before service commencement. The minimum requirements for such plans include sufficient measures in accordance with good industry practice to ensure continued operations of IT Services and details of timescales and parameters within which the Provider will aim to ensure that IT Services will be reinstated following a DR or BC event.

3.10 Document Management - the Supplier shall:

3.10.1 Have a documented policy on the management of hard and soft copy documents for PROMs and apply this policy at all times, within reason. This policy must be compliant with:

- The PROMs Consent Statement

- NHS Digital Information Governance Toolkit
 - Records Management: NHS Code of Practice (Parts 1 and 2)
 - Data Protection Legislation; and
 - The common law duty of confidentiality
 - Freedom of Information Act
 - Environment Information Regulations
- and must cover transportation and destruction of hard and soft copy documents.

3.10.2 Securely store completed Q1 questionnaires for 24 months from the date of consent unless otherwise notified by NHS Digital.

3.10.3 Securely store electronic Q1 questionnaire data as per paper questionnaires (i.e. for 24 months unless otherwise advised by NHS Digital).

3.10.4 Securely store completed Q2 questionnaires for 1 year from receipt (unless otherwise notified by NHS Digital)

3.10.5 The Supplier shall transfer data using a secure data link as set out in the PROMs Technical Guidance.

3.11 Data Confidentiality

3.11.1 The Supplier shall adhere to NHS Information Governance requirements and the associated legislation under which they will operate including the Data Protection Act 1998 and NHS Caldicott principles.

3.12 Processing and Storage of Data

3.12.1 The Supplier shall have in place a secure IT system with access control for all users including encryption in compliance with NHS Digital guidelines.

3.12.2 Data must be stored only in England.

3.13 The Supplier shall comply with the NHS Digital PROMs Technical Guidance.

Provision of Q1 Questionnaires

3.14 Suppliers must provide Q1 questionnaires in the required manner, volume and language types, in a timely manner and process as agreed with the Provider.

- 3.15 Suppliers must provide Q1 questionnaires in the most appropriate medium for their patient population (paper or electronic) as agreed with the Provider.
- 3.16 Where Q1 questionnaires are provided in an electronic format, the Supplier is responsible for ensuring the continuity of the service and maintenance of any hardware to support such collection, unless otherwise agreed with the Provider.
- 3.17 The Supplier is responsible for ensuring that the electronic representations of the Q1 questionnaire(s) are compliant with this guidance and licensing terms and conditions. This includes provision of all material, media and means required in order to administer the Q1 questionnaire unless otherwise agreed.

Electronic Questionnaires

- 3.18 Electronic representations of the PROMs questionnaires are permitted, provided that the Supplier fully complies with this guidance. Unless agreed otherwise in writing, the Supplier is explicitly not entitled to:
- Translate, modify, distribute, abridge, convert, alter, amend, or make available in whatever way the PROMs questionnaires.
 - Intellectual Property embodied in the PROMs questionnaires, including but not limited to any minor or significant change in wording or organisation of the PROMs questionnaires, without the prior written consent of NHS England.
- 3.19 Suppliers must be granted approval by the Licensors of the Intellectual Property comprised within the questionnaires to use any electronic representations of the PROMs questionnaires in advance of their use within the National PROMs Programme.
- 3.20 Rendering
- 3.20.1 PROMs questionnaires may be rendered electronically by devices including tablet computers, other touchscreen devices or other computers.
- 3.20.2 Electronic versions of the questionnaires should be rendered as per the owner of the measure's specifications. This is [Euroqol](#) for the EQ-5D and EQ-VAS and [Oxford University Innovation](#) for the condition specific measures.
- 3.20.3 All PROMs questionnaires must be displayed using a contrast ratio of at least 7:1. This value is used to account for the loss in contrast that can result from low visual acuity, congenital or acquired colour deficiencies, or the loss of contrast sensitivity that typically accompanies aging.

3.20.4 All electronic representations of the PROMs questionnaires must retain the same look and feel as the paper and pen versions of the questionnaires. This means:

- Unless otherwise specified in this guidance, the layout, format, font, font size, ordering, presentation of questionnaire items and response boxes should be equivalent to that of the paper and pen questionnaire format,
- All branding, colour (including NHS pantones) and styles employed should be equivalent to those used on the paper and pen versions of the questionnaires,
- All supplementary items included on the paper and pen questionnaires should be reflected in the electronic versions,
- Electronic versions should replicate and include trademark and copyright statements in an equivalent format to that used for the paper and pen versions of the questionnaires,
- Fonts used for displaying the PROMs questionnaires should be sans serif, and use the NHS Frutiger font, or similar, in line with NHS branding guidelines.

3.21 Navigation

3.21.1 The Patient is not required to complete each item of the PROMs questionnaires before being permitted to advance to a subsequent item or question. The Patient must be permitted to decline to complete any individual item,

3.21.2 The Patient must be permitted to revisit items and to change their responses. This should be possible during completion of the questionnaire and prior to the final confirmation step,

3.21.3 No default response should be selected for any item in the PROMs questionnaires.

3.22 Layout of other questionnaire items

3.22.1 Other questionnaire items should be laid out in a manner consistent with the paper versions of the questionnaires and with the rest of this guidance wherever possible.

Completion of Questionnaires

3.23 The Supplier shall, where applicable, provide assistance to patients for the completion of Q1 questionnaires if required.

3.24 The majority of fields on PROMs questionnaires should normally be completed

either by the selection of pre-coded boxes (as indicated on the PROMs questionnaires) or by the direct entry of text or numbers into designated fields. These data items will either be captured directly (electronic data capture) or indirectly (scanned from paper).

- 3.25 A minority of fields on the PROMs questionnaires will require alternative data entry, for example by drawing in or marking areas of the body affected by a condition or disease or by marking on visual scales a particular value.
- 3.26 For the EuroQol Visual Analogue Scale (EQ-VAS), instructions on how to score the scale are available at <http://www.euroqol.org/about-eq-5d/how-to-use-eq-5d.html>
- 3.27 For the Aberdeen Varicose Vein Questionnaire (AVVQ), the vein diagram question is completed by overlaying a scoring grid over the completed diagram (varicose veins marked on legs) and counting the number of squares covered by varicose veins.

Collection of Q1 Questionnaire Forms or Data

- 3.28 Suppliers must be responsible for the cost, unless otherwise agreed, of delivering completed Q1 questionnaires from the Provider to the Supplier, in accordance with this guidance.
- 3.29 This shall include, but is not limited to, agreeing a delivery protocol with the Provider, arrangement of transport method, verifying dispatch and receipting of delivery to minimise risk of delivery loss, identify data loss quickly and determine point of loss or responsibility as quickly as possible. For the avoidance of doubt, the secure transfer of completed Q1 questionnaires could be physical (transfer of completed paper questionnaire or electronic images on physical storage, e.g. disc) or electronic (transfer electronically).

Completion Check, Collation and Onward Transmission of Q1 Questionnaire Data

- 3.30 The Supplier must receive and handle Q1 questionnaire responses consistent with this guidance.
- 3.31 The Supplier must check Q1 questionnaire responses meet requirements of the PROMs Technical Guidance. This may include any checks for NHS numbers or addresses as required.
- 3.32 The Supplier must convert Q1 questionnaire responses into an electronic record and transmit to NHS Digital in a manner consistent with PROMs Technical Guidance

3.33 This shall include, but is not limited to, receiving Q1 questionnaire responses, assigning unique identifier codes to permit matching to subsequent Q2 questionnaire responses, scanning paper questionnaires, data error checking and correction, translating into the compliant format for transmission and checking for data file errors prior to transmission.

Patient Consent

3.34 Consent will be given by patients by completing the questionnaires. No further actions will be required of Suppliers beyond explaining any consent statements on the questionnaires if requested to do so by patients.

3.35 Patients are entitled to withdraw their consent at any point:

3.35.1 for further use of their patient data (up to the point at which their data have been pseudonymised and processed or published),

3.35.2 for their identifiable data to be shared with the clinical teams that treat(ed) them.

3.36 Notice of withdrawal of patient's consent may be given in writing to the Supplier or via the helpline (telephone or email). The Supplier is responsible for ensuring that:

- the withdrawal of consent is noted and flagged in the dataset to prevent further processing of that patient's data up to the point at which the data has been pseudonymised, processed or published,
- NHS Digital is notified of the withdrawal of consent where the patient's data have already been transferred or submitted to NHS Digital, by providing the PROMs serial number and date consent was withdrawn,
- the Provider is notified of the withdrawal of consent where the patient's data have already been shared with the Provider's clinical team as part of an identifiable dataset (subject to the patient not having previously opted out as part of the original consent process),
- there is no further use of the patient's data that would be inconsistent with their withdrawal of their consent.

3.37 Suppliers shall delete records where consent has been withdrawn unless otherwise required by law and be able to demonstrate that these records have been securely deleted. This process should be consistent with the Information Governance requirements and the requirements of the Data Protection Act.

3.38 The Supplier shall create and maintain a process for tracking responses to enable notification of withdrawal of consent to NHS Digital, FOI queries and/ or auditable tracking of PROMs data.

3.39 The Supplier shall operate an effective withdrawal of consent process to ensure appropriate parties are contacted and any data is handled appropriately.

Q2 Questionnaire Follow-up

3.40 The Supplier should put in place a process for ensuring that the latest Q2 questionnaire is sent to patients on the default date.

3.41 Suppliers will send out Q2 questionnaires after the follow-up interval, as set out in this guidance, has elapsed, but no more than a month after the follow-up interval has elapsed, except where the patient is deceased.

3.42 Suppliers will, at their cost, check that the patient is not deceased or has changed address before sending out any Q2 questionnaire. At a minimum, this will entail a check at their cost of the Personal Demographics Service (via the Clinical Spine Application or via the NHS Digital MRIS service by arrangement). This check may include any checks for NHS numbers or addresses as required. This shall not be any earlier than 5 days prior to sending any correspondence to patients.

3.43 Distribution of Q2 questionnaire may be postal or electronic. The Supplier should provide the option for the patient to complete the Q2 questionnaire electronically/online unless otherwise agreed with the Provider. Therefore, the Supplier may send a reference number for a patient to enter into an online portal to complete the relevant Q2 questionnaire.

3.44 The Supplier must provide a pre-paid return envelope when sending paper-based Q2 questionnaires unless otherwise agreed.

3.45 The Q2 questionnaire itself will not carry personal details about the patient. It will however be possible to link the Q2 to the relevant completed Q1 questionnaire data held on records by way of an appropriate unique identifier e.g. a serial code.

3.46 Where patients have not responded, Suppliers may follow-up to attempt to prompt a response, through the use of a follow up letter. In the case of written reminders, this may also include an additional copy of the questionnaire.

3.47 Completion of the Q2 questionnaire is voluntary for patients and they should not be placed under pressure to complete them in order to increase response rates. There should be no more than two separate attempts to follow-up the patient's Q2 response.

Completion Check, Collation and Onward Transmission of Q2 Questionnaire Data

- 3.48 The Supplier must receive and handle Q2 questionnaire responses consistent with Information Governance requirements.
- 3.49 The Supplier must convert the Q2 questionnaire response into an electronic record and transmit to NHS Digital consistent with this guidance and the PROMs Technical Guidance.
- 3.50 This shall include, but is not limited to, receipting Q1 questionnaire responses, assigning unique identifier codes to permit matching to Q2 questionnaire responses, scanning paper questionnaires, data error checking and correction, translating into the compliant format for transmission and checking for data file errors prior to transmission.

Data Errors

- 3.51 The Supplier must clear any data errors arising from the submission of data to NHS Digital. For the avoidance of doubt, the Supplier is responsible for the correction of data errors associated with its submission of its data to NHS Digital, at its cost.

Survey Performance Data

- 3.52 The Supplier must provide PROMs collection performance data to the Provider if requested. The performance data should apply to all eligible patients for which the Provider is responsible for unless other arrangements have been made.

Provision of Helpline Facilities

- 3.53 The Supplier must provide a helpline facility for the completion of questionnaires to the satisfaction of the Provider.
- 3.54 This requirement shall be applicable only to the Q1 and Q2 questionnaires administered by the Supplier on the Provider's site/s (whether administered by itself or by a sub-contractor). If Q1 questionnaire are completed on another Provider's site, that Provider shall be responsible for meeting this requirement.
- 3.55 The Supplier will provide contact points via a range of media (by mail, e-mail, free telephone and internet) for patients and Providers who have queries about the processes for administration of questionnaires to patients, how to complete the questionnaires or patient consent. These contact points will be referred to as the Patient Helpline.

- 3.56 Queries to the Patient Helpline received by the Supplier shall be dealt with promptly within 2 working days.
- 3.57 The Supplier should maintain a record of the volumes and natures of the enquiries received and should be able to provide summary details to NHS England/NHS Digital upon request in a timely manner.

Provision of a Patient Feedback and Complaints Process

- 3.58 The Supplier is expected to handle and deal with complaints from patients howsoever received in a professional and timely manner.
- 3.59 The Supplier will record all complaints about its Q2 questionnaire administration methodology and protocol and will make this record of complaints available to the Provider or NHS England/NHS Digital upon request.
- 3.60 The Supplier must respond promptly to complaints from patients and take no longer than 2 working days to respond.
- 3.61 The Supplier will adjust its processes in response to complaints where it is reasonable to do so.
- 3.62 The Supplier will have a clear escalation route for dealing with any complaints received, with NHS England as the ultimate arbiter.
- 3.63 The Supplier will undertake regular review of such feedback and in agreement with the Provider amend the process used.
- 3.64 This requirement shall be applicable only to the Q1 and Q2 questionnaires administered by the Supplier on the Provider's site/s (whether administered by itself or by a sub-contractor). If Q1 questionnaire are completed on another Provider's site, that Provider shall be responsible for meeting this requirement.

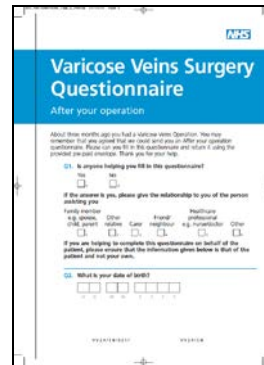
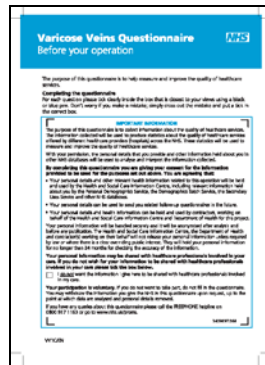
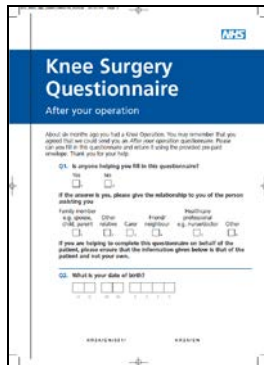
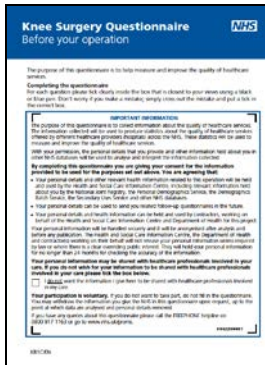
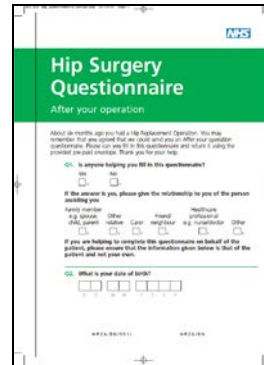
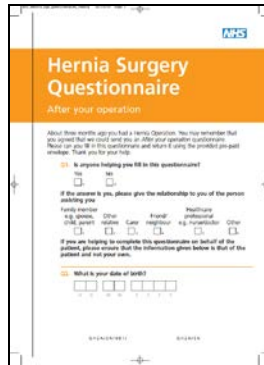
4. NHS England / NHS Digital

NHS England and/or NHS Digital shall:

- 4.1 Issue from time to time Guidance as to how Providers are required to collect and report PROMs.
- 4.2 Define the scope of the National PROMs Programme through the issuing of relevant Guidance as to the Eligible Procedures.
- 4.3 Develop and define PROMs questionnaires for use with Eligible Procedures and provide templates to be used by Providers and Suppliers, where appropriate.
- 4.4 Ensure there is a Clearing House function and/or alternative arrangements to receive and process submitted PROMs data in accordance with this guidance.

Appendix A - PROMs Questionnaires

(Double-click on the icon to see the full questionnaire pdf)



Appendix B – Supporting Documents – NHS Digital

This document should be read in conjunction with the following documents from NHS Digital:

- PROMs Supplier Accreditation Process
- PROMs Technical Guidance
- [Patient Reported Outcome Measures \(PROMs\) in England - A guide to PROMs methodology](#)
- PROMs Accredited Supplier Application Form