
Patient Reported Outcome Measures (PROMs)

Standards

A. Information Governance Requirement

This Information Governance Requirement Standard covers four Areas:

1. NHS Systems Requirements,
2. Data Sharing,
3. Data Confidentiality,
4. Processing and Storage of Data.

1. NHS System Requirements

These requirements are:

Information Governance
Organisational Requirements
IT Requirements
Document Management

1.1. Information Governance

1.1.1. The Supplier shall comply fully with the detailed compliance requirements as set out in the Accreditation Standard, specifically:

- i. Suppliers MUST submit the NHS Information Governance Toolkit (IGT) business partners self-assessment on an annual basis and attain and retain a minimum of Level 2 compliance as assessed by the DH Information Governance Team.
- ii. 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.
- iii. Where Suppliers do not attain IGT Level 2 within the deadline for accreditation, it will be at the discretion of the Authority to determine whether the Supplier may proceed with Accreditation subject to meeting minimum requirements and having an agreed improvement plan for the next annual IGT submission deadline. After the first year of accreditation, improvement plans to attain the required NHS IGT standard will not be acceptable and the attainment standard must be met and maintained.

- 1.1.2. 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 the HSCIC Clearing House without the meeting the requisite Information Governance Requirements.

1.2. Organisational Requirements

- 1.2.1. The Supplier shall register with the Organisation Data Service (formerly NACS) for an Organisational Code and for an Organisational Site Code for each site where the services will be delivered.

(Refer: [Organisation Data Service](#)).

1.3. IT Requirements

The Supplier shall, at their own cost:

- 1.3.1. Be solely responsible for providing (or procuring the provision of) the IT requirements so as to support the delivery of the services.
- 1.3.2. Register for NHS mail email accounts as required to provide secure email services for the transmission of Patient identifiable data.
- 1.3.3. Provide (or procure the provision of) the IT requirements so as to support interfaces with the Health and Social Care Clearing House for the purposes of secure data exchange, in accordance with the PROMs Data Interface Specification Standard.
- 1.3.4. The supplier shall produce Disaster Recovery and Business Continuity plans, on or before service commencement. The minimum requirements for such plans include sufficient measures in accordance with Good Industry Practice to ensure continued operations of IM&T Services and details of timescales and parameters within which the Provider will aim to ensure that IM&T Services will be reinstated following a DR or BC event.

1.4. Document Management

The Supplier shall:

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

- 1.4.1.1. Records Management: NHS Code of Practice (Parts 1 and 2)
- 1.4.1.2. Connecting for Health: Information Governance Toolkit
- 1.4.1.3. DP Legislation; and
- 1.4.1.4. FOIA

And must cover:

- 1.4.1.5. the transportation of hard and soft copy documents for the Patient Questionnaire Framework
- 1.4.1.6. the destruction of hard and soft copy documents for the Patient Questionnaire Framework
- 1.4.2.** Store completed Q1 questionnaires for 18 months from the date of consent unless otherwise notified by the Clearing House.
- 1.4.3.** Securely store electronic Q1 data as per paper questionnaires (ie for 18 months unless otherwise advised by the Clearing House).
- 1.4.4.** Securely store completed Q2s for up to 1 year from receipt (will be 1 year unless otherwise notified by the Clearing house)
- 1.4.5.** Destroy securely both electronic and hard copies of patient survey data when authorised by the HSCIC Clearing House

2. Data Sharing Agreement

The Supplier shall:

- 2.1.** Transfer records using a secure data link as set out in the PROMs Data Interface Specification Standard.
- 2.2.** Be required to agree to the HES protocol if and when they need to handle any HES data either separately or linked to PROMs data. The protocol is available at:

[Hospital Episode Statistics Online](#)

3. Data Confidentiality

The Supplier shall:

- 3.1.** 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.
- 3.2.** Be required to sign an Information Sharing Protocol with the HSCIC in accordance with the PROMs Data Interface Specification Standard.

4. Processing and Storage of Data

The Supplier shall:

- 4.1.** Have in place a secure IT system with access control for all users including encryption in compliance with NHS Connecting for Health guidelines.
- 4.2.** Data must be stored only in England.

B. PROMs Data Interface Specification

The detailed requirements of the interface between the Supplier and the HSCIC Clearing House are set out in the separate document, “PROMs Data Interface Specification”.

C. Accreditation

The detailed requirements of Supplier Accreditation are set out in the separate document, “PROMs Supplier Accreditation Standard”.

D. Eligible Patients

- (a) The patients who are eligible to be administered PROMs questionnaires are defined in terms of the procedures or interventions they are undergoing, or the diagnosis or condition that they are considered to have.
- (b) Procedures, interventions, diagnoses or conditions for which PROMs should be administered are set out in the attached technical guidance document.
- (c) The technical guidance document may be updated from time to time to include additional procedures, interventions, diagnoses or conditions which would affect the numbers of eligible patients.
- (d) Procedures and interventions may be defined in terms of OPCS4 Operational or ICD10 Diagnosis codes or combinations thereof.
- (e) Procedures and interventions may be defined in terms of Healthcare Resource Groups (HRGs), specialty codes or other coding systems.
- (f) The relevant PROMs questionnaires are set out in the Specified PROMs Questionnaires standard.

E. Assisted Patient Completion

- (a) All patients receiving one of the Eligible Procedures from a Provider are eligible to participate in completing questionnaires and should be invited to complete them by the Provider.
- (b) Although PROMs (and Other Patient 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.
- (c) In order to be as inclusive as possible and to comply with the equalities legislation, the Authority permits some assisted completion.
- (d) 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.
- (e) 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.
- (f) 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).

F. Patient Consent

- (a) Participation of Patients in completing the pre-operative PROMs questionnaire (or Other Patient Questionnaire) is voluntary. Patients are under no obligations to complete the questionnaires and should not feel obliged to.
- (b) Patients choosing to complete the pre-operative PROMs questionnaire will give their consent for their personal details and responses to be used for a set of defined applications.
- (c) 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.
- (d) Patients are entitled to withdraw their consent at any point:
 - for further use of their patient data (up to the point at which their data have been pseudonymised and processed or published,
 - for their identifiable data to be shared with the clinical teams that treat(ed) them.
- (e) 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,
 - the HSC IC Clearing House is notified of the withdrawal of consent where the patient's data have already been transferred or submitted to the Clearing House,
 - 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),
 - generally, there is no further use of the patient's data that would be inconsistent with their withdrawal of their consent.
 - 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.

G. Patient Helpline

- (a) 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.
- (b) Queries to the Patient Helpline received by the Supplier shall be dealt with promptly within 2 working days.
- (c) There should be a clear process for escalating queries where the enquiries are not straightforward or require careful handling.
- (d) Telephone calls to the Patient Helpline will be answered within 60 seconds.
- (e) The Patient Helpline is expected to be in operation 9am to 5pm weekdays (Monday to Friday).
- (f) The Patient Helpline will be staffed by appropriately trained personnel.
- (g) All Patients contacting the Patient Helpline will be treated in a professional manner irrespective of the nature of their enquiry.
- (h) The Supplier should maintain a record of the volumes and natures of the enquiries received and should be able to provide summary details to the Authority upon request in a timely manner.

H. Specified PROMs Questionnaires

- (a) There is a specific PROMs Questionnaire for use with each of the Eligible Procedures as set out in table 8.1, below;
- (b) The specific PROMs Questionnaires referred to in this section are appended as a separate schedule. .
- (c) The PROMs Questionnaires for use with specific Eligible Procedures may be modified, from time to time through the reissuing of this Standard in Guidance.
- (d) Additional PROMs Questionnaires may be added to table 8.1 from time to time to reflect changes to the Eligible Procedures Standard.
- (e) For each specific PROMs Questionnaire there is a defined sampling method and a defined follow-up interval as set out in table 8.1, below.
- (f) The follow-up interval is calculated based on the completion of the relevant Finished Consultant Episode, ie the Finished Consultant Episode in which the Eligible Procedure took place.
- (g) The follow-up periods may be modified from time to time, through the reissuing of Guidance.
- (h) The sampling methods may be modified from time to time, through the reissuing of Guidance.
- (i) The Follow-up interval may be modified from time to time, through the reissuing of Guidance.
- (j) 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 HSC IC Clearing House 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 post-operative questionnaires should be sent to patients in line with the default send out date.
- (k) The default send out date for post-operative questionnaires will be;
 - a. 12 weeks from the questionnaire scan date plus the duration based upon the PROMS Procedure Group type outlined below:

PROMS Procedure Group	Duration
Groin Hernia	3 months
Hip Replacement	6 months
Knee Replacement	6 months
Varicose Veins	3 months

- (l) The Supplier should put in place a process for ensuring that the latest that Q2 PROMs questionnaire are sent to patients is the default date

Table 8.1: table of procedures and specified PROMs Questionnaires

Procedure	Specified PROMs Questionnaires	Sampling method	Follow-up interval
Hip replacement surgery	Hip Surgery Questionnaire Before your operation; Hip Surgery Questionnaire After your operation	Census	After at least 6 months post-intervention
Groin hernia surgery	Groin hernia Surgery Questionnaire Before your operation; Groin hernia Surgery Questionnaire After your operation	Census	After at least 3 months post-intervention
Knee replacement surgery	Knee Surgery Questionnaire Before your operation; Knee Surgery Questionnaire After your operation	Census	After at least 6 months post-intervention
Varicose vein surgery	Varicose Vein Surgery Questionnaire Before your operation; Varicose Vein Surgery Questionnaire After your operation	Census	After at least 3 months post-intervention

I. Questionnaire Follow-up Standard

- (a) Suppliers will send out post-operative (Q2) questionnaires after the follow-up interval as set out in the Specified PROMs Questionnaire Standard has elapsed but no more than a month after the follow-up interval has elapsed, except where the patient is deceased.
- (b) Suppliers will, at their cost, check that the Patient is not deceased before sending any Q2 PROMs Questionnaires out. At a minimum, this will entail a check at their cost of the Personal Demographics Service (via the Clinical Spine Application or via the HSC IC MRIS service by arrangement). In the first Financial Year of operation, the Authority will make available the MRIS service at its cost. Suppliers are not obliged to use this service and are free to make their own arrangements at their cost.
- (c) Distribution of Q2 PROMs questionnaires may be postal or electronic,
- (d) The Q2 PROMs questionnaire itself will not carry personal details about the Patient. It will however be possible to link the Q2 questionnaire to the relevant completed Q1 questionnaire data held on records by way of eg a serial code which is compliant with all relevant Standards.
- (e) Where patients have not responded, Suppliers may follow-up to attempt to prompt a response, through the use of a standard follow up letter.
- (f) 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.
- (g) The format and content of any letters (paper based or electronic) used in correspondence with patients should be agreed with the Authority in advance of service commencement.

J. Patient Feedback and Complaints

- (a) The Supplier is expected to handle and deal with complaints from Patients howsoever received in a professional and timely manner.
- (b) The Supplier will record all complaints about its Q2 administration methodology and protocol and will make this record of complaints available to the Provider or Authority upon request.
- (c) The Supplier must respond promptly to complaints from Patients and take no longer than 2 working days to respond.
- (d) The Supplier will adjust its processes in response to complaints where it is reasonable to do so.
- (e) The Supplier will have a clear escalation route for dealing with any complaints received with the Authority as the ultimate arbiter.