

# Use of Patient Reported Outcome Measures within clinical practice

## Guidance for Independent Healthcare Providers of Cosmetic Surgery

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### Aim of guidance

This document outlines the patient reported outcome measures (PROMs) that are being launched by The Royal College of Surgeons of England (RCS), which should be routinely collected and reported on by all providers of most cosmetic surgical procedures.

Measurement of clinical effectiveness requires not only capture of data on the change to a clinical condition as a result of a treatment, but also the effects on the patient. Many of the clinical indicators routinely used by services do not reflect those areas of healthcare practice that are of particular importance to patients. Without this balance in measurement, the risk is development of services that do not meet the whole need of the patient or potentially end in harm.<sup>1</sup>

Recording the patient outcome is particularly important within cosmetic surgery, where the whole purpose of treatment is to address patient-related concerns, as opposed to addressing injury or disease.

Routine activity collection within all independent providers that deliver cosmetic surgery will require effort to implement, especially among smaller providers. However, there is a wide range of potential benefits both for patients and providers.

### Scope of this paper

#### Within scope

This paper explores how the data gathered from use of PROMs can be used in a variety of ways to empower patients, inform decision-making, identify patients most likely to respond to treatment, and support quality improvement.

#### Outside of scope

This is not a user manual for implementation of the PROMs tools, nor does it outline how the scoring of tools should be carried out or how results should be submitted to the Private Healthcare Information Network (PHIN) for national reporting. These aspects of implementation are covered in other documents, which are signposted at the end of this paper.

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<sup>1</sup> Atkinson T. *Atkinson Review: Final Report – Measurement of Government Output and Productivity for the National Accounts*. TSO: London; 2005.

## Background

In April 2013, the Department of Health published Sir Bruce Keogh's review into the regulation of cosmetic interventions,<sup>2</sup> highlighting an urgent need for robust regulation of cosmetic practice. It noted that 'the existing regulatory framework has not kept pace with changes and it does not provide enough protection against many of the potential risks from cosmetic procedures'.

The review made numerous recommendations to improve regulation of the industry. Specifically, the RCS was asked to set up a Cosmetic Surgery Interspecialty Committee (CSIC) to take forward the recommendations relating to cosmetic surgery. Membership of the CSIC has included representatives of all the relevant specialty and professional associations, as well as regulators and patient and provider representatives.

As part of the recommendations, the CSIC was asked to identify 'clear, credible outcome measures for cosmetic surgery that are published at individual surgeon and provider level on the NHS Choices website'.

The outcome measures that have been defined for cosmetic surgery providers through this programme of work are listed in Appendix 1.

The outcome measures discussed within this paper are the *patient reported outcome measures*, or 'PROMs'.

## What is a PROM?

A PROM is a series of questions that patients are asked in order to gauge their views on their own health. They are the patient's own assessment of their health and health-related quality of life.<sup>3</sup>

PROMs can either be generic or procedure-specific. Their viability for widespread use is assessed through the evidence of their reliability, validity, responsiveness, precision, acceptability to patients and feasibility of use in practice.

Completion of PROMs by patients pre- and postoperatively allows for a measurement of change in how patients feel, which is then attributable to the surgical intervention.

## Which PROMs should you use?

Oxford University Patient Reported Outcome Group<sup>4</sup> carried out a systematic review of PROMs for cosmetic surgery in 2013 and identified nine cosmetic surgery-specific PROMs and three generic PROMs.

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2 Department of Health. *Review of the Regulation of Cosmetic Interventions*. 2013. [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/192028/Review\\_of\\_the\\_Regulation\\_of\\_Cosmetic\\_Interventions.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf)

3 Devlin NJ, Appleby J. *Getting the most out of PROMs: putting health outcomes at the heart of NHS decision-making*. The King's Fund. 2010.

4 <http://phi.uhce.ox.ac.uk/home.php>

## Procedure-specific PROMs

The CSIC has reviewed the research on PROMs and has agreed that Q-PROMs represent the best choice for routine use in cosmetic surgery. There is a significant level of research evidence for the validity, reliability and usability of Q-PROMs within cosmetic practice.

The Q-PROMs that have been identified for use within cosmetic surgical practice are:

- » BREAST-Q – Augmentation mammoplasty
- » FACE-Q – Rhinoplasty
- » FACE-Q – Blepharoplasty
- » FACE-Q – Rhytidectomy
- » BODY-Q – Abdominoplasty
- » BODY-Q – Liposuction

The specific Q-PROM scales that you should use are listed in the Table below. Further information about the development and validation of the Q-PROMs is available on the following website: <https://qportfolio.org/publications/>. The website also includes User Guides that provide information about each Q-PROM and how to score their scales. It is best practice to collect patient-reported data both pre- and postoperatively. However, collection of postoperative data only is still valid.

Cosmetic Procedure	Q-PROM Module	Q-PROM Scale	Data Collection Timepoints
Breast augmentation	BREAST-Q – Augmentation Module	Satisfaction with Breasts	Pre and Post
Rhinoplasty	FACE-Q Aesthetics Module	Satisfaction with Nose Satisfaction with Face Overall	Pre and Post
Blepharoplasty	FACE-Q Aesthetics Module	Satisfaction with Eyes Adverse Effects Eyes Satisfaction with Face	Pre and Post Post Pre and Post
Rhytidectomy	FACE-Q Aesthetics Module	Satisfaction with Face Overall Adverse Effects Cheeks, Lower Face and Neck	Pre and Post Post
Abdominoplasty	BODY-Q	Satisfaction with Abdomen	Pre and Post
Liposuction	BODY-Q	Satisfaction with Body	Pre and Post

Use of the Q-PROMs requires completion of a licensing agreement. The use of Q-PROM scales in non-profit academic research and in clinical care is free of charge. The use of the Q-PROMs by “for-profit” organizations or for for-profit purposes (e.g., pharmaceutical companies, contract research organizations, ePRO companies, marketing) is subject to a licensing fee.

## Generic PROMs for cosmetic surgery

A review of the current evidence has concluded that there remains a lack of research validation for the use of any particular generic PROM within cosmetic practice. For this reason, CSIC has not suggested the use of a generic PROM within regular practice at this time. In the future, introduction of a suitably validated and reliable single measure may be considered.<sup>5</sup>

<sup>5</sup> Morley D, Jenkinson C, Fitzpatrick R. *A Structured Review of Patient-Reported Outcome Measures Used in Cosmetic Surgical Procedures*. University of Oxford. 2013.

# What do we know about the cosmetic surgery patient population?

There is evidence that cultural views within the UK are changing and that many young adults now find cosmetic surgery acceptable. This is reflected in a growing UK cosmetic procedures market.<sup>6</sup> Detailed information about those that seek surgery is not readily available, although we know that approximately 90% of surgery is carried out on women – and breast augmentation is the most popular choice.

Market research was carried out for the CSIC by Synergy Healthcare Research on a total of 448 people who have had, or were considering having, cosmetic surgery. This research showed some key themes, which are outlined below:

- » 54% of patients did not perceive this type of surgery as 'cosmetic' but instead 'corrective'
- » 26% felt they required surgery in order to improve their health
- » The commonest reasons for seeking surgery were improving overall appearance (51%) and increasing a person's confidence (49%).

When seeking information about a potential treatment:

- » 78% wanted information about the procedure
- » 17% wanted to know about the surgeon
- » 5% wanted to know about the clinic.

The market research also highlighted that patients felt that evidence of the impact of treatment in others (eg before/after pictures or surgeon/clinic recommendations) was some of the most important information required to make a decision prior to having a procedure.

Many saw patient feedback as the most valuable source of a rating system for surgeons or clinics.

Cluster analysis of the types of patients and their information needs was carried out as part of the market research. They identified four key types of person seeking surgery, which are outlined in the table below.

This market research shows how important data from PROMs may be to patients, especially prior to surgery when making a decision about whether or not to have a procedure.

Segment	% of respondents (n=448)	Median age (years)	% female	Types of information gathering	Reason for seeking surgery
Information averse	24%	30	59%	Low engagement: unlikely to proactively seek information	Seek to correct appearance
Selective safety information seekers	21%	50	90%	Discussion with surgeon is key source of information	Seek to correct appearance and feel more confident (NOT social factors)
Proactive information seekers	33%	40	66%	Cosmetic procedure consumers. Highest seekers of information, high use of digital media, wanting to look like a 'celebrity'	Seeking to enhance appearance/social life
Passive information seekers	22%	40	88%	Initial interest is in NHS options, clinic facilities and surgeon experience	Seeking to reduce signs of ageing

<sup>6</sup> Department of Health. *Review of the Regulation of Cosmetic Interventions*. 2013.

# Utilising data from PROMs within surgical practice

There are a wide range of benefits from collection of PROMs data that relate both to utilisation of benchmarking data at a service and clinician level but also by providing information to inform both patients and clinicians within individual consultations.

Although much of the evidence available from research on the benefit of data from PROMs comes from other areas of clinical practice, such as orthopaedics, cancer and mental health services, common sense indicates that much of this learning can potentially be extrapolated for use within cosmetic surgery.

## Measuring benefit of treatment

Patient satisfaction with the outcomes of cosmetic surgery is of singular importance. Technically perfect surgery cannot be considered a good result for a patient receiving a cosmetic procedure if they do not see the benefits postoperatively.<sup>7</sup>

## Quality improvement

Care is required when using data from PROMs, especially when looking at individual clinician-level performance, where the volume of completed pre and postoperative responses may be of insufficient number to calculate results of statistical significance. Despite this limitation, valuable information can be obtained from even simple analysis that can indicate areas of practice requiring further investigation or review.<sup>3</sup>

## Benchmarking services

If all providers routinely use PROMs in practice, as has happened in other areas within the NHS, benchmarking of the quality of care against the national average at unit level can be of great use in improving services and standardising care.

## Identifying potential outliers

If a number of patients treated by a consultant surgeon or within a team have unusually poor results, this prompts further enquiry. Care must be taken, of course, to avoid the assumption that this is the result of any one individual clinician, as opposed to organisational processes or other aspects of the care pathway. Following identification of an outlier, the next step would be to review all clinical, process and outcomes data relating to that clinician or team as part of the overall review of clinical performance, and then to use this to inform any decision regarding restriction of practice (or even referral to the General Medical Council).<sup>3</sup>

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7 F Urso-Baiarda, W Townley, OA Branford, RJ Rohrich. *Understanding how patients feel about their cosmetic surgery*. <https://personallyspeaking.wordpress.com/2015/02/11/proms-king-of-outcome-assessment-tools-understanding-how-patients-feel-about-their-cosmetic-surgery/> [last accessed 18 September 2015]

### **Reviewing care pathways**

The identification of positive outliers allow for investigation into differences in practice and the potential to share new and improved models of care.<sup>6</sup>

### **Supporting your case for change**

Engaging managers in discussions about improvements to services can be difficult for clinicians, and having data that shows the direct impact of an intervention on the patient can be very powerful.<sup>3</sup>

## **Value for money**

'Value for money' (VFM) is a term used to assess whether an organisation has obtained the maximum benefit from the goods and services it both acquires and provides, within the resources available to it.<sup>8</sup>

Value is important to all services and to patients and cannot be estimated by measuring the cost of a service by itself. In the independent sector, value is also likely to be of particular interest to the patient. The difference in PROMs data before and after a procedure is an important quality marker, although some caution must be used when estimating the potential gains. The value is more than cost; again, it should also take into account what would have happened to the patient if the procedure did not take place.<sup>3</sup>

## **Patient choice**

Our market research has shown that when choosing a healthcare provider there are several factors for which patients value information on the quality of care provided by hospitals. One of the most important of these is evidence on the likely the impact of treatment.<sup>3</sup>

### **Decide where and from whom to receive treatment**

There are many factors that are known to be important to patients when making a choice on which healthcare provider to choose. These vary from ease of access, quality of food, GPs recommendation and overall hospital facilities. Quality of care has been shown to be one of the crucial factors in shaping a patient's choices, but impact on their health as a result of treatment was found to be the single most important factor in choosing a healthcare provider.<sup>9</sup>

### **Judge the likely benefits of treatment in their own case**

As indicated in the evidence from the market research listed above, most respondents indicated that feedback from others was most useful when estimating the likely impact of treatment. Collating changes in PROMs scores for different procedures, linking this with basic demographic information about the patient type and providing it in an easy-to-understand format would be very valuable for potential patients during initial consultations.

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<sup>8</sup> University of Cambridge. Registry's Office [Online]. <http://www.admin.cam.ac.uk/offices/secretariat/vfm/guide.html> [last accessed 18 September 2015]

<sup>9</sup> Burge P, Devlin N, Appleby J et al. *Understanding Patients' Choices at the Point of Referral*. Technical report TR359-DOH. Cambridge. 2006.

## Shared decision-making and Informed consent

Analysis of outputs from PROMs at a local level is a powerful tool to enable discussion between patients and clinicians about likely benefits at the initial consultation.<sup>7</sup>

Publishing service- and clinician-level PROMs data should form part of the information that is provided to patients, in order for them to be able to make an informed choice about surgery and where it should take place. Essentially, this information becomes a patient decision aid.<sup>8</sup>

The importance of this type of information was supported by the results of the market research, which showed that the following aspects of information were either 'extremely' or 'very' important to respondents (total = 448):

- » Different surgical techniques/options available (69%)
- » List of questions to ask your surgeon (67%)
- » How to prepare for the procedure (65%)
- » How common is the procedure (62%)
- » Limitations of the procedure (60%)

Completion of preoperative PROMs can provide the patient and clinician with valuable information about perceptions of health status and can inform discussions on realistic benefits from surgery. This can also help to manage patients' expectations about the outcome of treatment.<sup>3</sup>

## Identification of patient sub-groups

Review of outcomes over a period of time can gather information about subtypes of patients who are unlikely to benefit from treatment.

In some orthopaedic practices, where PROMs have been collected routinely since 2009, providers have produced consultant-level scores. These have formed the basis for reviewing case notes in patients where improvements were not reported.<sup>10</sup>

Comparative analysis (between hospitals, and between clinicians within hospitals) of the 'before' PROMs data can also provide a starting point for further investigation of the 'threshold' decisions made by clinicians.<sup>3</sup>

Comparative analysis of the individual questions that comprise the PROMs scores will also be relevant, as responses to these questions are also likely to vary.<sup>3</sup>

## Identification of benefits of particular implants or surgical procedures

PROMs data has been used in other surgical specialties to assess differences between particular surgical techniques and type of implants. Work carried out with the use of PROMs in breast reconstruction following mastectomy, allowed surgeon level scores to be translated into descriptive labels that could inform them the areas requiring increased attention in their practice. For example, lower scores reflected women who found their breasts' shape to be

acceptable when clothed, whereas the highest scores represented women who report that their breasts are equal in size and shape when unclothed.<sup>11</sup>

In some orthopaedic practice, overview of PROM scores has been used to identify those implants associated with worst outcomes.<sup>7</sup>

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<sup>10</sup> Bassier MR. Benefits case study. HSCIC.

## **Informing Care Quality Commission inspection**

In September 2014, CQC introduced a new inspection methodology for acute trusts. One aspect of this is the formation of information data packs prior to inspection. These packs can be used to identify areas of care that may require specific attention during the inspection. PROMs are likely to form one of these data sources in the future.<sup>7</sup>

## **Surgeon appraisal and revalidation**

Use of evidence of impact from care, through analysis of Q-PROMs at a consultant level could provide much-needed evidence for whole practice appraisal.

## **Promoting your service**

Market research showed that 61% of patients (total = 448) were more likely to go to a clinic website for information prior to having a procedure, as opposed to only 39% seeking information from an independent source. Publication of evidence of impact through PROMs data could be a vital source of advertising information. BUPA (now Spire healthcare) has routinely collected PROMs on all elective surgery, and has used data about PROMs results in other areas on their websites, to promote the health-related quality-of-life benefits of the interventions they provided.<sup>3</sup>

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<sup>11</sup> Advances in the Use of Patient Reported Outcome Measures in Electronic Health Records.



# Additional supporting information

The following are freely available on the RCS website:

## Access to the Q-PROM tools

The Q Portfolio is free for non-profit use, but a license should be obtained at <https://qteam.mcmaster.ca/surveys/?s=9X73E834MCH4LPY3>. UK versions of the PROMs can also be accessed. There is a fee for for-profit/commercial use. MSKCC handles the for-profit licensing of many Q-PROMs and can be reached at [gotdtrm@mskcc.org](mailto:gotdtrm@mskcc.org)

For more information about the Q-PROM work, please visit: <https://qportfolio.org/>

## User manuals and data collection tools

User manuals and Q-PROM analysis spreadsheets are also freely available and can be accessed [here](#).

## Reporting of your Q-PROMs data

Information on how to submit data and how it will be reported will be available via the PHIN website (<http://www.phin.org.uk/>).

## Appendix 1: Quality and outcome measures to be launched by RCS

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Outcome measure	Details of data collection
Clinical quality indicators	Independent cosmetic surgery providers will be expected to collect these data items for all cosmetic surgical procedures
Patient reported outcome measures (PROMs)	To be collected pre- and postoperatively for certain cosmetic surgical procedures (augmentation mammoplasty, rhinoplasty, rhytidectomy, abdominoplasty, blepharoplasty and liposuction)
Consultation guidance and audit tool	A document to help guide patients through the preoperative consultation and a simple audit tool to check compliance