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Patient-reported outcomes study – Clinician Information

Introduction

An important aspect of this National Audit is our focus on using patient-reported outcomes as an integral part of the data collection process. This has three key advantages:

1. Patients will be able to report their own views on both their care pathway and those outcomes attained following mastectomy and breast reconstruction surgery.
2. All post-discharge data will be collected from patients, minimising the burden on individual units involved in prospective data collection.
3. All questionnaires will be distributed, collated and analysed centrally by the Audit team, without the need for further unit involvement.

This document aims to set out the methodology involved, and provide a detailed description of the areas to be covered by the three- and eighteen-month questionnaires.

Methods

Inclusion criteria:

All women with breast cancer undergoing unilateral mastectomy and / or unilateral primary breast reconstruction surgery are included. This may be with or without simultaneous symmetrisation surgery (e.g. contralateral augmentation, reduction or mastopexy).

All women undergoing prophylactic or risk-reducing surgery are excluded from the study.

Patient consent:

Explicit consent is only required for the patient-reported outcomes component of the Audit.

Consent is not required for collection of the prospective in-patient clinical data; as a National Cancer Audit we have obtained Patient Information Advisory Group (PIAG) Section 60 exemption.

Units will be asked to provide patients with a patient information leaflet and consent form pre-operatively. There will be three versions for the different pathways: mastectomy, mastectomy with immediate reconstruction, and delayed reconstruction.

If the patient wishes to participate, the signed form should then be filed in their case notes. That the patient has consented should be recorded on the paper datasheets provided (prior to transcription) or directly into the web-based server.

The questionnaires are only available in written English, and are to be completed by the patient themselves. If it is felt that the patient would be incapable of completing questionnaires, please record this along with the reason.

Questionnaire distribution:

By obtaining patient consent for this part of the National Audit, we will be able to use Office of National Statistics (ONS) mortality data and the NHS Strategic Tracing Service (STS) to ensure that the patient is alive and that we have their current and correct address. These checks will be carried out at both three and eighteen months prior to questionnaires being sent out by the Audit team.

Three-month questionnaires

There are three distinct versions for women who have undergone: mastectomy, mastectomy with immediate reconstruction, or delayed reconstruction.

With the exception of recording post-discharge complications, the three-month questionnaires do not measure clinical outcomes. They are primarily designed to assess satisfaction with the care provided during the patient pathway.

Section 1 - Dates

This confirms their date of birth, month and year of surgery, and records the date on which the form is completed.

Section 2 – Satisfaction with information provided

This asks about the type, format and quantity of information provided about mastectomy and breast reconstruction, and the woman's satisfaction with this information.

Section 3 – Satisfaction with options / choices

This asks about the options offered to the woman, the choices made with respect to mastectomy and breast reconstruction, and her satisfaction with these choices.

Section 4 – Pain management

This asks about the degree of pain experienced post-operatively and its management by the hospital staff.

Section 5 – Experiences after surgery

This asks primarily about post-discharge complications and additional cancer treatments undergone. In addition, it asks about access (if required) to psychology, physiotherapy and lymphoedema services after surgery.

Section 6 – Satisfaction with care

This asks about the woman's satisfaction with the care provided by her Consultant(s), other members of the clinical team, and that provided overall by the hospital.

Reporting of three-month questionnaire results

Results will be published in the Third Annual Report (January 2009).

Eighteen-month questionnaires

There are two distinct versions, for women who are post-mastectomy or post-reconstruction.

Their primary purpose is to measure patient-reported outcomes in these groups of women.

Section 1 – Dates

This confirms their date of birth, date of surgery, and the date on which the form is completed.

Section 2 – Experiences after surgery

This asks primarily about post-discharge complications and additional cancer treatments undergone, including secondary reconstructive procedures for the post-reconstruction group.

Section 3 – Cosmetic outcomes

This asks about satisfaction with appearance (clothed and unclothed), comfort with clothing, and the ability to wear fitted clothes in both groups.

Reconstructed women are additionally asked about their satisfaction with position, symmetry, softness, how natural their breast looks and feels, and how the reconstructed breast looks compared to before surgery. If applicable, they are also asked specifically about their donor site and implants.

Section 4 – Emotional well-being

This asks about how the woman feels in terms of confidence, self-worth, acceptance, normality, attractiveness, femininity, and being emotionally able to do things that she wants to do.

Section 5 – Pain and functional well-being

This asks about ongoing breast, chest, rib, neck, shoulder and arm pain. It also asks about tenderness, aching, tightness, pulling, movement, sleep and abdominal muscle function.

Section 6 – Sexual well-being

If applicable, this asks about how the woman feels in terms of their attractiveness and confidence (both clothed and unclothed), along with their satisfaction with their sex life.

Section 7 – Overall satisfaction with surgery

This asks about how they feel about the outcome of surgery, and whether the outcome matched their expectations.

Reporting of eighteen-month questionnaire results

Results will be published in the Fourth Annual Report (January 2010).

Further enquiries

Please contact Ranjeet Jeevan at rjeevan@rcseng.ac.uk or 0207 869 6619 if you have any queries regarding this part of the National Audit.