Development of a core outcome set for research and audit studies in reconstructive breast surgery

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Background: Appropriate outcome selection is essential if research is to guide decision-making and inform policy. Systematic reviews of the clinical, cosmetic and patient-reported outcomes of reconstructive breast surgery, however, have demonstrated marked heterogeneity, and results from individual studies cannot be compared or combined. Use of a core outcome set may improve the situation. The BRAVO study developed a core outcome set for reconstructive breast surgery.

Methods: A long list of outcomes identified from systematic reviews and stakeholder interviews was used to inform a questionnaire survey. Key stakeholders defined as individuals involved in decision-making for reconstructive breast surgery, including patients, breast and plastic surgeons, specialist nurses and psychologists, were sampled purposively and sent the questionnaire (round 1). This asked them to rate the importance of each outcome on a 9-point Likert scale from 1 (not important) to 9 (extremely important). The proportion of respondents rating each item as very important (score 7–9) was calculated. This was fed back to participants in a second questionnaire (round 2). Respondents were asked to reprioritize outcomes based on the feedback received. Items considered very important after round 2 were discussed at consensus meetings, where the core outcome set was agreed.

Results: A total of 148 items were combined into 34 domains within six categories. Some 303 participants (51.4 per cent) (215 (49.5 per cent) of 434 patients; 88 (56.4 per cent) of 156 professionals) completed and returned the round 1 questionnaire, and 259 (85.5 per cent) reprioritized outcomes in round 2. Fifteen items were excluded based on questionnaire scores and 19 were carried forward to the consensus meetings, where a core outcome set containing 11 key outcomes was agreed.

Conclusion: The BRAVO study has used robust consensus methodology to develop a core outcome set for reconstructive breast surgery. Widespread adoption by the reconstructive community will improve the quality of outcome assessment in effectiveness studies. Future work will evaluate how these key outcomes should best be measured.

*Members of the BRAVO Steering Group are co-authors of this study and can be found under the heading Collaborators.

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Introduction

Breast cancer affects almost 50,000 women in the UK each year1, up to 40 per cent of whom will require a mastectomy2. For some, the loss of a breast can be devastating and reconstructive breast surgery (RBS) is offered to improve outcomes3.

Decision-making in RBS, however, can be difficult. There are several procedures available, ranging in complexity from expander/implant-based reconstructions to more challenging autologous procedures4,5. Factors such as body habitus, co-morbidities and the need for postoperative radiotherapy6 may influence the choice of reconstructive method. However, the majority of
Table 1  Summary of methods used to develop a core outcome set

| Phase 1 | Identification of all outcomes that may be measured following reconstructive breast surgery |
|---------|-------------------------------------------------------------------------------------------------|
|         | Systematic literature searches to identify clinical outcomes, patient-reported and cosmetic outcomes |
|         | Qualitative interviews with patients and healthcare professionals regarding which outcomes they feel should be measured following reconstructive breast surgery |
|         | This produces a list of all potential outcomes |
|         | The list is grouped into outcome domains to avoid repetition |
|         | The domains inform questionnaire items to use in phase 2 |
| Phase 2 | Prioritization of outcomes by key stakeholders – Delphi survey |
|         | Stakeholders are surveyed and asked to prioritize each outcome |
|         | Results of the survey are fed back to stakeholders in a second survey (Delphi methods) and they are asked to reprioritize each outcome |
|         | Data are analysed by the research group using predefined criteria to reduce the list of information |
|         | This produces two outcome lists (from patients and healthcare professionals) ready for phase 3 |
| Phase 3 | Consensus meetings are held separately with key stakeholder groups |
|         | The items are presented to each group and items are rated as, ‘in’, ‘out’ or ‘unsure’ during anonymized voting |
|         | Items rated as ‘unsure’ are discussed and more voting is undertaken |
|         | The process produces two sets (1 selected by patients, 1 by professionals). These are compared and combined into one outcome set |

Patients and surgeons therefore face challenging decisions regarding the optimal type and timing of surgery. The provision of high-quality data, ideally from well designed, multicentre randomized clinical trials (RCTs) and prospective studies is central to this process. Systematic reviews summarizing the clinical, cosmetic and patient-reported outcomes of RBS, however, have demonstrated a paucity of well designed studies, and an inconsistent approach to outcome assessment and reporting in each of these areas. Cross-study comparison and meta-analysis is therefore difficult and the need for improvement in outcome reporting in RBS is increasingly being recognized.

The standardization of endpoints (core outcome sets) for use in effectiveness studies is one way in which inappropriate and non-uniform outcome reporting may be addressed. A core outcome set is defined as an agreed set of outcomes to be reported as a minimum in all studies of a particular condition. Uptake of a core outcome set has the potential to reduce reporting bias, create homogeneity in outcome reporting and improve meta-analysis. It is hypothesized that development of a core outcome set may result in similar improvements in the value of research in RBS.

The aim of the BRAVO (Breast Reconstruction And Valid Evidence) study was to use a robust consensus process to develop a core outcome set for effectiveness studies in RBS.

Methods

Development of the core outcome set involved three phases: phase 1, development of a questionnaire with a list of potential outcomes; phase 2, sequential surveys with key stakeholders using Delphi methods to prioritize outcomes; and phase 3, consensus meetings with patients and professionals to agree the core outcome set (Table 1, Fig. 1). Full ethical approval was obtained for the study (REC-11/SW/0305).

Phase 1: questionnaire development

A long list of outcomes was generated from systematic reviews of the clinical, cosmetic and patient-reported outcomes of breast reconstruction, and semistructured interviews with patients and professionals were undertaken as part of the BRAVE (Breast Reconstruction And Valid Evidence) study, which aimed to determine the feasibility of clinical trials in breast reconstruction. The list was constructed by two independent researchers extracting verbatim each of the outcomes reported in papers included in the systematic reviews. They scrutinized the transcripts of 62 semistructured interviews with patients (implant-based reconstruction, 11 patients; latissimus dorsi flap reconstruction, 10; abdominal flap reconstruction, 11) and professionals (oncoplastic breast surgeons, 11; plastic surgeons, 11; clinical nurse specialists, 11; psychologists, 2) conducted within the BRAVE study during which outcome selection for research studies was discussed. Duplicate items were removed and the outcomes categorized into domains by two independent researchers using the qualitative technique of content analysis, and dual extraction and categorization of outcomes with senior discussion if discrepancies occurred. A domain was defined as a broad class of outcome; for example, the domain wound-related problems included infection, wound dehiscence, skin necrosis and delayed wound healing. Domains were further categorized into overarching outcome themes or ‘categories’ using the same methodology; for example, systemic complications and...
Fig. 1 Summary of the development of a core outcome set for reconstructive breast surgery. *Donor-site symptoms and donor-site complications were merged into one item.
wound-related problems were classified as early complications and the identified domains were operationalized into a questionnaire item, which involved asking respondents how important it was to measure each item in research and audit studies in RBS. Each item was structured with the medical terminology in bold italics followed by a lay description, as in the example: ‘How important is it to assess implant-related complications – implant-related problems such as infection that would require the implant to be removed?’ This allowed the questionnaire to be read and understood by all stakeholders. Respondents were asked to score the importance of evaluating each item in effectiveness studies in RBS on a 9-point Likert scale from 1 (not important) to 9 (extremely important). The scoring system was selected after discussion with the study statistician and experts in core outcome set development to facilitate maximum discrimination between questionnaire items based on previous experience in this area, and has been used widely in this field\textsuperscript{14,32}. The questionnaire was piloted with patients and professionals to check face validity, understanding and acceptability.

**Phase 2: Delphi consensus methods**

Delphi survey methods, with anonymized feedback of results, involving key stakeholders were used to develop the core outcome set\textsuperscript{33}.

**Stakeholder selection**

Key stakeholders were defined as individuals who may be involved in decision-making for RBS and would have an in-depth understanding of which outcomes should be measured in research and audit studies in this area. These were identified by the BRAVO Steering Group as patients, breast and plastic surgeons, clinical nurse specialists and psychologists. The steering group elected \textit{a priori} to recruit patients and professionals in a 2:1 ratio such that patients’ views were represented preferentially when the groups were combined because RBS is a patient-selected optional intervention.

Patients were purposively sampled from three centres (Bristol, Liverpool and Glasgow). All women who had undergone RBS using expander/implants, latissimus dorsi or abdominal flaps as either immediate or delayed procedures, or who had undergone therapeutic mammoplasty, defined as reduction pattern wide local excision and contralateral symmetrization, within 5 years of the start of the study were eligible to participate. Maximum variation sampling\textsuperscript{35} with a sampling matrix was used to ensure adequate inclusion of all identified groups with regard to procedure type (implant, latissimus dorsi and abdominal flaps, therapeutic mammoplasty), timing of surgery (immediate, delayed), age at time of surgery (less than 45 years, 45–65 years, over 65 years), time since surgery (less than 2 years, 2–4 years, more than 4 years) and treatment centre, such that a complete breadth of perspectives was included. Attention was also paid to demographic factors such as educational background, employment and marital status to ensure that no group was excluded\textsuperscript{35}.

Professionals were recruited purposively from breast and plastic surgical units across the UK. Maximum variation sampling was used with regard to type of centre (teaching hospital \textit{versus} district general hospital), sex and duration of practice to ensure a comprehensive representation of views. \textit{A priori}, the aim was to recruit 200 patients, 30 breast surgeons, 30 plastic surgeons, 30 clinical nurse specialists and ten psychologists. This was detailed in the full protocol written for this study, which is available from the author.

**Delphi surveys**

Potential patient participants from all three centres were approached by post. Responders consenting to participate were sent a questionnaire with a prepaid envelope. Non-responders were sent a reminder 3 weeks later. Healthcare professionals (HCPs) at breast and plastic surgery centres in the UK were identified from previous research participation and recent publications. Each professional was contacted by post with a study invitation letter and questionnaire. Non-responders were sent a reminder 3 weeks later. Batches of invitations were sent until the desired sample size was achieved or until the sample pool had been exhausted.

The first-round questionnaires were analysed by calculating the proportions of participants rating each item as very important (score 7, 8 or 9). All respondents were sent a second-round questionnaire containing summary round 1 scores for each item; all feedback was anonymous. First-round non-responders were considered to have declined study participation and were not contacted again. In round 2, participants were asked to reprioritize the outcomes based on feedback from round 1. Participants were also asked to identify the seven outcomes of most importance, those ‘core’ to measure in effectiveness studies in RBS.

**Phase 3: consensus meetings**

Separate consensus meetings for key stakeholders were held to prevent professionals dominating the meetings. The patients’ meeting was held in Bristol in February 2014, and the professionals’ meeting in Liverpool in July 2014. All patients and professionals who had completed the round 2 questionnaire were invited to attend the consensus meetings. Travel expenses were offered to encourage...
Data analysis

Items were retained for round 2 if more than 50 per cent of respondents in either the patient or the professional group, or both groups combined, scored the item 7–9, and less than 15 per cent of either group or both combined scored the item as not important (score 1–3). The patient and professional groups were analysed separately initially and also together. The separate analysis ensured that outcomes important to individual stakeholder groups were not excluded from the analysis prematurely.

In round 2, participants received group feedback from round 1 in the form of the percentage of respondents rating each item as very important (score 7–9), in addition to their own score for that item from round 1. It was hypothesized that the type of feedback received would influence how items were prioritized in round 2. The feedback was therefore provided from either the participants’ group alone (patients or professionals) or both groups separately (patients and professionals) via random allocation to allow this to be explored. Full details of the impact of different stakeholder feedback on responses in round 2 will be reported separately.

Round 2 responses were analysed with more stringent criteria. Items rated as very important (score 7–9) by at least 70 per cent of respondents in either the patient or professional group, or both groups combined, were retained and carried forward for discussion at the phase 3 consensus meetings. These cut-offs were selected for pragmatic reasons as there is currently no consensus regarding cut-off selection in Delphi studies. Before the consensus meetings, criteria for consensus regarding item inclusion and exclusion were agreed. Items scored as extremely important (score 8 or 9) by more than 70 per cent of participants and not important (score 1–3) by less than 15 per cent were definitely included in the final core outcome set. Items considered as extremely important (8 or 9) by less than 30 per cent of participants were definitely excluded from the final set. Ratification was sought for the items definitely included or excluded following the initial vote, and items that were scored 8 or 9 by between 30 and 70 per cent of participants were discussed by the group in an attempt to reach consensus. A second round of anonymous interactive voting followed the discussion to determine whether these remaining items should be included or excluded from the final core outcome set based on the predetermined criteria. If uncertainty remained after the second vote, further discussion was facilitated to allow consensus to emerge. The consensus meetings concluded with all participants ratifying the core outcome set for RBS.

Results

Phase 1: questionnaire development

Review of all data sources identified 148 individual outcomes that were categorized using content analysis into 34 domains. These were further classified using the same methodology into six categories: short and long-term complications, symptoms, psychosocial well-being, practical issues and cosmesis. Each domain was operationalized to generate a questionnaire item (Table S1 and Appendix S1, supporting information).
Table 2  Demographics of participants in the BRAVO study

|                        | Round 1 | Round 2 | Consensus meetings |
|------------------------|---------|---------|--------------------|
| **Patient participants** |         |         |                    |
| Centre                 |         |         |                    |
| Bristol                | 77 (35-8) | 68 (35-8) | 13 (87)            |
| Liverpool              | 74 (34-4) | 62 (32-6) | 2 (13)             |
| Glasgow                | 64 (29-8) | 60 (31-6) | 0 (0)              |
| Age (years)*           |         |         |                    |
| < 45                   | 21 (9-8)  | 20 (10-5) | 2 (13)             |
| 45–65                  | 166 (77-2)| 146 (76-8)| 9 (60)             |
| > 65                   | 28 (13-0) | 24 (12-6) | 4 (27)             |
| Median (range)         | 54 (29–76)| 54 (29–76)| 55 (43–76)         |
| Time since breast reconstruction (months)†|         |         |                    |
| 0–24                   | 72 (33-5) | 67 (35-3) | 4 (27)             |
| 25–48                  | 88 (40-9) | 75 (39-5) | 10 (67)            |
| > 48                   | 49 (22-8) | 42 (22-1) | 1 (7)              |
| Unknown                | 6 (2-8)   | 6 (3-2)  | 0 (0)              |
| Median (range)         | 33 (4–97) | 32 (4–97) | 35 (21–72)         |
| **Timing of surgery**  |         |         |                    |
| Immediate reconstruction| 110 (51-2)| 100 (52-6)| 10 (67)            |
| Delayed reconstruction  | 80 (37-2) | 66 (34-7) | 4 (27)             |
| Therapeutic mammoplasty| 25 (11-6) | 24 (12-6) | 1 (7)              |
| **Type of surgery**    |         |         |                    |
| Implant-based reconstruction| 54 (25-1)| 47 (24-7) | 4 (27)             |
| Latissimus dorsi flap  | 59 (27-4) | 52 (27-4) | 5 (33)             |
| Abdominal flap         | 74 (34-4) | 64 (33-7) | 5 (33)             |
| Therapeutic mammoplasty| 25 (11-6) | 24 (12-6) | 1 (7)              |
| Other‡                 | 3 (1-4)   | 3 (1-6)  | 0 (0)              |
| **Education**          |         |         |                    |
| Compulsory only        | 65 (30-2) | 57 (30-0) | 3 (20)             |
| Additional education   | 139 (64-7)| 125 (65-8)| 11 (73)            |
| Unknown                | 11 (5-1)  | 8 (4-2)  | 1 (7)              |
| **Marital status**     |         |         |                    |
| Single                 | 23 (10-7) | 18 (9-5)  | 0 (0)              |
| Married/living with partner| 153 (71-2)| 138 (72-6)| 13 (87)            |
| Separated or divorced  | 28 (13-0) | 26 (13-7) | 2 (13)             |
| Widowed                | 6 (2-8)   | 4 (2-1)  | 0 (0)              |
| Unknown                | 5 (2-3)   | 4 (2-1)  | 0 (0)              |
| **Employment status**  |         |         |                    |
| Full- or part-time employment| 130 (60-5)| 118 (62-1)| 11 (73)            |
| Homemaker/housewife    | 17 (7-9)  | 11 (5-8)  | 0 (0)              |
| Retired                | 45 (20-9) | 42 (22-1) | 3 (20)             |
| Not working            | 16 (7-4)  | 13 (6-8)  | 0 (0)              |
| Unknown                | 7 (3-3)   | 6 (3-2)  | 1 (7)              |
| **Professional participants** | n = 88 | n = 69 | n = 23 |
| **Sex**                |         |         |                    |
| F                      | 46 (52)   | 37 (53-6) | 14 (61)            |
| M                      | 42 (46)   | 32 (46-4) | 9 (39)             |
| **Profession**         |         |         |                    |
| Consultant breast surgeon| 40 (45)  | 35 (51)  | 11 (48)            |
| Consultant plastic surgeon| 21 (24)  | 15 (22)  | 5 (22)             |
| Clinical nurse specialist| 20 (23)  | 15 (22)  | 6 (26)             |
| Psychologist           | 7 (8)     | 4 (6)    | 1 (4)              |
| **Time in post (years)**|         |         |                    |
| < 5                    | 18 (20)   | 12 (17)  | 4 (17)             |
| 5–10                   | 30 (34)   | 24 (35)  | 9 (39)             |
| 10–20                  | 29 (33)   | 25 (36)  | 9 (39)             |
| > 20                   | 8 (9)     | 6 (9)    | 0 (0)              |
| Unknown                | 3 (3)     | 2 (3)    | 1 (4)              |

Values in parentheses are percentages unless indicated otherwise. *At time of breast reconstruction. †At time of entering study. ‡Patients undergoing bilateral complex surgery who could not be classified into any one group.
% rating item ‘very important’ (score 7–9)

| Items combined in final core outcome set. HCP, healthcare professional. |

Table 3  Summary of item scores by round and outcome of consensus meetings by item

| Problems that may occur in the first month after operation | Consensus meetings (item voted ‘in’, ‘out’ or ‘unsure’) | Round 1 | Round 2 |
|----------------------------------------------------------|--------------------------------------------------------|---------|---------|
| Systemic complications 71.6%                          | Patients (n=215) HCPs (n=88)            | 60      | 68.3    |
| Bleeding-related complications 83.3%                   | Patients (n=190) HCPs (n=69)            | 54.4    | 50.8    |
| Wound-related complications 85.1%                      | All (n=303)                               | 64.6    | 56.3    |
| Implant-related complications 87.7%                    | Yes*                                     | 90      | 85.4    |
| Flap-related complications 89.7%                       | Yes*                                     | 91      | 88.2    |
| Major complications 92.1%                              | Yes*                                     | 92.6    | 92.6    |

Problems that may occur in the months or years after operation

| Long-term wound-related complications 69.8%          | Yes*                                     | 66.7    | 55.5    |
| Long-term implant-related complications 83.0%       | Yes*                                     | 69.6    | 55.5    |
| Long-term flap-related complications 81.3%          | Yes*                                     | 77.7    | 77.3    |
| Donor-site complications 82.2%                      | Yes*                                     | 82.7    | 77.3    |
| Unplanned surgery for any reason 83.7%              | Yes*                                     | 82.1    | 82.2    |

Symptoms that may occur after reconstructive breast surgery

| Fatigue 42.8%                                         | No                                       | 28.7    | 24.2    |
| Breast symptoms 75.4%                                 | No                                       | 62.4    | 56.0    |
| Arm and shoulder symptoms 73.5%                       | No                                       | 67.7    | 65.0    |
| Implant-related symptoms 72.5%                        | No                                       | 62.4    | 61.4    |
| Donor-site symptoms 79.3%                             | Yes*                                     | 72.5    | 70.4    |
| Self-esteem 81.4%                                     | Yes*                                     | 83.5    | 84.4    |
| Body image 84.7%                                      | Yes*                                     | 85.6    | 87.1    |
| Normality 86.1%                                       | Yes*                                     | 89.4    | 89.5    |
| Emotional well-being 83.7%                            | Yes*                                     | 87.8    | 86.8    |
| Sexual well-being 77.9%                               | Yes*                                     | 72.0    | 73.3    |
| Quality of life 87.4%                                  | Yes*                                     | 92.5    | 93.7    |

Practical issues relating to reconstructive breast surgery

| Physical well-being 80.5%                             | Yes*                                     | 82.1    | 84.9    |
| Recovery time 73.5%                                   | No                                       | 66.0    | 59.8    |
| Duration of the procedure 48.6%                       | No                                       | 28.0    | 24.2    |
| Time to complete reconstruction 66.7%                 | No                                       | 47.3    | 41.2    |
| No. of procedures required 75.9%                      | No                                       | 69.0    | 63.4    |
| Clothing issues 65.9%                                  | No                                       | 66.1    | 65.2    |
| Financial issues 54.2%                                 | No                                       | 39.2    | 36.7    |
| Economic issues 35.1%                                  | No                                       | 23.9    | 27.8    |

Issues relating to the appearance of the reconstructed breast

| Patient-reported cosmetic outcome 91.6%               | Yes*                                     | 92.1    | 95.3    |
| Objective cosmetic outcome 76.2%                      | No                                       | 74.8    | 67.2    |
| Cosmetic appearance assessed by patient’s partner 56.3%| No                                       | 51.4    | 47.4    |
| Women’s cosmetic satisfaction 92.6%                   | Yes*                                     | 92.6    | 94.2    |

*Carried forward to meeting on basis of patient scores. †Items combined in final core outcome set. HCP, healthcare professional.

Phase 2: Delphi consensus methods

A total of 434 patients from three high-volume breast units were invited to participate in round 1. Of these, 281 (64.7 per cent) responded; 39 (9.0 per cent) declined. Of 242 (55.8 per cent) who consented to participate, 215 (88.8 per cent) completed and returned the questionnaire. Participants had a median age of 54 (range 29–76) years and had undergone the full range of reconstructive techniques (expander/implants 54, 25.1 per cent; latissimus dorsi flaps 59, 27.4 per cent; abdominal flaps 74, 34.4 per cent) and therapeutic mammoplasty (25, 11.6 per cent). These were carried out as immediate (110, 51.2 per cent)
and delayed (80, 37.2 per cent) procedures at a median of 33 (range 4–97) months before the study (Table 2). Some 156 professionals were invited to participate, of whom 88 (56.4 per cent) completed and returned the questionnaire. Respondents included 40 (45 per cent) breast surgeons, 21 (24 per cent) plastic surgeons, 20 (23 per cent) specialist nurses and seven (8 per cent) psychologists. No professional actively declined to participate in the study (Table 2).

In round 1, none of the items met the exclusion criteria, so all 34 items were carried forward to round 2. All round 1 respondents were invited to participate in round 2. Of these, 259 (190 patients, 88.4 per cent; 69 HCPs, 78 per cent) completed and returned the questionnaire. Demographics of patient and professional participants were similar between rounds 1 and 2 (Table 2). Round 1 scores were also similar between responders and non-responders to round 2 scores for both stakeholder groups (data not shown).

Provision of feedback, advice regarding reprioritization of the most important items and application of the more stringent cut-off criteria resulted in the exclusion of 15 items following round 2 (Fig. 1). Nineteen items were carried forward for discussion in the phase 3 consensus meetings. These included three items (bleeding, wound-related complications and donor-site symptoms) that were excluded by the professional group, but retained on the basis of patients’ views. Scores for individual items in each round are shown in Table 3.

**Phase 3: consensus meetings**

Of the 190 patients invited, 16 agreed to participate in the consensus meetings, and 15 who were representative of the patient stakeholder group attended the meetings (Table 2). Following the initial vote, five items (major complications, normality, quality of life, physical well-being and women’s cosmetic satisfaction) were definitely included in the core outcome set and four items were definitely excluded (Table 3). The remaining ten items were discussed and revoted on. This led to four further items (unplanned surgery, emotional well-being, self-esteem, and a composite of donor-site complications and symptoms termed ‘problems’) being included in the final core outcome set and five items being excluded. All group members ratified the nine-item core outcome set.

Of the 69 professionals invited, 25 agreed to participate in the consensus meeting and 23 who were representative of the professional stakeholder group attended the meetings (Table 2). Following the first vote, five items (major complications, implant-related complications, quality of life, normality and women’s cosmetic satisfaction) were definitely included and four items were definitely excluded from the core outcome set based on the prespecified criteria (Table 3). The remaining ten items were discussed and revoted on. This led to three further items (flap-related complications, unplanned surgery, and a composite of donor-site complications and symptoms) being included in the core outcome set and the remaining six being excluded. All members of the professional group then ratified the eight-item core outcome set.

Combining the patient and professional sets generated a final 11-item core outcome set (Fig. 1, Table 4).

**Discussion**

The BRAVO study has used rigorous consensus methods involving key stakeholders to develop a core outcome set for use in effectiveness studies in RBS. Effectiveness studies are important to both patients and healthcare...
providers as they determine whether interventions work in the real world, and therefore inform both clinical decision-making and health policy. The core outcome set was developed following detailed scrutiny of the literature and qualitative work with patients and professionals to identify all potentially relevant outcomes, followed by an iterative consensus process using the views of over 250 key stakeholders representative of women undergoing RBS and professionals involved in the provision of specialist care. The final core outcome set therefore includes 11 items that are important to both patients and professionals, such as major complications requiring readmission or reoperation, unplanned surgery, quality of life, normality, self-esteem, physical and emotional well-being, and women’s satisfaction with the cosmetic outcome of their surgery. It is now recommended that researchers use the core outcome set to inform the selection of measures used in future effectiveness studies in RBS.

The concept of standardizing outcomes to reduce the use of inappropriate outcomes, eliminate reporting bias and facilitate data synthesis is not new. The OMERACT (Outcome Measures in Rheumatoid Arthritis Clinical Trials) initiative championed the methodology by describing a ‘filter of truth, discrimination and feasibility’ to determine outcome selection in rheumatoid arthritis over 20 years ago, but it is only recently that the potential for core outcome sets to improve the value of research has been realized in a broader context. To this end, the UK Medical Research Council-funded COMET (Core Outcome Measures in Effectiveness Trials) Initiative (www.comet-initiative.org) was launched in January 2010, with the ultimate aim of developing core outcome sets for all conditions and treatments. COMET aims to support the development of core outcome sets by bringing together researchers with an interest in the development, reporting and application of core outcome sets, with a view to establishing robust and efficient methods by which new sets may be developed. COMET provides a means of identifying existing, ongoing and planned core outcome sets, and provides a free, publicly available internet-based resource containing over 306 studies relevant to the development of core outcome sets to facilitate the exchange of ideas and information. Over 300 core outcome sets are currently under development, and standardized endpoints have already been proposed for use in adjuvant breast cancer treatment trials.

Although this work is novel and was conducted using robust consensus methodology with key stakeholders who were representative of women undergoing reconstructive surgery and the professionals involved in the provision of specialist care, there are some methodological limitations. There is no agreement regarding the optimal methodology for the development of a core outcome set and it is possible that an alternative consensus method may have led to a different final set of items. However, given the scope and setting of this core outcome set, the Delphi process and consensus meetings were considered appropriate and enabled a much larger sample of participants to be involved than other purely face-to-face methods would have allowed. The response rate in round 1 was only 51–4 per cent, suggesting that the use of questionnaires and consensus meetings may not have appealed to all stakeholders. Non-responders may have valued different outcomes to the participants. Data were not collected on these individuals as they did not give consent to participate, so variations between responders and non-responders could not be explored fully. The use of a robust maximum variation sampling strategy, however, ensured that all pre-defined stakeholder subgroups were sampled adequately such that the sample was as representative as possible of the women undergoing reconstructive surgery and professionals involved in their care. It was therefore unlikely that any major group was not represented. It is also possible that the composition of the stakeholder groups may have influenced the outcomes selected for inclusion in the final core outcome set. Although early subgroup analysis suggested that different specialties may initially prioritize different outcomes, as the study progressed there was less heterogeneity in the outcomes selected. This convergence of views is likely to represent the fact that the selected items in a core outcome set are only the baseline minimum number to include in all studies, and the stakeholders appreciated that future studies in their particular field could result in the inclusion of additional and specific items as required.

The main limitation of the study is that it was conducted solely within the UK, which has a state-funded healthcare system. It is unclear to what degree the outcomes valued in this setting would be concordant with those valued in other healthcare systems or cultural settings. This may limit the generalizability of the results. Finally, the core outcome set was developed specifically for RBS without reference to breast cancer or its treatment. As many women undergo RBS following a diagnosis of malignancy, there may be a need to develop and integrate a breast cancer surgery core outcome set to ensure that outcomes that are important in this context are included.

This work has identified a list of core outcome domains to be measured and reported as a minimum in effectiveness studies in RBS. As a core outcome set is not itself a measurement instrument, the next crucial step will be to determine how these key outcomes should be measured;
the recently published OMERACT Filter 2.0 provides guidance in this area. Literature reviews will be required to generate a list of available measurement instruments and, where no instruments are available, these will need to be developed. Application of further consensus methods will therefore be necessary to determine what constitutes major, implant-related and flap-related complications, and how these should be defined. In addition, the development of a robust instrument to evaluate domains such as normality will be vital if the core outcome set is to be applied in a meaningful way. Application of the principles of truth, discrimination and feasibility or, more formally, the COSMIN (COmmittee on Standards for the selection of health Measurement INstruments) checklist may help to inform the selection of the most appropriate instrument for domains such as physical well-being and health-related quality of life where more than one instrument could be used. This additional work will be essential for the core outcome set in RBS to gain widespread acceptance and use.

The BRAVO study has used robust consensus methodology to develop a core outcome set for effectiveness studies in RBS. Its widespread adoption by the reconstructive community will improve the quality of outcome assessment and the value of the work to patients and surgeons. Future work will be necessary to evaluate how these key outcomes should best be assessed.

**Collaborators**

Members of the Steering Group are collaborators in the study: S. T. Brookes (Centre for Surgical Research, School of Social and Community Medicine, University of Bristol, Bristol, UK), S. J. Cawthorn (Bristol Breast Care Centre, North Bristol NHS Trust, Bristol, UK), D. Harcourt (Centre for Appearance Research, University of the West of England, Bristol, UK), R. Macefield (Centre for Surgical Research, School of Social and Community Medicine, University of Bristol, Bristol, UK), R. Warr (Department of Plastic Surgery, North Bristol NHS Trust, Bristol, UK), E. Weiler-Mithoff (Canniesburn Plastic Surgery Unit, Glasgow, UK), P. R. Williamson (Medical Research Council (MRC) North West Hub for Trials Methodology Research, Department of Biostatistics, University of Liverpool, Liverpool, UK) and S. Wilson (Department of Plastic Surgery, North Bristol NHS Trust, Bristol, UK).

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**Supporting information**

Additional supporting information may be found in the online version of this article:

Table S1 Categorization of items into domains and categories (Word document)

Appendix S1 Round 1 Delphi questionnaire (Word document)

**Snapshot quiz 15/10**

**Question:** A 5-year-old girl underwent elective left inguinal herniotomy. The photograph shows the operative findings. How should this be managed?

The answer to the above question is found on p. 1387 of this issue of *BJS*.

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