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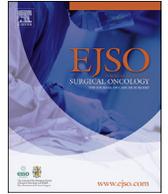
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Adherence to best practice consensus guidelines for implant-based breast reconstruction: Results from the iBRA national practice questionnaire survey

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ABSTRACT

Introduction: The 2008 National Mastectomy and Breast Reconstruction Audit demonstrated marked variation in the practice and outcomes of breast reconstruction in the UK. To standardise practice and improve outcomes for patients, the British professional associations developed best-practice guidelines with specific guidance for newer mesh-assisted implant-based techniques. We explored the degree of uptake of best-practice guidelines within units performing implant-based reconstruction (IBBR) as the first phase of the implant Breast Reconstruction Evaluation (iBRA) study.
Methods: A questionnaire developed by the iBRA Steering Group was completed by trainee and consultant leads at breast and plastic surgical units across the UK. Simple summary statistics were calculated for each survey item to assess compliance with current best-practice guidelines.
Results: 81 units from 79 NHS Trusts completed the questionnaire. Marked variation was observed in adherence to guidelines, especially those relating to clinical governance and infection prevention strategies. Less than half (n = 28, 47%) of units obtained local clinical governance board approval prior to offering new mesh-based techniques and prospective audit of the clinical, cosmetic and patient-reported outcomes of surgery was infrequent. Most units screened for methicillin-resistant staphylococcus aureus prior to surgery but fewer than 1 in 3 screened for methicillin-sensitive strains. Laminar-flow theatres (recommended for IBBR) were not widely-available with less than 1 in 5 units having regular access. Perioperative antibiotics were widely-used, but the type and duration were highly-variable.

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Conclusions: The iBRA national practice questionnaire has demonstrated variation in reported practice and adherence to IBBR guidelines. High-quality evidence is urgently required to inform best practice.

Introduction

National Institute for Health and Care Excellence (NICE) guidelines recommending the routine offer of immediate breast reconstruction to women requiring mastectomy for breast cancer were introduced in 2002 [1], but in 2008, the National Mastectomy and Breast Reconstruction Audit (NMBRA) demonstrated marked variation in the availability and outcomes of breast reconstruction in the UK [2–5].

There was a need to standardise practice and to improve outcomes for patients. In response to the NMBRA findings. The British breast and plastic surgical professional associations (Association of Breast Surgery, ABS and British Association of Plastic Reconstructive and Aesthetic Surgeons, BAPRAS) subsequently developed 'Oncoplastic Breast Reconstruction: Guidelines for Best Practice' [6]. The guidelines were based on consensus opinion informed by best published evidence. They covered all types of breast reconstruction and included recommendations for each stage of the clinical pathway from diagnosis to post-operative follow-up. The guidelines included 25 quality criteria (QC) and were proposed as a standardized 'framework that should be used to assess current practice and deliver high quality care' [7].

Implant-based breast reconstruction (IBBR) is the most commonly performed reconstructive procedure in the UK [8] and a rapidly-evolving technique. Traditionally a two-stage procedure, the introduction of biological (e.g. acellular dermal matrix, ADM) and synthetic (e.g. titanium-coated polypropylene) meshes for lower pole coverage offered patients the possibility of single-stage, direct-to-implant reconstruction without the need for painful and time-consuming expansions and a second operation [9]. The more natural-looking ptotic breasts created using mesh also resulted in increasing numbers of women being offered the procedure and led to a decline in more traditional latissimus dorsi flap-based reconstruction [8,10].

Despite the proposed benefits of mesh, concerns were raised that complication rates in mesh-assisted IBBR were unacceptably high [11–13]. The ABS and BAPRAS therefore published supplemental guidance on mesh-assisted implant reconstruction [14] to support surgeons offering the technique. The guidelines included recommendations for patient selection and unit and organization criteria for centres wishing to be commissioned to perform mesh-assisted reconstruction. Evidence to support the recommendations was acknowledged to be lacking and in the absence of evidence, the guidelines were based largely on expert opinion [14]. The need for outcome data was highlighted and one of the main aims of the guidance was to identify clinical standards and quality indicators against which centres offering the technique could audit their results [14]. Key recommendations for the practice of IBBR from both the Oncoplastic Breast Surgery Guidelines for Best Practice [6] and supplemental ADM guidelines [14] are summarized in Table 1.

The practice of IBBR has continued to develop and over 85% of immediate breast reconstructions in the UK are now implant-based [8]. Despite the widespread adoption of mesh-assisted reconstruction into routine clinical practice, robust evidence for the safety and effectiveness of the techniques remains elusive [15,16]. Various biological and synthetic meshes have been introduced with

significant variations in cost and in the absence of evidence of effectiveness, product selection is dependent on surgeon preference.

High-quality research is therefore required to establish best practice in IBBR [15,16] and the iBRA (implant Breast Reconstruction evAluation) study is a national trainee-led multicentre cohort study which aims to inform the feasibility, design and conduct of a randomized clinical trial in IBBR [17]. The first phase of iBRA was a national practice questionnaire (NPQ) where we aimed to explore current practice [10] and the degree to which units performing IBBR in the UK adhered to existing best practice guidelines to inform the design of a future trial.

Methods

The national practice questionnaire (NPQ, Appendix 1) was developed in February 2014 by members of the iBRA steering group based on a comprehensive review of the literature [15], current professional guidelines [6,14] and clinical expertise. It included unit demographic data and items assessing adherence to quality criteria and practice recommendations made in the joint ABS/BAPRAS oncoplastic breast reconstruction [6] and ADM reconstruction guidelines [14] with particular focus on clinical governance issues such as audit and infection reduction strategies to inform future trial design. The questionnaire was piloted with surgeons at two hospitals to ensure face and content validity prior to distributing the questionnaire nationally.

All breast and plastic surgical units performing mastectomy with or without immediate breast reconstruction in the UK were eligible for inclusion. Trainees were invited to participate via the Mammary Fold breast trainees' group and the Reconstructive Surgery Trials Network (RSTN). ABS and BAPRAS endorsed the study and encouraged units to participate. Each participating trainee was required to identify a consultant lead in their unit. The trainee completed the questionnaire with this consultant ensuring that responses reflected the practice of the unit as a whole, rather than those of an individual surgeon.

Data were collected and managed using REDCap electronic data capture tools hosted at University of Edinburgh [18].

Analysis

Descriptive summary statistics were calculated for each survey item to evaluate adherence to each guideline or recommendation. Categorical data was summarized by counts and percentages. Continuous data was summarized by median, interquartile range (IQR) and range. No data imputation methods were used for items with no response and when a unit did not complete a specific section of the questionnaire, it was assumed that the unit did not offer that approach. Statistical Analysis Software (SAS® 9.1.3; SAS Institute Inc., Cary, NC, USA) was used for all analyses. Free text responses were collated and analysed using content analysis.

Results

Participation

81 responses were received from 79 NHS Trusts. Two trusts had independent responses from the breast and plastic surgical units.

Table 1
Summary of current best practice guidelines for implant-based breast reconstruction.

Guideline	Source
Organizational criteria for units wishing to be commissioned for ADM assisted reconstruction	
• Approval from New Procedure Policy/Clinical Governance Board specific to each hospital Trust	Joint ABS/BAPRAS ADM guidelines
• Patient awareness that they are being offered a relatively new procedure	
• Clear pathway and service arrangement to manage drains up to 3 weeks post-operatively	
• Ongoing audit of all complications arising from all breast reconstruction operations	
• Agreement to participate in future national clinical ADM audit and submit all cases	
Unit criteria for units wishing to be commissioned for ADM assisted reconstruction	
• Experience breast reconstruction team	Joint ABS/BAPRAS ADM guidelines
• Prospective record and photographic collection	
• Guidelines to staff on post-operative management with agreed protocols of care (drains, follow-up, antibiotics)	
• All cases should be audited prospectively	
Participation in research and audit	
• Eligible patients are invited to take part in local and national clinical trials and audits of OPBS	OPBR-guidelines for best practice
• Target: Screening for eligibility for clinical trials and national audits occurs in 100% of OPBS patients (QC22)	
Target standards from the National Mastectomy and Breast Reconstruction Audit (NMBRA)	
Pre-operative guidelines and proposed quality standards	
Medical photography	OPBR - guidelines for best practice
• Medical photography (pre-and post-operative) is part of the clinical record	
• Target: Medical photography is offered in 100% of BR patients (QC4)	
Information provision	OPBR-guidelines for best practice
• Patients receive information in a format and level of detail that meets their individual needs. The letter to the GP summarises the information provided and is copied to the patient	
• Target: Written information about the risks and benefits of breast reconstruction is provided to 90% of mastectomy patients	
Peri-operative guidelines and recommendations to reduce the risk of infection	
Preoperative MRSA and MSSA screening	OPBR-guidelines for best practice and NICE Surgical Site Infection Clinical Guideline 2008
• Patients are MRSA (+MSSA in implant cases) screened prior to admission and have topical suppression where positive in accordance with national/local policy	
• Target: MRSA screening occurs in 100% of patients prior to admission (QC7)	
Peri-operative antibiotic use	
• Patients undergoing implant-based reconstruction are given a single intravenous dose of appropriate antibiotic(s) on induction	
• The antibiotic spectrum of prophylaxis should cover both Gram positive and Gram negative bacteria, particularly the most common cause of post-operative infection, Staphylococcus aureus	
• Regimens may differ between hospitals and local prescribing policies but flucloxacillin and gentamicin or cefuroxime are appropriate options. In truly penicillin allergic patients, clindamycin and gentamicin or vancomycin/	
• teicoplanin and gentamicin may be considered. The latter regimen should be used for patients known to be colonised with MRSA	
• Target: All patients undergoing implant-based reconstruction receive intravenous antibiotics on induction (QC11)	
Use of laminar flow theatres	
• Ultra Clean Ventilation (UCV, 'laminar flow') is recommended in OPBS where such facilities are available:	
• If unavailable, the number of personnel in theatre and 'theatre traffic' should be actively reduced to a minimum to reduce turbulent air flow and minimize the bacterial load in the theatre air.	
• A policy of minimal movement of personnel within the operating theatre is a recommended principle whatever the theatre ventilation system	
Skin preparation	
• 2% chlorhexidine with 70% isopropyl alcohol with tint provides the best skin decontamination for the most prolonged period. It should be applied to the whole area to be decontaminated, but sparingly to avoid pooling.	
• Povidone iodine or isopropyl alcohol are less effective alternatives.	
Implant cavity irrigation	
• The implant cavity may be washed out to remove any necrotic material	
Minimal implant handling and glove change	
• The implant should be opened just before use to reduce contamination from airborne bacteria.	
• The surgeon should use a 'minimal or no touch' technique where possible to reduce the risks of contamination of the implant. Care should be taken when changing gloves. A safe option is to leave existing gloves on and double glove just before handling the implant or to wear two pairs of gloves from the start of the procedure, removing the outer gloves before handling the implant.	
Post-operative guidelines and proposed quality standards	
Antibiotic use for suspected post-operative infection	Joint ABS/BAPRAS ADM guidelines
• Infection <10% of patients require antibiotics within 3 months of their surgery for suspected infection	
Assessment of clinical outcomes	OPBR-guidelines for best practice
• Implant loss, unplanned return to theatre, unplanned readmission (QC15, QC16, QC17) at 3 months are assessed and audited	
• Post-operative complications, return to theatre and length of stay are documented in departmental BR database	
• Target: There is a regular audit and discussion of all patients with post-operative complications (QC18)	
Assessment of patient reported outcomes	OPBR-guidelines for best practice
Patients' satisfaction with BR outcome is measured using standardized assessment tools:	
• Satisfaction with information at 3 months (QC19); Target: Satisfaction with information provision is reported by 80% of patients at 3 months	
• Satisfaction with appearance clothed at 18 months (QC20); Target: At 18 months, over 90% of BR patients report satisfaction with their appearance clothed (QC20)	

Each of these was considered an independent unit with different practices despite stemming from the same trust. 67 of 144 (47%) breast units and 14 of 53 (26%) plastic units in the UK participated. Responses were received from both high and low volume centres with participating units performing a median of 35 IBBR per year (range 0–230). Of the participating breast units, 23/67 (34%) had on-site plastic surgical services with access to free-flap reconstruction. Demographics of participating units are summarized in Table 2.

Compliance with clinical governance guidelines for mesh-assisted procedures

79/81 (98%) units provided details of the types of IBBR performed. Of these 60/79 (76%) performed biological mesh (BM) assisted reconstruction and 24/79 (30%) offered patients IBBR with synthetic mesh (SM).

Compliance with recommendations for the introduction of mesh-assisted IBBR was low. Only 28/60 (47%) units offering BM and 4/24 (17%) units offering SM had sought approval from a 'New Techniques and Devices' or other appropriate clinical governance committee prior to introducing the technique. Formal written unit protocols regarding the management of patients undergoing mesh-assisted reconstruction were uncommon with only a third (n = 21, 35%) of units using BM and less than 20% (4/24, 17%) of those using SM reporting having agreed policies for the management of drains and antibiotics in this group. Specific written information for patients undergoing mesh-assisted reconstruction was similarly lacking with only a third (23/60, 38%) of units offering BM and a quarter (4/24) of units offering SM reporting that this was available locally.

Routine prospective audit of the clinical, cosmetic and patient-reported outcomes of reconstructive surgery is a key recommendation, but compliance was also low. Only half of units (31/60 BM units and 12/24 SM units) prospectively audited the short and long-term clinical outcomes of mesh-assisted IBBR with a further 25–30% (15/60 (24%) BM units and 7/24 (29%) SM units) reporting that audit was undertaken retrospectively. Cosmetic outcomes were audited by approximately half of units (33/60, 55% BM and 10/24, 42% SM units) but less than a third assessed patient-reported outcomes (Table 3).

Procedure coding for reimbursement is important for the integrity of national data sets and units were asked how mesh-assisted IBBR was coded locally. Two-thirds of respondents provided either an OPCS (Office of Population Censuses and Surveys) or a HRG (Healthcare Resource Group) code and the responses varied. Commonly-reported OPCS codes were of 'skin-sparing mastectomy' (B27.6) with 'insertion of prosthesis for breast' (B30.1) and 'reconstruction of the breast, Other specified' (B30.8). The generic HRG code JA16Z 'Mastectomy and breast reconstruction' was often used but between 20% (12/60 BM units) and 30% (7/24 SM units) units offering mesh-assisted IBBR reported being unsure how the procedure was coded (Table 3).

Compliance with strategies to reduce infection

80/81 (99%) units responded to items relating to compliance with best-practice for infection prevention. Most units (66/80, 83%)

Table 2
Demographics of participating units.

Unit characteristic	N = 79
Types of breast reconstruction offered	
Implant-based reconstruction	79 (100)
Pedicled flaps	
Latissimus dorsi	76 (96)
Pedicled TRAM	31 (39)
Free flaps	
DIEP	34 (43)
Other autologous (e.g SGAP, IGAP, TUG, SIEA)	24 (30)
Therapeutic mammoplasty	75 (95)
Revisional surgery	77 (97)
Number of staff performing breast and reconstructive surgery	
Breast surgery	
Number of consultant surgeons with an interest in breast surgery (FTE, median, IQR, range)	3.0 (2.0–3.8) (0.0–7.0)
Number of consultant breast surgeons who perform reconstructive surgery (FTE, median, IQR, range)	2.5 (2.0–3.0) (0.0–7.0)
Plastic surgery	
Number of consultant plastic surgeons with an interest in breast surgery (FTE, median, IQR, range)	1.0 (0–3.0) (0.0–21.0)
Number of consultant plastic surgeons who perform reconstructive surgery (FTE, median, IQR, range)	2.0 (1.0–3.0) (0.0–10.0)
Number of immediate implant-based breast reconstructions performed per year (median, IQR, range)	35 (20–50) (0–230)
Percentage of immediate breast reconstructions that are implant-based (median, IQR, range)	70.0 (50.0–80.0) (0.0–100.0)
Approaches to implant-based reconstruction offered	
Standard 2 stage submuscular placement	60 (75.9)
Reduction pattern with dermal sling	66 (83.5)
Acellular dermal matrix assisted reconstruction	59 (74.7)
Other non-dermal biological-assisted reconstruction	19 (24.1)
TiLOOP assisted reconstruction	19 (24.1)
Other synthetic assisted reconstruction	8 (10.1)

DIEP – deep inferior epigastric perforator; FTE – full time equivalent; IQR – interquartile range; TRAM – transverse rectus abdominis myocutaneous flap.

Table 3
Adherence to clinical governance guidelines for implant-based breast reconstruction.

	ADM (n = 60, %)	TiLOOP (n = 24, %)
Approval from the New Techniques and Devices Committee/Clinical Governance Board prior to introducing technique		
Yes	28 (47)	4 (17)
No	14 (23)	13 (54)
Unsure	18 (30)	5 (21)
Missing	0 (0)	2 (8)
Formal written unit protocol or agreed guidelines for the management of patients undergoing mesh assisted (e.g regarding antibiotic prophylaxis and drain management)?		
Yes	21 (35)	4 (17)
No	34 (57)	15 (63)
Unsure	5 (8)	2 (8)
Missing	0 (0)	3 (13)
Availability of specific written information available to women considering mesh assisted reconstruction		
Yes	23 (38)	6 (25)
No	30 (50)	15 (63)
Unsure	6 (10)	1 (4)
Missing	1 (2)	2 (8)
Audit of outcomes		
Short term complications (<3 months)		
Prospectively	31 (52)	12 (50)
Retrospectively	15 (25)	7 (29)
Not audited	11 (18)	3 (13)
No response/missing	3 (5)	2 (8)
Long term complications (>3 months)		
Prospectively	24 (40)	9 (38)
Retrospectively	15 (25)	8 (33)
Not audited	17 (28)	4 (17)
No response/missing	4 (7)	3 (13)
Cosmetic outcomes using pre and post-operative photographs		
Prospectively	24 (40)	6 (25)
Retrospectively	9 (15)	4 (17)
Not audited	24 (40)	10 (42)
No response/missing	3 (5)	4 (17)
Patient reported outcomes		
Prospectively	6 (10)	2 (8)
Retrospectively	8 (13)	6 (25)
Not audited	44 (73)	14 (58)
No response/missing	2 (3)	2 (8)
Procedure coding		
OPCS Codes		
B27.4 Total mastectomy NEC	1	0
B27.6 Skin-sparing mastectomy	9	2
B29 Reconstruction of breast	2	2
B29.8 Reconstruction of breast, Other specified	13	6
B30 Prosthesis for breast	1	2
B30.1 Insertion of prosthesis for breast	10	5
B30.8 Prosthesis for breast, Other specified	1	0
S37.4 Xenograft of skin NEC	1	0
Y27.3 Xenograft to organ NOC	2	0
Y27.6 Prosthetic graft NOC	0	1
Y36.2 Introduction of therapeutic implant into organ	1	0
B3014/B3013 Mastectomy and immediate reconstruction using a fixed prosthesis (B3013) expandable prosthesis (B3014)	1	0
HRG codes		
JA16Z Mastectomy and breast reconstruction	7	1
Unsure/no specific code	12	7
Missing	20	8

screened patients for methicillin-resistant Staphylococcus aureus (MRSA) prior to implant surgery but less than a third (25/80, 31%) screened for the methicillin-sensitive strain, MSSA. Use of ultra clean ventilation is recommended for implant cases but just 1 in 5 centres (15/80, 19%) routinely had access to laminar flow theatres. Skin preparation with 2% chlorhexidine with 70% isopropyl alcohol is the recommended but almost 20% of units (14/80, 18%) reported using iodine preparations for skin decontamination and a further third (27/80, 34%) reported the selection of skin preparation to be surgeon dependent. Surgeon glove change prior to implant handling was routinely performed (59/80, 74%) but mastectomy pocket wash to remove debris was standard practice in just 60% of

units (47/80) (Table 4). In line with best practice guidelines, all units reported the use of prophylactic antibiotics in IBBR but significant variability was seen in both the type and duration of antibiotics used. Broad-spectrum antibiotic prophylaxis with coverage of both Gram-positive and Gram-negative organisms is recommended and while most units reported using appropriate regimens either alone (e.g co-amoxiclav) or in combination (e.g teicoplanin and gentamicin), one in 10 units used narrower spectrum drugs such as flucloxacillin only (6/60, 10%). Few units (8/60, 8% BM units and 2/24, 8% SM units) adhered to the recommended single intravenous dose at induction. Duration of antibiotic courses following both BM and SM-assisted reconstruction were highly-variable ranging for

Table 4
Use of strategies to reduce risk of infection.

Strategy	N = 80 (%)
Routine pre-operative screening	
MRSA	
Yes	66 (83)
No	4 (5)
Missing	10 (13)
MSSA	
Yes	25 (31)
No	45 (86)
Missing	10 (13)
Proportion of implant reconstruction cases performed in a laminar flow theatre	
None	38 (48)
Approximately 25%	7 (9)
Approximately 50%	6 (8)
Approximately 75%	3 (4)
All cases	15 (19)
Missing	11 (14)
Type of skin preparation solution routinely used in patients having implant based reconstruction	
Aqueous iodine	11 (14)
Alcoholic iodine	3 (4)
Chlorhexidine	19 (24)
2% chloraprep	10 (13)
Surgeon dependent	27 (34)
Missing	10 (13)
Use of cavity irrigation following mastectomy prior to implant insertion	
Yes	47 (59)
No	5 (6)
Surgeon dependent	18 (23)
Missing	10 (13)
Surgeon glove change (or equivalent) prior to implant handling	
Yes	59 (74)
No	3 (4)
Surgeon dependent	8 (10)
Missing	10 (13)
Antibiotic use for mesh based reconstruction	
Biological mesh assisted implant reconstruction	N = 60
Antibiotic choice	
Co-amoxiclav only	33
Flucloxacillin only	6
Flucloxacillin and gentamicin	5
Co-amoxiclav in combination with another antibiotic (e.g. gentamicin)	3
Teicoplanin and gentamicin	3
Cefuroxime	2
Flucloxacillin and ciprofloxacin	1
Flucloxacillin and teicoplanin	1
Teicoplanin only	1
Benzylpenecillin and flucloxacillin	1
Benzylpenecillin and gentamicin	1
Not specified	5
Antibiotic duration	
One dose only	5
<24 h post-operative antibiotics	6
2 days	1
3 days	1
5 days	7
7 days	5
7—14 days	1
14 days	2
Until drains are out	25
Variable/surgeon dependant	4
Not stated	5
Synthetic mesh assisted implant reconstruction	N = 24
Antibiotic choice	
Co-amoxiclav only	13
Flucloxacillin and gentamicin	2
Co-amoxiclav in combination with another antibiotic (e.g. gentamicin)	2
Teicoplanin and gentamicin	2
Teicoplanin only	1
Flucloxacillin/metronidazole/gentamicin	1
Surgeon dependant	1
Antibiotic duration	
One dose only	2
Up to 24 h post-operative antibiotics (2—3 post operative doses)	4
2 days	1
5 days	2

Table 4 (*continued*)

Strategy	N = 80 (%)
6 days	1
7 days	3
7–10 days	1
7–14 days	1
Until drains are out	7
Variable/surgeon dependant	1
Not stated	1

MRSA — methicillin resistant staphylococcus aureus; MSSA — methicillin sensitive staphylococcus aureus.

24 h to 14 days with oral antibiotics frequently continued until the surgical drains were removed (BM 25/60, 40%; SM 7/24, 29%) (Table 4).

Discussion

The iBRA national practice questionnaire suggests that adherence to current best practice guidelines for IBBR in the UK is poor. Few units reported obtaining clinical governance approval prior to offering the new technique; having unit-specific protocols for the management of patients undergoing mesh-assisted procedures or specific written information for patients considering surgery. Despite offering techniques with limited evidence for safety or effectiveness and guidelines recommending robust prospective evaluation of surgical outcomes, routine audit of cosmetic and patient reported outcomes was infrequent. Clinical outcomes were more commonly audited but this was often undertaken retrospectively. Procedure coding was highly variable making future study of the procedure through routinely available data sources such as Hospital Episode Statistics (HES) difficult. Despite the significant impact of infection and implant loss, adherence to current best-practice guidelines to minimize these complications is inconsistent [6]. Strategies such as MRSA screening; glove changes and peri-operative antibiotic usage were standard practice in many units, but few units screened for MSSA or had access to laminar flow for implant cases and antibiotic choice and duration was variable. There is therefore a need for units to consider implementing the best practice guidance and for high quality research to establish best practice.

Guidelines aim to reduce variability and standardise practice to improve outcomes for patients but despite these potential benefits [19], compliance with clinical guidelines in many settings [20] including breast [21] and plastic surgery [22] is known to be poor. Reasons why guidelines are not implemented in practice for this have been extensively investigated [20,23] and are likely to be multifactorial. One element key to successful implementation, was guideline validity and users' confidence that the guidelines were evidence-based [23]. Evidence to support the practice of breast reconstruction in general and IBBR in particular is lacking. This is openly acknowledged in both the oncoplastic [6] and ADM [14] guidelines and the lack of evidence to support proposed 'best' practice may partially explain why observed compliance with the guidelines is poor. A recent review [24] evaluated the evidence for infection prevention strategies in IBBR, many of which are currently considered best practice. The review found evidence to support the use of antibiotics; MRSA/MSSA screening; mastectomy pocket irrigation and surgeon glove change in reducing the risk of infection, but suggested the evidence to support the use of laminar flow and recommendation of specific skin preparation solutions in IBBR to be less strong [24]. Evidence regarding the optimal duration of antibiotics for infection prevention is also lacking. A recent single-centre RCT of two-stage IBBR with ADM compared infection rates in patients receiving 24 h of antibiotic treatment vs. continuing antibiotics until the surgical drains were removed [25]. This non-inferiority study which included 112 patients, demonstrated no significant difference in infection rates between the treatment groups (19.4% vs 22.0%). These results conflicted with earlier observational studies which suggest significant benefits with extended antibiotics in ADM-assisted reconstruction [26]. More research is needed and well-designed multicentre prospective studies and ideally RCTs are required to establish best practice.

This study has identified poor compliance with best practice guidelines for IBBR in the UK but several factors require consideration. This is a national practice survey and it is possible that the reported practice differs from actual practice. As the survey suggests poor compliance with guidelines however, this is unlikely. It is also possible that the survey responses reflected the practice of a single surgeon rather than the unit as a whole. While this is possible, a significant proportion of units reported 'surgeon dependent' practice which suggested the views of the whole unit were included. Overall response rate was relatively low with only 50% of breast units and 25% of plastic surgical units in the UK completing the survey. This suggests that plastic surgical units were relatively underrepresented but the poor response rate may reflect the fact that the majority of IBBR in the UK is now performed by breast rather than plastic surgeons. Plastic surgical units therefore may not have perceived the study to be relevant to their practice. Despite relatively low response rates the study population represents a geographically diverse sample that includes data from both high and low volume centres and those with and without on-site specialist plastic surgical services. This suggests that the results reflect an accurate snap-shot of broad national practice.

While it may be justifiable that surgeons do not adhere to guidelines that they do not perceive to be evidence-based or cannot comply with recommendations due to lack of organizational infrastructure (e.g access to theatres with laminar flow systems), failure of units to comply with clinical governance recommendations such as obtaining appropriate local approvals prior to offering a new technique; providing specific written information for patients considering surgery and failure to routinely audit the results of the new technique is a previously unappreciated finding and harder to defend. Adopting new techniques and devices into practice without appropriate evaluation should not be acceptable and in the wake of recent controversy surrounding the use of mesh in gynaecological procedures [27], attention is increasingly focused on the need for transparent and robust evaluation of novel interventions, particularly if meshes are used. The IDEAL [28] (Idea, Development, Exploration, Assessment and Long-term study) framework provides a methodology by which this may be achieved and the iBRA-NET initiative supported by the professional associations ABS and BAPRAS aims to promote the development and delivery of IDEAL phase 2a/2b studies in reconstructive breast surgery using a multicentre collaborative approach. Early phase protocol-driven prospective studies and registries of new techniques can provide early safety data, capture shared learning and determine if and when an intervention is sufficiently stable for formal evaluation, ideally in the context of a well-designed trial.

The project is still in the development phase but breast and plastic surgeons will need to work together and commit to the concept of 'no innovation without evaluation' if this approach is to become standard practice.

There is a need for high quality evidence to inform best practice in all areas of breast reconstruction but implant-based surgery is an area where this is particularly lacking. The iBRA study [17], which aims to inform the feasibility, design and conduct of a future trial in IBBR may be the first important step in generating this evidence. The prospective cohort stage of iBRA has recruited over 2000 patients from 70 centres across the UK and suggests that surgeons are willing to evaluate when appropriate resources and infrastructure are available. iBRA is the largest prospective study of new approaches to IBBR worldwide and so in addition to informing key trial feasibility parameters such as outcome selection and sample size, it is also anticipated that the dataset will provide a significant resource for exploring best practice. This data will inform the 'Getting it Right First Time' (GIRFT) initiative in breast surgery (http://gettingitrightfirsttime.co.uk/surgical-specialty/breast-surgery/) which aims to improve the quality of care within the NHS by reducing variation and disseminating best practice.

Conclusions

Compliance with breast practice guidelines for IBBR in the UK is variable. Reasons for this are likely to be multifactorial but the lack of high-quality evidence to support practice together with a lack of infrastructure to meet recommendations may partially explain these findings. Units' failure to comply with clinical governance recommendations, in particular registration of new procedures and prospective audit of outcomes was a previously unanticipated finding and potentially a cause for concern. A development of surgical culture with a commitment to a policy of 'no innovation without evaluation' and a focus on undertaking high-quality collaborative research is urgently needed to guide and support best practice in breast reconstruction.

Author contributions

SM analysed the data and wrote the first draft of the paper; EJC designed the study provided methodological and statistical expertise and analysed the data; PW designed the study provided methodological and statistical expertise for the study; MG inputted on the study design and provided plastic surgical and collaborative expertise and leadership; LW designed the study and provided surgical expertise; JS designed the study and provided surgical expertise; JB designed the study, was involved in gaining grant funding, read and appraised the manuscript; NB designed the study, refined the questionnaire based on pilot experience and provided surgical expertise; RC designed the study and provided surgical and methodological expertise and critically reviewed the manuscript; ST designed the study and questionnaire and provided surgical expertise; SP designed the study and questionnaire, wrote the initial proposal, provided trainee collaborative expertise and critically revised the manuscript; CH designed the study, developed the protocol and provided surgical expertise and leadership. SP and CH are joint senior authors on the paper All authors read and approved the final manuscript.

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Conflicts of interest statement

The authors have no conflicts of interest to declare.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.ejso.2018.01.098.

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