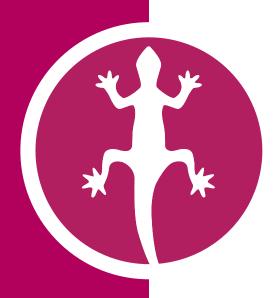
The British Association of Plastic Reconstructive and Aesthetic Surgeons



First UK National Flap Registry Report

2019

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in collaboration with











funded by The British Association of Plastic Reconstructive and Aesthetic Surgeons

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The British Association of Plastic Reconstructive and Aesthetic Surgeons operates the UK National Flap Registry in partnership with Dendrite Clinical Systems Limited. The Association gratefully acknowledges the assistance of Dendrite Clinical Systems for:

- building, maintaining & hosting the web registry
- data analysis and
- · publishing this report

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Introduction

It is a privilege and honour to present the UK National Flap Registry First Report. It has taken six years from inception of the registry to delivery of this first report, with data from over 5,500 cases from 97 hospitals across the United Kingdom. This registry, and certainly the first report, would not have been possible without data entry by flap reconstruction colleagues from various surgical specialties. Often these cases are long and physically demanding. The UKNFR team is very grateful to all of you who, at the end of a strenuous operating day, have taken the time to enter data, so that ultimately, we can improve the care we provide to our patients. Contributors can continue to be reassured that all data in the report remains anonymised throughout.

In a year marked by escalation of polarised divisions within our society over Brexit, this report has been a unifying force amongst flap reconstruction surgeons. The motivation for individuals across the collaborating specialties has come with a shared belief in the need to verify and improve clinical standards and a desire to breakdown historic specialty barriers. Thank you to surgical colleagues from BAPRAS, BAOMS, BAHNO and ABS who have helped with this report, interpreting the graphs, tables and charts in a manner that is clinically relevant and avoids inherent problems of over interpretation of data. A special thanks to the Dendrite team, in particular, Robin Kinsman, Senior Data Analyst, for working tirelessly on the production of this report.

The UKNFR team is forever indebted to Graeme Perks, BAPRAS President 2013–2014, as without his stewardship and vision, the UK National Flap Registry would have never come to fruition. Professor Andrea Pusic was an early collaborator and we are grateful to her for guidance in integrating the Breast-Q questionnaire into the registry. Thank you to subsequent BAPRAS presidents, Nigel Mercer, David Ward and Mark Henley, who have continued to provide support and make this report possible. Our special thanks to the Presidents of ABS, BAOMS, BAHNO and BSSH and the respective association secretariats for encouraging the use of this registry amongst their memberships. We are beholden to the Breast GIRFT (Getting It Right First Time) leads for championing UKNFR during breast GIRFT hospital visits. We now have over 180 surgeons regularly entering data into the registry.

UKNFR is the first national registry of its type in the world to collect data on all major pedicled and free flap operations. Data entry is voluntary, and it is acknowledged that unit data in this first report may not be a true representation of the case load of each participating unit. However, this report is the first step in a process that will span years. In the words of Carly Fiorina, former CEO Hewlett-Packard:

The goal is to turn data into information, and information into insight.

It is hoped that ease of data entry, the ability to import data from existing third-party databases *via* an Upload-My-Data module and the usefulness of a surgeon dashboard as a personal audit of performance in real-time for appraisal and revalidation, will see increasing participation from surgeons in the United Kingdom.

on behalf of the UKNFR Team Anita Hazari, UK National Flap Registry Audit Lead

the UKNFR Team Richard Cole

Andrew Schache Mike Nugent Clare Fowler Michael Ho



Executive summary

The aim of the UK National Flap Registry (UKNFR) is to collect information about all major free and pedicled flap operations carried out in the United Kingdom and, through that, to assess the quality of care we provide for our patients. Participation in audit is part of professional practice, and integral to appraisal and revalidation as required by the GMC. This audit will eventually allow appropriate comparison of clinical performance with national and international standards, and provide useful data on changing trends in flap reconstruction.

In overview

- This is the first report of the UK National Flap Registry.
- The first patient record was added to the UKNFR on 1 August 2015.
- Up to 8 August 2019, 5,751 operation records had been added to the UKNFR, with over 180 registered consultant users actively adding data to the registry.
- Cases have been included from 97 private and NHS hospitals in England, Wales, Northern Ireland and Republic of Ireland. Surgeons in Scotland are awaiting permission to join this project from the Public Benefit and Privacy Panel (PBPP) for Health and Social Care.
- Participating speciality associations include the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS), the British Association of Oral and Maxillofacial Surgeons (BAOMS), the British Association of Head and Neck Oncologists (BAHNO), the Association of Breast Surgery (ABS) and the British Society for Surgery of the Hand (BSSH).

Case-mix and indications

- The majority of operations were for cancer, mostly with the reconstruction being performed at the time of the tumour excision; the other large group involved traumatic injuries, mostly to the limbs.
- Of the 5,021 records compromising the group for the main analysis, 50.1 % were breast operations, 32.2% head & neck, the rest were limbs, trunk and perineum operations.

Risk factors and co-existing conditions

- Risk factors were selected from previously published work on causes of compromised flap survival, unplanned re-operation and increased post-operative length-of-stay (LoS).
- Other technical variables may also influence these outcomes.
- Significantly more breast reconstruction patients had no risk factors than any of the other groups.
- Patients undergoing head & neck surgery were much more likely to have 3 or more risk factors when compared to the other groups.

Data completeness

- At least 12 of the 14 risk factors data-items were completed in over 75% of records.
- At least 7 of the 8 **operation** data-items were completed in 85% of records.
- Incomplete data limited some analyses.

Outcomes

Interpretation of the data has taken into account that some records may be incomplete and that not every case from each unit will have been included. There were variations according to recipient site in the key outcomes:

- Overall total flap survival: breast 97.6%, head & neck 94.2%, limbs 94.5%, trunk and perineum 94.2%.
- Unplanned re-operation rate for the donor site: similar in all recipient groups at 4%.
- Unplanned re-operation rate for the recipient site: breast 7.0%, head & neck 10.9%, limb 13.4%, trunk and perineum 9.4%.
- Re-operations to the recipient site were recorded as specific data-items, including partial or total removal of the flap, graft or second flap and are useful particularly when the impact of partial flap loss is considered.

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- Average LoS in days: breast 4.7, head & neck 18.6, limb 12.9, trunk and perineum 11.5.
- **Duration of surgery:** significantly more head & neck operations took >9 hours compared to the other flap procedures.
- Patency rates: anastomotic patency of blood vessels is an objective measure of surgical outcome in free tissue transfer. More couplers were used in breast reconstruction, constituting 81% of end-to-end vein anastomoses, whereas in head & neck surgery couplers were used in 58% of end-to-end vein anastomoses with over 97% patency rates.
- Outcomes were also analysed according to other groupings, such as risk factors or co-existing conditions: smoking, diabetes and ASA score ≥3 were all associated with a significantly increased flap failure rate.
- The majority of flaps were from a single donor site to a single recipient site (85.0% of operations).
- The most common donor flap in breast reconstruction (77.5% of operations) was the deep inferior epigastric perforator flap (DIEP).
- The majority of breast reconstructions were delayed (49.0%) *i.e.*, after completion of cancer treatment, compared to immediate (45.2%) *i.e.*, mastectomy and reconstruction performed at the same time.
- The most common donor flaps in head & neck reconstructions were radial forearm flaps (29.0%), anterolateral thigh flaps (20.9%) and fibula flaps for bone defects (18.1%).
- The majority of head & neck reconstructions were performed at the same time as the cancer resection (75.4%).
- The most frequently used flaps in lower limb reconstruction were antero-lateral thigh (24.7%) and gracilis flaps (22.9%).
- In perineum reconstruction, the most commonly used flaps were gracilis (23.0%) and vertical rectus abdominis myocutaneous (16.1%).
- After breast reconstruction, Patient Reported Outcome Measures (PROMS) were measured using the Breast-Q questionnaire at 6 months. Using a benchmark of a Breast-Q score of ≥70 (range 0–100) to define satisfaction, 72.5% of patients were satisfied with the breast reconstruction, 83.5% were satisfied with the outcome and 87.8% were satisfied with the information that they were given. Though a further questionnaire was sent out at 18 months after reconstruction, the numbers of returned questionnaires were inadequate for analysis in this first report.

The future

With increasing numbers of UKNFR users, together with capture of a greater proportion of each participant's activity, issues with case ascertainment and sample bias should be reduced. For the purposes of this report, patient records included in the analysis should be considered to be a sample of activity and therefore cannot be assumed to be truly representative. Patient-related or operation-related parameters, other than the designated risk factors, which may also be shown to influence outcome can be included in future analyses.

The next iteration of the registry will include defined categories of partial flap survival, and therefore a clearer reporting of the process of flap reconstruction rather than its current binary representation. This specifically relates to head & neck flap surgery, and lower limb reconstructions.

Future iterations will also include information on whether or not Enhanced Recovery After Surgery (ERAS) was applied to flap reconstruction patients. ERAS is a multi-modal, multi-disciplinary, evidence-based approach to the care of the surgical patient for quicker recovery after major surgery,

Conclusions

The UKNFR has seen a steady uptake and increase in the number of patient records entered, and in the number of users from multiple surgical specialties.

Over 5,000 flap reconstructions have been recorded in all anatomical sites up to August 2019.

Data analysis allows preliminary reporting of individual unit outcomes in comparison with database averages but, without accurate denominators, conclusions regarding performance cannot yet be made.



Foreword

In an era of evidence-based practice, BAPRAS is delighted that an initiative of unprecedented inter-specialty collaboration has resulted in this ground breaking UK National Flap Registry Report. The quantity and quality of the data contained within it will provide a unique resource to permit benchmarking and evolution of surgical practice.

On behalf of BAPRAS, I would like to congratulate Anita Hazari, Richard Cole and our colleagues in ABS, BAOMS, BAHNO and BSSH who have been outstanding in their endeavours.

The UK National Flap Registry offers all surgeons undertaking flap reconstruction the opportunity to engage in reflective practice and to contribute to ever improving outcomes simply by contributing to the project and entering data appropriately. The greater the engagement the more robust the data will become and the more our patients will benefit.

To have achieved registration of over 5,000 flaps within 4 years is a terrific achievement of which all concerned can be justifiably proud.

The findings are encouraging in reflecting best practice and satisfactory outcomes, but the data also indicates areas of practice such as in the consideration of co-morbidities where continued collaborative working has the potential to significantly improve outcomes. I commend this report to you as the first stage in a new era of reconstructive surgical practice and look forward to future developments.

Mark Henley FRCS (Plast)
BAPRAS President

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Comment

Patients put their trust in surgeons, often at the most difficult time of their lives. It has always been my view that in return for that trust:

all surgeons have a professional, moral and social responsibility to know what they are doing and how well they are doing it..

Beyond the philosophical there is a practical element. All surgeons want to improve their skills and practice. That aspiration is greatly enhanced by data: data on technical aspects of surgery, data on clinical outcomes and data on patient experience. It's this data that forms the baseline for personal and organisational quality improvement. But data is only of any value if it is used.

There are several striking things about this report.

The first is that this is the result of a collective endeavour between the NHS and the independent sector driven by a coalition of respected specialist associations. Importantly the funding has come from surgeons themselves, so they have a vested interest in the future growth and success of the enterprise. This is a very powerful combination.

Secondly, the presentation of personal and comparative data through online benchmarking gives the data a reality and utility in day to day practice that will only grow as the data richness improves. It will catalyse improvement and add value to consent, appraisal and revalidation.

Thirdly, the seamless ability to acquire the patients' views on outcomes through mobile connectivity will have particular value in specialties where there are often genuine choices and decisions to be made by patients.

Finally, this first report on flap reconstruction surgery in the United Kingdom describes outstanding national results across a range of measures.

This is a world first. The British Association of Plastic, Reconstructive and Aesthetic Surgeons should be commended for leading this collaborative effort.

In my view, data entry to this registry should be a peer driven prerequisite for any surgeon or institution wishing to undertake such complex surgery.

Prof. Sir Bruce Keogh KBE

Former National Medical Director (2007-18)



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Contributors

Hospitals represented in the data

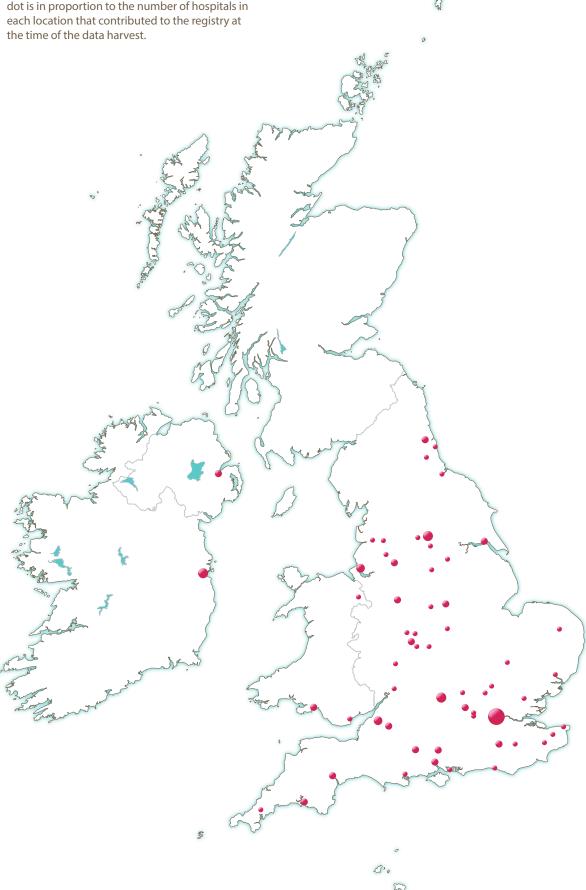
- Addenbrooke's Hospital, Cambridge
- Aintree University Hospital, Liverpool
- Belfast City Hospital
- BMI Bath Clinic
- BMI Sarum Road Hospital, Winchester
- BMI The Chaucer Hospital, Canterbury
- BMI The Priory Hospital, Birmingham
- BMI The Shelburne Hospital, High Wycombe
- Bradford Royal Infirmary
- Bristol Royal Hospital for Children
- Castle Hill Hospital, Hull
- Churchill Hospital, Oxford
- Cromwell Hospital, London
- Derriford Hospital, Plymouth
- Doncaster Royal Infirmary
- Freeman Hospital, Newcastle
- Gloucestershire Royal Hospital, Gloucester
- Guy's Hospital, London
- HCA The Harley Street Clinic, London
- HCA The Lister Hospital, London
- Hull Royal Infirmary
- Ipswich Hospital
- James Cook University Hospital, Middlesbrough
- John Radcliffe Hospital, Oxford
- Leeds General Infirmary
- Leicester Royal Infirmary
- Lister Hospital, Stevenage
- London Clinic
- Mater Misericordiae University Hospital, Dublin
- McIndoe Surgical Centre, East Grinstead
- Morriston Hospital, Swansea
- New Hall Hospital, Salisbury
- Norfolk and Norwich University Hospital
- Nottingham City Hospital
- Nuffield Exeter Hospital
- Nuffield Leeds Hospital
- Nuffield Orthopaedic Centre, Oxford
- Nuffield Plymouth Hospital
- Nuffield The Manor Hospital, Oxford
- Our Lady's Hospital for Sick Children, Dublin
- Parkside Hospital, London
- Pinderfields General Hospital, Wakefield
- Poole Hospital, Dorset
- Princess Anne Hospital, Southampton
- Queen Alexandra Hospital, Portsmouth
- Queen Elizabeth Hospital, Birmingham
- Queen Elizabeth The Queen Mother Hospital
- Queen Victoria Hospital, East Grinstead
- Queen's Medical Centre, Nottingham
- Royal Blackburn Hospital

- Royal Bolton Hospital
- Royal Brisbane and Women's Hospital
- Royal Cornwall Hospital, Truro
- Royal Derby Hospital
- Royal Devon and Exeter Hospital
- Royal Free Hospital, London
- Royal Hallamshire Hospital, Sheffield
- Royal Hampshire County Hospital
- Royal Liverpool University Hospital
- Royal Marsden Hospital, London
- Royal Preston Hospital
- Royal Stoke University Hospital, Stoke on Trent
- Royal Sussex County Hospital, Brighton
- Royal United Hospital, Bath
- Royal Victoria Infirmary, Newcastle
- Royal Wolverhampton Hospital
- Salisbury District Hospital
- Sancta Maria, Swansea
- Southampton General Hospital
- Southmead Hospital, Bristol
- Spire Bristol Hospital
- Spire Harpenden Hospital
- Spire Leeds Hospital
- Spire Little Aston Hospital, Sutton Coldfield
- Spire Parkway Hospital, Solihull
- St Andrew's Centre for Plastic Surgery & Burns, Chelmsford
- St Bartholomew's Hospital, London
- St George's Hospital, London
- St James's University Hospital, Leeds
- St. James's Hospital, Dublin
- Stoke Mandeville Hospital, Aylesbury
- Sunderland Royal Hospital
- Temple Street Children's Hospital, Dublin
- The Christie Hospital, Manchester
- The Ulster Hospital, Belfast
- Tunbridge Wells Hospital, Pembury
- University College Hospital, London
- University Hospital of North Durham
- University Hospital of North Staffordshire
- University Hospital of Wales, Cardiff
- Walsgrave Hospital, Coventry
- Watford General Hospital
- Wexham Park Hospital, SloughWhiston Hospital, Liverpool
- William Harvey Hospital, Kent
- Worcestershire Royal Hospital
- Wrexham Maelor Hospital
- Wycombe Hospital, High Wycombe
- Wythenshawe Hospital, Manchester

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The red dots on the map represent towns/cities across the United Kingdom & Ireland where flap surgery data have been collected. The size of the dot is in proportion to the number of hospitals in each location that contributed to the registry at the time of the data harvest.





A note on the conventions used throughout this report

There are several conventions used in the report in an attempt to ensure that the information is presented in a simple and consistent way. These conventions relate largely to the tables and the graphs, and some of the key conventions are outlined below.

The specifics of the data used in any particular analysis are made clear in the accompanying text, table or chart. For example, many analyses sub-divide the data on the basis of the recipient site in the flap operation, and the titles for both tables and charts will reflect this fact.

Conventions used in tables

On the whole, unless otherwise stated, the tables and charts in this report record the number of procedures (see the example below).

UK National Flag	p Registry	: age and	l gender

			Ge	nder	
		Male	Female	Unspecified	All
	<19	10	12	0	22
LS	20–29	43	36	0	79
at surgery / years	30–39	54	160	0	214
7	40–49	90	552	0	642
rge	50–59	180	759	0	939
t su	60–69	223	405	0	628
Age a	>69	242	188	0	430
ď	Unspecified	6	12	0	18
	All	848	2,124	0	2,972

Each table has a short title that is intended to provide information on the subset from which the data have been drawn, such as the patient's gender or particular operation sub-grouping under examination.

The numbers in each table are colour-coded so that entries with complete data for all of the components under consideration (in this example both the patient's age and gender) are shown in regular black text. If one or more of the database questions under analysis is blank, the data are reported as unspecified in **blue** text. The totals for both rows and columns are highlighted as emboldened text.

Some tables record percentage values; in such cases this is made clear by the use of an appropriate title within the table and a % symbol after the numeric value.

Rows and columns within tables have been ordered so that they are either in ascending order (age at procedure: <20, 20–24, 25–29,30–34, 35–39 years, etc.; post-procedure stay 0, 1, 2, 3, >3 days; etc.) or with negative response options first (No; None) followed by positive response options (Yes; One, Two, etc.).

Row and column titles are as detailed as possible within the confines of the space available on the page. Where a title in either a row or a column is not as detailed as the authors would have liked, then footnotes have been added to provide clarification.

There are some charts in the report that are not accompanied by data in a tabular format. In such cases the tables are omitted for one of a number of reasons:

- there is insufficient space on the page to accommodate both the table and graph.
- there would be more rows and / or columns of data than could reasonably be accommodated on the page (for example, Kaplan-Meier curves).
- the tabular data had already been presented elsewhere in the report.

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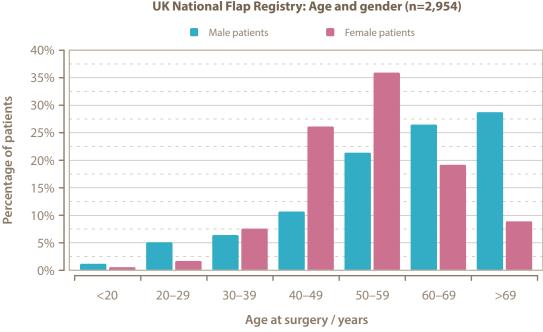
Conventions used in graphs

The basic principles applied when preparing graphs for this First UK National Flap Registry Report were based, as far as possible, upon William S Cleveland's book *The elements of graphing data* ¹. This book details both best practice and the theoretical bases that underlie these practices, demonstrating that there are sound, scientific reasons for plotting charts in particular ways.

Counts: the counts associated with each graph (shown in parentheses at the end of each graph's title as n=) can be affected by a number of independent factors and will therefore vary from chapter to chapter and from page to page. Most obviously, many of the charts in this report are graphic representations of results for a particular group (or subset) extracted from the database, such as patients who are having breast reconstruction. This clearly restricts the total number of database-entries available for any such analysis.

In addition to this, some entries within the group under consideration have data missing in one or more of the database questions under examination (reported as unspecified in the tables); all entries with missing data are excluded from the analysis used to generate the graph because they do not add any useful information.

For example, in the graph below, only the database entries where the patient is having flap surgery and both the patient's age and gender are known are included in the analysis; this comes to 2,954 patient-entries (the 18 entries with **unspecified** data are excluded from the chart).



Confidence interval: In the charts prepared for this report, most of the bars plotted around rates (percentage

values) represent 95% confidence intervals ². The width of the confidence interval provides some idea of how certain we can be about the calculated rate of an event or occurrence. If the intervals around two rates do not overlap, then we can say, with the specified level of confidence, that these rates are different; however, if the bars do overlap, we cannot make such an assertion.

Bars around averaged values (such as patients' age, post-operative length-of-stay, etc.) are classical standard error bars or 95% confidence intervals; they give some idea of the spread of the data around the calculated average. In some analyses that employ these error bars there may be insufficient data to legitimately calculate the standard error around the average for each sub-group under analysis; rather than entirely exclude these low-volume subgroups from the chart their arithmetic average would be plotted without error bars. Such averages without error bars are valid in the sense that they truly represent the data submitted; however, they should not to be taken as definitive and therefore it is recommended that such values are viewed with extra caution.

- 1. Cleveland WS. The elements of graphing data. 1985, 1994. Hobart Press, Summit, New Jersey, USA.
- 2. Wilson EB. Probable inference, the law of succession, and statistical inference. *Journal of American Statistical Association*. 1927; 22: 209–212.



Probability, odds and likelihood ratios

Risk stratification

Risk stratification is a method that allows for the adjustment of observed outcome rates on the basis of the incidence of risk factors within a patient population. It can make for fairer comparisons between hospitals, between surgeons or to an accepted standard outcome rate.

The Bayesian method is one approach to risk stratification. Proper, validated risk stratification models need enough data to assemble a statistical model, to make sure that the model's ability to predict real outcomes is good. Another set of patient-data is also needed to test the model, to make sure that any *good* model is generally applicable, and not simply a statistical anomaly that applies only to the small group of patients whose data were used to build the model.

Probabilities, odds and likelihood ratios are used in Bayesian risk models, and these quantities can help to quantify the effect of various sub-divisions of risk factors on various outcomes. The scope of this report does not reach as far as risk modelling, because there is not yet enough validated, high-quality data to go through this process. But this is one of the aspirations for the Registry in the long term, to make inter-group comparisons fair and robust.

The following section will explain a little bit about how probability, odds and likelihood ratios relate to one another, and how they can be used in the analysis of data from the UK National Flap Registry.

How probability and odds are used in Bayesian risk models

The Bayes-table approach is a particularly simple way of building a risk stratification system from a database. Based only on tables relating to single risk factors, the probability of an outcome can be estimated for a patient with any combination of risk factors.

The method is based on the repeated use of Bayes theorem, which is a basic formula in probability theory, first discovered by the Rev. Thomas Bayes in 1763. Bayes theorem tells us how the probability of an event should be revised when additional relevant information is obtained. This technique has been successfully applied in the realm of cardiac surgery risk stratification. For example, suppose that the outcome under assessment is in-hospital mortality after a cardiac operation: in-hospital mortality is denoted **D** and survival is denoted **S**.

Since the patient must either survive or die, the probabilities of both events must add up to 1, so, in mathematical notation:

$$p(D) + P(S) = 1$$

It is convenient to think in terms of the **odds** on D, defined as:

odds =
$$\frac{p(D)}{p(S)}$$
 = $\frac{p(D)}{1-p(D)}$

Thus, a probability of death of 0.10 turns into odds of 0.10/0.90 = 1/9, or, in betting parlance, 9 to 1 against death. An assessment of these odds, based on no data specific to our patient is known as the **prior odds**, and will simply give the average for all patients.

Suppose we now wish to take into account some risk factor data that we hold for our individual patient. One such risk factor might be the patient's age, which happens to be >75 years old. We could denote this piece of evidence **a**. Suppose that the total number of patients in the database is 1,000, and the relationship between age and patient mortality is as follows:

In-hospital r	mortality	outcome
---------------	-----------	---------

		Survivors	Deaths	Total
		Survivors	Deatils	iotai
	a: >75	90	30	120
Age at surgery / years	not a: <=75	810	70	880
	Total	900	100	1,000

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This shows an overall proportion of mortality of 100/1,000 = 0.10. However, when we add conditional information that the patient is aged >75 years at the time of surgery, this probability is increased to 30/120 = 0.25, corresponding to odds of 30/90 = 1 to 3. The revised probability, allowing for the patient's age, is known as the posterior probability and is denoted p(D|a); the posterior odds is:

posterior odds =
$$\frac{p(D \mid a)}{p(S \mid a)}$$

Bayes theorem is the formula that provides the relationship between the prior and posterior odds:

posterior odds =
$$prior odds \times likelihood ratio$$

where the likelihood ratio expresses how much more likely it is that a patient with such an age should fall amongst those that who die than those who have a survive:

likelihood ratio =
$$\frac{p(a \mid D)}{p(a \mid S)}$$

Looking at our table, we can see that p(a|D) = 30/100 = 0.30 and p(a|S) = 90/900 = 0.10. So, the likelihood ratio is 0.30/0.10 = 3 *i.e.*, this age group is three times more common amongst those whose die than those whose survive. Any likelihood ratio >1 implies that the risk factor is associated with an **increase** in the patient's risk compared to the overall average, and a likelihood ratio of <1 implies that the risk factor is associated with a **decrease** in risk. Bayes theorem says that in our example described above the posterior odds = $3 \times \text{prior odds}$, which is $3 \times 1/9 = 1/3$. This corresponds to a posterior probability of 0.25, which can be obtained directly from the data in the table (30/120).

The application of Bayes theorem can be extend to include any number of risk factors (items of evidence, from 1 to p);

posterior odds
$$= \frac{p(D \mid s_1, \dots, s_p)}{p(S \mid s_1, \dots, s_p)}$$

$$= \frac{p(s_1, \dots, s_p \mid D)}{p(s_1, \dots, s_p \mid S)} \times \frac{p(D)}{p(S)}$$

$$= \frac{p(s_1 \mid D)}{p(s_1 \mid S)} \times \dots \times \frac{p(s_p \mid D)}{p(s_p \mid S)} \times \frac{p(D)}{p(S)}$$

$$= \text{likelihood ratio}_1 \times \dots \times \text{likelihood ratio}_p \times \text{prior odds}$$

So, the ideas of probability, odds and likelihood ratios are useful in the assembly of Bayesian risk models, and can help us understand how risk factors affect the outcome rates for sub-groups of patients compared to the overall average rate for all patients.

Box and whisker plots

The box-and-whisker plots shown later in this report use a number of well-known statistical measures of spread to provide a visual representation of a distribution: the median, surrounded by the lower and upper quartiles (the inter-quartile range, or IQR); this is the middle portion of the rank-ordered numbers in the distribution, in which half of all the numerical values fall.

There are two more measures of spread that describe the more extreme ends of the distribution: the lower and upper adjacents. Formally, these values are determined as:

- lower adjacent: the smallest observation that is greater than or equal to the Lower Inner Fence (LIF) value; the LIF = lower quartile $[1.5 \times IQR]$
- upper adjacent: the largest observation that is less than or equal to the Upper Inner Fence (UIF) value; the UIF = upper quartile + $[1.5 \times IQR]$



The history of flap surgery and everyday heroes in free tissue transfer

Sushruta, an Indian surgeon in 600 BC, wrote the ancient treatise *Sushruta Samhita*. In his book, Sushruta emphasized all the basic principles of plastic surgery including the technique of pedicle flap, repair of ear lobe defects and repair of traumatic and congenital clefts of the lip. However, his description of the reconstruction of the nose with a cheek flap remains his greatest surgical achievement. This later came to be known as the Indian rhinoplasty when a forehead flap was used to resurface the nasal tip defect.

In the 15th century Italy, Gaspare Tagliacozzi reconstructed the nose by using the skin of the upper arm. The principle of the Italian procedure was precisely the same as of the pedicle flap which was described by Sushruta.

The term *flap* may have originated in the 16th century from the Dutch word *flappe*, something that hangs broad and loose, fastened only by one side. In reconstructive surgery, it involves moving healthy living tissue from one part of the body to another, keeping its blood supply intact. A flap may be composed of various types of tissue such as skin, fat, muscle or bone, either alone or in combination.

Fast forward to the first world war, and three surgeons dealing with a high volume of facial injuries, Filatov in Odessa, Ganzer in Berlin and Harold Gillies in London developed the idea of tubing the pedicle of a distant skin flap, independently of each other. Tubing a pedicle was part of an evolutionary rather than a revolutionary development of the Italian method.

From 1917 to 1925, the British army concentrated its facial war casualties in Queen Mary's Hospital, Sidcup. Under the direction of Harold Gillies, the tubed pedicle flap became the workhorse for large facial reconstructions. With the outbreak of the Second World War, Harold Gillies' cousin, Archibald M'Indoe moved to the newly rebuilt Queen Victoria Hospital in East Grinstead and founded a Centre for Plastic and Jaw Surgery. He developed various tubed flaps for the treatment of burn injuries to the face and hands in injured airmen, who formed the Guinea Pig Club.

These flaps were all *pedicled* flaps, which meant that the piece of tissue was left attached to its original site by a narrow base providing its blood supply.

Though the first surgical microscope was invented in 1921 by a Swedish otolaryngologist, Carl-Olof Nylén at the University of Stockholm, it was only in 1960 that it was first used to couple vessels as small as 1.4 mm when Julius H Jacobson II of Vermont performed this anastomosis and coined the term microsurgery.

Hence, began the golden age of free tissue transfer. A free flap involves detaching the tissue from one part of the body along with its blood supply, moving it another part of the body and re-connecting the blood supply.

Harold Kleinert and Morton Kasdan performed the first revascularization of a partial digital amputation in 1963 at the University of Louisville, Kentucky. The first human microsurgical transplantation of the second toe to thumb was performed in February 1966 by Dong-yue Yang and Yu-dong Gu in Shanghai, China. The first great toe to thumb transfer in the western world was performed in April 1968 by John Cobbett, East Grinstead. In Australia, lan Taylor developed the free fibula and deep circumflex iliac artery (from the hip bone) to reconstruct head and neck cancer defects.

As our indications, techniques and repertoire of flaps increased, principles of flap surgery have been consolidated through the years and taught to trainee surgeons:

- replace 'like for like'
- think of the body as units and subunits
- don't forget the donor site (the site from which the flap is taken)
- and have a back-up plan



A key milestone in the progress of microsurgery occurred in 1976, when Robert Acland, a British Surgeon received an invitation from Harold Kleinert and Joseph Kutz in Lousiville to run their microsurgery lab. He developed one of the first microsurgical instruments, the Acland micro-vessel clamp, a vessel for end-to-end anastomosis. At the time, needles fine enough for microvascular work were not available. Bob Acland overcame this hurdle by obtaining the finest available wire of 100 microns, thinned it down to 80 microns by electro-polishing and demonstrated it to a device company that produced the extra-fine needle to his specifications. Needles of this dimension and the Acland microvascular clamps are now the everyday heroes for surgeons, used in hospitals all over the world.

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A further key milestone has been the venous coupler, an adaptation of the Nakayama device. This device subsequently evolved into a microvascular anastomotic coupling device. Since its introduction in 1990, this device has been widely used for venous and some arterial microvascular anastomosis in almost all types of free flaps in the head and neck, breast, and extremities.



Another of the everyday heroes in free flap surgery is the Doppler device for intra and post-operative monitoring, taking the form of an external probe or an implantable device. The work of one man has resulted in the Doppler effect being used in many everyday things we take for granted: sirens, satellite communication, foetal heart monitoring, police radars and monitoring blood flow in free flap surgery. The Doppler signal is the change in frequency of a sound wave for an observer, moving relative to its source, named after an Austrian physicist Christian Doppler, in 1842. It is commonly heard when a vehicle with a siren approaches, passes and recedes. He described the effect at the age of 38, published many articles as a Professor and then died at the age of 49 from lung disease.

Changes and improvement in other fields leads to changes in our surgical lives, making surgery easier for us and safer for patients. Other useful devices, to name a few, are the diathermy for flap dissection, venous thromboprophylaxis boots for preventing blood clots in legs, various warming devices to ensure that the patient's temperature is maintained during surgery and finally, thrombolytics such as tissue plasminogen activator (TPA) and urokinase for the salvage of struggling flaps.

Modern day service lines for cancer resection and reconstruction are established around the concept of the multi-disciplinary team (MDT). In the management of any cancer, in addition to the oncologist, radiotherapist, and supporting healthcare personnel such as the cancer nurse specialist, the surgical team members will consist of a cancer surgeon and a reconstructive surgeon.

In the management of breast cancer, the cancer surgery is often performed by general surgeons specialising in breast surgery. Though historically reconstructive surgery was within the remit of the plastic surgeon, with cross-pollination of surgical techniques, some reconstructive techniques of the breast, such as implant based reconstructions and local or regional flaps are also offered by breast surgeons. Women who wish to have their own tissue used for reconstruction require microsurgery, which is performed by plastic surgeons in specialist centres.

The MDT plays a critical part in the management of head and neck cancer too. However, head & neck cancer resection can be performed by surgeons from specialties such as ENT (ear, nose and throat), general or maxillofacial surgery. Reconstruction is carried out by plastic or maxillofacial surgeons. As to which surgical specialty offers the resection and/or reconstruction depends on local structuring of the service lines in hospitals.

Collaboration between different specialties is key in achieving high quality outcomes for patients.



Development of the UK National Flap Registry

Clinical audit, quality assurance and performance measurement have been increasingly accepted and incorporated into surgical practice over the last two decades. A more recent requirement to collect supporting information for annual consultant appraisal is now a part of (General Medical Council) GMC Revalidation.

The impetus for the formation of the UK National Flap Registry came from the national political climate around reporting clinical outcome publications by the NHS Commissioning Board for 7 surgical specialties in 2012, with a further 3 following suit in autumn 2013. All ten specialties had national registries, some funded by their own professional society, and others supported by public money through the Healthcare Quality Improvement Partnership. As the NHS moved towards a culture of assessment based on outcome measures, within Plastic surgery, there was a need for clear metrics on performance to help target and monitor improvements and maintain high-quality care. Mortality after a Plastic Surgery operation is a rare event, with the exception of burns emergency management. Therefore, there was a requirement for outcome measures in Plastic Surgery to reflect clinical relevance, be quantifiable and above all, reflect the width and scope of the specialty. Publication of such data would, in addition, emphasize the reconstructive side of plastic surgery, rather than the perception of a specialty widely regarded as *cosmetic surgery* with its associated media scandals.

First steps in comparative flap audit

For most surgeons performing complex surgery, clinical audit of results is instrumental in their professional development. To work towards this goal, the Clinical Effectiveness Subcommittee (CESC) was set up by British Association of Plastic Surgeons (BAPS) in 1999. Collaborating with the Clinical Effectiveness Unit (CEU) at Royal College of Surgeons of England, five criteria for a complex surgery marker procedure were identified:

- high volume, performed in all plastic surgery units.
- representative of the range of challenges within plastic surgery.
- must have frequent outcome events.
- have widely accepted and easily measured patient risk factors.
- have reliable and valid outcome measures.

Free and pedicled flaps were selected as appropriate index procedures. Although these flaps may have different anatomical donor and recipient sites, flap composition and indications, the objective is the same in every case: to achieve high rates of flap survival and no unplanned re-operations during the same admission. Free and large pedicled flaps constitute a significant proportion of the workload of all reconstructive surgery units. Past research has shown that there are a number of risk factors that influence flap survival rates, and prolong hospital stay, and increase re-operation rates. These include smoking, previous radiotherapy, delay from time of injury to reconstruction, body mass index and ASA grade. A proforma was designed that included these risk factors and also the flap type, composition, operation time, and operator grade. The CESC met for a final time in 2001.

A three-month pilot study involving 5 units was published in JPRAS 2006. The study consisted of data collected on flap surgery for breast, head & neck and limb reconstructions, using the CESC/CEU proforma. An on-line database based on this study was set up in Salisbury, the results of which were presented to BAPRAS and the European Society of Plastic, Reconstructive and Aesthetic Surgeons (ESPRAS).

Proposal for a national flap registry

Then, in 2013, a formal proposal was made to BAPRAS to establish a new national flap registry, following the same principles as the CESC/CEU design brief, using a web-based platform to collect the data, and incorporating Patient Reported Outcome Measures (PROMS) as a key part of the registry. The emphasis was on establishing a database that could be used by any speciality involved in reconstructive surgery, and so encourage collaboration across the key sub-specialties, including the British Association of Oral and Maxillofacial Surgeons (BAOMS), the British Association of Head and Neck Oncologists (BAHNO), the Association of Breast Surgery (ABS) and the British Society for Surgery of the Hand (BSSH).

Flap surgery and the UKNFR

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Web based software

BAPRAS had several important requirements for the registry:

- the web-based software should exist on a single central server, allowing for updates to be rolled out
 with immediate effect for all users to enjoy, rather than requiring a cycle of distributing software on
 CDs or downloads. This also helps to keep down the ongoing maintenance costs.
- the registry software needed to be configured so that access *via* mobile platforms was possible so that data can be entered on smart devices or tablets, in addition to desktop computers.
- a variety of different methods for reporting and visualising data had to be incorporated into the web-based registry.
- the data had to be stored securely and within the United Kingdom, with sufficient primary and secondary backup facilities.

Security of patient data was the most challenging task, since the data would be necessarily kept off-site and exposed to the Internet.

- the data had to be on a secure platform, compliant with the Data Protection Act 1998 and subsequently General Data Protection Regulation (GDPR) 2018.
- the data had to be stored within the United Kingdom, with sufficient primary and secondary server facilities.

Data structure of the registry

The design of the registry was complicated by the need to include operations on all anatomical areas, and to allow for each donor and recipient site to have one or more re-operations added as part of the overall operation record. Following a rigorous procurement process, Dendrite Clinical Systems was chosen to develop the required platform, as they were a specialist company with a strong track record in the field of developing and implementing successful national registries, and they had a specialist team in place who have many years of experience dealing with precisely these kinds of issues.

A small team of clinicians worked with the team at Dendrite Clinical Systems to design the UK National Flap Registry (UKNFR) based on the on-line CEU database, and also incorporating elements from similar systems from other units, such as Oxford, Chelmsford, East Grinstead and Liverpool. Dendrite created a registry that allows for either Direct-Data-Entry *via* a secure NHS server data with access from both desktop PCs and *via* mobile platform such as an iPad, or using an Upload-My-Data portal for bulk upload of data.

Good outcomes based on clinical data are evidence of high-quality care. Clinical data alone, however, fails to completely measure the patient experience. PROMs (Patient Reported Outcome Measures) are pertinent from the perspective of the patient, as they measure the patient's perception of the success of the operation. To accurately reflect patient views, the questionnaires that were selected for UKNFR had to be reliable, validated, responsive, and precise, as well as be acceptable to the patient in terms of ease of administration. Internationally validated disease-specific PROMs for breast reconstruction (Breast-Q) and lower limb reconstruction (Modified Enneking score) were therefore integrated into the registry. Patients are contacted at a time-triggered point after their procedure to complete an online questionnaire about their experience. These results are then electronically accumulated within the registry.

An editorial published in 2015 in the Journal of Plastic Reconstructive and Aesthetic Surgery (JPRAS) formally outlined the details of the whole Registry project to a wide readership. The UKNFR then went live on 1 August 2015, and the first NHS operation-record was entered. Several related presentations were made during the development of UKNFR between 2014 and 2017 at national and international meetings to encourage surgeons to join this important BAPRAS registry initiative.



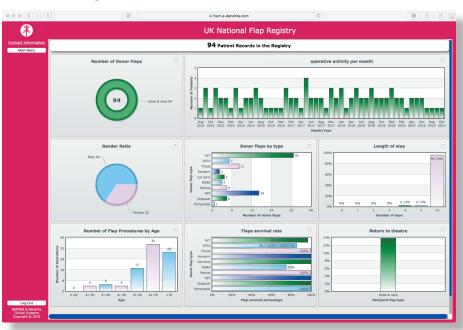
The surgeon dashboard

One of the big successes of the registry has been the surgeon dashboard. The registry displays the surgeon's own data on a dashboard, which allows easy visualisation of the data in real time. The dashboard includes the number of procedures performed, case-mix, flap survival, unplanned return to theatre and length of hospital stay. The dashboard is very useful during appraisal and revalidation as it provides evidence of the surgeon's performance in the form of a real-time audit. The feedback from UKNFR users who have used the dashboard for appraisal and/or revalidation has been very positive. It is a powerful personal audit tool.

A breast reconstruction surgeon's dashboard



A head & neck surgeon's dashboard



Flap surgery and the UKNFR

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Registry regulation

Confidentiality

Patient confidentiality is maintained throughout the data flow cycle. Data transfer for Direct-Data-Entry into the UKNFR can be *via* either N3 network or from personal iPads/tablet devices. The UKNFR has a secure server with TSL, which offers encrypted data traffic between the server and the client computers. The https server ensures that any data traffic to/from the server is encrypted, which, in simple terms, means that anyone listening in will hear only *white noise*. Once a surgeon enters patient data into the registry, all patient identifiable information is anonymised: a number is allocated automatically by the registry to each patient entry. Any data used for analysis and interpretation is presented only in an anonymised format and patient details are not visible.

Only the surgeon who operated on the patient, or their nominated delegates, can see any patient identifiable information. The patient data stored on the server is encrypted, security-protected and cannot be seen by any other registry users. Administrators, programmers and support staff at Dendrite have access to set up user accounts, fix reported data entry errors, diagnose problems, upgrade and repair the database software. Dendrite holds all the necessary information governance certificates required to perform the work required as the UKNFR's formally appointed data processor.

Consent

England and Wales: Section 251

BAPRAS has applied for and obtained Section 251 exemption for the UKNFR (CAG reference: 16/CAG/0006, IRAS project ID: 180468), which was approved by the Secretary of State on the advice of the Confidentiality Advisory Group (CAG) on 14 January 2016 under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002, which allows for processing of patient identifiable information in the registry without the patient's consent. This enables the data controller to avoid being in breach of the common law duty of confidentiality, although other relevant legislative provisions are still applicable. Ongoing approval is subject to submission of an annual review report no later than 11 July each year.

As such, the data is collected for a medical purpose as defined in the 2006 National Health Service Act Section 251 (12) A, being (for the) provision of care and treatment and the management of health and social care services. The database does this by collecting data on pre-operative health status, details of the surgery performed and principal healthcare professionals responsible, vital status and development of recognised complications following reconstructive flap procedures. The approval is granted for.

- Class IV Support: to link patient identifiable information obtained from more than one source and,
- Class V Support: for auditing, monitoring and analysing patient care and treatment.

General consent

Section 251 does not apply outside of England and Wales. So, specific consent is therefore required from patients in Scotland, Northern Ireland and the Republic of Ireland before data on their operation can be added to the UKNFR. Section 251 does not cover the collection of e-mail addresses and mobile numbers for the purpose of automating the remote data-collection of Patient Reported Outcome Measures (PROMs). Therefore, for Breast-Q (Breast Reconstruction) and Enneking score (Lower limb reconstruction), for which specific additional consent is required; this is usually requested and obtained during the initial patient consultation. A copy of the patient consent form is available in the appendices of the report (see page 172).



Registry mechanics

Registry access

The UKNFR Registry software platform is hosted on a secure N3 server (Carelink) with access from the Internet and the NHS N3 network. Clinicians and database administrators only have access to the Registry *via* an internet browser using authenticated user-names and passwords. Each user account profile ensures that users will only view patient records associated with their hospital. Dendrite has direct access to these servers and the database using secure virtual private network (VPN) connections from their two offices in the United Kingdom, to provide registration desk services, software maintenance and software support. Access is strictly limited to those key Dendrite staff who are directly involved in the support and/or management of the database and its associated applications. All access to the server is logged and audited using best practice guidelines.

Registry and data security

The Dendrite services are hosted by Piskel within the Telehouse data centre in London. This is a tier 4 data centre that meets the highest levels of building security including constant security by trained security staff 24/7, electronic access management, proximity access control systems and CCTV. The service platform is held within a secure enclosed suite (TFM20) where access requests are managed *via* the Piksel Service Desk and restricted to Piksel engineers and trusted third-party support. Piksel managed CCTV is also installed within the suite and managed 24/7. Hardened base Operating System images are created as templates to ensure all virtual machines are created with a known baseline level of security and the images are incorporated within a patching policy. Planned monthly maintenance schedule is centred around the release of patches. Patches are released on the second Tuesday of every month and reviewed by the Operations Team before issuing e-mail notification of when servers will be patched (during the third week of the month), where they are patched automatically, rebooted and tested on each occasion. All servers have Forefront Endpoint Protection anti-virus (AV) installed and are configured to use real-time scanning on all file systems specific file types excluded (*e.g.*, database & log files).

Piskel's Data Security Policy is fully implemented and complies with current management and control guidelines described in ISO 27001/2 standards. All data entry and storage is GDPR-compliant. Service delivery and information governance complies with ISO 20000 & ISO 9001 accreditation and the security structure is aligned alongside Piskel's ISO27001 for continuous assurance and compliance. Internal audits are completed approximately every 3 months and external audits every 6 months.

Registry users

There are three levels of user:

- Administrator: restricted to Dendrite personnel for the purpose of creating and administering user accounts for UKNFR and maintaining the central registry software.
- Surgeon / clinician user: any surgeon or other clinician who registers to use the UKNFR website database for the purpose of data being added *via* the UKNFR website database about surgical procedures that he or she has carried out (with or without the participation of trainee surgeons or other clinicians), or for which he or she has otherwise been responsible. Surgeon / Clinician users can create new patients, but only for the site(s) with which they are associated / registered. The ability to create new patients (or to edit the demographics of existing patients) can be controlled if necessary on a user-by-user basis. Surgeon / Clinician Users have the ability to export data extracts only for their patients for which they have permission to enter data (restriction is by assigned hospital).
- **Delegated user**: means any person who, from time-to-time, a Surgeon/Clinician User has authorised to enter data to the UKNFR Database on behalf of the Surgeon/Clinician User. This could be a trainee surgeon, specialist nurse or audit personnel.

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Patient Reported Outcome Measures

PROMs software in the UKNFR



Clinical outcomes based on clinical data are evidence of high-quality care. Just clinical data alone, however, fails to measure the patient experience. PROMs (patient reported outcome measures) are pertinent from the perspective of the patient, as these measure the patient's perception of the success of the operation. An ideal PROM instrument assesses domains such as satisfaction with the operated part of the body, satisfaction with outcome of surgery and satisfaction with the care pathway in addition to quality of life domains such as physical, psychosocial and sexual well-being.

Conventionally, PROMs questionnaires are completed by patients in a clinic setting. This setting, which can often be a time-pressured and a high-anxiety environment for the patient, is not ideal to administer a PROMs questionnaire. Hence the need for to get these questionnaires completed by the patient at their leisure some time after discharge, when they are back at home.

The current version of the UKNFR has two sets of PROMs questionnaires included: one for patients who have had a breast reconstruction, and the other for patients who have had lower limb surgery:

Breast reconstruction

The Breast-Q PROMs instrument for measuring breast reconstruction outcomes has been validated in 26 countries by Prof. Andrea Pusic (Harvard Medical School). It was developed with the involvement of patients and focus groups; it has been fully tested, and has now been translated into thirty languages. It quantifies the impact of reconstructive breast surgery on health-related quality of life (HR-QOL, including physical, psychosocial, and sexual well-being) and patient satisfaction (including satisfaction with breasts, outcome, and care).

The collaboration with Prof Pusic has resulted in three Breast-Q Reconstructive modules:

- satisfaction with outcome,
- satisfaction with information and
- satisfaction with breast,

An e-mail link to the questionnaire is sent directly to each breast reconstruction patient 6 months after surgery and again 18 months after their operation. The questionnaire link is only sent to patients who specifically consent to receive automated PROMs questionnaires by e-mail/text.

The decision to use only 3 Breast-Q modules was based upon the premise that the number of questions should be relatively few so that the return-rate from our patients would be as high as possible; a high return rate is more likely to provide valid and valuable information in the long term.

Lower limb reconstruction

The modified Enneking score questionnaire is sent to patients 9 months after their operation. Again, the questionnaire is sent to the patient electronically as an e-mail with a link that allows them to add their responses directly into the registry. The fact that the patient's data are added directly into the registry by the patient themselves greatly simplifies the process of data collection, and keeps costs of administering this PROMs down to a minimum.

In summary

- the UKNFR is the first national registry of this type in the world designed to collect data on all major pedicled and free flap operations.
- this report is the first publicly available set of analyses from the registry.



Definitions for flap survival / failure in the UK National Flap Registry

For the purposes of this report, the current iteration of the UK National Flap Registry has three outcomes of flap survival: 100% (complete) survival, partial survival and zero survival. A further category of a buried flap can also be recorded in the registry.

However, the outcome of flap reconstruction is not always binary in nature and can be somewhere along the spectrum between complete success and failure. The resultant process required to appropriately manage the residual defect can range from allowing the wound to heal by secondary intention or the need for a second flap.

A classification of flap reconstruction outcomes has been proposed by Ho $et\,al.$, which suggests a move away from primarily reporting the binary nature of flap reconstruction results and more towards the process of flap reconstruction.

This specifically relates to head and neck reconstruction, but can also be applied to lower limb reconstruction, wherein the flap has failed to survive over bone or exposed metalwork and necessitates a second flap or procedure. In breast reconstruction, partial flap necrosis will leave a defect in situ, which can be addressed with revision surgery such as lipo-filling at a second stage.

Hence, the Ho classification has been adapted to measure outcomes in all flap reconstructions and make these meaningful for breast, head & neck, limb, trunk and perineum reconstructions. The next iteration of UKNFR will therefore include the following in a drop-down menu format for recording the outcome of flap reconstruction:

Flap reconstruction outcome		Description
1 Reconstruction successful	1	complete success (100 % survival)
2 Partial failure 2a		partial failure with loss of some components of flap, however secondary reconstruction or prosthesis was not required or performed
	2b	second flap (free or pedicled) required to rehabilitate residual defect
	2c	prosthesis utilised to address residual defect
3 Complete flap failure	3a	second flap (free or pedicled) required to rehabilitate residual defect
	3b	prosthesis utilised to address residual defect
	3с	residual defect left in situ

Further detail on the clinical impact of partial flap failure affecting any of the anatomical locations can be extracted from the recipient re-operation data-items; such as part of flap removed, skin graft or new flap.

Flaps can be completely buried in a variety of circumstances. These can include breast reconstructions in nipplepreserving mastectomy, free muscle, bone or myo-osseous in reconstructions of the limb or head & neck, skull base and pharyngectomy. Though buried flaps are currently recorded in the registry, the outcome of a totally buried flap is difficult to ascertain. Monitoring of buried flaps is now more mainstream with the availability of an implantable Doppler device for arterial and venous anastomoses, and venous coupler flow monitoring devices for end to end anastomoses. Therefore, the following drop-down options will be available in buried flaps, with the ability to record survival of the flap.

Buried flap	a	implantable Doppler used for monitoring
	b	venous coupler flow monitoring
	c	not monitored

^{1.} Ho MW, Nugent M, Puglia F, Shaw RJ, Blackburn TK, Parmar S, Dhanda J, Fry AM, Brennan P, Barry CP, McMahon J. Results of flap reconstruction: categorisation to reflect outcomes and process in the management of head and neck defects. British Journal of Oral Maxillofacial Surgery. 2019. DOI: 10.1016/j.bjoms.2019.08.005



The growth of the database

The UK National Flap Registry went live in August 2015. The Dendrite team took a cut of the registry data required for the analyses presented in this report on 8 August 2019. The vast majority of the 5,751 entries recorded in the registry at that time were added using Dendrite's web-based Direct-Data-Entry module, but amongst these there were also 151 records that had been uploaded using the Dendrite Upload-My-Data module; these uploaded data came from two centres that had been maintaining their own local databases. At least one of these uploads was a one-off, as the user decided to subsequently migrate over to using the on-line version of the UKNFR.

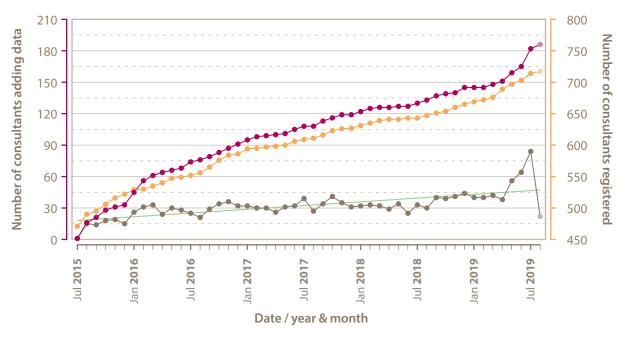
The data analysis team began by carefully inspecting the data and ironing out some minor issues, such as inadvertent duplication of operation records. After the duplicate records and a handful of orphaned records had been excluded, the final count of procedures was 5,688. The remainder of this report is based on this group of patients and their operations, and also sub-sets taken from this group.

The following pages are designed to show the growth of the database, both in terms of user-engagement and in the number of operation records added over time. The first chart below shows that 475 consultant users were registered prior to go-live (the left-hand extremity of the yellow line); these surgeons were all the BAPRAS members at that time, but only a proportion of them actually perform flap surgery. Since then, over 280 additional consultants have registered as users; the addition of new users seems to have been fairly steady over time, with a noticeable upswing in July 2019, as the deadline for the proposed cut-off date for this report grew closer and closer. This tends to suggest positive engagement with the UKNFR project from consultants involved in flap surgery.

The chart also shows that more and more consultants have added data to the registry over time (the red line). At the time that the current sample of data was taken, over 180 individual consultants had added one or more operation records to the UKNFR. There is also evidence that recording data for these operations is becoming part of everyday practice for more and more surgeons: across these last 4 years, the number of consultants adding data in any one month has shown a steady upward trend, with a distinct upswing in the last three months prior to August 2019 (the green line). Looking at the data tells us that surgeons were logging in to the web registry in order to back-populate the registry with data on their operations from months past, which shows a clear desire to contribute as much data as possible for this first report.

The UK National Flap Registry: Registered users

- Cumulative number of consultants registered
- Cumulative number of consultants adding one or more registry entries
- Number of users adding data in the time-period

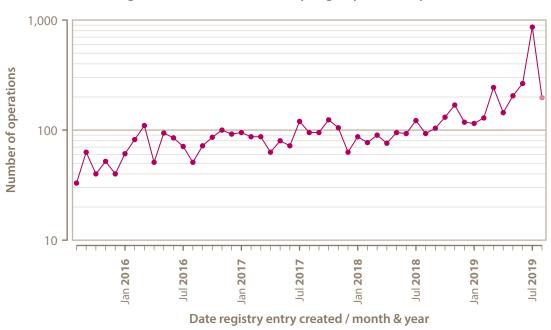


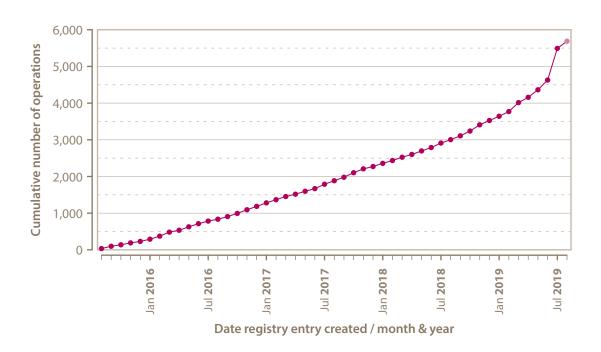


This next pair of charts shows the number of operations added to the registry in each month since the UKNFR first became operational. When the registry was launched about 30 operation records were added to the system in the first month. Since then there has been a steady upward trend in the number of records added each month, reaching almost 300 in June 2019; the chart's y-axis is plotted using a logarithmic scale, so this growth over time is actually much more impressive than it might appear on first inspection. The peak of data-entry was in July 2019, when the monthly count hit almost 900 operations, which must be due to the *last minute* efforts of all the users doing their best to get their data added before the deadline for the data-cut for this report. This is also the month in which the bulk uploads were executed, adding a further 100+ records to the registry.

The data-point for August sits at around 200 operations added, which is above the count for all but three of the preceding months, which is astonishing considering the fact that this month of August represents only 7 complete days of data-entry. Again, users were working all hours to get their data into the registry in time for this analysis.

The growth of the UK National Flap Registry since inception (n=5,688)





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The next pair of charts below shows the same information plotted on two different scales: the left-hand chart uses a normal, natural scale for the x-axis, whereas the second plot uses a logarithmic scale on the horizontal x-axis. They are designed to show the timing of data-entry after the operation for three distinct time periods.

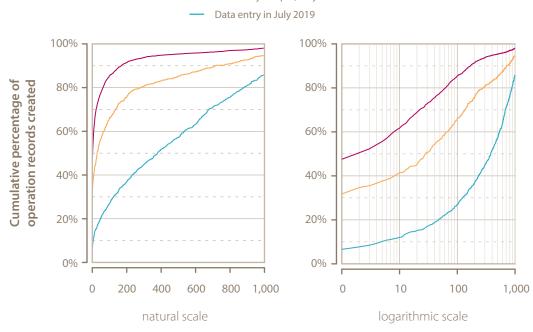
As shown in the charts on previous pages, the data added later in 2019 represents an unusual time-period in the life of the UKNFR, as users were working overtime to make sure their historical and current data were entered in time for this current report. July 2019 was a month in which more data was added than in any previous month, by quite some margin. So the data shown here are separated out into three groups: up to the end of March 2019 (the normal state-of-affairs), data entry in April–June 2019 (the beginnings of a big push to add data), and July 2019 (the final efforts to complete data entry prior to the report).

The steady state for the UKNFR is represented by the red line, which shows the cumulative number of operation records added at each time-point (time-lag between operation and initial data-entry). What this demonstrates is that over half of all operation records are added on the day of the operation, and the vast majority of records are created within 200 days of the operation. From that point on there is a steady rise in the line as the last 10% of operations are added.

In April, May and June 2019 the pattern changes somewhat, as normal practice is masked by the effect of users doing more retrospective data entry, and this switch from data-entry for contemporary operations to retrospective data-entry goes up another level in July 2019 as the deadline for data-harvest loomed. Throughout the life of the registry, we expect new users will want to add data for operations performed some time ago, and this will make the UKNFR ever more inclusive and ever more valuable.

Direct data entry records: The time-lag between surgery and data entry (n=5,432)

- Data entry up to the end of March 2019
- Data entry in April, May & June 2019



Time between operation date and UKNFR record creation / days



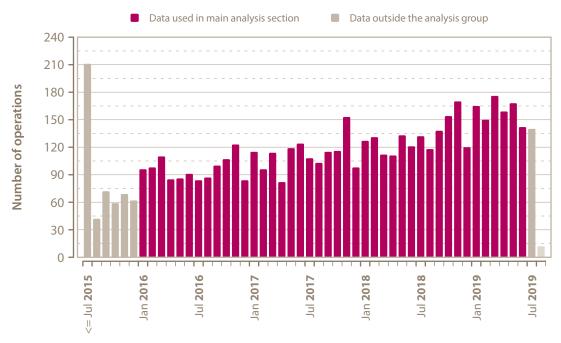
The chart below shows the number of operation records in each month, when grouped according to the date of operation rather than the date the record was created in the UKNFR.

What this shows is that the 900 or so records added in July 2019 must have represented operations that had occurred recently and in months past: there was significant retrospective data entry in July 2019.

From the chart, it seems that the number of operations generally increases across time, but this is definitely an artefact associated the number of active users increasing over time, rather than in increase in the volume of flap surgery *per* se.

The red bars indicate the operation records that will be used for analysis in the main sections of the report: a continuous and contemporary group of operations, that should represent a modern cohort of patients undergoing various kind of flap surgery.

Operation records dated in each month (n=5,688)



Date of operation / month & year

Funded by BAPRAS



Data completeness

One key aim for any registry is to collect complete and accurate data. Missing data is clearly an issue because it reduces the certainty around any output that is generated from the database.

In the main, it is busy surgeons who enter their data into the UK National Flap Registry, a task that comes on top of all their other clinical commitments. This data-entry is all done on a voluntary basis, in the midst of a busy working day, on the basis that the data will become a valuable resource for the surgical community and for patients.

However, until the registry becomes firmly embedded in everyone's normal working day, there is likely to be a degree of missing data, not least because the task of going back to the registry to add in outcome data and discharge information can get over-looked. However, experience shows that as a registry matures and output is generated, people start to actually see real evidence of the benefits of entering data, and data quality consequently improves.

Later on in this report missing data are reported in tables under an **unspecified** column title; rates of co-existing conditions and outcomes can only be calculated on the basis of what we know, which means that the operation records with missing data for any item being analysed are excluded from the calculations. The certainty around any calculated rate, represented by 95% confidence intervals in most of the charts, is directly related to the volume of data used in the calculations: bigger numbers result in tighter confidence intervals, which are visualised as the *whiskers* around a plotted rate (percentage) in a chart.

The following table and charts presented here show data completeness in the baseline sections of the UK National Flap Registry.

UK National Flap Registry: missing data in the baseline, operation record

	,	Database section						
		Risk factors		Operation		Discharge		
		Count	Percentage	Count	Percentage	Count	Percentage	
ing data-items	0	2,903	51.0%	2,337	41.1%	3,211	56.5%	
	1	179	3.1%	2,407	42.3%	235	4.1%	
	2	1,372	24.1%	315	5.5%	179	3.1%	
	3	191	3.4%	29	0.5%	159	2.8%	
	4	64	1.1%	17	0.3%	211	3.7%	
	5	31	0.5%	33	0.6%	17	0.3%	
	6	22	0.4%	12	0.2%	1,676	29.5%	
	7	27	0.5%	68	1.2%			
niss	8	47	0.8%	470	8.3%			
ofr	9	38	0.7%					
ber	10	18	0.3%					
Number of missing	11	28	0.5%					
_	12	23	0.4%					
	13	133	2.3%					
	14	612	10.8%					
	Total count	5,688		5,688		5,688		



The counts of missing data in the **risk factor section** do not take any account of the age field nor the gender field as these two data-items are absolutely required at the time that an operation record is created, and so they will always be 100% complete. The risk factor section seems to be largely complete: generally the record has no missing data in this section, two missing data-items or, in about 10% of all cases, have no questions completed. It is most likely that the records with no risk factor data can be explained by users creating the operation record, but then saving and exiting the software without going through the process of adding any additional data. The reasons for this are not clear. There are details of the completion rates of each question in this section on the following page.

Again, the **operation section** seems to be largely complete: the missing data is mostly confined to a single question in this section (see the following page for details). Over 80% of the operation records have less than 2 missing data-items, which means, in general, there has been very diligent data collection.

The vast majority of records have no missing data in the **discharge section**. When there are missing data in this section, it seems that all six of the questions are blank, which tends to suggest that the users have not returned to this section to complete the patient's discharge information.

Missing data in the baseline record (n=5,688)



Baseline section & number of missing data-items

This volume of missing data is not unusual in a new registry. Most clinical database projects find that there is a small issue with data completeness in the early stages, but as time passes compliance improves. We expect to see this happen with the UKNFR as well.

We would urge all flap surgeons not only to register for the UK National Flap Registry, but to enter their data, and complete the operation record wherever possible, so that the registry can become an evermore valuable data resource to help assess and improve patient-care in the long-run.

- 1. See 145 in the database form in the Appendix.
- 2. See 146 in the database form in the Appendix.
- **3**. See 167 in the database form in the Appendix.

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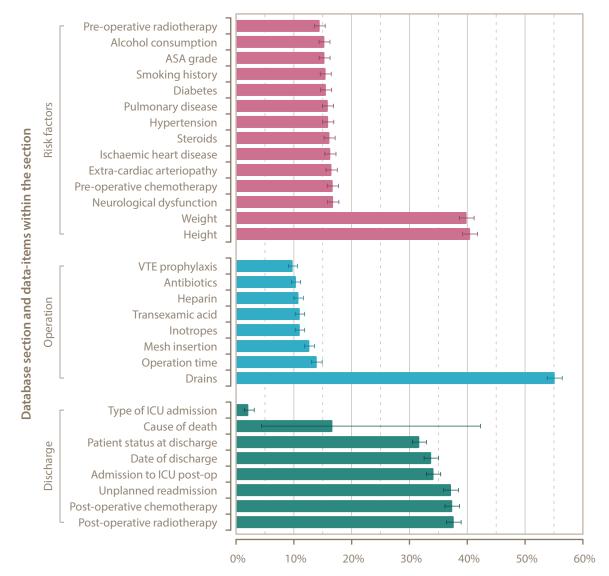


The chart below clearly shows that there are no systematic omissions in data collection in the baseline section for risk factors, apart from the height and weight questions. Perhaps this is because these data are more pertinent to the anaesthetist rather than the surgeon at the time of the operation. The fact that these two questions are over-looked is a pity, as they are used to calculate the patient's body mass index (BMI), and BMI is known to be a factor that is often correlated with surgical outcomes. It would be valuable to have these two questions completed more often. In the operation section, the data on drains are missing in just over half of all operation records. The reasons for this are unclear.

In the discharge section two questions are largely complete: type of ICU admission and cause of death. Users only have access to these questions when other conditions are met (admission to ICU after procedure is recorded as yes, and patient status at discharge is recorded as deceased respectively). This is a design feature (a conditional question) used in the registry to drive up data-quality by making it impossible to enter conflicting information. But, this means that the two dependent questions can only be missing when the appropriate condition in the controlling question has been met, both of which are infrequent.

Otherwise, there is a fairly even spread of missing data rates in the other discharge questions, hovering at or around 35% of all operation records. This is consistent with the supposition that the users probably either come back to the discharge page and enter all the required data at a later date (around 65% of all cases), or alternatively skip this step entirely.

Missing data in the baseline record (n=5,688)



Percentage of database entries with missing data

Database overview



Overview section

Recipient sites as context for analysis

The following table shows that about half of the reconstructive flaps recorded in the registry were to the breast. The second largest group in terms of recipient site was the head & neck area. Together with the breast operations, these comprise over 80% of all the reconstructions recorded in the UK National Flap Registry.

UK National Flap Registry: recipient sites; operations dated Jan 2016–Jun 2019

			Count	Percentage
	Breast		2,312	50.1%
	Upper limb	101	2.2%	
	Lower limb		446	9.7%
	Head & neck		1,485	32.2%
	Trunk	170	3.7%	
(s)	Perineum	87	1.9%	
Recipient site(s)		Breast and Trunk	10	0.2%
ent		Lower limb and Perineum	1	0.0%
cipi		Lower limb and Trunk	1	0.0%
Re	Combinations	Lower limb, Trunk and Perineum	1	0.0%
		Lower limb and Breast	1	0.0%
		Head & neck and Trunk	1	0.0%
		Head & neck and Upper limb	1	0.0%
	No information on	recipients	404	
	All		5,021	

The graph on the next page show the distribution of practice according to recipient site on a hospital-by-hospital basis. The hospital names have been replaced by a numerical code.

It is interesting to note that the majority of hospitals appear to provide a mixed service that includes breast and head & neck reconstructions. For the most part, these kinds of operations are performed by surgeons who have a sub-specialty interest in breast and head & neck reconstruction respectively. There were, however, some units that exclusively recorded breast (shown here as pink bars) or head & neck (shown here as green bars) reconstructions, seen at either end of the graph.

Of course, it could be that hospitals that seem to do only one kind of flap surgery are actually hospitals with a mixed practice, but not all the flap surgeons at that hospital have signed up to the UKNFR; hence, this pattern of practice in the graph may be artificially skewed.



This apparent variation in practice means that is does not make sense to make direct comparisons between hospitals based on the global data held in the UKNFR. Rates of co-existing conditions and outcomes are greatly impacted by the kind of condition being treated and by the recipient site in the flap operation, as will become evident later in this report. Inter-hospital comparisons should be confined to particular sub-groups of patients, *e.g.*, just breast reconstruction surgery, or just head & neck surgery.

Operations records submitted from each hospital;

operation records dated Jan 2016-Jul 2019 Breast surgery Head & neck surgery Other procedures Others (<30 records)

40%

Percentage of operations

60%

80%

100%

20%

0%

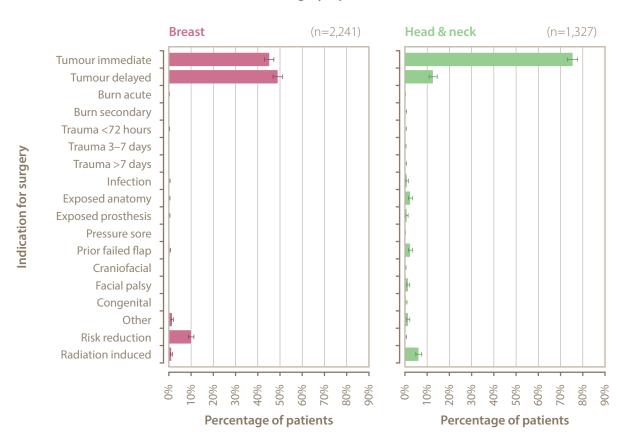


Flap indication

The graphs on these facing pages show the indications for different kinds of flap reconstructions. Cancer was by far the most common indication for surgery, which is relevant to all of the recipient sites, the exception being limb surgery where most cases were for trauma or infection; other common indications for reconstruction in the limbs were for exposed prostheses or exposed anatomical structures.

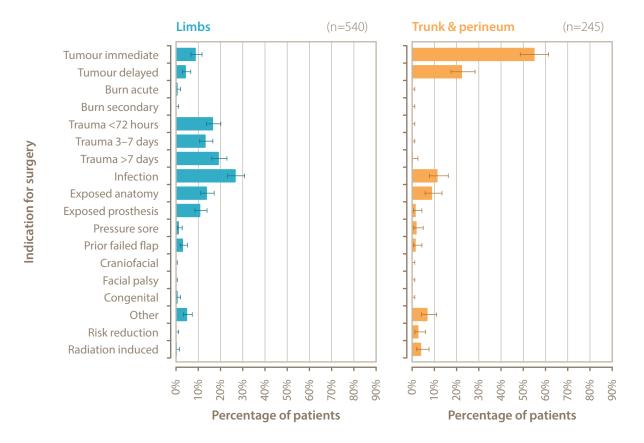
There is a more detailed information on the various indications for surgery in each of the recipient-specific sections of this report.

Indications for surgery; operation records dated Jan 2016-Jun 2019





Indications for surgery; operation records dated Jan 2016–Jun 2019





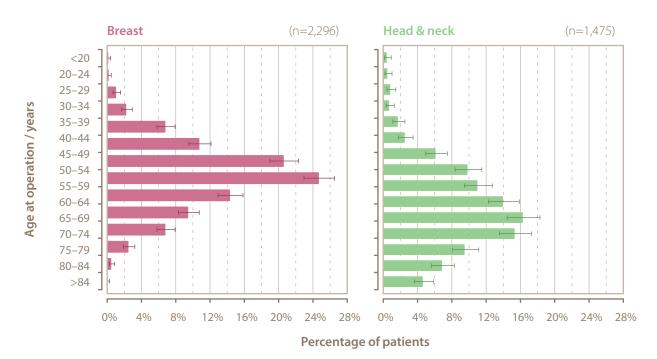
Pre-operative patient characteristics

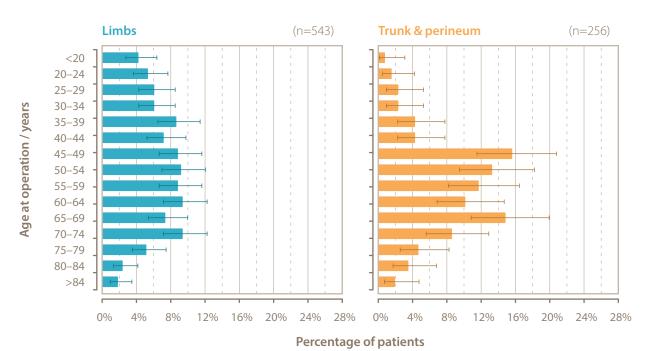
Demographics

Age at surgery

The following charts show the variation in age distribution according to the recipient sites. While both the head & neck and breast reconstructions tended to be for cancer, this disease usually affects an older age group in the head & neck population. There were few patients over the age of 80 years. Some reconstructions were for congenital conditions, but not many have been recorded and there are only a few records of reconstructive flaps in children.

Age profiles for patients according to the anatomical site treated; operation records dated Jan 2016–Jun 2019





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Gender

This chart shows the gender split by recipient site and demonstrates that there was a significant difference in gender distribution according to recipient site. And, as might be expected, the vast majority of breast reconstructions were for women (99.5%). To the uninitiated, it is surprising, perhaps, that there are any breast reconstructions for male patients at all.

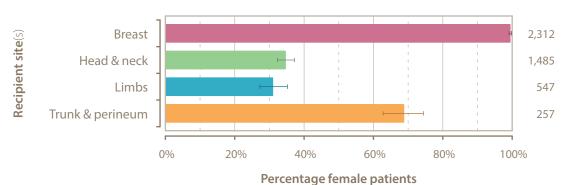
More men than women were treated with head & neck and limb reconstructive surgery. The uneven gender distribution in head & neck reconstruction is explored in a detailed section later in this report.

In the limb reconstruction group, the predominance of male patients is mainly due to the indication for surgery being trauma, which is more prevalent in men.

UK National Flap Registry: gender; operations dated Jan 2016–Jul 2019

			Gender				
		Со	Count		ntage	Ratio	
		Male	Female	Male	Female	M:F	
a	Breast	11	2,301	0.5%	99.5%	1:210	
Recipient site	Head & neck	969	516	65.3%	34.7%	15:8	
ien	Limbs	377	170	68.9%	31.1%	20:9	
ecip	Trunk & perineum	80	177	31.1%	68.9%	9:20	
~	Other complex	4	12	25.0%	75.0%	1:3	

Gender; operation records dated Jan 2016–Jun 2019





Co-existing conditions

Overview

The data on *risk factors* in the pre-operative section of the registry are shown in the table below, split by recipient site group, and then presented graphically over the next few pages. These co-existing conditions may be relevant to the aetiology of the underlying indication for reconstruction and for outcomes following flap procedures.

UK National Flap Registry: pre-operative co-existing conditions for each treated recipient site; operations dated Jan 2016–Jun 2019

			F	resence of	the condition	
			No	Yes	Unspecified	Rate
		Breast	1,795	353	164	16.4%
	Smoking now / in	Head & neck	451	827	207	64.7%
	the past	Limbs	219	210	118	49.0%
		Trunk & perineum	148	66	43	30.8%
		Breast	1,927	188	197	8.9%
	I la managara a da m	Head & neck	717	564	204	44.0%
	Hypertension	Limbs	328	111	108	25.3%
		Trunk & perineum	167	46	44	21.6%
		Breast	2,125	19	168	0.9%
	Alcohol	Head & neck	1,044	263	178	20.1%
	consumption over limits	Limbs	386	42	119	9.8%
	Over mints	Trunk & perineum	201	2	54	1.0%
Pre-operative co-existing conditions		Breast	2,044	93	175	4.4%
	Pulmonary	Head & neck	1,052	216	217	17.0%
	disease	Limbs	394	44	109	10.0%
5		Trunk & perineum	190	20	47	9.5%
ting		Breast	2,120	16	176	0.7%
<u>אַ</u>	Extra-cardiac arteriopathy	Head & neck	1,032	198	255	16.1%
ט ס		Limbs	418	27	102	6.1%
ט א		Trunk & perineum	205	9	43	4.2%
בו בו		Breast	2,120	23	169	1.1%
<u>5</u>	Ischaemic heart	Head & neck	1,031	202	252	16.4%
ָ ע	disease	Limbs	395	48	104	10.8%
_		Trunk & perineum	187	26	44	12.2%
		Breast	2,071	67	174	3.1%
	Diabetes	Head & neck	1,126	161	198	12.5%
	Diabetes	Limbs	390	51	106	11.6%
		Trunk & perineum	188	20	49	9.6%
		Breast	2,115	18	179	0.8%
	Neurological	Head & neck	1,147	74	264	6.1%
	dysfunction	Limbs	417	21	109	4.8%
		Trunk & perineum	203	11	43	5.1%
		Breast	2,131	19	162	0.9%
	Ctoroid usa	Head & neck	1,175	56	254	4.5%
	Steroid use	Limbs	423	23	101	5.2%
		Trunk & perineum	206	8	43	3.7%

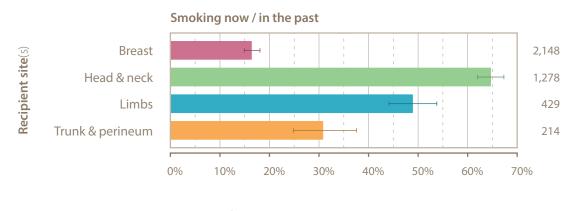
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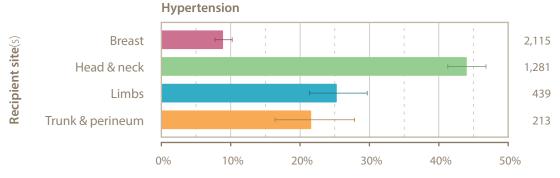


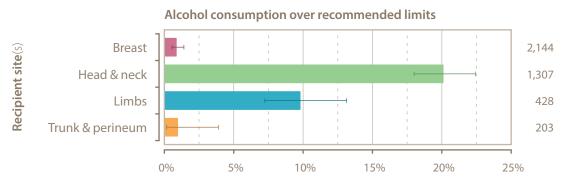
The relative rates of these co-existing conditions varies across the different recipient sites; for example, any history of smoking and alcohol consumption are known to be closely associated with the incidence of head & neck cancer, which is confirmed by the observational data in the UKNFR (see below). Extra-cardiac arteriopathy and ischaemic heart disease are much more prevalent in head & neck patients than in patients undergoing breast reconstruction, but these are not aetiological factors for these patients.

The following charts show the distribution of the main co-existing conditions and confirm that the head & neck group have significantly higher rates of most of these conditions, particularly when compared to patients who were having a flap reconstruction of the breast. This might suggest that the head & neck patients are at greater risk of an adverse outcome after surgery.

Pre-operative co-existing conditions; operation records dated Jan 2016–Jun 2019



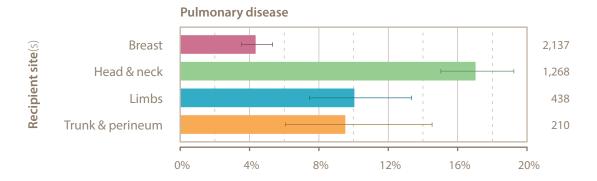


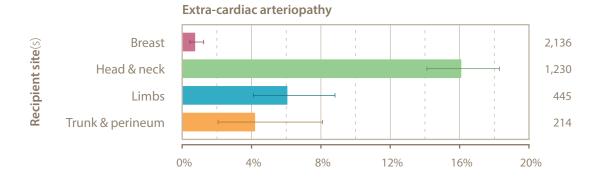


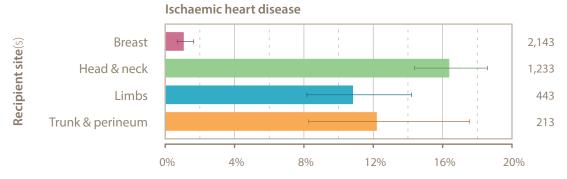
Percentage of patients with the condition



Pre-operative co-existing conditions; operation records dated Jan 2016–Jun 2019





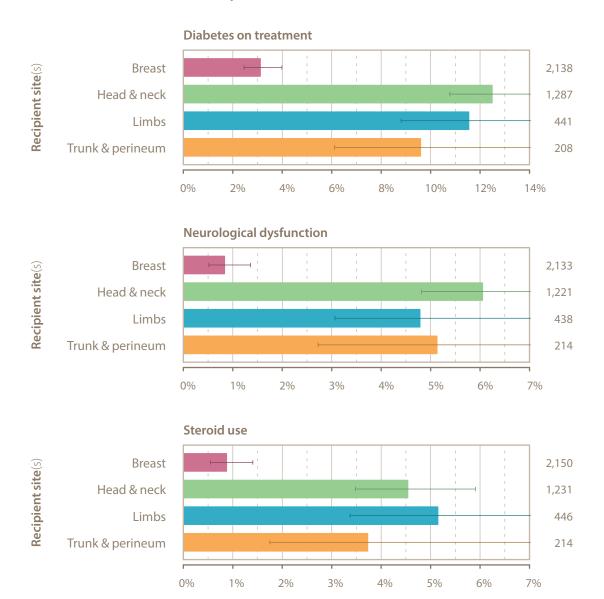


Percentage of patients with the condition

Funded by BAPRAS



Pre-operative co-existing conditions; operation records dated Jan 2016–Jun 2019





ASA grade

The American Society of Anesthesiologists (ASA) status is a classification system designed to assess the fitness of patients before surgery. The distribution of ASA grade for each recipient site is shown below. The grades are:

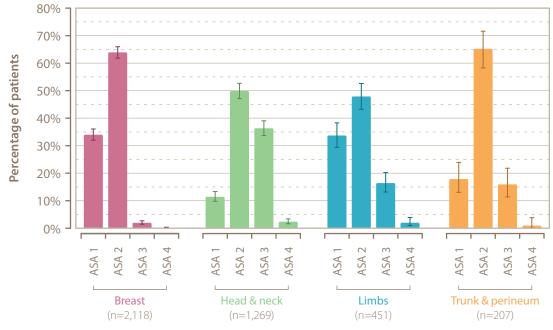
- **ASA 1** patient has no organic, physiological or psychiatric disturbances
- ASA 2 mild to moderate systemic disturbances or distress
- **ASA 3** severe systemic disturbance or disease whatever the cause
- **ASA 4** severe systemic disorders already life-threatening, not always correctable by surgery
- **ASA 5** moribund person with little chance of survival submitted to operation in desperation

As many of the breast reconstructions were delayed, elective operations after a prior cancer resection, there was an opportunity to work with these patients to help them lower their operative risk or to select only lower risk patients for reconstructive surgery. This principle does not apply to the head & neck group for whom most of the reconstructions were performed immediately at the time of the cancer resection, hence their higher ASA grade.

UK National Flap Registry: pre-operative ASA grade and recipient site

				ASA grade		
		ASA 1	ASA 2	ASA 3	ASA 4	Unspecified
a	Breast	720	1,354	42	2	194
	Head & neck	145	633	461	30	216
t site	Limbs	152	216	74	9	96
ien	Trunk & perineum	37	135	33	2	50
Recipient	Other complex	4	9	3	0	0
	No information	60	130	26	1	187
	All	1,118	2,477	639	44	743

ASA grade and recipient site; operation records dated Jan 2016–Jun 2019



Recipient site and ASA grade

Funded by BAPRAS



Body mass index

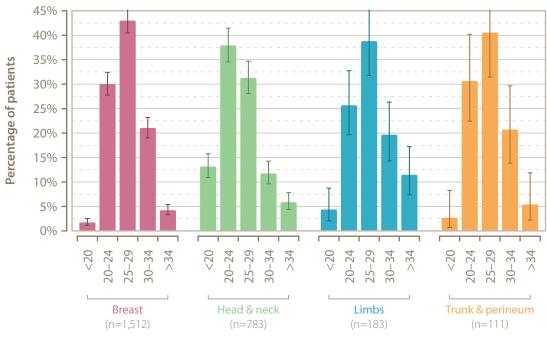
The following table and associated chart provide information on the distributions of patients' body mass index (BMI) at the time of surgery for each recipient site group.

Surgeons often plan the reconstruction dependent on a patient's BMI. For example, in breast reconstruction, there were more patients in the 30–34 kg m⁻² BMI range; these women will generally have more tissue on the abdomen available for use in reconstruction.

UK National Flap Registry: body mass index and recipient site

				Body mass	index / kg m	2	
		<20	20-24	25–29	30-34	>34	Unspecified
	Breast	26	454	650	318	64	800
a	Head & neck	103	297	245	92	46	702
t site	Limbs	8	47	71	36	21	364
Recipient	Trunk & perineum	3	34	45	23	6	146
ecip	Other complex	0	5	5	1	1	4
X.	No information	0	35	44	30	3	292
	All	140	872	1,060	500	141	2,308

Body Mass Index and recipient site; operation records dated Jan 2016–Jun 2019



Recipient site and BMI / kg m⁻²



Chemotherapy and radiotherapy

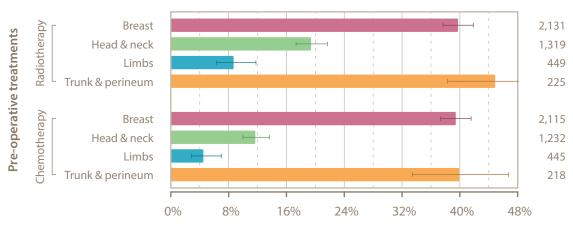
The following two charts show that patients having either breast reconstruction or surgery to the trunk/perineum were more likely to have had pre-operative radiotherapy and chemotherapy than the patients who had head & neck or limb reconstructive surgery.

Many of the breast cancer patients will have had treatment of the breast cancer with mastectomy, followed by chemotherapy and radiotherapy. The timing of the flap reconstruction is usually a year after the mastectomy.

In cancer of the perineum, which will include ano-rectal and vulvo-vaginal cancers, the mainstay of treatment is often neo-adjuvant chemo-radiation, with flap reconstruction for defects after radical excision.

In limb reconstructions, the majority of which were performed for trauma, significantly fewer of these patients were likely to have received either of these two non-surgical interventions pre-operatively.

Pre-operative radiotherapy and chemotherapy; operation records dated Jan 2016–Jun 2019



Percentage of patients treated

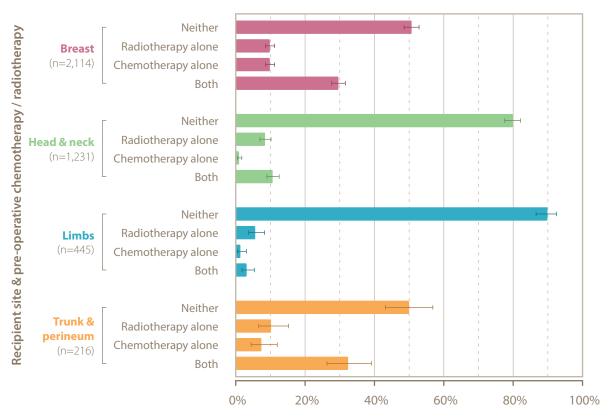
Funded by BAPRAS



The following graph shows that half of all patients having a breast reconstruction had not received radiotherapy or chemotherapy prior to flap reconstruction. These included patients who had had an immediate reconstruction *i.e.*, mastecomy and reconstruction at the same operation for breast cancers such as DCIS (ductal carcinoma in situ), which may not require any radiotherapy or chemotherapy post-operatively. Patients who would have had a mastectomy previously, and did not require any post-mastectomy radiation or chemotherapy prior to flap reconstruction, were also part of this group.

In head & neck cases, 80% of patients did not have pre-operative radiotherapy or chemotherapy. For resectable tumours, excisional surgery coupled with reconstruction often form the mainstay of treatment with post-operative adjuvant treatment (often chemotherapy and/or radiotherapy) if required.

Pre-operative radiotherapy and chemotherapy; operation records dated Jan 2016–Jun 2019



Percentage of patients treated



The breast reconstruction group had significantly fewer patients with 4 or more co-existing conditions when compared to patients in the other recipient site groups, as shown below. The head & neck reconstruction group tended to have the most co-existing conditions.

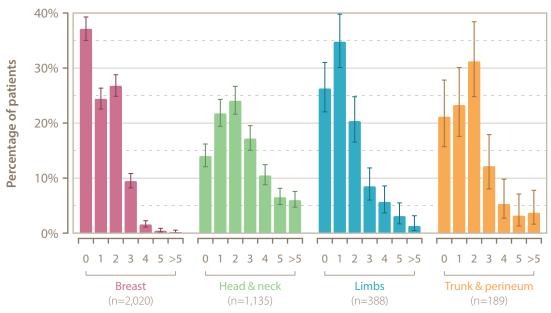
Again, this is not surprising, as the head & neck reconstruction group are generally much older than the patients in the breast reconstruction cohort. The head & neck group also included more smokers and more patients with excess alcohol consumption, both of which are known to increase the risk of developing head & neck cancer in the first place.

Common co-existing conditions were diabetes, pulmonary disease (such as asthma), and hypertension. Ischaemic heart disease and extra-cardiac arteriopathy, when present, were more common in the head & neck group.

The counts of co-existing conditions exclude the data on both the ASA grade and the patient's BMI.

The ASA grade is not included in this analysis as it is a grading system and not a condition in its own right, and BMI is excluded partly because there is no firm consensus on the definition of a problematic BMI and also because the two data-items used to calculate the BMI were poorly represented in the database. Its inclusion would have meant that many more operation records would have been excluded from this analysis.

Number of co-existing conditions and recipient site; operation records dated Jan 2016–Jun 2019 with complete data



Recipient site and number of co-existing conditions

Funded by BAPRAS



Donors and recipients

Number of donors & recipients

As is shown in this table, most reconstructions involved a single donor flap to a single defect, but some operations such as bilateral mastectomies required bilateral reconstruction using two flaps. The transfer of two flaps to one recipient site in breast cases can be explained by the use of bi-pedicled deep inferior epigastric perforator (DIEP) flaps or bilateral transverse upper gracilis (TUG) flaps to reconstruct one breast.

In head & neck surgery, reconstruction with two flaps typically occur in situations where there is an in-continuity defect *e.g.*, a through and through segmental mandibular defect with loss of oral mucosa, bone and facial skin. These defects are more demanding in terms of the requirements for tissue volume, composition and aesthetics. These flap operations involving multiple donors and / or recipients are among the most complex reconstructions intended to restore orofacial form and function. There is some evidence in the published literature that the risk of flap compromise and / or failure is higher is such cases.

UK National Flap Registry: number of donors & recipients; linked data only; operations dated Jan 2016–Jun 2019

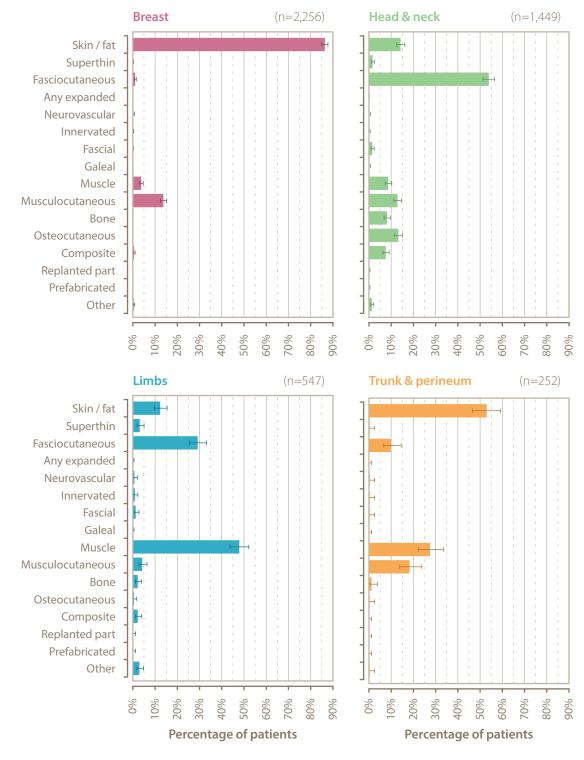
	Recipient class					
	Breast	Head & neck	Limbs	Trunk & perineum	Other complex	No data
0=>0	0	0	0	0	0	404
1=>1	1,818	1,388	527	193	0	0
1=>2	27	3	1	1	6	0
2=>1	69	60	14	36	0	0
2=>2	355	14	4	15	4	0
2=>3	3	0	1	0	0	0
3=>1	3	3	0	4	0	0
3=>2	3	1	0	0	0	0
3=>3	1	2	0	0	1	0
4=>1	0	1	0	2	0	0
4=>2	1	0	0	1	0	0
Unspecified / indeterminate	32	13	0	5	5	0
All operations	2,312	1,485	547	257	16	404



Composition

The composition of a donor flap is principally determined by the nature and also the dimensions of the recipient defect. Most of the reconstructions, as shown in the charts below, included skin, but, for some defects, muscle-only flaps were used with split thickness skin grafts subsequently applied to the surface; this is particularly relevant in limb reconstruction. Fasciocutaneous flaps are utilised for reconstruction of the majority of oral cavity and oropharyngeal soft tissue defects. Where there is loss of bone and soft tissue, the defects are reconstructed with composite flaps. Pharyngeal defects can either be partial or complete / circumferential, depending on the extent of the tumour. Partial pharyngeal defects are generally reconstructed with *patch* fasciocutaneous flaps *e.g.*, ALT, whilst circumferential defects can be reconstructed with either jejunal free flaps or tubed fasciocutaneous flaps.

Donor composition; operation records dated Jan2016-Jul 209



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Type of donor

This table cross-tabulates data on the type of donor and the recipient site. The highest proportion of free microvascular reconstructions were to the breast, with the lowest proportion to the trunk and the perineum, for which sites pedicled flaps were utilised more frequently.

Commonly-used free flaps in breast reconstruction were deep inferior epigastric perforator (DIEP) and muscle-sparing transverse rectus abdominis (MSTRAM) flaps, whereas in the head & neck, these were radial forearm (RFF) and the antero-lateral thigh (ALT) flaps.

In limb reconstruction, 64% of flaps were microvascular free flap reconstructions, usually required for defects in the lower third of the lower limb. These were often muscle flaps such as gracilis, or fasciocutaneous flaps such as an antero-lateral thigh flap.

UK National Flap Registry: type of donor; operations dated Jan 2016–Jun 2019

		Type of donor				
		Free	Pedicled	Free and pedicled	Unspecified	Free flap rate
	Breast	2,044	234	2	32	89.7%
a	Head & neck	1,244	212	16	13	85.6%
t site	Limbs	352	193	2	0	64.7%
ien	Trunk & perineum	103	149	0	5	40.9%
Recipient	Combination	6	5	0	5	54.5%
	No information	0	0	0	404	
	All	3,749	793	20	459	82.6%



Operative information

Duration of operation

The table and chart below show the duration of the operation for each of the recipient site groups; the duration of surgery varies according to the recipient site.

A possible reason for the differences shown here may be that the primary cancer surgery had been performed previously, as in the delayed breast reconstruction cases.

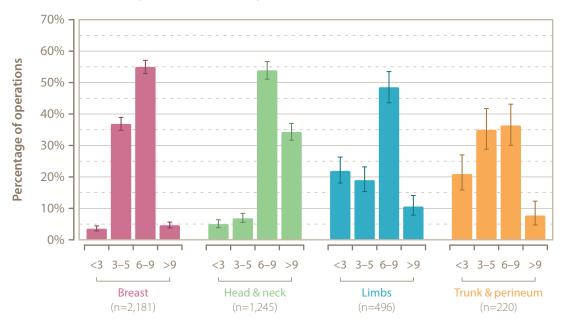
Some of the shorter duration operations for limbs, and for the trunk and perineum, may be for pedicled flaps that do not require time-consuming micro-surgical anastomoses.

Head & neck reconstruction operations had significantly more cases taking over 9 hours compared to the other groups, partly because these are very complex procedures.

UK National Flap Registry: duration of operation; operations dated Jan 2016–Jun 2019

		Duration of operation				
		<3 hours	3–5 hours	6-9 hours	>9 hours	Unspecified
	Breast	77	804	1,199	101	131
a	Head & neck	62	85	671	427	240
t site	Limbs	89	167	197	43	51
Recipient	Trunk & perineum	46	77	80	17	37
ecip	Combinations	1	4	8	2	1
&	No information	32	49	71	48	204
	All	307	1,186	2,226	638	664

Operation duration; operation records dated Jan 2016-Jun 2019



Recipient site and duration of operation / hours

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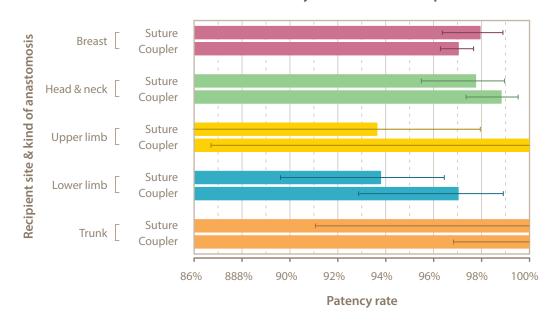
Anastomosis

3,299 couplers were used successfully (patent anastomosis) compared to 1,232 hand sutured anastomoses out of 4,543 end-to-end vein anastomoses. Venous couplers have become mainstream as they are easy to use, reducing the time taken to perform the anastomosis, and the design prevents accidental occlusion of the vein while performing the manoeuvre. More couplers were used in breast reconstruction, constituting 81% of end-to-end vein anastomoses, whereas in head & neck surgery, couplers were used in 58% of end-to-end vein anastomoses.

UK National Flap Registry: patency of **venous end-to-end anastomoses** according to the use of coupler; operations date Jan 2016–Jun 2019

		_		P	atent	
			No	Yes	Unspecified	Rate
	Dunnet	No coupler (suture)	12	576	3	98.0%
	Breast	Coupler	73	2,401	19	97.0%
er	Head & neck	No coupler (suture)	8	351	7	97.8%
e of coupler		Coupler	6	510	3	98.8%
	Upper limb	No coupler (suture)	4	59	0	93.7%
sn pi		Coupler	0	21	0	100.0%
Recipient site and use	Lower limb	No coupler (suture)	14	212	3	93.8%
intsi	Lower IIIID	Coupler	5	164	4	97.0%
cipie	Trunk	No coupler (suture)	0	32	0	100.0%
Re	ITUNK	Coupler	0	93	0	100.0%
	Perineum	No coupler (suture)	0	2	0	100.0%
	Perineum	Coupler	0	0	0	NA

Venous end-to-end recipient site anastomoses: Patency for suture *versus* coupler





Outcomes

Immediate operative outcomes overview

The following tables show three key outcomes according to recipient site:

- unplanned re-operation
- flap survival
- in-hospital mortality

The recorded unplanned re-operation rates varied from 8.6% following breast reconstruction to 15.5% following limb reconstruction.

In microvascular surgery for free tissue transfer, a higher unplanned return-to-theatre rate accompanied by a higher flap survival rate tends to suggest a successful salvage of a compromised free flap.

Flap reconstructions for lower limb trauma have a higher unplanned re-operation rate, as the microvascular anastomoses may have been performed within the zone of trauma, using recipient vessels that may have some elements of damage. In head & neck reconstruction, operations often take in excess of 9 hours due to the extent of the cancer being resected, which may include soft tissue and/or bone (craniofacial skeleton) and also the resultant complexity of the reconstruction, often performed in patients with significant co-existing conditions.

Overall, >90% total flap success was confirmed across all recipient groups. The flap survival rates here are in line with those reported in the scientific literature. The registry records flap survival as complete survival of flap versus partial survival versus zero survival (also known as total flap failure). Partial flap loss is especially pertinent in head & neck reconstruction, where loss of part of the flap necessitating a second flap reconstruction influences the final outcome including length-of-stay and potential delay to adjuvant radiotherapy \pm chemotherapy, which have been known to have an adverse impact in disease control and long-term survival rates and rehabilitation of the patient.

In cases of partial flap survival, some may not require any further intervention. However, if partial flap loss is clinically significant then further analysis of the detailed data on the re-operations performed at the recipient site (such as whole of flap removed or part of flap removed) would provide more information.

Breast reconstruction patients had the highest total flap survival rates, which may be related to the distribution of co-existing conditions, as these patients were generally younger and fitter.

Finally, although in-hospital mortality was very low (with 100% patient survival after breast and trunk & perineum reconstructions), **there was a 1.6% recorded in-hospital mortality rate following head & neck reconstructive surgery.**

Patients undergoing these latter head & neck procedures are at higher risk of an adverse outcome partly because of the proximity of key anatomical structures encountered during surgery such as the airway, and the major blood vessels in the neck. In addition, the fact that these patients tend to have elevated rates of most co-existing conditions (for example, pulmonary disease and ischaemic heart disease) goes some way to explaining the higher rates of adverse outcomes seen in this group when compared to patients undergoing other kinds flap surgery.

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UK National Flap Registry: immediate outcomes

Any unplanned re-operations (only operations with linked donor & recipients)

		No	Yes	Unspecified	Rate
Recipient site	Breast	2,033	192	55	8.6%
	Head & neck	1,095	151	226	12.1%
	Limbs	440	81	26	15.5%
	Trunk & perineum	212	29	11	12.0%
	Combinations	11	0	0	0.0%
	No information	0	0	343	
	All	3,791	453	661	

Flap survival (only operations with linked donor & recipients)

		100%	<100%	Unspecified	Rate
	Breast	2,143	52	85	97.6%
a	Head & neck	1,242	76	154	94.2%
t site	Limbs	478	28	41	94.5%
ien	Trunk & perineum	211	13	28	94.2%
Recipient	Combinations	10	0	1	100.0%
8	No information	0	0	343	
	All	4,084	169	652	

Patient survival

		Yes	No	Unspecified	Rate
	Breast	1,929	0	383	100.0%
a	Head & neck	863	14	608	98.4%
t site	Limbs	341	1	205	99.7%
ien	Trunk & perineum	168	0	89	100.0%
Recipient	Combinations	9	0	7	100.0%
~	No information	176	1	227	
	All	3,486	16	1,519	



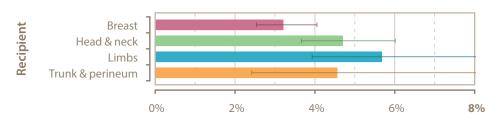
Unplanned re-operation

Detailed unplanned re-operation information

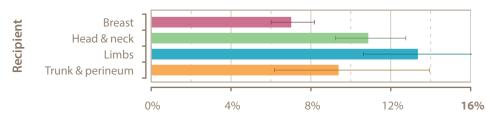
The following graphs show the unplanned re-operation rates for each of the anatomical regions. These are further divided into re-operations for recipient and donor sites. The last two graphs show the low rates of flap removal: either partial removal or whole-flap removal, usually for a flap failure.

Unplanned re-operations to the recipient site were significantly more frequent after reconstructions of the head & neck and limbs than after breast flap surgery. Given some of the complexities of reconstruction, there is clearly something distinct about head & neck and limb reconstruction patients that increases the risk of unplanned return to theatre for recipient site re-operations. However, the rates reported here are within the range of previous published case series in the surgical journals.

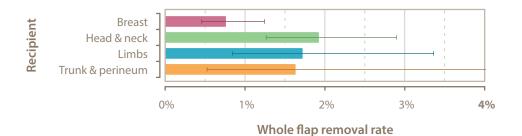


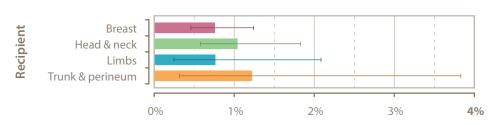


Overall unplanned donor re-operation rate



Overall unplanned recipient re-operation rate





Part of flap removal rate

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Although the unplanned re-operation rate by recipient site were higher in head & neck and limb reconstructions, it is interesting to note that the donor site return to theatre/unplanned re-operation rate was consistently within a narrow range across all the recipient site groups (generally between 3% and 6%).

Detailed unplanned re-operation information for each recipient site group

		Unplanned re-operation					
	No	Yes	Unspecified	Rate			
Donor unplanned re-operation f	or any reason						
Breast	2,169	72	39	3.29			
Head & neck	1,277	63	132	4.79			
Limbs	498	30	19	5.7%			
Trunk & perineum	230	11	11	4.69			
Other complex	11	0	0	0.09			
No information	0	0	343	N			
All	4,185	176	544	4.0%			
Recipient unplanned re-operation	n for any reason						
Breast	2,081	157	42	7.0%			
Head & neck	1,123	137	212	10.99			
Limbs	454	70	23	13.49			
Trunk & perineum	222	23	7	9.49			
Other complex	11	0	0	0.09			
No information	0	0	343	N			
All	3,891	387	627	9.0%			
Whole flap removed							
Breast	2,218	17	45	0.89			
Head & neck	1,223	24	225	1.99			
Limbs	514	9	24	1.79			
Trunk & perineum	241	4	7	1.69			
Other complex	11	0	0	0.09			
No information	0	0	343	N.			
All	4,224	54	627	1.39			
Part of flap removed							
Breast	2,218	17	45	0.89			
Head & neck	1,234	13	225	1.09			
Limbs	519	4	24	0.89			
Trunk & perineum	242	3	7	1.29			
Other complex	11	0	0	0.09			
No information	0	0	343	N			
All	4,241	37	627	0.9%			



Post-operative stay

Overview

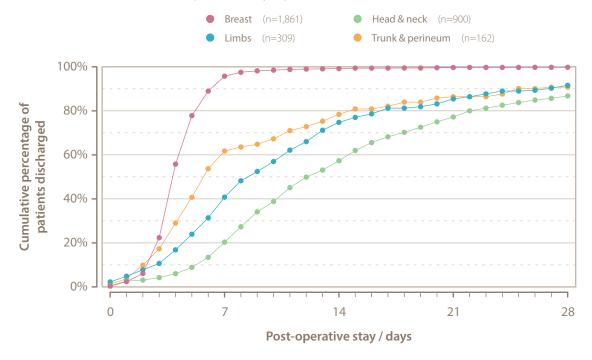
Variations in post-operative length-of-stay are shown in the following table and chart. The majority of breast reconstruction cases were discharged within 7 days of surgery, whereas for head & neck cases 80% were still in-patients after 7 days.

The delay to discharge after head & neck reconstruction, limb and trunk & perineum reconstructions might reflect the need for more extensive in-hospital, post-operative rehabilitation that is often needed for these patients. In particular the head & neck reconstructive surgery patient population is, in general, older and more likely to have significant co-existing conditions that need careful management during the in-patient stay.

UK National Flap Registry: summary statistics for post-operative stay data

		Count	Average (95% CI)	Median (IQR)
Recipient site	Breast	1,861	4.7 (4.5– 4.8)	4.0 (4.0– 5.0)
	Head & neck	900	18.6 (17.1–20.1)	13.0 (8.0–20.5)
	Limbs	309	12.9 (11.3–14.4)	9.0 (6.0–15.0)
	Trunk & perineum	162	11.5 (9.4–13.6)	6.0 (4.0–13.5)
	Combination	9	6.6 (3.4– 9.9)	4.0 (3.0– 9.5)

Post-operative stay; operation records dated Jan 2016-Jul 209



First UK National Flap Registry Report 2019 Funded by BAPRAS





Post-operative stay and the count of co-existing conditions.

The table below and the accompanying chart opposite show the average length-of-stay for patients according to the recipient site of the reconstructive surgery and the patients' number of co-existing conditions. After breast flap surgery and lower limb reconstruction, there is no clear indication that the number of co-existing condition has any effect on the patient's post-operative stay.

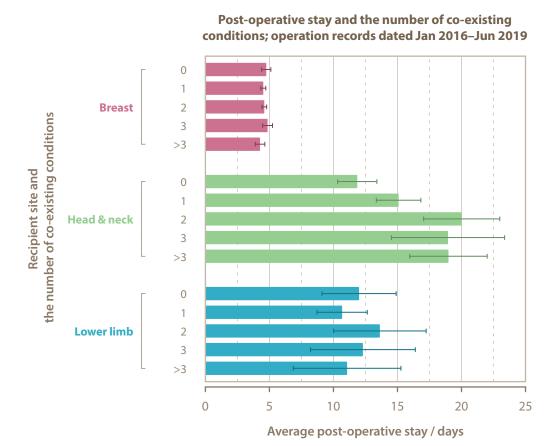
Post-operative stay and the number of co-existing conditions pre-operatively: operations with complete data on co-existing conditions; operations dated Jan 2016–Jun 2019

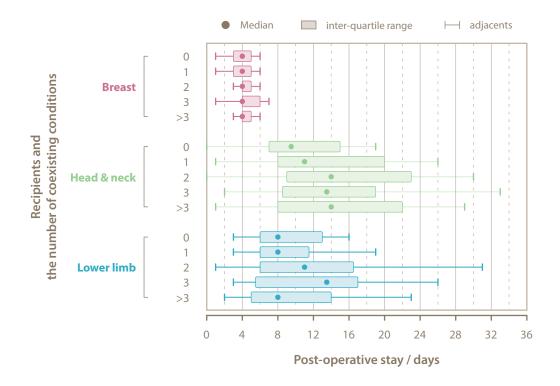
			Count	Average (95% CI)	Median (IQR)
	Breast	0	633	4.7 (4.4–5.1)	4.0 (3.0–5.0)
		1	364	4.5 (4.3–4.7)	4.0 (3.0–5.0)
		2	452	4.6 (4.4–4.7)	4.0 (4.0–5.0)
		3	146	4.8 (4.4–5.2)	4.0 (4.0-6.0)
		>3	34	4.2 (3.8–4.6)	4.0 (4.0–5.0)
	Head & neck	0	108	11.8 (10.3–13.4)	9.5 (7.0–15.0)
		1	147	15.0 (13.3–16.8)	11.0 (8.0–20.0)
		2	176	20.0 (17.0–22.9)	14.0 (9.0–23.0)
ns		3	110	18.9 (14.5–23.3)	13.5 (8.5–19.0)
ditio		>3	157	18.9 (15.9–22.0)	14.0 (8.0–22.0)
sting cond	Upper limb	0	8	8.3 (4.0–12.7)	7.0 (4.5–10.0)
		1	18	5.1 (3.3–6.8)	5.0 (2.0–6.5)
-exi		2	9	8.3 (5.2–11.3)	8.0 (4.5-13.0)
Recipient site and the number of co-existing conditions		3	4	4.7 (1.5–7.9)	3.5 (2.0–7.5)
		>3	3	6.0 (-1.3-13.3)	3.0 (0.0–15.0)
	Lower limb	0	41	12.0 (9.1–14.9)	8.0 (6.0–13.0)
		1	53	10.6 (8.7–12.6)	8.0 (6.0–11.5)
nd t		2	40	13.6 (10.0–17.2)	11.0 (6.0–16.5)
te a		3	10	12.3 (8.2–16.3)	13.5 (5.5–17.0)
nt sit		>3	15	11.0 (6.8–15.2)	8.0 (5.0–14.0)
cipie	Trunk	0	19	6.0 (4.6–7.5)	5.0 (4.0–7.0)
Re		1	20	5.4 (4.3–6.6)	5.0 (3.5–7.0)
		2	25	7.6 (4.8–10.5)	5.0 (4.0–6.5)
		3	5	4.8 (3.5–6.0)	4.0 (3.5–6.5)
		>3	8	25.1 (8.3–41.9)	12.5 (5.0–50.5)
	Perineum	0	3	2.0 (1.0–2.9)	2.0 (1.0–3.0)
		1	8	12.6 (3.5–21.6)	7.0 (2.5–20.5)
		2	11	19.7 (11.1–28.3)	17.0 (7.0–29.0)
		3	6	23.3 (7.4–39.1)	16.0 (9.0–45.0)
		>3	8	28.8 (15.3–42.4)	27.0 (16.0–33.5)

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But, after head & neck reconstruction, there is a suggestion that post-operative stay was lowest for patients with no co-existing conditions, increased a little for those who have a single comorbidity, and then increased again to around 19–20 days for patients with more than one co-existing condition. Whether the patients had 2, 3 or more co-existing conditions did not seem to impact on their length-of-stay after surgery.





Breast reconstruction surgery



Breast reconstruction surgery

A patient's story



My mother had breast cancer in her early fifties so I was always aware and on high alert, regularly requesting mammograms every 5 years or so from my thirties onwards.

The first scare came in 2015 when a small amount of ductal carcinoma in situ (DCIS) was detected in my right breast. I was booked in to have a lumpectomy as a day patient at the Royal Surrey Hospital. On the day of the operation I went to have the wire inserted to guide the consultant to the area but, frustratingly for everyone concerned, the area could not be found. This was extremely distressing because all I wanted was for it to be gone but to be told that it had disappeared was unfathomable. I was sent home and put on 6-monthly mammograms; this was reduced to annually and I had a couple of happy, clear years!

It was in May 2018 that another mammogram picked up a 30 mm area of calcification which, after a biopsy, was confirmed to be DCIS. This was not the end of the story though because another area of 10 mm was spotted and another

mammogram was booked. After a rather fraught 2 mammograms the difficult area was found and a further biopsy confirmed an area of 24 mm high-grade DCIS; but, the worst news for me was that it included a micro invasion of 0.4 mm. I was told that the 2 areas were 37 mm apart, which meant there was really only one option and that was a mastectomy. During this time period it seemed that every time I went along for an appointment the news was worse than the last time, and I found it very upsetting and difficult to come to terms with. The final diagnosis with the mastectomy option was devastating and it took me quite a few weeks to come to terms with.

In addition to the proposed 8-hour DIEP reconstruction operation, I was told I would also need to have a sentinel lymph node biopsy to determine whether it had spread; this could either be done during the main operation (which I learnt was going to be at the Queen Victoria Hospital in East Grinstead) or it could be done the week before at Guildford in a separate short day operation. The decision was made to have it done beforehand, which would mean me going into the main operation knowing whether I would have to have my lymph nodes removed or not which, for me, was a better option – if it was bad news I would have a week to prepare.

It was around this time that I decided to step up my gym programme – I was a regular gym-goer anyway, but if this was happening I wanted my body to be in the best possible shape and I knew that my recovery would be quicker and the healing process better; it also gave me something to focus on and it was something I could control – unlike the cancer!

I had my first visit to the Queen Victoria Hospital in mid-July and met the Consultant Plastic Surgeon and some of his team where I was shown some before-and-after pictures of previous patients. Looking at these images I asked the question: 'would it be possible to retain my nipple'? I wasn't backward in coming forward, and expressed my desire to look exactly the same and was pleased when his response was that it could be possible, but really up to the Breast Surgeon. Both operations were confirmed at this time – the smaller op at Guildford was set for Tuesday 4th September 2018 and the big one was a week later at East Grinstead on Tuesday 11th September 2018.

After my holiday in mid-August I had to visit yet another hospital in Tunbridge Wells for a CT scan. Then, later that week, I was back to East Grinstead for the Pre-Assessment appointment and I also had to attend the Anaesthetic Clinic. Then, a week later, I went along to Guildford for their Pre-Assessment.

On the day of the first, smaller operation in Guildford I arrived at the hospital by 7: 30 am and was immediately taken to the Nuclear Medicine Dept. There I had radio-active tracer injected into my breast so the lymph nodes would show up in the operation and, I was then left for a couple of hours. Then I was then taken back to the department and I had to lie in a scanning machine but, unfortunately, the radio-active tracer hadn't spread far enough across, so I had to wait another hour and after this time we had success. Because of all this I was one of the last to go through to theatre in the late afternoon. The operation was less than an hour, but I felt the effects of the anaesthetic and was quite sick, but I was able to make it home that night.

Two days later, on Thursday 6th I had the first bit of good news in ages. The Breast Care Nurse called to say that there was no sign of cancer in the lymph nodes and they had only needed to take out one node. This for me was a turning point, without realising it I had been getting quite worked up about this result, but it was all good and I could now go into the big operation knowing exactly what was going to happen.

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At the pre-assessment appointment the nurse had given me some little bottles of a high calorie liquid, but was told, if possible, to drink them through the day on the Monday before I was admitted on the Tuesday, to give me the extra calories my body would need to cope with the operation.

I arrived at hospital at around 7: 00 am and was immediately taken into a large room with screened off areas, I was the only patient there with a couple of nurses. I had to get into my gown and then the surgeons arrived. I was drawn over with pens and then after a short while was taken to the room attached to the theatre where the lovely anaesthetist did her stuff.

I awoke to the news that they had, indeed, saved my nipple – it was ridiculous how happy I felt. It was over and I had survived, I remember singing all the way to the ward!

Over-night I was woken, as promised, every 4 hours to check everything was OK; I'm not great on no sleep, but it really wasn't that bad and the nurses were wonderful, in fact all the staff were. The only time I had ever been in hospital previously was to have my 2 boys by caesarean section, I had private rooms on both occasions, so wasn't looking forward to sleeping in a ward. I needn't have worried and, in fact, it was great to have people to chat to all day. On the day after the operation I remember one of the nurses saying that my aim for the day was to sit up, get up and walk around the bed; I did all of this and, in fact, was walking up and down the corridor. What was amazing was that there was no pain, which was astonishing and not at all what I was expecting. The next couple of days came and went with, believe it or not, lots of laughter – I met so many incredible people with stories to tell it really was quite an uplifting experience in a bizarre way.

My surgeon had commented on the Wednesday 12th (day 1 after the operation) that I was fit to go home – both the nurse and I were horrified (although we knew he was joking) but on the Friday 14th he came to see me and said he was happy to discharge me, which was great because it meant I would be home for the weekend.

The follow up appointments a few weeks later went well – I had been (and still am) applying Bio Oil™ to all the scars and they have all healed really well. Although I was walking my dog almost immediately after leaving hospital, I was itching to get back to the gym and, literally after the 6 weeks, I was back starting with low impact stuff, and gradually building up as the days and weeks progressed. This has definitely helped me not just physically, but mentally as well.

To summarise, I would say that the reality no way matched the fear I felt on that Tuesday morning going into the operating theatre. I would say that the outcome far exceeded my expectations and I put this down to the fantastic care I received at both the Royal Surrey and East Grinstead, my fitness levels and, once I'd got over the shock, a positive mental attitude. When I was asked at the follow up appointment if I was happy for my photos to be shown to patients I readily agreed. I am so happy with the result and hope that it gives confidence to anyone going into the same operation.

I have just had my first (post-op) mammogram and it was clear: another hurdle over! I would say that my life is completely back to the way it was pre-diagnosis, which is amazing.

Caroline Gatford



Foreword

I would like to congratulate Anita Hazari, the National Audit Lead for the UK National Flap Registry and all her team for the publication of an outstanding first report. This report is unique, being the first national registry in the world to collect data on all major pedicled and free flap operations.

Since its inception in 2015, 5,751 operation records have been added by over 180 registered consultant users. Of the 5,021 records comprising this first analysis, 50.1% were breast cases, the majority of which were for breast reconstruction. Interestingly more reconstructions performed were delayed, 49% compared to immediate 45%, presumably due to caution in patients requiring radiotherapy.

This registry has given us accurate outcome data, which will be invaluable in aiding patients in decision-making regarding breast reconstruction. Outcome data was excellent, with an overall flap survival rate of 97.6% and an unplanned re-operation rate of 8.6%. The average length-of-stay was only 4.7 days. The report has clarified that patients who smoke, are diabetic, or have an ASA score of >3, have an increased flap failure rate. This will help both patient and surgeon in decision-making.

Patient reported outcomes measured at six months revealed 83.5% of patients were satisfied with the outcome.

As data entry is voluntary, it is remarkable that this is such a comprehensive report and I hope that surgeons continue to contribute their data. For those surgeons who have not yet contributed, I hope that they will be inspired by what has been achieved and will now participate. Participation results in a personal audit, which can be used for appraisal and revalidation.

Julie Doughty

President Association of Breast Surgery

Preface

The UK First National Flap Registry Report is an extremely impressive achievement. Only by working together across multiple centres can we fully appreciate the success of autologous reconstruction and identify opportunities to improve and advance.

This report is also a wonderful synthesis of both clinician and patient-reported outcomes. As we continue to innovate and improve reconstructive surgery techniques, this approach to collaborative outcomes measurement will most certainly lead the field.

I wholeheartedly congratulate the UKNFR team and all the surgeons who contributed their outcomes.

Andrea L Pusic

Chief, Plastic and Reconstructive Surgery
Director, Patient-Reported Outcomes, Value & Experience (PROVE) Center, Brigham Health
Joseph E Murray Professor of Surgery, Harvard Medical School

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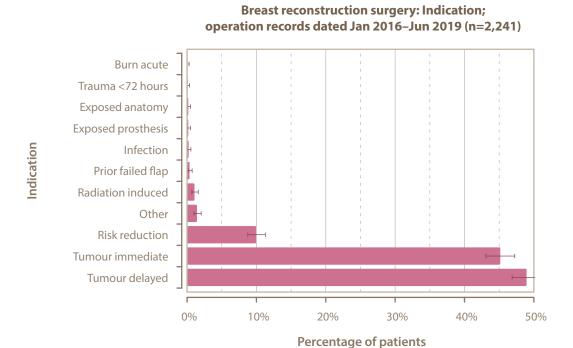
Indication

The chart below shows that the vast majority of breast flap reconstructions were for cancer. These reconstructions are either performed at the time of the cancer resection (immediate reconstruction) or as a separate procedure at a later date (delayed reconstruction). Approximately the same number of patients have an immediate reconstruction as have a delayed reconstruction (45% *versus* 49% respectively). A minority of cases were for risk reduction (10%).

Patients with ductal carcinoma in situ (DCIS) may not require radiotherapy, and can often have their reconstruction performed at the same time as their mastectomy (immediate reconstruction).

Most patients who have cancers such as **invasive** ductal or lobular cancer with positive axillary lymph nodes often require radiotherapy as part of their primary treatment. These patients also tend to have a delayed breast reconstruction. Surgeons report that small vessels often become more friable in tissues that have had recent exposure to radiotherapy, and friable blood vessels make micro-surgical anastomosis in flap surgery technically more challenging; these difficulties can lead to elevated rates of flap failure. So, as a consequence, reconstructive breast surgery is often purposefully delayed to allow these small vessels to recover, which should improve the chances of a successful micro-surgical reconstruction.

Risk reduction is where cancer has not yet been diagnosed but the likelihood of the patient developing a tumour later down the line is deemed to be unacceptably high; for example, individuals who have a BRCA gene (BReast CAncer gene), which predisposes them to a much higher risk of breast cancer. BRCA1 and BRCA2 are two different genes that have been found to impact a person's chances of developing breast cancer. Around 5–10% of breast cancers result from a mutation in the BRCA1 and BRCA2 genes. BRCA mutations increase the risk of developing breast and ovarian cancer, and patients with BRCA mutations tend to develop breast cancer at a younger age. Women with an abnormal BRCA1 or BRCA2 gene have up to an 80% risk of developing breast cancer by the age of 90 years.



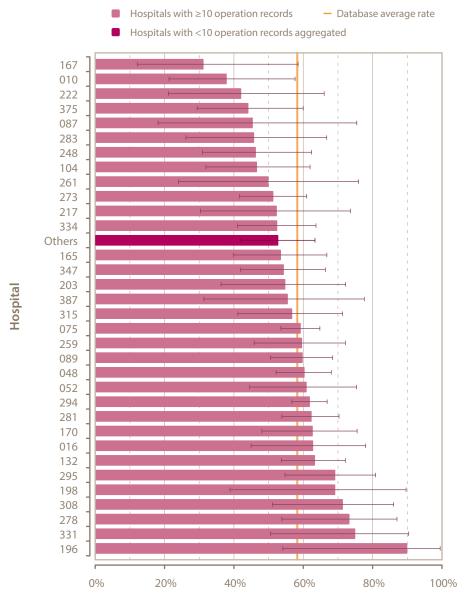


Demographics and co-existing conditions

Age at surgery

The chart below show the percentage of patients who were over the age of 50 years at the time of surgery (which is around the average age in this group of patients; average 51.4 years, median 51.0 years) at each hospital; the hospitals are ordered by increasing percentage of patients over the age of 50 (the hospital names have been anonymised and replace with a code). The chart suggests that while there were differences between units in terms of the percentage of patients above 50 years of age, the overlapping confidence intervals indicate that the current variation in these rates is not statistically significant. This pattern may change as more data are accumulated in the UKNFR, and then, perhaps, meaningful difference might emerge.

Breast reconstruction surgery: Age at surgery *per* hospital; operation records dated Jan 2016–Jun 2019



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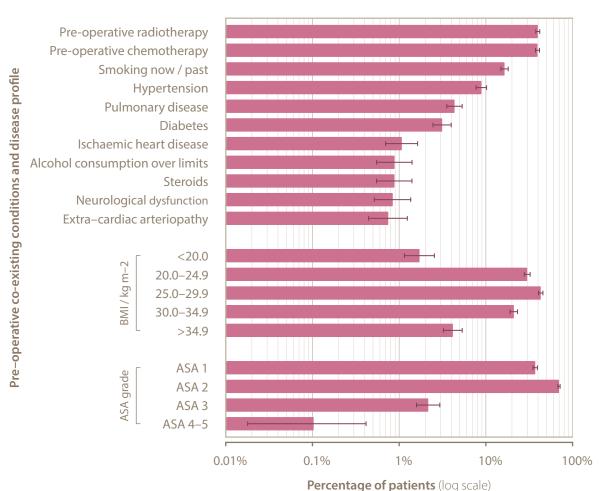
Co-existing conditions and disease profile

Overview

The graph below shows the prevalence of each co-existing condition, together with the rates of the standard BMI groups, and the distribution of pre-operative ASA grades. Please note that the horizontal y-axis on this chart uses a logarithmic scale, so the percentages of patients who have had pre-operative radiotherapy and/or chemotherapy are significantly higher than most of the other rates reported.

Overall the cohort of women undergoing reconstructive breast surgery were generally fit and healthy, with low rates of co-existing conditions and mostly falling into ASA groups 1 and 2. As might be expected, up to 40% have had chemotherapy and / or radiotherapy prior to reconstruction; most of these would be delayed reconstructions. Patient selection is key in getting good outcomes and there were very few patients recorded with ischaemic heart disease (IHD), pulmonary disease, a history of excess alcohol consumption, or steroid usage.

Breast reconstruction surgery: Pre-operative co-existing conditions and disease profile; operation records dated Jan 2016–Jun 2019





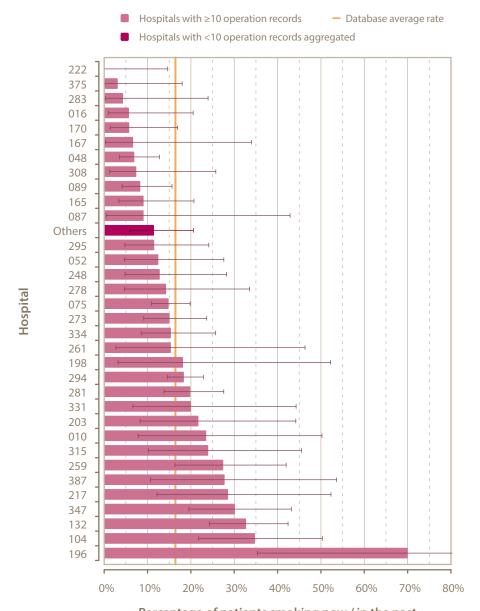
Smoking history

The following series of charts show the percentages of patients at each contributor hospital with the four most-commonly recorded co-existing conditions in this group of patients. Again, the hospital names have been anonymised and replaced with 3-digit codes. The hospitals are sorted according to increasing rates of the condition plotted. The hospital's position in the distribution can vary from one chart to another.

At the extremes there were some significant differences between the rates reported at individual hospitals and the database average for each parameter. This could be for any one of a number of reasons, ranging from different local demographic and referral patterns, to differences in clinical practice, and even to chance variation.

The average percentage of patients with a smoking history (past or present) is 16%. There is wide variation between hospitals (range: 0–70%).

Breast reconstruction surgery: Smoking history *per* hospital; operation records dated Jan 2016–Jun 2019



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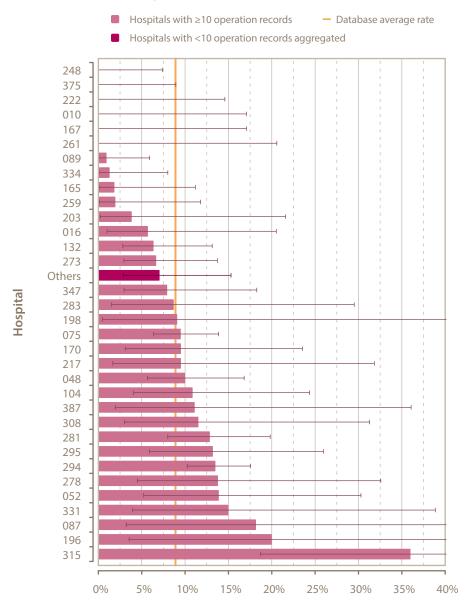


Hypertension

The chart below shows that the average percentage of patients with hypertension was 8.9%. Again, there is variation between hospitals, but the relatively low numbers contributed by each centre means that there is not yet any substantive evidence of statistically significant differences.

Hypertension leads to changes in the intima and adventitia of blood vessels affecting various organs. In microvascular surgery, these vessel-wall changes can affect the blood flow, thereby affecting flap survival. Though hypertension is known to be generally associated with adverse outcomes after surgery, when it is well-controlled it is not considered important enough to act as a barrier to breast reconstruction in and of itself.

Breast reconstruction surgery: Hypertension *per* hospital; operation records dated Jan 2016–Jun 2019



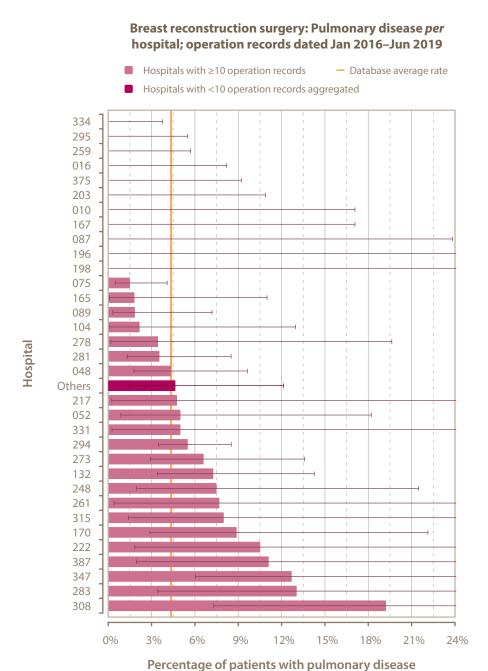
Percentage of patients with hypertension



Pulmonary disease

The number of patients with pulmonary disease undergoing breast reconstructive surgery is relatively small; the database as a whole reported an average rate of only 4.4%. The chart shows that there was quite some variation in the reported rates of this condition amongst the contributor hospitals, but the wide confidence intervals remind us that the calculated rates are based on relatively small numbers of patients *per* hospital, so the apparent differences might be simply due to random variation rather than anything systematic. It will be interesting to see how these distributions change over time as the UKNFR accumulates more data, and the error bars get tighter and tighter.

However, it is likely that patients with significantly reduced lung capacity might not offered breast reconstruction as this condition would impact the anaesthetic risks associated with that operation.



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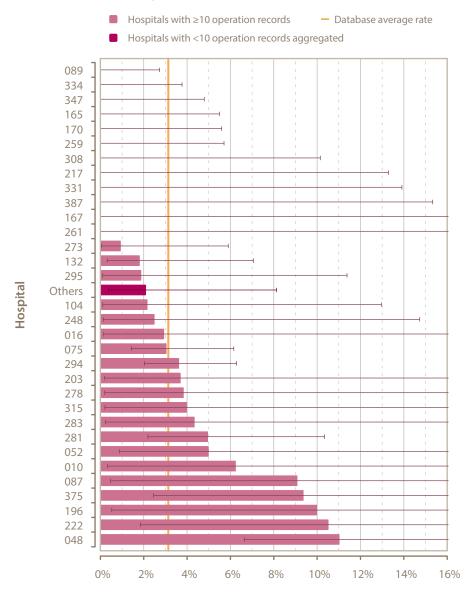
Treatment for diabetes

In keeping with the charts seen in the preceding pages, the proportion of patients who were receiving treatment for diabetes is relatively small in this sub-group of patients; overall the reported rate was 3.1%. Contrast this with the estimate of 6.7% for the general population in the United Kingdom.

It is likely that patients with poorly-controlled diabetes would not have been offered breast free flap reconstructions because it is associated with an increased risk of flap loss and also with wound healing problems.

Again, there is marked variation between hospitals, ranging from 0% up to 11% at the other extreme. But, the confidence intervals are very wide, which means that it is impossible to say whether these differences are meaningful or not from a statistical perspective.

Breast reconstruction surgery: Diabetes *per* hospital; operation records dated Jan 2016–Jun 2019



Percentage of patients on treatment for diabetes



Flap names

The following table and chart show the frequency of the most-commonly-used donors used in breast flap reconstructions.

The majority of flaps (>75%) for breast reconstruction recorded in the database were deep inferior epigastric perforator (DIEP) flaps, which take tissue from the lower abdomen. A small number of latissimus dorsi pedicled flaps (7%) were used as donor flaps. Only small numbers of transverse upper gracilis (TUG) and lateral intercostal artery perforator (LICAP) flaps were recorded (see the glossary in the appendix for details on the acronyms used here).

Approximately 15% of the operations were for bilateral breast reconstruction.

Breast reconstruction surgery: linked donors and recipients; operations dated Jan 2016–Jun 2019

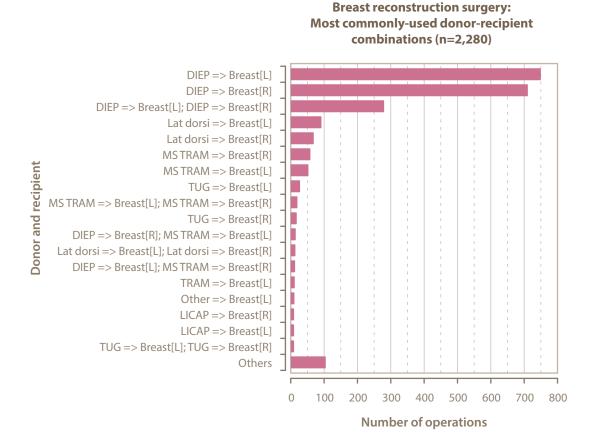
		Count	Percentage
	DIEP => Breast[L]	750	32.9%
	DIEP => Breast[R]	711	31.2%
	DIEP => Breast[L]; DIEP => Breast[R]	280	12.3%
	Lat dorsi => Breast[L]	92	4.0%
	Lat dorsi => Breast[R]	69	3.0%
	MSTRAM => Breast[R]	59	2.6%
	MS TRAM => Breast[L]	53	2.3%
Donors and recipients	TUG => Breast[L]	28	1.2%
pie	MS TRAM => Breast[L]; MS TRAM => Breast[R]	20	0.9%
eCi.	TUG => Breast[R]	18	0.8%
pu D	DIEP => Breast[R]; MS TRAM => Breast[L]	15	0.7%
Sal	Lat dorsi => Breast[L]; Lat dorsi => Breast[R]	14	0.6%
nor	DIEP => Breast[L]; MS TRAM => Breast[R]	13	0.6%
ဝိ	TRAM => Breast[L]	12	0.5%
	Other => Breast[L]	11	0.5%
	Lateral Intercostal Artery Perforator flap => Breast[R]	10	0.4%
	LICAP => Breast[L]	10	0.4%
	TUG => Breast[L]; TUG => Breast[R]	10	0.4%
	Others (count <10)	105	4.6%
	Unspecified	0	
	AII	2,280	

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The DIEP was used in 1,769 of the 2,280 breast flap operations. This involves taking excess skin and fat from the lower abdomen (below the level of the umbilicus) with its blood supply and using this flap to reconstruct the patient's breast. The surgery entails dissection through the rectus abdominis muscle to deliver the deep inferior epigastric blood vessels; however, this muscle is not taken with the flap. On the other hand, if part of the rectus abdominis muscle is harvested with the flap, then it is called a muscle sparing transverse rectus abdominis muscle flap (MS TRAM), which constituted 5.8% of donors (144 of all breast flaps). In the table opposite, a full TRAM (harvesting all of the rectus abdominis muscle on the same side as its blood supply) comprised only 0.5% of all the breast flaps recorded. This is encouraging as a trend, as it implies that surgeons have modified surgical technique for abdominal flaps to take into account the increased risk of hernia following harvest of the rectus abdominis muscle.

If the patient has inadequate abdominal tissue for a successful DIEP procedure, then a second option for autologous breast free flap reconstruction is to utilise a TUG flap, which account for just 2.4% of donors (56 out of 2,280 breast flaps) recorded in the UKNFR.





Anastomosis

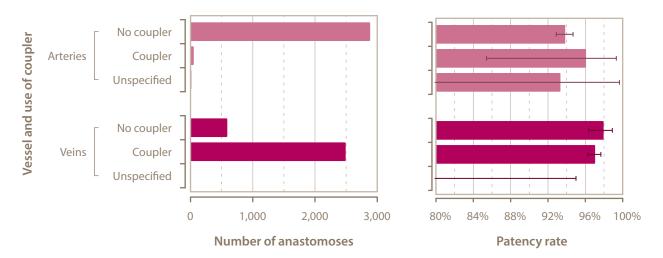
Couplers were used in 80% of end-to-end venous anastomoses with a 97% patency rate. A coupler anastomosis can take an average time of 5–10 minutes. The widespread use of a venous coupler for anastomoses suggests that the mechanical anastomotic coupling device contributes to reduced operative time, decreased probability of surgical re-exploration, and mitigation of flap loss.

The low rate of coupler usage with arteries is unsurprising. With the current coupling system, arterial coupling is only reliable where there is a large diameter artery with thin walls relative to the size of the lumen. In smaller arteries with thicker walls, such as the internal mammary artery in breast reconstruction, the inflexible ring design of the coupler tends to lack enough space for both the arterial wall and the lumen and there is a high risk of the artery being occluded by the coupling ring. Furthermore, thickness of the arterial wall can be affected by the presence of atherosclerosis and also by previous radiotherapy, making peri-operative thrombosis more likely, increasing the risk of a flap failure.

Breast reconstruction surgery: patency of end-to-end anastomoses; operations dated Jan 2016–Jun 2019

			Patent					
			No	Yes	Unspecified	Rate		
		No coupler (suture)	176	2,684	26	93.8%		
Arte		Coupler	2	49	1	96.1%		
Arte	ery	Unspecified	1	14	0	93.3%		
use of o		All arteries	179	2,747	27	93.9%		
		No coupler (suture)	12	576	3	98.0%		
	. •	Coupler	73	2,401	19	97.0%		
Ve	ein	Unspecified	1	0	0	0.0%		
		All veins	86	2,977	22	97.2%		

Breast reconstruction surgery: End-to-end anastomosis and the use of coupler; operation records dated Jan 2016–Jun 2019



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Outcomes

Flap survival

The most striking finding in the table below is the effect of smoking on flap survival: smoking history was associated with much poorer flap survival rates. Nicotine is a known vasoconstrictor, resulting in a reduction in blood flow. Nicotine and carbon monoxide in smoke also have a deleterious effect on wound healing.

Although there also appeared to be a reduced flap survival in patients with ASA of 3 or more, this result has not yet reached statistical significance; note the wide confidence intervals around the flap survival rate for the ASA \geq 3 group, which was based on a small number of patients.

Unsurprisingly pedicled flaps had better survival rates than free flaps.

Other technical aspects of surgery may influence flap survival and may be investigated in future analyses.

Breast reconstruction surgery: flap survival outcome; operations with linked donors and recipients; operations dated Jan 2016–Jun 2019

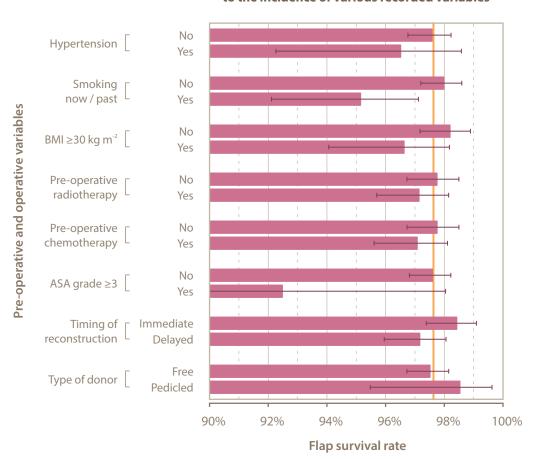
			Flap survival					
			100%	<100%	Missing	Rate	Odds	LR
	All		2,143	52	85	97.6%	41.2	
	Lhanautanaian	No	1,788	44	70	97.6%	40.6	0.986
	Hypertension	Yes	167	6	10	96.5%	27.8	0.675
Pre-operative and operative variables	Smoking	No	1,675	34	63	98.0%	49.3	1.195
	now / past	Yes	315	16	16	95.2%	19.7	0.478
	ВМІ	No	1,045	19	53	98.2%	55.0	1.335
e vari	>=30 kg m ⁻²	Yes	346	12	17	96.6%	28.8	0.700
ativ	Pre-operative	No	1,184	27	59	97.8%	43.9	1.064
l oper	radiotherapy	Yes	786	23	22	97.2%	34.2	0.829
anc	Pre-operative	No	1,185	27	54	97.8%	43.9	1.065
rative	chemotherapy	Yes	769	23	27	97.1%	33.4	0.811
ope	ASA grade ≥3	No	1,922	47	76	97.6%	40.9	0.992
Pre-	ASA grade 23	Yes	37	3	4	92.5%	12.3	0.299
	Timing of	Immediate	949	15	48	98.4%	63.3	1.535
	reconstruction	Delayed	1,035	30	32	97.2%	34.5	0.837
	Type of donor	Free	1,937	49	58	97.5%	39.5	0.959
	Type of dollor	Pedicled	204	3	27	98.6%	68.0	1.650

The funnel plot on the following page shows that most hospital's flap failure rates fall within the bounds of acceptable practice (within the funnel plot's alarm lines); the reported failure rate for only two hospitals fell between the red upper alert and upper alarm lines; this is approaching significant deviation from the average rate.

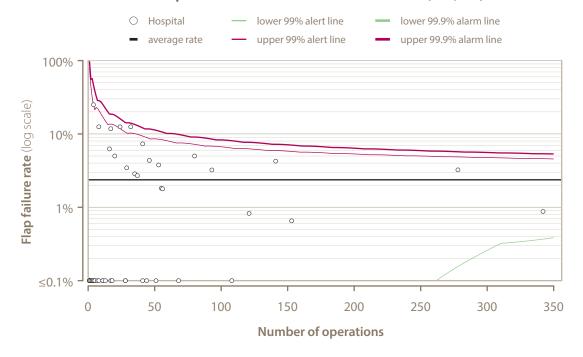
Before drawing any conclusions about performance at any of these hospitals based on this analysis, it would be important to check the validity of the data on which the results are based. Nevertheless, these data can be useful for internal review to identify potential departure from average performance.



Breast reconstruction surgery: Flap survival according to the incidence of various recorded variables



Breast reconstruction surgery: Funnel plot on flap failure; operation records dated Jan 2016–Jun 2019 (n=2,195)



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Unplanned re-operation

Any unplanned re-operation overview

The table below and chart on the following page show the association between the various recorded co-existing conditions / operative factors and the *any unplanned re-operation* outcome. None of the variables included in the table below showed any significant relationship to the need for re-operation, apart from pre-operative radiotherapy, as confirmed by a 2×2 chi-squared test.

Breast reconstruction surgery: any unplanned re-operation; operations with linked donors and recipients; operations dated Jan 2016–Jun 2019

			Any unplanned re-operation					
			No	Yes	Missing	Rate	Odds	LR
	All		2,033	192	55	8.6%	0.094	
		No	1,696	165	41	8.9%	0.097	1.030
	Hypertension	Yes	157	16	10	9.2%	0.102	1.079
	Smoking	No	1,583	148	41	8.5%	0.093	0.990
S	now / past	Yes	307	32	8	9.4%	0.104	1.104
able	BMI >=30 kg m ⁻²	No	996	95	26	8.7%	0.095	1.010
e vari		Yes	327	35	13	9.7%	0.107	1.133
ativ	Pre-operative	No	1,113	124	33	10.0%	0.111	1.180
Pre-operative and operative variables	radiotherapy	Yes	755	58	18	7.1%	0.077	0.813
and	Pre-operative	No	1,114	121	31	9.8%	0.109	1.150
rative	chemotherapy	Yes	739	60	20	7.5%	0.081	0.860
ope	ASA grade ≥3	No	1,820	177	48	8.9%	0.097	1.030
Pre-	ASA grade 25	Yes	38	3	3	7.3%	0.079	0.836
	Timing of	Immediate	900	91	21	9.2%	0.101	1.071
	reconstruction	Delayed	986	83	28	7.8%	0.084	0.891
	Type of donor	Free	1,823	170	51	8.5%	0.093	0.987
	Type of dollor	Pedicled	208	22	4	9.6%	0.106	1.120

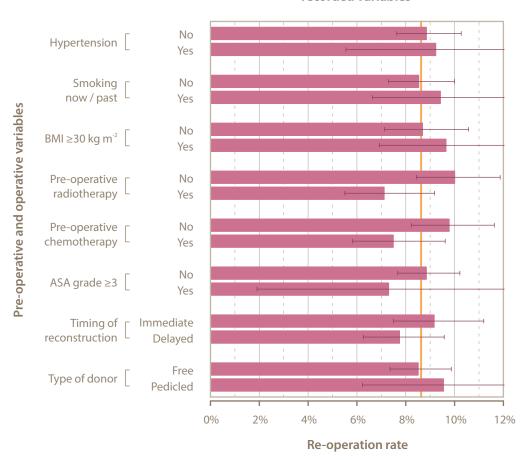
The funnel plot on the next page shows that there was some variation in re-operation rates at the contributing hospitals.

Two hospitals reported re-operation rates that fell between the red upper alert and upper alarm lines. This is approaching significant deviation from the average rate. Again, the outcome data need to be verified and further analysis made of other parameters including casemix and risk factors regarding these apparently above average re-operation rates.

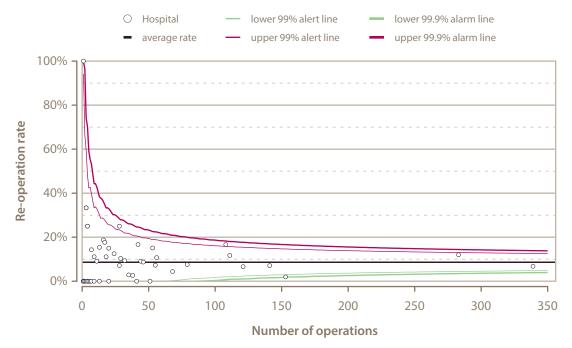
Another hospital seems to have a re-operation rate that is significantly lower than average (at or around the green lower alarm line), which would also be worthy of further investigation.



Breast reconstruction surgery: Any unplanned re-operations according to the incidence various recorded variables



Breast reconstruction surgery: Funnel plot on any unplanned re-operation rate; operation records dated Jan 2016–Jun 2019 (n=2,225)



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Detailed unplanned re-operation information

Re-operation

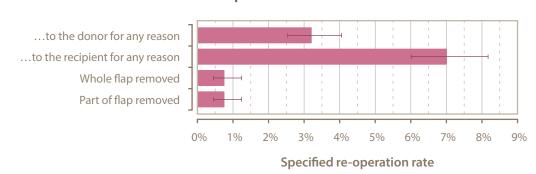
In breast reconstructions, unplanned return to theatre was most frequently for recipient site problems (7.0%). Compromise in flap blood flow is often detected in the first 24–48 hours after surgery during regular monitoring of the flap reconstruction. Changes in blood flow often result in these emergency unplanned re-operations and include re-exploration of the arterial or venous anastomoses, straightening of a twisted or kinked pedicle, repositioning of the flap or evacuation of any haematoma(s) which might be exerting external pressure on one or more of the anastomoses. Sometimes, the anastomoses are intact and an inadequate outflow manifesting as venous congestion of the flap may require a second vein anastomosis to provide extra venous drainage for the flap, *e.g.*, cephalic vein turn-down in DIEP flaps.

Some unplanned re-operations can be weeks after the initial reconstruction, and may be for debridement of partial flap necrosis, removal of all/part of the flap, or for fat necrosis, infection or abscess.

Breast reconstruction surgery: detailed unplanned re-operation information; operations with linked donors and recipients; operations dated Jan 2016–Jun 2019

		Unplanned re-operation				
		No	Yes	Unspecified	Rate	
	Donor re-operation for any reason	2,169	72	39	3.2%	
Kind of	Recipient re-operation for any reason	2,081	157	42	7.0%	
re-operation	Whole flap removed	2,218	17	45	0.8%	
	Part of flap removed	2,218	17	45	0.8%	

Breast reconstruction surgery: Detailed unplanned re-operation information; operation records dated Jan 2016–Jun 2019





Elevated post-operative stay

Using a definition of prolonged post-operative stay as greater than 4 days, the table below and the chart opposite show that a greater proportion of patients who had microvascular reconstructions also had an elevated post-operative stay, compared to those who had a pedicled reconstruction. The same applied to immediate *versus* delayed reconstruction. Patients who had an immediate reconstruction may stay longer in hospital due to recipient drains being kept in place for a longer time due to continued drainage of blood or serous fluid following mastectomy and axillary lymph node surgery.

The graph opposite also shows that less healthy patients, such as those with ASA grade 3 or more, were more likely to have an elevated length-of-stay. This is not entirely surprising and is most likely due to complications of the procedure as well as of the anaesthetic; for example, those with pre-existing pulmonary disease may have post-operative issues such as basal consolidation in the lungs.

Patients with higher BMI may have complications associated with donor site such as abdominal wound problems or increased drainage from abdominal drains necessitating a longer stay in hospital.

The majority of the factors reported here did not seem to have any significant influence on length-of-stay.

Breast reconstruction surgery: post-operative stay outcome (>4 days); operations dated Jan 2016–Jun 2019

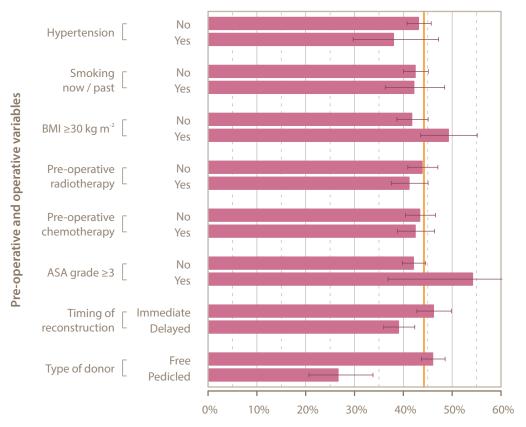
			Post-operative stay >4 days					
			No	Yes	Missing	Rate	Odds	LR
	All		1,038	823	451	44.2%	0.793	
	Llumantancian	No	895	681	351	43.2%	0.761	0.960
	Hypertension	Yes	78	48	62	38.1%	0.615	0.776
	Smoking	No	847	627	321	42.5%	0.740	0.934
	now / past	Yes	153	112	88	42.3%	0.732	0.923
ples	BMI >=30 kg m ⁻²	No	545	392	193	41.8%	0.719	0.907
varia		Yes	152	148	82	49.3%	0.974	1.228
Pre-operative and operative variables	Pre-operative radiotherapy	No	576	452	256	44.0%	0.785	0.990
pera		Yes	404	284	159	41.3%	0.703	0.887
o pue	Pre-operative	No	580	446	255	43.5%	0.769	0.970
tive	chemotherapy	Yes	389	288	157	42.5%	0.740	0.934
pera		No	968	706	400	42.2%	0.729	0.920
re-o	ASA grade ≥3	Yes	16	19	9	54.3%	1.188	1.498
<u>. </u>	Timing of	Immediate	426	367	219	46.3%	0.862	1.087
	reconstruction	Delayed	568	365	164	39.1%	0.643	0.810
		Free	896	767	381	46.1%	0.856	1.080
	Type of donor	Pedicled	137	50	47	26.7%	0.365	0.460

There is a wide variation in the rates of this outcome when the data are divided up on a hospital by hospital basis, with some contributing hospitals achieving a stay of <4 days for the majority of their patients and others where more than 90% of patients stay more than 4 days in hospital after surgery. Notably a number of the higher-volume centres reported significantly lower rates of elevated length-of-stay, as seen in the funnel plot opposite.

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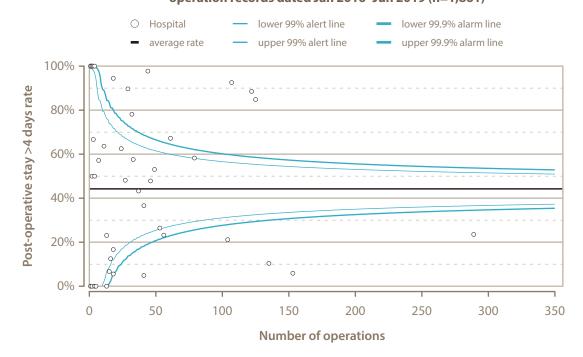
Breast reconstruction surgery

Breast reconstruction surgery: Elevated length of stay according to the incidence of various recorded variables



Percentage post-operative stay >4 days

Breast reconstruction surgery: Funnel plot on elevated length of stay; operation records dated Jan 2016–Jun 2019 (n=1,861)



Funded by BAPRAS

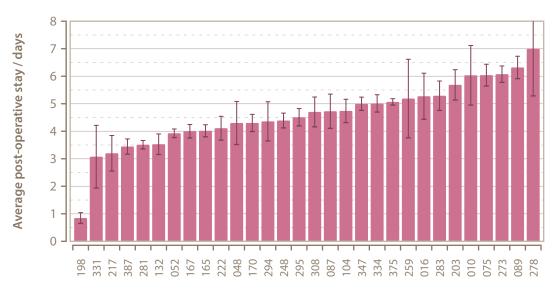
The wide variation in average length-of-stay *per* hospital is shown in the chart below. The hospitals at the extremes of the ordered distribution reported average post-operative stays of around 1 and around 7 days respectively; results from the vast majority of hospitals fall within the range 3–6 days on average.

As shown in the funnel plot on the previous page, some of these differences appear to be statistically significant, but it is important to remember that these charts are designed simply to demonstrate that there are differences between hospitals in terms of this outcome. The existence of a difference is not a value-judgement in and of itself.

In the charts on previous pages, the cut-off of >4 days was arbitrarily selected because 4 days is around the median stay after breast reconstruction according to the UKNFR as a whole. It was always likely that some hospitals would report high rates for this Boolean outcome, whereas others would report relatively low rates.

The inter-hospital variation seen in the chart below may be due, at least in part, to the mix of flaps being used in reconstruction *e.g.*, shorter length-of-stay for LICAPs compared with DIEP flaps. Units undertaking a larger number of bilateral surgery may report a higher average length-of-stay. Of course, other factors may also be at play, such as local treatment protocols that can vary from unit to unit.

Breast reconstruction surgery: Average post-operative stay at each contributor hospital; operation records dated Jan 2016–Jun 2019



Funded by BAPRAS

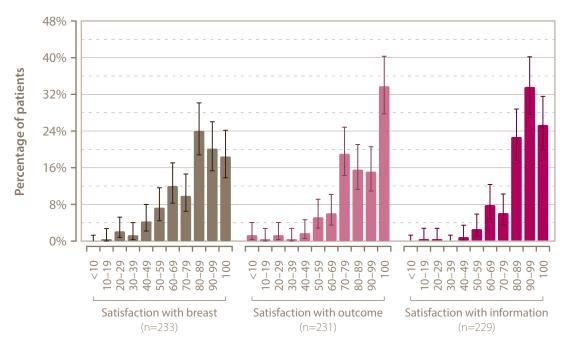


Patient reported outcomes

Patient Reported Outcome Measures (PROMS) were measured with the Breast-Q at 6 months following surgery. These charts show the results with an overall satisfaction appeared to be high. Taking a Breast-Q score of \geq 70 as indicating satisfaction, 72.5% of patients were satisfied with the breast reconstruction, 83.5% were satisfied with the outcome and 87.8% were satisfied with the information that they were given.

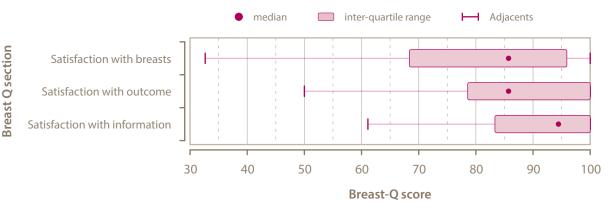
Though a further questionnaire was sent out at 18 months after reconstruction, the numbers of returned questionnaires were inadequate for the timespan covered in this report and will be presented in future reports. Detailed analysis of these results in the context of previous publications would require much larger numbers and will provide very important additional outcome information in the next report.

Breast reconstruction surgery: Breast-Q follow up questionnaire at 6 months; operation records dated Jan 2016–Jun 2019



Breast Q follow up sections

Breast reconstruction surgery: Breast Q follow up questionnaire; operation records dated Jan 2016–Jun 2019



Head & neck reconstruction surgery



Head & neck reconstruction surgery

A patient's story



The start of my journey began in November 2018 when I was referred by my dentist due to a tooth socket not healing after an extraction in 2017.

I attended South Tyneside Hospital for x-rays and I was informed I had a fistula; this was repaired and a biopsy was taken. The biopsy was inconclusive, but in February 2019 I was informed it was cancer. This came as a great shock leaving me numb and I was referred to Sunderland Royal Hospital.

At the time I thought my world had fallen apart but with strong, positive and loving support from my

husband and family I was ready to undergo the necessary treatment to hopefully cure the cancer. As advised, we told remaining family and friends of my cancer.

The treatments were explained to us both, although sounding daunting for me including the scars associated with the surgery, I realised that the treatment would hopefully eliminate the cancer. Surgery was carried out to obtain a further biopsy to identify the type of cancer and soft tissue from the roof of my palate, which was removed and an obturator fitted.

After the cancer was identified the treatment option was chosen and the surgery carried out on the 24 April 2019, and our Ruby wedding anniversary, celebrations were put on hold. My right neck lymph glands were removed, a skin flap with blood supply was taken from my left arm and three implants inserted into my cheekbone. After a night in ICU, I was taken up to the ward listening to my Doppler being checked every four hours.

Although the surgery was major, I only felt minor discomfort and some restriction of movement. However, I feel I progressed quickly and was allowed home after 8 days in hospital and this I'm sure speeded up my recovery.

In the past six months post surgery, I have learned to accept my scars as it serves as a reminder of a battle won. I class myself as lucky as I did not require chemotherapy or radiotherapy. The support and skill of everyone involved in my journey has been excellent and I have utmost confidence in their continued care.

I feel I am on the path to a full recovery once my remaining reconstruction is complete.

Kathryn Grainger

Head & neck reconstruction surgery

First UK National Flap Registry Report 2019

Funded by BAPRAS



Preface

On behalf of the British Association of Oral & Maxillofacial Surgeons (BAOMS), I would like to congratulate the team behind the UKNFR for their initiative and effort in delivering this outstanding resource with its potential for benchmarking in a complex area of surgery. This report delivers clear and concise evidence of outcomes for free flap reconstructive surgery, uniquely, encompassing all specialties involved in this surgery within the United Kingdom. As such, it is the product of collaboration between each of the specialist associations involved in reconstructive surgery. Head & neck reconstructive surgery, in particular, has undergone rapid growth and evolution especially in the area of flap reconstruction. Currently, one third of all free flap reconstructions undertaken are within the head & neck. Oral and Maxillofacial surgeons deliver a high proportion of these within our multi-disciplinary teams. The findings reported within this document are both reassuring and informative: suggesting that amongst the surgeons who utilise the UK National Flap Registry, the rate of successful reconstruction is high and remains broadly comparable to rates in the published literature. In-depth and more specific aspects of flap reconstructive surgical practice such as the impact of co-morbidities on outcomes supports calls for a more robust means of risk stratification of casemix. The advent of adjuncts, such as the anastomotic coupling device, demonstrates that refinements in surgical techniques have been adopted by a significant proportion of our colleagues with reassuring outcomes.

BAOMS would like to take this opportunity to encourage all colleagues to engage with this registry. It represents an ideal platform for self-credentialing in an era where increased levels of scrutiny hold the potential to facilitate improvements in standards and outcomes for patients. Increased uptake by surgeons will provide evermore robust data and ideally, a full representation of the practice of flap reconstructive surgery in the United Kingdom within the next iteration of the UK National Flap Registry report.

Perhaps it's worth considering Lord Kelvin's view that If you cannot measure it, you cannot improve it.

Patrick Magennis

BAOMS Council Chair

Consultant Oral and Maxillofacial Surgeon, Liverpool University Hospital NHS Trust

Foreword

I am delighted to have been asked to contribute a brief preface to the first UK National Flap Registry Report.

Anita Hazari and the wider Registry group deserve our congratulations for having delivered such a timely, concise and comprehensive document. There is no doubt that this will be of considerable interest to all those who strive to deliver excellence in head and neck cancer care.

Since the Registry was first conceived the British Association of Head and Neck Oncologists (BAHNO) has offered its continuing support to the project which is far more than a simple audit tool since it will hopefully be a potential driver of progress and improvement in patient outcomes. This report not only succinctly conveys the demographics and features unique to head and neck reconstruction but also provides valuable evidence to support current techniques and the potential for future evolution. Our BAHNO representative on this project Andrew Schache is to be congratulated for his part in its delivery.

The document will prove to be essential reading for all those working in the critical area of head and neck reconstruction. It also provides important benchmarking detail that is likely to reach a wider audience including those invested in healthcare provisioning but, most importantly, the patients for whom outcomes are of the greatest relevance.

As president of BAHNO I would like to lend my voice to those who call for this essential quality referencing project to be utilised by all those who deliver this technically demanding facet of head and neck surgery.

Cyrus Kerawala

President BAHNO

Consultant Maxillofacial / Head and Neck Surgeon, The Royal Marsden NHS Foundation Trust



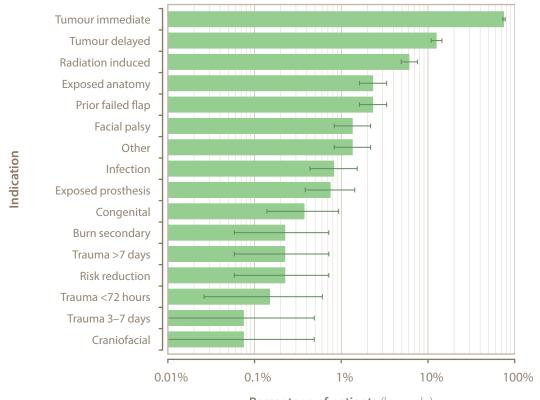
Indication

The majority of head & neck reconstructive surgery using flaps is for cancer patients. Although some procedures are performed as delayed operations some time after the patient's tumour resection, most are performed immediately. These can be complex and time-consuming operations and, as will be demonstrated later on in this section, tend to be for patients with a greater number of risk factors, which may be associated with compromised outcomes as well as potentially reduced flap survival.

The most common type of head & neck cancer is squamous cell carcinoma (SCC). Squamous cells line the mouth, the nose and the throat.

The graph below has a logarithmic scale on the horizontal y-axis, and shows that the bulk (over 70%) of the head & neck flap operations were for patients with a *tumour immediate* indication, which means that these were cancer resections and reconstructions performed at the **same time**, as opposed to delayed, where reconstructive surgery is usually carried out many **months after** the initial tumour resection.

Head & neck reconstruction surgery Indication; operation records dated Jan 2016–Jun 2019 (n=1,327)



Percentage of patients (log scale)

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Demographics and co-existing conditions

Demographics

The proportion of patients over the age of 64 years (the average age for patients having a head & neck procedure) varied from hospital to hospital. There are two hospitals at either extremes of the ordered distribution that reported a proportion of patients that apparently diverged noticeably from the database average rate.

Regarding gender, the table below shows that there were a relatively greater number of men undergoing head & neck reconstructive surgery, but the measures of average age seem to be largely independent of gender. However, a separate analysis showed that men are over-represented in the <40 year-old age group, and there are greater proportion of women over the age of 79.

Hospitals that reported fewer than 10 cases during the study period represent *low-volume* activity levels. It would be interesting to know whether these data truly reflect the totality of head & neck flap surgery at each of these hospitals. Perhaps this is an issue that can be investigated in future reports as this goes to the heart of questions around the completeness and representativity of the data in the UKNFR.

Head & neck reconstruction surgery: basic age statistics

			Age at operation / years				
		Count Average (95% CI) Median (IQR)					
Gender	Male	964	64.1 (63.3–64.8)	65.0 (56.0–72.0)			
Gender	Female	511	64.1 (62.8–65.3)	66.0 (55.0–74.0)			

Head & neck reconstruction surgery: Age at surgery; operation records dated Jan 2016–Jun 2019



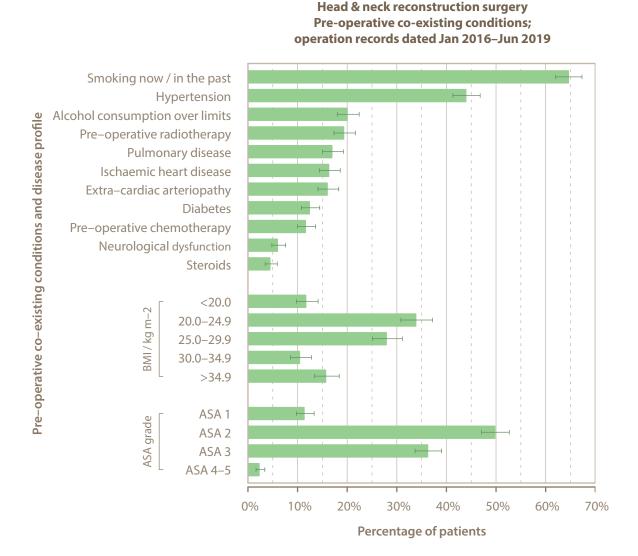
Contributor hospital



Co-existing conditions and disease profile

Overview

The co-existing conditions overview shown in the chart below shows that a high percentage of head & neck reconstruction patients have a positive a smoking history and/or are hypertensive.



Tobacco use in the commonly available forms (cigarettes, cigars, pipes and roll-ups) and high alcohol intake increase the risk of cancer of the oral cavity, some oropharyngeal cancers (p16/HPV negative) and laryngeal cancers. The risk increases again with the combined use of both tobacco and alcohol. Apart from the causative effect of tobacco use in head & neck cancer, nicotine is a known vasoconstrictor, and leads to a reduction in blood flow in flap reconstructions, which can result in increased flap loss with poorer wound healing.

Pulmonary disease is an established, independent risk factor for compromised flap survival in head & neck reconstructions. Hypertension is known to damage the intima and adventitia of vessel walls and can affect blood flow through the flap anastomoses.

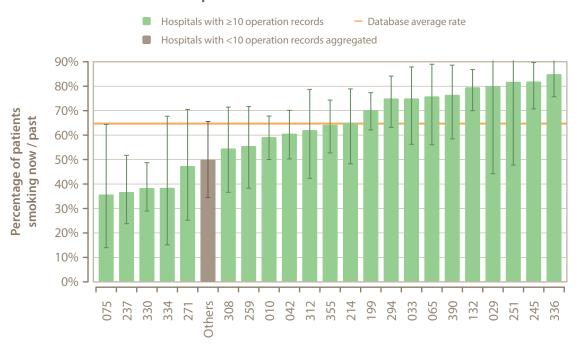
Ischaemic heart disease is a major risk factor for an adverse post-operative outcomes after head & neck flap reconstruction. Extra-cardiac arteriopathy (also known as peripheral vascular disease) is known to influence flap survival by increasing the rate of flap vessel thrombosis. In terms of recording extra-cardiac arteriopathy (ECA) as a co-existing condition, one hospital seems be significantly at variance with respect to the others. If the UKNFR data are to be used to inform clinical practice or compare outcomes it is essential that they are as accurate and complete as possible. It would be interesting to confirm the rate of ECA at this hospital.

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Smoking history

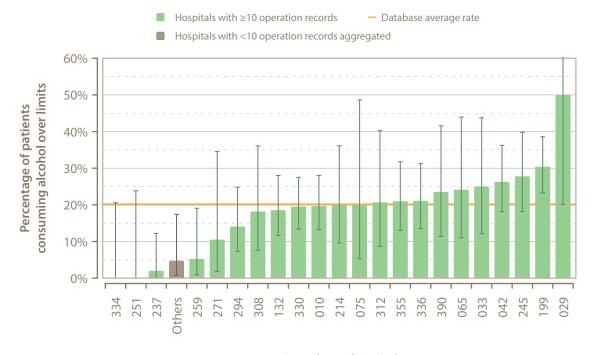
Head & neck reconstruction surgery: Smoking history *per* hospital; operation records dated Jan 2016–Jun 2019



Contributor hospital

Alcohol consumption

Head & neck reconstruction surgery: Alcohol consumption over limits *per* hospital; operation records dated Jan 2016–Jun 2019

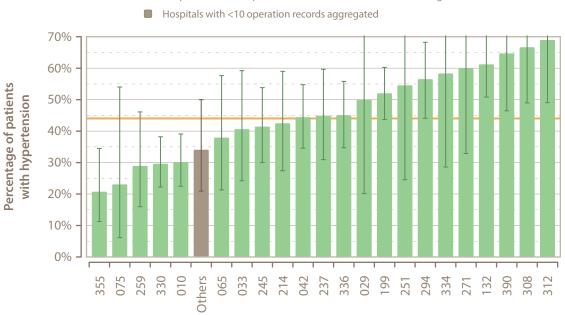




Hypertension

Head & neck reconstruction surgery: Hypertension *per* hospital; operation records dated Jan 2016–Jun 2019

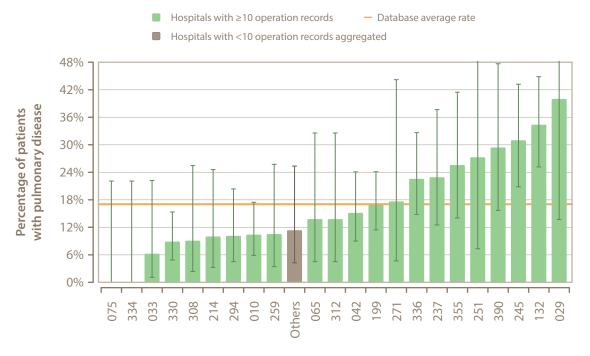




Contributor hospital

Pulmonary disease

Head & neck reconstruction surgery: Pulmonary disease *per* hospital; operation records dated Jan 2016–Jun 2019

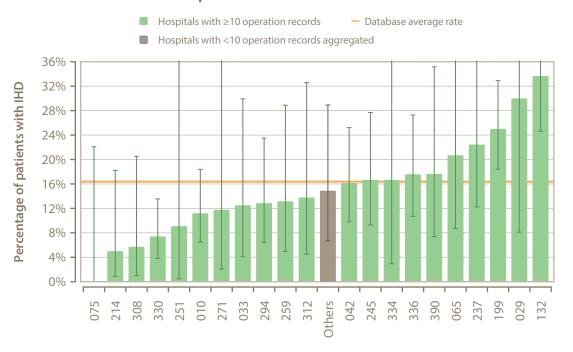


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Ischaemic heart disease

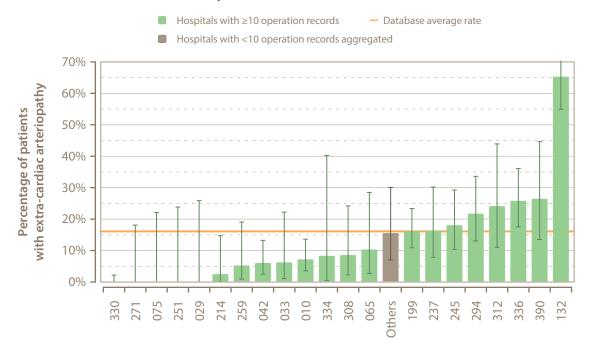
Head & neck reconstruction surgery: Ischaemic heart disease *per* hospital; operation records dated Jan 2016–Jun 2019



Contributor hospital

Extra-cardiac arteriopathy

Head & neck reconstruction surgery: Extra-cardiac arteriopathy *per* hospital; operation records dated Jan 2016–Jun 2019





Flap names

The most frequently-used flaps for head & neck reconstruction are shown in the table below. Almost all of the operations involved just one flap being transferred to one recipient defect (1=>1). Common flaps used for head & neck reconstruction were the radial forearm flap (RFF) and the antero-lateral thigh (ALT) flap. The most frequently-used flap for mandibular reconstructions was the free fibula (often with a skin paddle).

Head & neck reconstruction surgery: linked donors and recipients; operations dated Jan 2016–Jun 2019

			Number of donors => number of recipients							
		1=>1	1=>2	2=>1	2=> 2	3=>1	3=>2	3=>3	4=>1	Total
	RFF => Head & neck	420	1	4	0	0	0	0	0	425
	ALT => Head & neck	303	1	2	1	0	0	0	0	307
	Fibula => Head & neck	262	0	3	0	0	0	0	0	265
	Pect major => Head & neck	103	0	0	0	0	0	0	0	103
ints	MSAP => Head & neck	46	0	0	0	0	0	0	0	46
and recipients	DCIA => Head & neck	44	0	0	0	0	0	0	0	44
rec	Scapular => Head & neck	39	0	0	0	0	0	0	0	39
	Lat dorsi => Head & neck	23	0	0	0	0	0	0	0	23
Donors	Temporalis => Head & neck	19	0	0	1	0	0	0	0	20
Don	Other => Head & neck	19	0	0	0	0	0	0	0	19
_	Forehead => Head & neck	15	0	0	0	0	0	0	0	15
	Scalp => Head & neck	10	0	0	0	0	0	0	0	10
	Others	81	1	51	12	3	1	2	1	152
	Total	1,384	3	60	14	3	1	2	1	1,468

Reconstruction surgery in the head & neck anatomical area is challenging due to the combination of resultant defects after resection of a variety of structures such as skin, mucosa, soft tissue and bone. In particular, the anatomy of the oral cavity is complicated, and each structure plays a specific role in speech, swallowing, and facial expression. Furthermore, defects in one specific functional unit can affect adjacent structures.

Though pedicled flaps are adequate for reconstruction, they have several draw-backs, such as limited arc of rotation and reach of the flap, which sometimes results in partial flap necrosis due to decreased blood flow to its most distal portion. It may also necessitate revision surgery for a bulky flap.

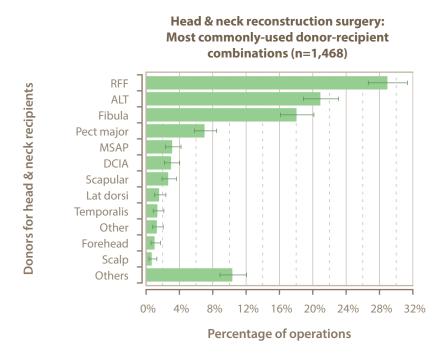
The antero-lateral thigh (ALT) and radial forearm (RFF) flaps are suitable for head & neck reconstructions, particularly in the intra-oral cavity, hypopharynx, and oropharynx as these flaps are thin and pliable. However, an ALT flap in obese patients can be bulky or, in a hairy patient, could subsequently grow hair in unwanted areas. The RFF flap has the advantage of a short operative time, and is generally thinner, more pliable and well suited to smaller defects. However, it has the disadvantages of leaving a visible scar on the forearm and requiring the elective sacrifice of a major vessel of the hand.

Where bone is required to reconstruct the mandible after its resection, the free fibula flap, often with a skin paddle for lining the inside of the mouth, is used. The fibula can be osteotomised to fit the mandibular defect.

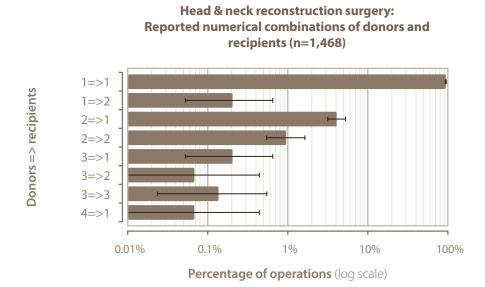
Funded by BAPRAS



The chart below confirms that the radial forearm flap (RFF), antero-lateral thigh (ALT) flap and fibula represented the majority of flaps used for head & neck reconstructions. There were relatively few pedicled flaps utilised such as pectoralis major, temporalis and forehead or scalp.



The next chart shows the percentage of operations that involved various combinations of donors and recipients; note the logarithmic scale on the horizontal axis. The chart shows that the vast majority of recorded operations involved a single donor and a single recipient (over 94%). Next most common were the procedures that involved two donors and one recipient site, at around 4% of all head & neck flap procedures. Each of the other donor =>recipient combinations comprised <1% of the total.



Funded by BAPRAS

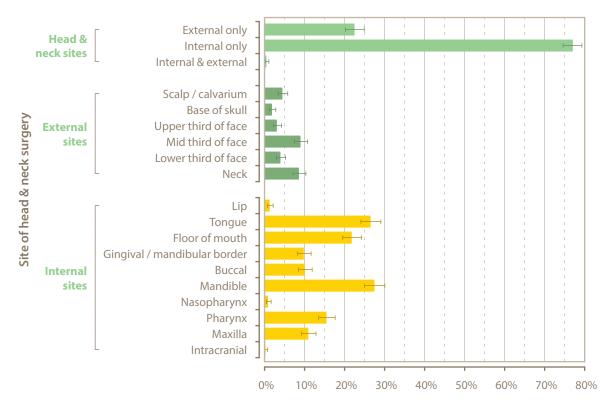


The recipient sites for head & neck reconstruction are divided into **internal** and **external** sites in the database, as shown in the following chart. These sites are further sub-divided according to anatomical sub-units.

The majority of reconstructions were for internal sites, such as the intra-oral cavity or the mandible, which are the commonest locations for squamous cell carcinoma (SCC). In this chart, because a patient may have more than one overlapping recipient sub-sites, the percentages of all sites can add up to more than 100%.

The most common primary tumour sites were the tongue and the mandible, followed by floor of mouth. The most common tumour diagnosis is likely to be squamous cell carcinoma.

Head & neck reconstruction surgery: Detailed surgery sites; operation records dated Jan 2016–Jun 2019



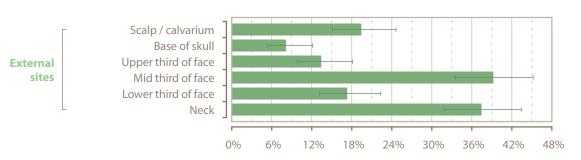
Percentage of all head & neck operations

Funded by BAPRAS



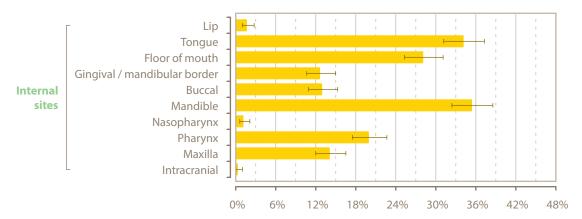
The charts below present the recipient site data in a different way, separating out internal and external sites into their own chart, and adjusting the denominator accordingly. The commonest external sub-units for flap reconstruction were the middle third of face excluding maxilla and also the neck. For internal sub-units, tongue, mandible and floor of mouth were the commonest, the majority of which are for defects arising from resection of squamous cell carcinoma (SCC).

Head & neck reconstruction surgery: External surgery sites; operation records dated Jan 2016–Jun 2019



Percentage of operations involving an external site

Head & neck reconstruction surgery: Internal surgery sites; operation records dated Jan 2016–Jun 2019

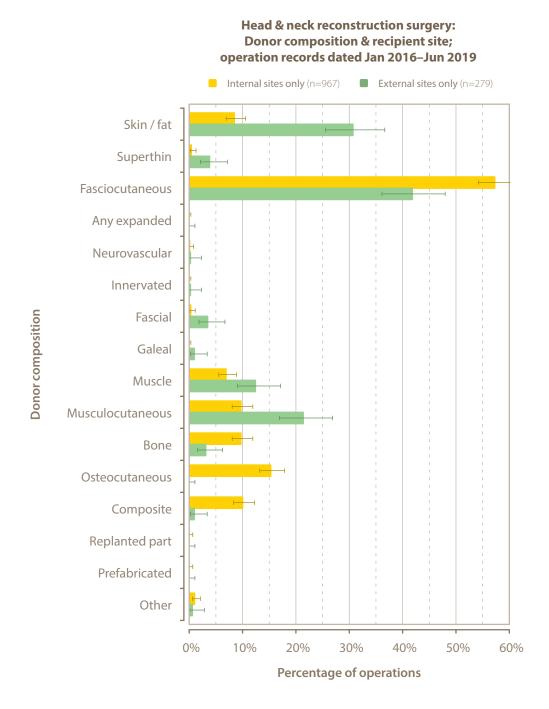


Percentage of operations involving an internal site



Donor composition

The chart below shows that most flaps for head & neck reconstruction incorporated skin, mostly as fasciocutaneous flaps. This is to reconstruct a lining for intra-oral or pharyngeal reconstructions, and also for skin or scalp defects. In fewer than 10% of cases, muscle or musculocutaneous flaps are utilised if there is a large cavity, dead space or a vital structure that necessitates more robust tissue cover.



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Anastomosis

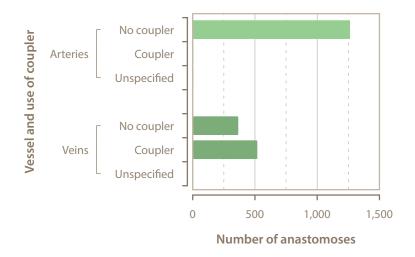
Venous couplers were used in 58% of end-to-end vein anastomoses with patency rates of 98.8%. Most anastomoses have conventionally been hand-sewn; however, in the last decade, there has been an increased uptake of the venous coupler by micro-surgeons due to its ease of use, reduced operative time and its reliability.

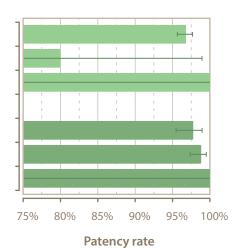
The low rates of couplers usage in arterial anastomoses is unsurprising. The wall of arteries in the head & neck tend to be thick, and therefore, cannot be turned over the metal spikes of the rigid venous coupling ring.

Head & neck reconstruction surgery: patency of end-to-end anastomoses; operations dated Jan 2016–Jun 2019

		Patent					
		No	Yes	Unspecified	Rate		
Artery	No coupler (suture)	40	1,213	11	96.8%		
	Coupler	1	4	0	80.0%		
Artery	Unspecified	0	6	0	100.0%		
	All arteries	41	1,223	11	96.8%		
	No coupler (suture)	8	351	7	97.8%		
	Coupler	6	510	3	98.8%		
Vein	Unspecified	0	4	0	100.0%		
	All veins	14	865	10	98.4%		

Head & neck reconstruction surgery: End-to-end anastomosis and the use of coupler; operation records dated Jan 2016–Jun 2019







Outcomes

Flap survival

The table and chart below on these facing pages show the association between various pre-operative and operative factors and flap survival. There was uniformly high flap survival except where free and pedicled flaps were combined, but the numbers in this sub-group were too small to provide a conclusive result. Those operations where combinations of flaps were used usually represent larger or more complex defects.

Head & neck reconstruction surgery: flap survival outcome; operations with linked donors and recipients; operations dated Jan 2016–Jun 2019

					Flap sı	urvival		
		-	100%	<100%	Missing	Rate	Odds	LR
	Operations		1,242	76	154	94.2%	16.3	
	Hypertension	No	593	33	88	94.7%	18.0	1.100
	riypertension	Yes	466	34	56	93.2%	13.7	0.839
	Smoking	No	375	24	49	94.0%	15.6	0.956
	now / past	Yes	679	46	93	93.7%	14.8	0.903
	BMI	No	530	28	81	95.0%	18.9	1.158
les	>30 kg m ⁻²	Yes	109	6	20	94.8%	18.2	1.112
ariab	Pre-operative	No	895	53	108	94.4%	16.9	1.033
Pre-operative and operative variables	radiotherapy	Yes	197	18	37	91.6%	10.9	0.670
erati	Pre-operative	No	911	55	112	94.3%	16.6	1.014
do p	chemotherapy	Yes	103	8	32	92.8%	12.9	0.788
e an	ASA grade ≥3	No	628	46	98	93.2%	13.7	0.835
rativ		Yes	420	22	44	95.0%	19.1	1.168
edo-i	Timing of	Immediate	830	59	112	93.4%	14.1	0.861
Pre	reconstruction	Delayed	162	3	2	98.2%	54.0	3.304
	Type of donors	Free only	1,054	56	134	95.0%	18.8	1.152
	used in the	Pedicled only	183	11	18	94.3%	16.6	1.018
	operation	Free & pedicled	5	9	2	35.7%	0.6	0.034
	Decimient site	Internal alone	810	54	109	93.8%	15.0	0.918
	Recipient sites	External alone	241	14	29	94.5%	17.2	1.053
		I						
	Donors		1,324	80	157	94.3%	16.6	
	Type of donor	Free	1,118	64	138	94.6%	17.5	1.056
	Type of dollor	Pedicled	206	16	19	92.8%	12.9	0.778

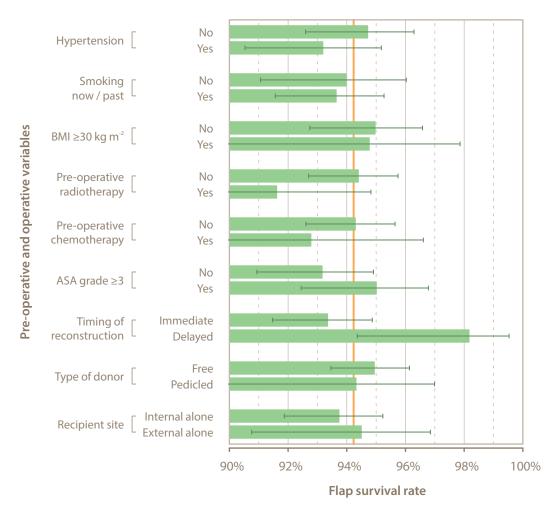
Funded by BAPRAS



Flap survival rates were high, regardless of the presence of co-existing conditions and pre-operative / operative variables, which are often regarded as risk factors. Some patients who experienced a partial flap failure may not have required any further procedure. However, if partial flap loss was clinically significant then further analysis of the detailed re-operation data for the recipient site (whole of flap removed or part of flap removed are options in the re-operation question) would provide more information.

Similarly, a second flap to the same recipient site may have been recorded. If no re-operation was needed then that partial failure can be regarded to have been of less clinical significance. This means that rather than recording an estimated percentage of tissue loss for an individual flap, an evaluation of the real clinical impact can be used to assess and evaluate the outcome.

Head & neck reconstruction surgery: Flap survival; operation records dated Jan 2016–Jun 2019



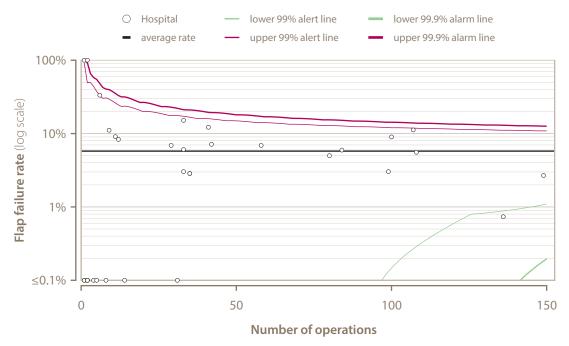
In the next version of the UKNFR, a new classification of the flap survival outcome is going to be adopted that distinguishes between the different grades of partial flap failure, the need for a second flap or prosthesis, impacting patient recovery. The use of second flaps to the original defect could be analysed in future reports.



There appeared to be some variation in the flap survival rate between contributing hospitals, as shown in the following funnel plot; however, most of these differences are not statistically significant. There is only one hospital that reports a significant deviation from the database average: the surgeons at this hospital reported a significantly lower flap failure rate than average and it is represented by a point just below the green lower alert line.

In future reports data reported from statistical outliers can be analysed by a more detailed examination of casemix, co-existing conditions and risk factors.

Head & neck reconstruction surgery: Funnel plot on flap failure; operation records dated Jan 2016-Jun 2019 (n=1,318)



The table and chart on the facing page demonstrate that zero flap survival (total flap loss) occurred in less than 1% of reconstructions involving the tongue, floor of mouth and mandible. However, partial flap loss was significantly greater than 1% at these sites. It is not known how many of these then necessitated a second flap reconstruction.

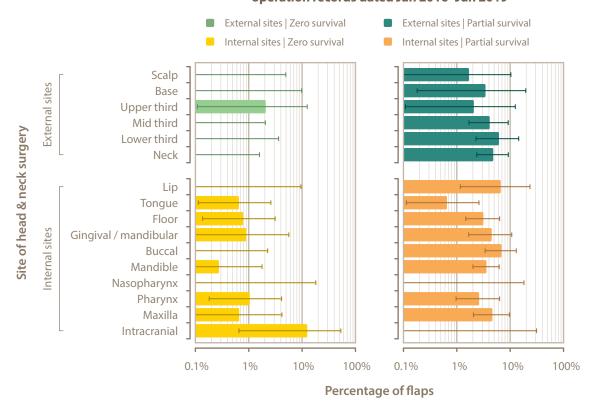
Funded by BAPRAS



Head & neck reconstruction surgery: site of head & neck surgery and flap survival; operations dated Jan 2016–Jun 2019

			Flap survival					
			Zero	Partial	Complete	Buried flap	Unspecified	
		Scalp	0 (0.0%)	1 (1.7%)	58 (98.3%)	0	5	
	sites	Base	0 (0.0%)	1 (3.4%)	28 (96.6%)	0	2	
	al s	Upper third	1 (2.1%)	1 (2.1%)	46 (95.8%)	0	4	
	External	Mid third	0 (0.0%)	6 (4.2%)	138 (95.8%)	1	14	
neck surgery	Ext	Lower third	0 (0.0%)	5 (6.2%)	76 (93.8%)	0	18	
	_	Neck	0 (0.0%)	9 (4.8%)	177 (95.2%)	1	23	
		Lip	0 (0.0%)	2 (6.7%)	28 (93.3%)	0	3	
Z W		Tongue	2 (0.7%)	2 (0.7%)	302 (98.7%)	0	56	
		Floor	2 (0.8%)	8 (3.1%)	244 (96.1%)	0	55	
of head	sites	Gingival / mandibular	1 (0.9%)	5 (4.5%)	105 (94.6%)	0	19	
e of		Buccal	0 (0.0%)	9 (6.9%)	121 (93.1%)	1	21	
Site	Internal	Mandible	1 (0.3%)	13 (3.6%)	347 (96.1%)	1	62	
	Inte	Nasopharynx	0 (0.0%)	0 (0.0%)	15 (100.0%)	0	0	
		Pharynx	2 (1.1%)	5 (2.7%)	178 (96.2%)	6	26	
		Maxilla	1 (0.7%)	7 (4.6%)	143 (94.7%)	0	20	
		Intracranial	1 (12.5%)	0 (0.0%)	7 (87.5%)	0	0	

Head & neck reconstruction surgery: Detailed zero | partial flap survival information; operation records dated Jan 2016–Jun 2019





Unplanned re-operation

Any unplanned re-operation overview

The association between re-operation rates and some of the pre-operative / operative variables are shown in the table below. Operations requiring a combination of free and pedicled flaps together had a higher re-operation rate. In the chart shown opposite, the re-operation rates in relation to the same factors do not suggest that they significantly influenced the re-operation rate. However, it is known that co-existing conditions such as hypertension, smoking and high BMI will adversely affect the outcome of flap reconstruction.

Head & neck reconstruction surgery: any unplanned re-operations; operations with linked donors and recipients; operations dated Jan 2016–Jun 2019

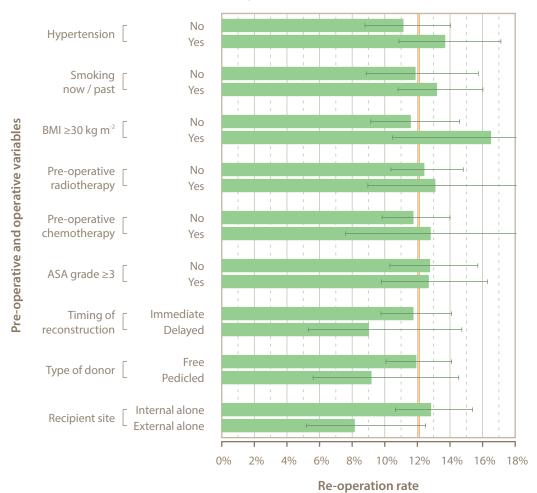
			Any unplanned re-operation					
			No	Yes	Missing	Rate	Odds	LR
	Operations		1,095	151	226	12.1%	0.138	
	Hypertension	No	526	66	122	11.1%	0.125	0.910
	. Typer terision	Yes	428	68	60	13.7%	0.159	1.152
	Smoking	No	326	44	78	11.9%	0.135	0.979
	now / past	Yes	598	91	129	13.2%	0.152	1.104
	BMI	No	503	66	70	11.6%	0.131	0.952
Pre-operative and operative variables	>30 kg m ⁻²	Yes	96	19	21	16.5%	0.198	1.435
	Pre-operative	No	782	111	163	12.4%	0.142	1.029
ive v	radiotherapy	Yes	179	27	46	13.1%	0.151	1.094
erat	Pre-operative	No	855	114	109	11.8%	0.133	0.967
do pu	chemotherapy	Yes	102	15	26	12.8%	0.147	1.066
/e ar	A.C.A	No	546	80	146	12.8%	0.147	1.063
erativ	ASA grade ≥3	Yes	378	55	53	12.7%	0.146	1.055
do-	Timing of	Immediate	795	106	100	11.8%	0.133	0.967
Pre	reconstruction	Delayed	151	15	1	9.0%	0.099	0.720
	Type of donors	Free only	922	125	197	11.9%	0.136	0.983
	used in the	Pedicled only	168	17	27	9.2%	0.101	0.734
	operation	Free & pedicled	5	9	2	64.3%	1.800	13.053
	Posiniont sites	Internal alone	706	104	163	12.8%	0.147	1.068
	Recipient sites	External alone	225	20	39	8.2%	0.089	0.645

Any unplanned re-operation at the donor site

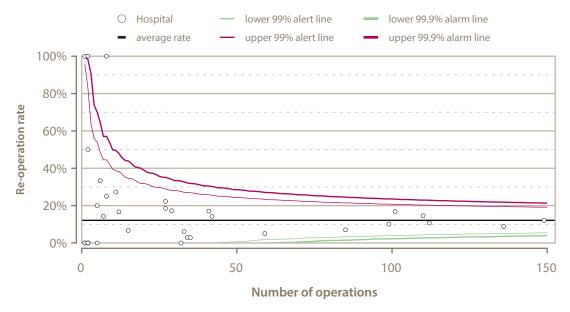
			· ·				
		No	Yes	Missing	Rate	Odds	LR
Donors		1,363	63	135	4.4%	0.046	
Type of donor	Free	1,155	50	115	4.1%	0.043	0.937
rype or donor	Pedicled	208	13	20	5.9%	0.063	1.352

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Head & neck reconstruction surgery: Any unplanned re-operation; operation records dated Jan 2016–Jun 2019



Head & neck reconstruction surgery: Funnel plot on any unplanned re-operation rate; operation records dated Jan 2016–Jun 2019 (n=1,246)





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Detailed unplanned re-operation information

In head & neck flap reconstructions, unplanned return to theatre was more frequent for recipient site problems (10.9%). This is not surprising, as the anatomy of the oral cavity is complicated, and reconstructions restoring the structures involved in speech, swallowing and facial expression are complex. Furthermore, these patients have more co-existing conditions including a positive history of smoking and hypertension, which have both been shown to adversely affect outcomes of reconstruction including unplanned return to theatre rates.

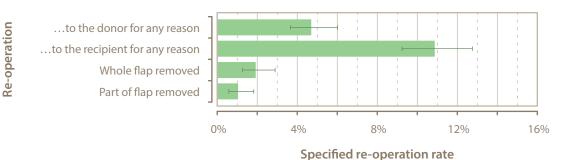
The flap reconstructions are monitored clinically and with Doppler signals at regular intervals in the first 2–3 days after surgery, often in an ITU or HDU setting. Any compromise in flap blood flow results in emergency unplanned re-operations, which can include re-exploration of the arterial or venous anastomoses, straightening of a twisted or kinked pedicle, repositioning of the flap or evacuation of a haematoma exerting external pressure on one or more of the anastomoses. It may also include removing part or all of the flap in case of irreversible flap damage or ischaemia re-perfusion injury.

In addition to the above, should there be partial loss of a vital part of the flap, it may necessitate a second flap reconstruction or a prosthesis, adversely impacting disease control and the patient's rehabilitation.

Head & neck reconstruction surgery: detailed unplanned re-operation information; operations with linked donors and recipients; operations dated Jan 2016–Jun 2019

		Unplanned re-operation				
		No	Yes	Unspecified	Rate	
	Donor re-operation for any reason	1,277	63	132	4.7%	
Kind of	Recipient re-operation for any reason	1,123	137	212	10.9%	
re-operation	Whole flap removed	1,223	24	225	1.9%	
	Part of flap removed	1,234	13	225	1.0%	

Head & neck reconstruction surgery: Detailed unplanned re-operation information; operation records dated Jan 2016–Jun 2019



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Elevated post-operative stay

The same set of operative and pre-operative factors are reported here in relation to elevated post-operative length-of-stay. The following were associated with low rates of post-operative stay >13 days:

- no history of smoking
- ASA grade 1-2
- delayed reconstruction
- external defect reconstructions

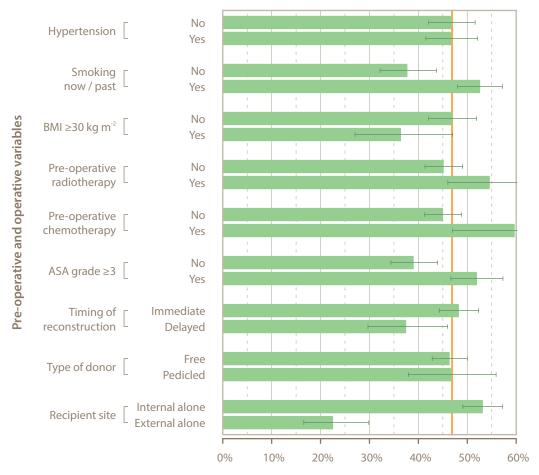
Head & neck reconstruction surgery: post-operative stay outcome (>13 days)

			Post-operative stay >13 days					
			No	Yes	Missing	Rate >13	Odds	LR
	All		478	422	585	46.9%	0.883	
	Hypertension	No	235	207	275	46.8%	0.881	0.998
	riypertension	Yes	190	167	207	46.8%	0.879	0.996
	Smoking	No	178	108	165	37.8%	0.607	0.687
	now / past	Yes	225	250	352	52.6%	1.111	1.259
Pre-operative and operative variables	BMI	No	220	195	230	47.0%	0.886	1.004
	>30 kg m ⁻²	Yes	61	35	42	36.5%	0.574	0.650
	Pre-operative	No	364	300	399	45.2%	0.824	0.934
	radiotherapy	Yes	64	77	115	54.6%	1.203	1.363
erati	Pre-operative	No	382	313	393	45.0%	0.819	0.928
do p	chemotherapy	Yes	27	40	77	59.7%	1.481	1.678
/e an	ACA do > 2	No	256	164	358	39.0%	0.641	0.726
rativ	ASA grade ≥3	Yes	169	183	139	52.0%	1.083	1.227
obe-	Timing of	Immediate	317	296	395	48.3%	0.934	1.058
Pre	reconstruction	Delayed	90	54	24	37.5%	0.600	0.680
		Free only	410	355	486	46.4%	0.866	0.981
	Type of donor	Pedicled only	67	59	86	46.8%	0.881	0.997
		Free & pedicled	1	8	9	88.9%	8.000	9.062
		Internal alone	279	317	382	53.2%	1.136	1.287
	Recipient sites	External alone	127	37	120	22.6%	0.291	0.330

Head & neck oncology resections and reconstructions are challenging operations. In particular, the anatomy of the oral cavity is complicated, and each structure plays a specific role in speech and swallowing. Post-operative management of the airway, and therapy to help restore the patient's swallowing and speech will usually increase the post-operative length-of-stay. This is often evident after flap operations involving the reconstruction of internal head & neck sites such as the tongue, floor of mouth and mandible.

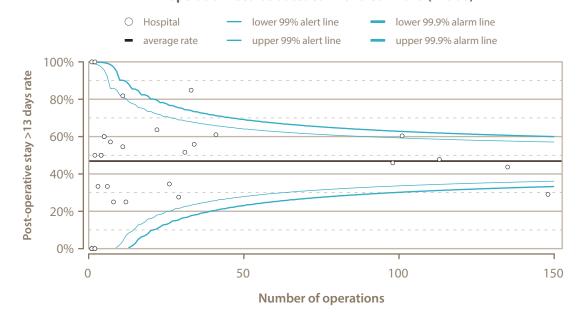
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Percentage post-operative stay >13 days

Head & neck reconstruction surgery: Funnel plot on elevated post-operative stay; operation records dated Jan 2016–Jun 2019 (n=900)



Limb reconstruction surgery



Limb reconstruction surgery

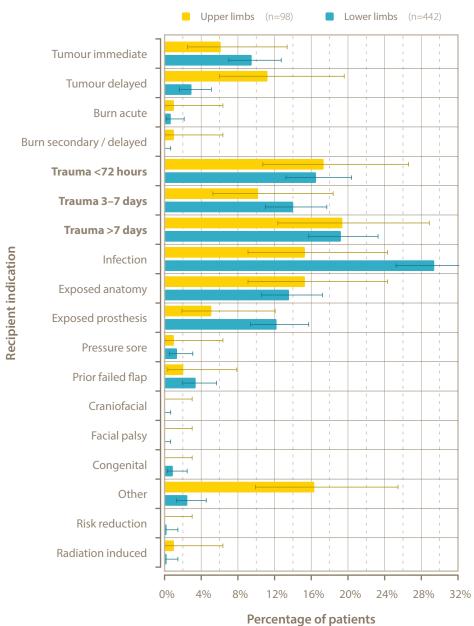
Indications

The commonest indication, as shown in the following chart for limb reconstructions, was trauma (adding together the three recipient indications for trauma). The timing of flap coverage of a fracture site after the causative injury is recorded according to whether it is <72 hours, between 3 and 7 days and finally >7 days. The latest national standards state that definitive soft tissue closure or coverage should be achieved within 72 hours of injury if it cannot be performed at the time of debridement.

There is strong evidence that delayed soft tissue cover increases the chances of deep infection and also amputation. For other injuries guidance is less specific.

Infection is another significant indication, along with exposed structures, which may include defects arising from complications of other elective limb surgery.

Limb reconstruction surgery: Indications; operations dated Jan 2016–Jun 2019



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The British Orthopaedic Association Standards for Trauma document, BOAST4, outlines the current guidelines for management of trauma. Open fractures require timely multi-disciplinary management. Trauma networks and hospitals require the appropriate pathways and infra-structure to manage these patients, to enable optimum recovery and to minimise the risk of infection.

The guidelines state that patients with open fractures of long bones, the hind- and the mid-foot should be treated in a specialist centre that can provide orthoplastic (combined orthopaedic and plastic surgery) care, whether the patient is taken directly to such a hospital or is transferred there as soon as is appropriate. The management of these injuries should be shared by consultants in orthopaedic and plastic surgery. Debridement is indicated immediately for highly contaminated wounds or those with vascular compromise, within 12 hours for solitary high-energy fractures and within 24 hours for low energy open fractures. Definitive soft tissue coverage (including flap coverage) should be achieved within 72 hours of injury if it cannot be performed at the time of debridement. When indicated, a delayed primary amputation should be performed within 72 hours of injury. The data on these operations should also be submitted to TARN (Trauma Audit and Research Network).

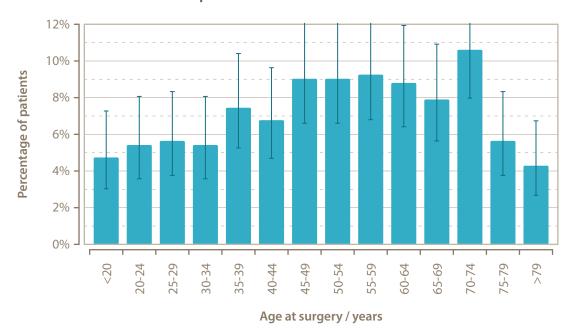
Demographics and co-existing conditions

Age at surgery

The chart below shows that the age distribution for patients undergoing lower limb surgery was *relatively* flattened; there is not the usual normal / skewed normal distributions as is seen for patients in the breast reconstruction and head & neck reconstruction groups (see page 40). For younger patients, the indication for surgery is more likely to be related to a trauma, such as a road traffic accident, whereas older patients, over the age of 70 years, are more likely to have had a fall.

The number of upper limb surgeries recorded is as yet too low to do any meaningful kind of age-distribution analysis.

Limb reconstruction surgery: Age distribution; operation records dated Jan 2016–Jun 2019



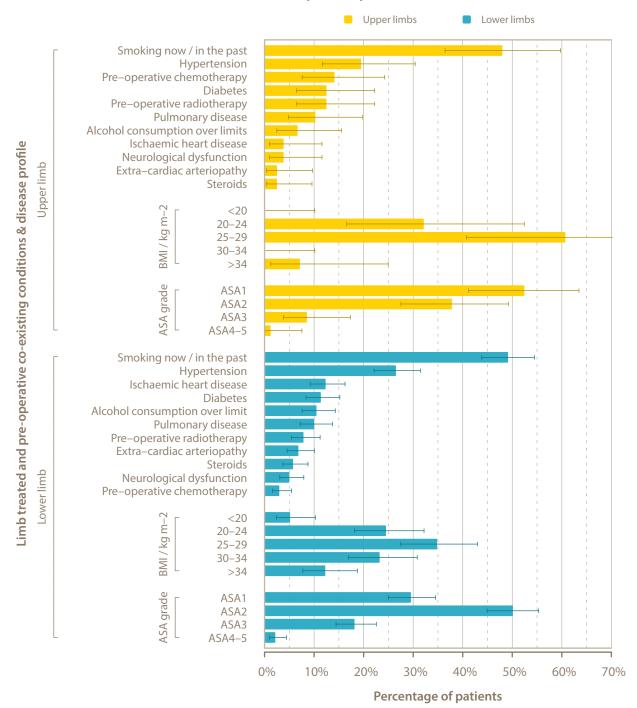


Co-existing conditions and disease profile

Overview

The chart below gives an overview of the percentage of patients with each of the main co-existing conditions. Just under half of all patients undergoing limb reconstruction surgery had a smoking history. Although some hospitals might not offer certain kinds of elective limb reconstruction procedures to heavy smokers, this is less relevant in trauma cases, which is the most frequent indication. In these cases, although choice of the specific type of reconstruction might be influenced by the presence of any of these co-existing conditions, it would be very unlikely that all reconstructive procedure-options would be contraindicated.

Limb reconstruction surgery: Co-existing conditions and disease profile; operation records dated Jan 2016–Jun 2019

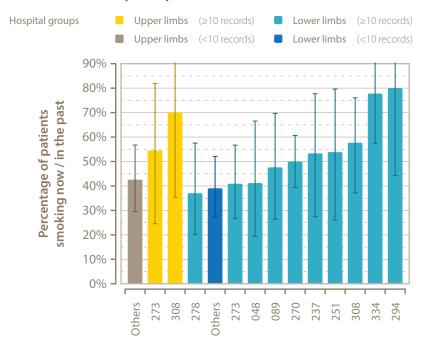


Je,

Limb reconstruction surgery

Smoking history

Limb reconstruction surgery: Smoking history at each hospital; operation records dated Jan 2016–Jun 2019



Contributor hospital

Hypertension

Limb reconstruction surgery: Hypertension at each hospital; operation records dated Jan 2016–Jun 2019

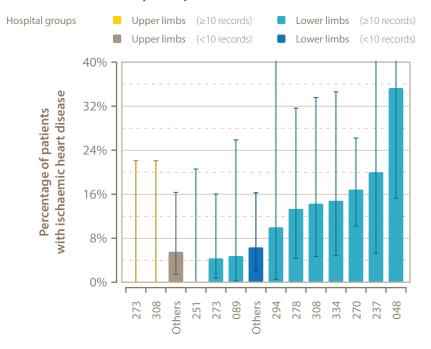


Contributor hospital



Ischaemic heart disease

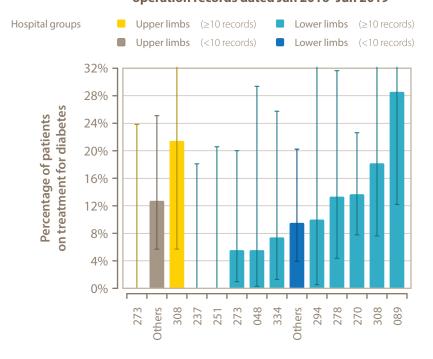
Limb reconstruction surgery: Ischaemic heart disease at each hospital; operation records dated Jan 2016–Jun 2019



Contributor hospital

Diabetes

Limb reconstruction surgery: Diabetes at each hospital; operation records dated Jan 2016–Jun 2019



Contributor hospital

Funded by BAPRAS



Flap names

The chart below shows the most common donors used for upper limb and lower limb reconstructions. Details of acronyms used for the donors are to be found in the appendices (see page 141).

The table shows that muscle flaps are used in most cases of lower limb reconstruction, many of which will be for trauma. The antero-lateral thigh (ALT) flap, which is a fasciocutaneous in composition, is increasingly used in lower limb trauma reconstruction.

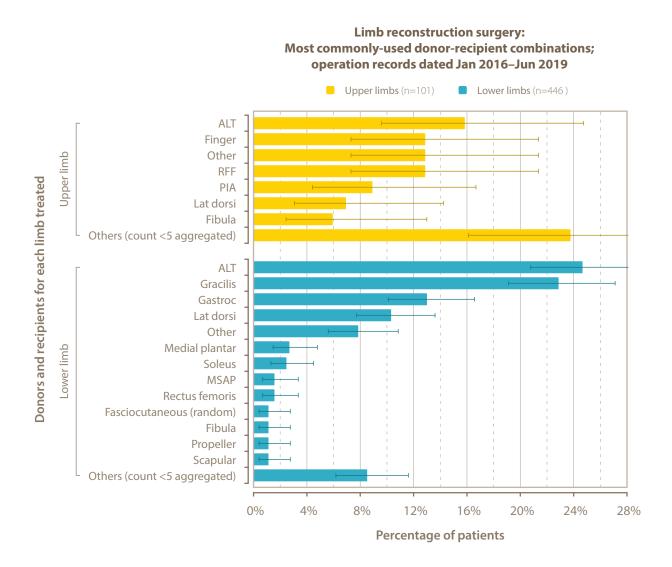
Limb reconstruction surgery: limb treated and linked donors and recipients; operation dated Jan 2016–Jun 2019

			Count	Rate
		ALT => Upper limb	16	15.8%
		Finger => Upper limb	13	12.9%
		Other => Upper limb	13	12.9%
	Upper	RFF => Upper limb	13	12.9%
	limb	PIA => Upper limb	9	8.9%
ted		Lat dorsi => Upper limb	7	6.9%
rea		Fibula => Upper limb	6	5.9%
Donors and recipients for each limb treated		Others (count <5 aggregated)	24	23.8%
ach l		ALT => Lower limb	110	24.7%
or ea		Gracilis => Lower limb	102	22.9%
ts fo		Gastroc => Lower limb	58	13.0%
ient		Lat dorsi => Lower limb	46	10.3%
ci p		Other => Lower limb	35	7.8%
d re		Medial plantar => Lower limb	12	2.7%
an	Lower	Soleus => Lower limb	11	2.5%
Jors	limb	MSAP => Lower limb	7	1.6%
Dor		Rectus femoris => Lower limb	7	1.6%
		Fasciocutaneous (random) => Lower limb	5	1.1%
		Fibula => Lower limb	5	1.1%
		Propeller => Lower limb	5	1.1%
		Scapular => Lower limb	5	1.1%
		Others (count <5 aggregated)	38	8.5%



Although the anterolateral thigh flap (ALT) was one of the most commonly-used donors employed in lower limb reconstruction, many of the others shown in the chart below are also muscle flaps. These are particularly relevant in lower limb trauma.

Skin and fasciocutaneous flaps were more widely used than muscle flaps for upper limb reconstruction.



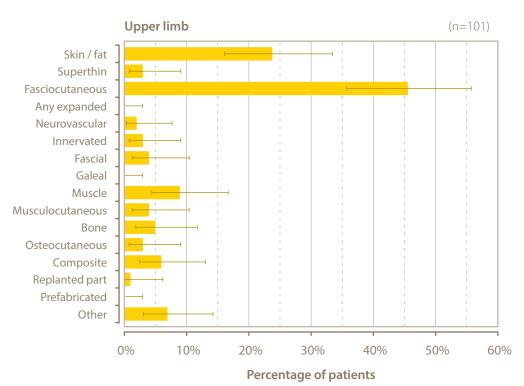
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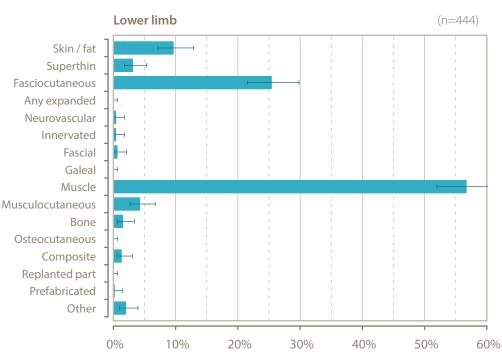


Composition

This chart confirms that the muscle flaps were particularly indicated for lower limb reconstruction. They have favourable characteristics in this context including robust blood supply and the ability to conform to irregular contours or cavities following excision of traumatic wounds. This is less relevant for upper limb reconstructions, where the trauma may represent lower energy transfer and the defects following wound excision may be shallower or less complex in configuration.

Limb reconstruction surgery: Donor composition; operation records dated Jan 2016–Jun 2019





Percentage of patients



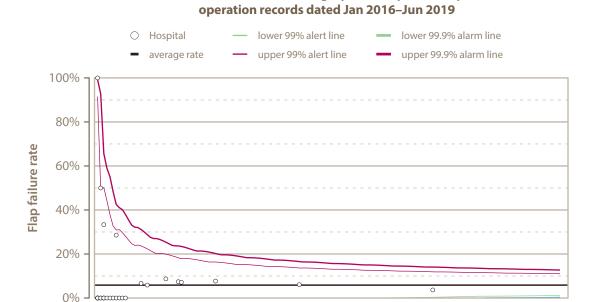
Outcomes

Flap survival

0

The relatively high success rate in terms of **lower limb** flap survival in the higher-volume hospitals is confirmed in the funnel plot below.

Lower limb reconstruction surgery: Funnel plot on flap failure;



Few hospitals reported more than ten cases of **upper limb** reconstructive flap surgery in the analysis period. Coupled with fact that the total number of operations recorded for this recipient site group was relatively low, the hospital-by-hospital flap failure rates for upper limb reconstruction are not plotted here. Analysis showed that twenty-three hospitals reported one or more upper limb flap procedures; of these, only two reported more than 10 procedures in the analysis period. All of the flaps recorded as <100% survival were for patients treated at the two hospitals with more than ten operation records; each of these two hospital had an average 90% flap survival rate.

Number of operations

100

150

50

The table opposite shows the relationship between the patients' co-existing conditions / operative variables and flap survival. For sub-groups where there were no flap failures reported, the odds ratio and the likelihood ratio cannot be calculated.

For the lower limb, the use of pedicled flaps appeared to be associated with a lower rate of flap failure, but the indications for pedicled flaps may be different; for example, they may be utilised for less complex defects that are associated with lower energy transfer mechanisms and may therefore be less extensive. In the distal lower limb even smaller defects may require microvascular reconstruction because of the lack of local pedicled flap options or because of the extent of the zone of injury.

Some of the pedicled flaps may be used in either an elective procedure and/or for some indication other than trauma; these operations usually carry a lower risk of partial or total failure because there is no tissue damage to the surrounding area nor any associated zone of trauma.

Funded by BAPRAS



Limb reconstruction surgery: flap survival outcome; operations with linked donors and recipients; operations dated Jan 2016–Jun 2019

			Flap survival					
			100%	<100%	Missing	Rate	Odds	LR
	Upper limb							
	All		93	4	4	95.9%	23.25	
	Uhmantanaian	No	56	2	4	96.6%	28.00	1.204
	Hypertension	Yes	15	0	0	100.0%	Not a	pplicable
	Smoking	No	37	0	2	100.0%	Not a	pplicable
	now / past	Yes	32	2	2	94.1%	16.00	0.688
	BMI	No	21	2	3	91.3%	10.50	0.452
so.	>30 kg m ⁻²	Yes	2	0	0	100.0%	Not a	pplicable
dno	Pre-operative	No	64	2	4	97.0%	32.00	1.376
sub groups	radiotherapy	Yes	10	0	0	100.0%	Not a	pplicable
אַ	Pre-operative	No	62	2	3	96.9%	31.00	1.333
	chemotherapy	Yes	10	0	0	100.0%		pplicable
		No	67	3	4	95.7%	22.33	0.961
	ASA grade ≥3	Yes	8	0	0	100.0%		pplicable
		1						
	Donors	Free Pedicled	55 38	2	0	96.5% 95.0%	27.50 19.00	1.183 0.817
		realciea	30	۷	· ·	JJ.0 /0	15.00	0.017
	Lower limb	1						
	All		385	24	37	94.1%	16.04	
	Hypertension	No	226	15	25	93.8%	15.07	0.939
	riypertension	Yes	82	6	8	93.2%	13.67	0.852
	Smoking	No	156	7	17	95.7%	22.29	1.389
	now / past	Yes	144	14	16	91.1%	10.29	0.641
	BMI	No	85	7	8	92.4%	12.14	0.757
10	>30 kg m ⁻²	Yes	43	2	10	95.6%	21.50	1.340
dno	Pre-operative	No	288	19	33	93.8%	15.16	0.945
sub groups	radiotherapy	Yes	26	2	1	92.9%	13.00	0.810
N N	Pre-operative	No	304	21	33	93.5%	14.48	0.902
	chemotherapy	Yes	8	0	1	100.0%		pplicable
		No	252	16	26	94.0%	15.75	0.982
	ASA grade ≥3	Yes	252 58	6	26 11	94.0%	9.67	0.982
	Donors	Free	253	19	19	93.0%	13.32	0.830
		Pedicled	131	4	18	97.0%	32.75	2.042

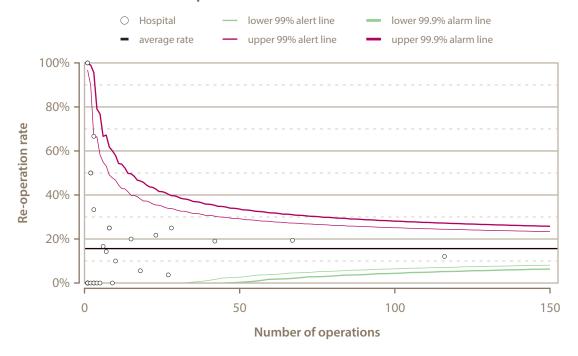


Unplanned re-operation

Any unplanned re-operation overview

The funnel plot below shows that although there was variation in the number of re-operations after lower limb reconstruction surgery at each hospital, there were no statistical outliers.

Lower limb reconstruction surgery: Funnel plot any unplanned re-operation; operation records dated Jan 2016–Jun 2019



An equivalent funnel plot was not generated for upper limb reconstruction surgery, as the overall numbers for this procedure were so low. Analysis showed that of the 23 hospitals that reported upper limb flap surgery, only two recorded more than 10 operations. Ten of the fifteen patients who had a re-operation were treated at the two *high-volume* hospitals; five patients required a re-operation at each of these centres. This equates to an overall re-operation rate after upper limb flap surgery of 15.6% and around 25% at the high-volume hospitals. Again, there were no outliers.

The association between the various pre-operative / operative variables and the need for any re-operation is shown in the table opposite. The apparent relationship between the need for a re-operation and hypertension is not the same for upper and lower limb reconstructions; the same is true for the relationship between smoking history and re-operations for upper and lower limb reconstruction surgery.

There may be a less frequent need for re-operation for pedicled as compared to free flaps. Further analysis here would demonstrate, for example, if these re-operations are for revision to an anastomosis or for other problems such as haematoma. However, the number of operations is currently small, so we cannot make any definite statements or conclusions about the relationship between outcome and the variables recorded in the UKNFR; but, with the addition of more operation records with complete data, it may be possible to draw more clinically useful conclusions in regard to this in future reports.

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Limb reconstruction surgery: any unplanned reoperation outcome; operations with linked donors and recipients; operations dated Jan 2016–Jun 2019

			Any unplanned re-operation						
			No	Yes	Missing	Rate	Odds	LR	
	Upper limb								
	All		84	15	2	15.2%	0.18		
		No	49	11	2	18.3%	0.22	1.257	
	Hypertension	Yes	14	1	0	6.7%	0.07	0.400	
S	Smoking	No	35	3	1	7.9%	0.09	0.480	
able	now / past	Yes	27	8	1	22.9%	0.30	1.659	
Pre-operative and operative variables	BMI	No	19	6	1	24.0%	0.32	1.768	
tive	>30 kg m ⁻²	Yes	2	0	0	0.0%	0.00	0.000	
era		l No	T.6	10	2	17.6%	0.21	1.200	
фор	Pre-operative radiotherapy	No Yes	56 10	12	0	0.0%	0.21	0.000	
an	.,								
ative	Pre-operative chemotherapy	No	54	11	2	16.9%	0.20	1.141	
pera	Chemotherapy	Yes	10	1	0	9.1%	0.10	0.560	
re-o	ASA grade ≥3	No	59	13	2	18.1%	0.22	1.234	
۵	71371 grade ±3	Yes	7	1	0	12.5%	0.14	0.800	
		Free	49	11	1	18.3%	0.22	1.257	
	Donors	Pedicled	35	4	1	10.3%	0.11	0.640	
	Lower limb								
	All		356	66	24	15.6%	0.19		
		No	207	42	17	16.9%	0.20	1.094	
	Hypertension	Yes	77	12	7	13.5%	0.16	0.841	
10	Smoking	No	144	26	10	15.3%	0.18	0.974	
ple	now / past	Yes	133	27	14	16.9%	0.20	1.095	
/aria		l NI.	7.6	10		10.10/	0.24	1 270	
ive	BMI >30 kg m ⁻²	No Yes	76 47	18 5	3	19.1% 9.6%	0.24	1.278 0.574	
erati	, , , , , , , , , , , , , , , , , , ,								
ob	Pre-operative	No	269	48	23	15.1%	0.18	0.962	
and	radiotherapy	Yes	22	6	1	21.4%	0.27	1.471	
tive	Pre-operative	No	280	54	24	16.2%	0.19	1.080	
oera	chemotherapy	Yes	9	0	0	0.0%	0.00	0.000	
Pre-operative and operative variables		No	235	41	18	14.9%	0.17	0.941	
P	ASA grade ≥3	Yes	56	13	6	18.8%	0.23	1.252	
		Free	229	50	12	17.9%	0.22	1.178	
	Donors	Pedicled	126	15	12	10.6%	0.12	0.642	



Re-operation

First UK National Flap Registry Report 2019

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Detailed unplanned re-operation information

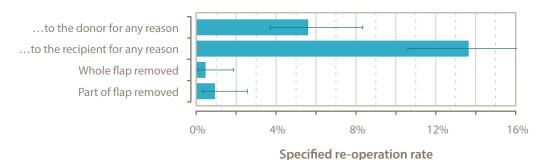
The unplanned recipient re-operation rate in lower limb reconstructions was 13.6%, which is much higher than the return to theatre rate for donor site problems (5.6%). This is not entirely unexpected, as the most common indication for flap reconstructions in the lower limb is trauma. Often, these trauma cases can be high-impact or high-velocity with an extensive zone of injury, sometimes resulting in Gustilo IIIb fractures (an exposed fracture site requiring flap cover) or occasionally Gustilo IIIc fractures, which present as an ischaemic limb. In these instances, there may have been anastomoses performed to vessels within the zone of injury, but only after ascertaining that there was adequate perfusion of the lower limb using a pre-operative CT angiogram to establish the presence of two or three patent vessels in the leg.

These flaps are then monitored clinically and also using Doppler to check for adequate blood flow. Inadequate arterial flow or venous congestion would necessitate an emergency return to theatre for re-exploration of the anastomoses, repositioning of the flap or evacuation of a haematoma that might be exerting external pressure on one or more of the anastomoses. The re-operation may also include removing part or all of the flap in cases of irreversible flap damage or ischaemia re-perfusion injury. Should there be partial loss of the flap covering the exposed bone, fracture site or exposed metalwork, a second flap reconstruction may be required, delaying the patient's recovery and rehabilitation.

Lower limb reconstruction surgery: detailed unplanned re-operation information; operations with linked donors and recipients; operations dated Jan 2016–Jun 2019

		Unplanned re-operation			
		No	Yes	Unspecified	Rate
	Donor re-operation for any reason	404	24	18	5.6%
Kind of	Recipient re-operation for any reason	367	58	21	13.6%
re-operation	Whole flap removed	422	2	22	0.5%
	Part of flap removed	420	4	22	0.9%

Lower limb reconstruction surgery: Detailed unplanned re-operation information; operation records dated Jan 2016–Jun 2019



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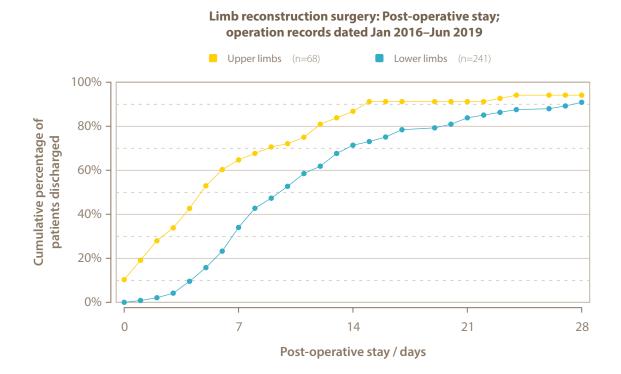
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Post-operative stay

The following graph shows that, on average, patients having lower limb flap surgery tended to stay longer in hospital after their operation than patients having reconstructive surgery to the upper limb.

Part of the explanation for this may be the relative frequency of trauma in the two recipient-site groups, and the size and type of any such traumas: as stated previously, both the size and complexity of any traumatic injury is likely to be greater in patients undergoing a lower limb reconstruction. Furthermore, lower limb reconstruction will often delay the patient's mobilisation, which itself leads to a prolonged length-of-stay.



Trunk and perineum reconstructions



Surgery for the trunk and the perineum

Indications

The indications for reconstructive surgery to the trunk & perineum are shown below. The most frequently-recorded reason for surgery was cancer, with significantly more reconstructions performed at the time of resection particularly in the perineum group.

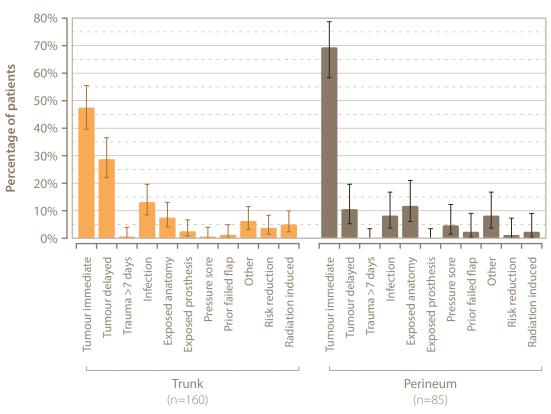
Cancers in the perineum can be anorectal, mostly commonly squamous cell carcinomas (SCC), for which the mainstay of treatment is chemo-radiation, as combined radiotherapy and chemotherapy is more effective in these cancers. Pre-operative neo-adjuvant radio-chemotherapy is also used to downstage tumours, before radical aggressive surgery is performed with flap coverage.

Vulval cancers, also SCC, are rare and radical vulvectomy will require flap cover.

Reconstruction of this area poses functional as well as aesthetic challenges. General prerequisites of an adequate reconstruction of perineal defects include provision of skin cover, well vascularised tissue to fill the dead space (reducing fluid collection and infection), ano-genital and/or vulvo-vaginal reconstruction and avoidance of faecal or urinary contamination.

Infection and exposure of vital anatomical structures constituted the next commonest indications.

Surgery for the trunk and the perineum: Indications for surgery; operation records dated Jan 2016–Jun 2019



Recipient site and indication

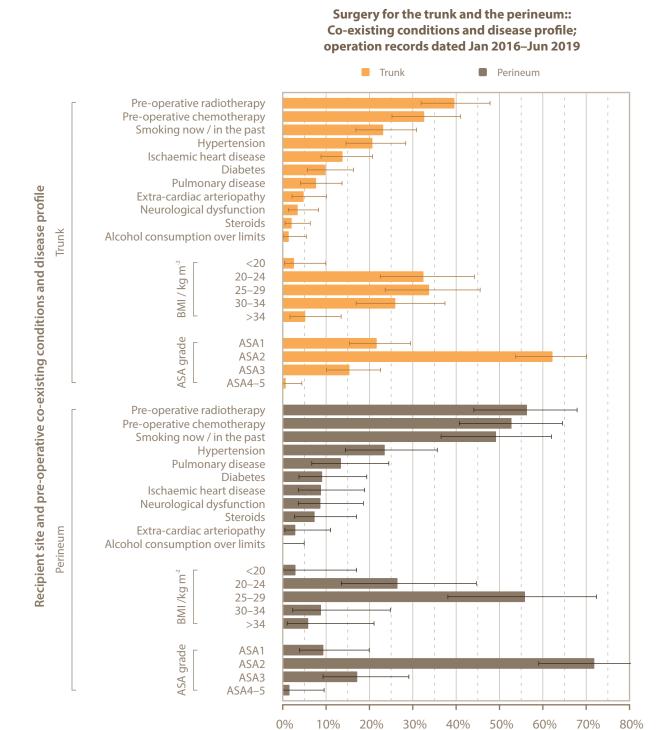
(unrepresented indications excluded from the chart)

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Co-existing conditions and disease profile

The percentage of patients with each of the co-existing conditions is shown in the chart below. Although the numbers were smaller than for the other recipient site groups, there appeared to be a significantly higher percentage of patients with a history of smoking in the perineal group compared to the trunk recipient site group. Approximately 80% of the perineal patients were being treated for cancer, mostly with the reconstruction performed at the time of the resection. About 50% of these patients will have received pre-operative radiotherapy with or without pre-operative chemotherapy.



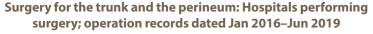
Percentage of patients

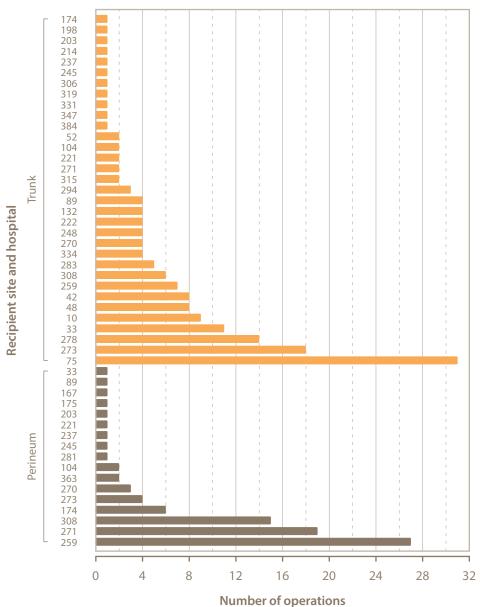


Hospitals

There were many hospitals that reported a small numbers of operations. Few constitute large-volume operators where there are more than an average of 5 reconstructions *per* year at each of the two recipient sites. In future it is hoped that more hospitals will participate in UKNFR, and this should allow more detailed analysis of the more clinically relevant data.

Defects of the perineum usually result from ablative procedures of different malignancies, such as gynaecological (cervix, vagina, endometrial), urological (urinary bladder, prostate), and colorectal (anal and rectal carcinoma) tumours. Radical excisional surgery techniques result in large defects of the perineum. The perineo-genital region *per* se has many different functions for urination, bowel evacuation, sexual function, and reproduction, so resection in this region results often in functional deficits for the patient and requires a multi-disciplinary approach involving surgeons from various specialities. These operations are therefore performed in specialist centres.





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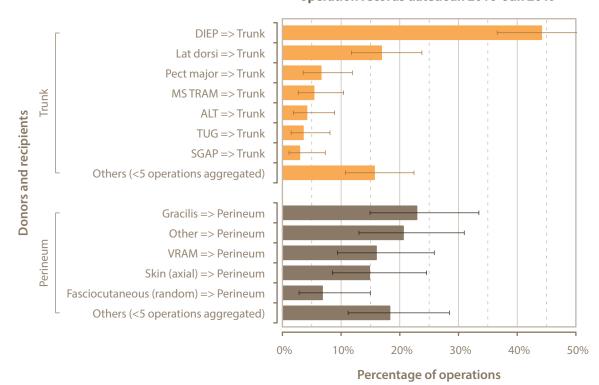
Flap name

The table and chart below show the most frequent combinations of flaps used for the two recipient sites. Deep inferior epigastric artery perforator (DIEP) flaps and latissimus dorsi flaps constituted over 60% of the flaps used for trunk reconstruction. The majority of flaps in these two areas (just under 60%) were pedicled flaps. Most flaps used in reconstruction of the perineum were pedicled gracilis and VRAM (vertical rectus abdominis) flaps.

Trunk and perineum reconstructions: recipient and linked donors; operations dated Jan 2016–Jun 2019

			Count	Rate
		DIEP => Trunk	73	44.2%
w		Lat dorsi => Trunk	28	17.0%
and recipients for the perineum recipients		Pect major => Trunk	11	6.7%
		MS TRAM => Trunk	9	5.5%
	Trunk	ALT => Trunk	7	4.2%
		TUG => Trunk	6	3.6%
cipi rine		SGAP => Trunk	5	3.0%
nd re		Others (<5 operations aggregated)	26	15.8%
and the		Gracilis => Perineum	20	23.0%
Donors nk and		Other => Perineum	18	20.7%
Donors the trunk and	D. d.	VRAM => Perineum	14	16.1%
	Perineum	Skin (axial) => Perineum	13	14.9%
Ŧ		Fasciocutaneous (random) => Perineum	6	6.9%
		Others (<5 operations aggregated)	16	18.4%

Surgery for the trunk and the perineum: Most commonly-used donor-recipient combinations; operation records dated Jan 2016–Jun 2019

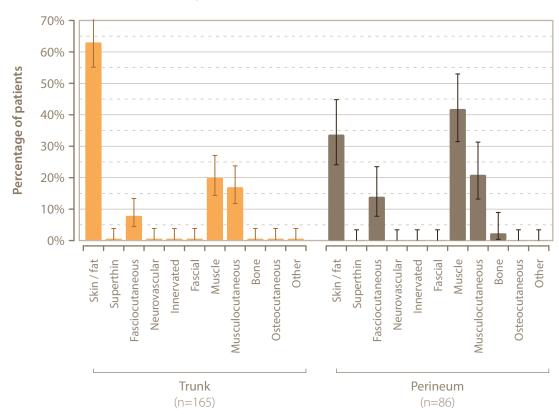




Donor composition

The chart on this page confirms that the commonest flaps used for trunk reconstruction were composed of skin and fat; the majority of these were DIEP (deep inferior epigastric perforator) flaps (see graph on previous page). In perineal surgery, a greater percentage of patients received muscle flaps. Larger perineal defects following excision of anorectal and vulvo-vaginal cancers, will require large muscle flaps such as gracilis or VRAM (vertical rectus abdominis myocutaneous) flaps to fill the dead space following pelvic exenteration. If the defect is restricted to the perineum, it is often reconstructed with a pedicled musculocutaneous gracilis or a lotus petal flap, which are perforator flaps based on blood vessels that perforate the deep fascia to supply the subcutaneous vascular networks.

Surgery for the trunk and the perineum: Donor composition; operation records dated Jan 2016–Jun 2019



Recipient site and donor composition

(unrepresented indications excluded from the chart)

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Immediate operative outcomes

There were no reported patient deaths in these groups, but the patient survival information was unspecified in a good many records. Re-operation and flap survival rates were broadly similar across these two groups.

Trunk and perineum reconstructions: immediate outcomes; operations dated Jan 2016–Jun 2019

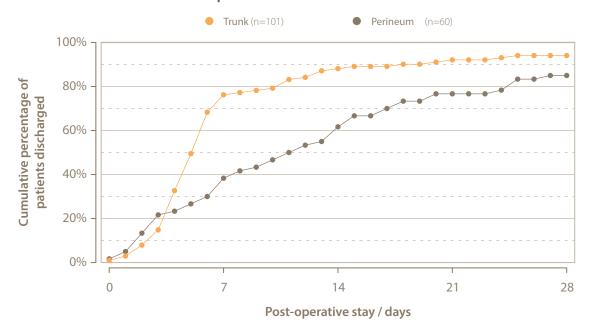
		_	Outcome			
			No	Yes	Unspecified	Rate
		Any unplanned re-operation	137	19	9	12.2%
Recipient site	Trunk	Flap survival	8	145	12	94.8%
		Patient survival	0	105	60	100.0%
	Perineum	Any unplanned re-operation	75	10	2	11.8%
Ř		Flap survival	5	66	16	93.0%
		Patient survival	0	62	25	100.0%

Post-operative stay

The post-operative length-of-stay chart below indicates that patients usually stayed in hospital for more than 10 days after perineal reconstruction, whereas the majority of the trunk reconstruction patients had been discharged by that time. Operations on the perineal area are not surprisingly associated with slower mobilisation.

Furthermore, large perineal defects from pelvic exenterations are reconstructed with flaps that have to provide well vascularised tissue to fill the dead space (reducing fluid collection and infection), and avoidance of faecal or urinary contamination. The hospital stay for these groups of patients was generally longer.

Surgery for the trunk and the perineum: Post-operative stay; operation records dated Jan 2016–Jun 2019



Appendix



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Appendices

Appendices

Glossary

Items in the risk factor section

Definitions

•	Average alcohol consumption	within limits or over limits (\geq 24 per week units for men, \geq 14 units per week
		for women)

• **Diabetes** diabetes mellitus: with controlled through an appropriate diet, controlled by oral medication, or with insulin (with/without oral medication).

• Extra-cardiac arteriopathy any disease arising from intrinsic occlusion of arterial inflow to a body part.

Hypertension treated blood pressure (BP) or BP >140/90.

• **Ischaemic heart disease** symptoms arising from reduced blood supply to the heart.

• **Neurological dysfunction** impairment or disease of the central or peripheral nervous system.

Pulmonary disease COPD/emphysema or asthma.

Steroids patient currently taking steroid medication.

• **Smoking history** ex-smoker or current smoker.

Abbreviations

• **ASA** American Association of Anesthesiologists grade (see page 46) is a classification system to assess the patient's anaesthetic risk or fitness prior to surgery.

• **BMI** body mass index; (calculated from the patient's height and weight; it allows for categorisation into standard groups that range from underweight through to very obese).

• **COPD** chronic obstructive pulmonary disease.

• **DVT** deep vein thrombosis.

• **GIRFT** Getting It Right First Time, a project by NHS England.

• **PE** pulmonary embolus.

VTE venous thromboembolism (the formation of blood clots in the peripheral venous circulation that may break free and lodge in the lungs or other organ leading to morbidity or mortality).

Other technical information

Definitions

•	Anastomosis	surgical creation of a connection between two tubular structures, in this report usually referring to blood vessels.
•	Donor site	anatomical location from which tissue is taken for use elsewhere in the body.
•	Flap	tissue transferred from one part of the body to another with an intact or immediately restored blood supply.
•	Graft	tissue transferred from one part of the body to another without its blood supply. The new blood supply grows in after it has been placed at its new site <i>e.g.</i> , skin graft.
•	Microsurgery	surgical procedures using the operating microscope.
•	Microvascular	reconnection of small blood vessels to restore blood flow to tissue or an organ.
•	Pedicle	connection between the flap and the rest of body, which contains the blood supply. The pedicle is either preserved intact during transfer, or divided and then

Recipient site anatomical location to which tissue is transferred.

vessels.

re-established at the recipient site by microvascular anastomosis of the blood

Appendice:

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Abbreviations

- AICAP anterior intercostal artery perforator flap.
- **ALT** anterolateral thigh flap.
- BCC basal cell carcinoma, a type of skin cancer.
- CT as in CT 1/CT 2/CT 3; core trainee, year 1, 2 or 3.
- DCIA deep inferior circumflex iliac artery flap.
- **DIEP** deep inferior epigastric artery perforator flap.
- **FY** as in FY 1/FY 2; foundation year trainee, years 1 or 2.
- GAP gluteal artery perforator flap.
- **IGAP** inferior gluteal artery perforator flap.
- IMAP inferior internal mammary artery perforator flap.
- LICAP lateral intercostal artery perforator flap.
- LMWH low molecular weight heparin, an injection given to reduce the risk of VTE.
- MM malignant melanoma, a type of skin cancer.
- MSAP medial sural artery perforator flap.
- MS TRAM muscle-sparing transverse rectus myocutaneous flap.
- PAP profunda artery perforator flap.
- PIA posterior interosseous artery flap.
- **RFF** radial forearm free flap.
- **SCC** squamous cell carcinoma, a type of skin cancer.
- **SAS** staff grade, associate specialist and specialty doctor.
- SCIA superficial circumflex iliac artery flap.
- **SIEA** superficial inferior epigastric artery flap.
- **SGAP** superior gluteal artery perforator flap.
- **ST** as in ST 3 ... ST 8; surgical trainee, years 3 to 8.
- STF superficial temporal fascial flap
- TPF temporoparietal fascial flap.
- TDAP thoracodorsal artery perforator flap.
- **TEDS** thromboembolic deterrent stockings, a variety of garments applied to the legs to provide compression of the veins thereby reducing the risk of DVT.
- TFL tensor fascia lata flap (tissue taken from the lateral thigh including the underlying deep fascia).
- TMG transverse myocutaneous gracilis flap.
- TRAM transverse rectus abdominis myocutaneous flap.
- **TUG** transverse upper gracilis flap.
- VAC vacuum assisted closure (the use of a negative pressure device applied to a wound or defect which helps to speed up healing or to prepare for tissue cover).
- VC venae comitantes (small veins, often paired, which accompany arteries).



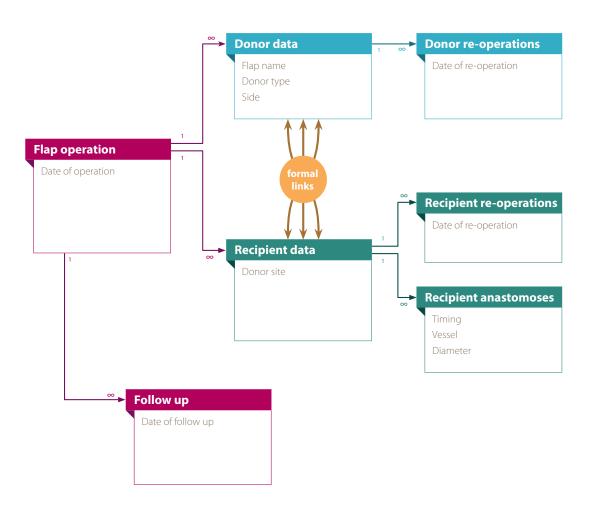
The UK National Flap Registry

Registry schema

This section is a technical description of the underlying data structure of the registry, and may only be of interest to the more technically-minded reader!

Flap surgery can be complex. As shown throughout this report, most of these procedures involve a single donor that is transferred to a single recipient site. However, there are some flap operations that involve more than one donor site and / or more than one recipient site. At the very beginning of the UKNFR project part of the brief was to allow data entry for these very complex procedures, without making the database unwieldy, and yet making analysis as robust as possible.

The schema below shows the relationships between the database tables in the *back-end* of the registry system. Each of the boxes represents a separate database table; each database table contains a set of data-items, including index numbers that are used to link the tables together. The lines with arrows that join the boxes together represent the formal links between the database tables. There are many kinds of links in database systems, but the only one used here is a one-to-many relationship, indicated by a 1 at the start of the line and an **infinity symbol** (∞) at the other end. This indicates a relationship in which there can be one record in the **parent** table (for example, The Flap operation table) and any number of linked records in the **child** table (for example, the Donor data table when considered in relation to the Flap operation table).



Data entry begins with the addition of a new operation. An entry in the **Flap operation** table must have the date-of-operation as a bare minimum. The software automatically adds an unique identifying number called the **FlapOpId** to the record in the **Flap operation** table; this **FlapOpId** is a simple, incremental integer number, so the first operation is given a **FlapOpId** equal to 1, and the second a **FlapOpId** of 2, and so on.

After the operation record has been created, the software guides the user through the process of adding the data-items stored in the Flap operation table (see the database forms on pages 144–146).

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Then, the user is prompted to add information on the donor flap(s) that have been used. The user can add data on as many donor sites as they wish (see the database forms on pages 147–151). Despite the fact that there are different types of donor, classified accord to the anatomical origin (head & neck; trunk front; trunk back; upper limb; lower limb), the data are all stored in the same **Donor data** table. The same **Side** question is used for all the types of donor; likewise, the same **Donor type** field is used throughout. The same **Flap name** question is also used across all kinds of donor, but the list of response-options available on-screen to the user is filtered so that only appropriate answers are available. Again, this avoids redundancy and duplication, whilst driving up data quality by preventing inappropriate data entry.

At the time that the user creates a new entry in the **Donor data** table, the system automatically copies the **FlapOpId** from the parent entry into the **Flap operation** table to the record in the **Donor data** table (this means that the **Flap operation** record is formally linked to the entry in the **Donor data** table). It also adds an unique identifying number to the **Donor data** entry, called the **EntryId**.

The user is also prompted to add data on the recipient sites; again, the user can add as many different recipients as needed. These data are all stored in the **Recipient data** table (see the database form on pages 153–164). As with the donor data, the recipients are split out according to anatomical site (head & neck; upper limb; trunk; perineum; lower limb; breast). Again, some fields are used across all the anatomical sites; *e.g.*, **Side and Recipient indication**. In this table there are some data-items that relate to only one recipient site, such as the **Head & neck internal** and **Head & neck external** fields. This keeps the number of data-items in the Recipient data table down to an absolute minimum, whilst accommodating some questions that are specific to a particular kind of recipient.

The same linking process described for the donor data is applied to the recipient data: when a new entry is added into the Recipient data table, the system automatically copies the FlapOpld from the parent entry in the Flap operation table into the record in the Recipient data table (this means that the Flap operation record is formally linked to the entry in the Recipient data table). It also adds an unique identifying number to the Recipient data entry, also called the Entryld.

A donor is inset into the recipient site, and sometimes blood vessels in the donor are joined on to blood vessels in the recipient site. This joining is called an anastomosis. There can be multiple anastomoses for each recipient site, and the data relating to these anastomoses are stored in the **Recipient anastomoses** table. The diagram shows that there is a one-to-many relationship between the **Recipient data** table (the parent in this instance) to the **Recipient anastomosis** table (the child table in this relationship). At the time that a new record is added to the **Recipient anastomosis** table the system copies the **Entryld** from the parent table into the **Recipient anastomoses** table, and also ascribes the new record its own unique identifying number. This provides the formal link between the data for recipients to the data for anastomoses.

If there is a single donor site recorded for the flap operation, no matter how many recipient sites are involved, the link between donor and recipient(s) is obvious; likewise, if there is a single recipient site the relationships to the donor sites(s) is also obvious. However, of there are two or more donors **and** two or more recipients involved in the reconstruction, then the user has to record information on which donors are linked to which recipients. This is represented by the yellow *formal links* circle in the schema. This linking uses the **Entryld** in the **Donor data** record and the **Entryld** in the **Recipient data** record to formalise the relationship(s).

After a flap reconstruction, patients can have complications, and some complications have to be treated in the operating theatre. These re-operations can be either to the donor site and/or the recipient site. A patient may have one or more re-operations at each of their donor or recipient sites. The **Donor data** and the **Recipient data** tables have their own tailored re-operation table, as shown in the schema. The re-operation records are much like the records in the **Recipient anastomoses** table: each record has a copy of its parent's **EntryId**, and its own unique identifying number, so that the data in the two tables are formally linked.

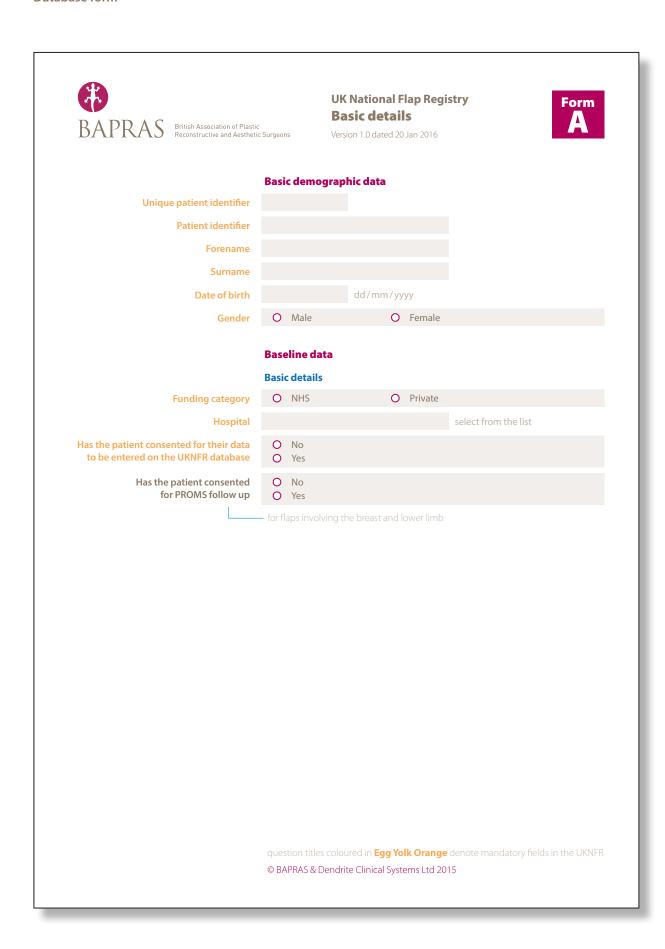
At discharge, the user should go back into the **Flap operation** record to add the discharge data, such as the date-of-discharge and other information around the patient's immediate outcomes.

Later down the line, the patient might be sent a an automated, time-triggered PROMs questionnaire by the system; each patient is asked to fill out the questionnaire at various time-points; for example, the breast reconstruction patients are contacted 6 months and 18 months after their operation. These PROMs data are held in the **Follow up** table. The records in the **Follow up** table (the child table in this relationship) are linked back to the records in the parent **Flap operation** table *via* another one-to-many relationship, so as to allow for the repeated collection of these important post-discharge data.

So, all the data in the UKNFR are housed in seven relatively simple database tables, all of which are linked together to make a functioning whole.



Database form



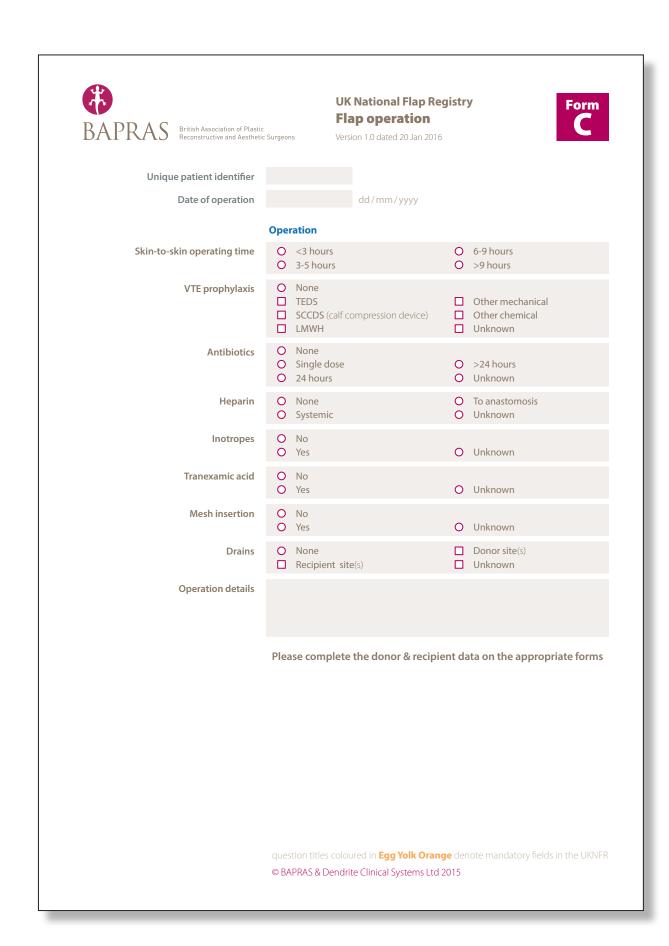
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BAPRAS British Association of Plastic Reconstructive and Aesthetic S	urgeon	Ris	National Flap Regi k factors on 1.0 dated 20 Jan 2016	istr	Form B
Unique patient identifier					
Date of operation			dd/mm/yyyy		
	Dick	factors at ope	ration		
		Never smoked			
Smoking history	_	Ex-smoker	1	0	Current smoker
Average alcohol consumption	0	Within limits		0	Over limits
	With	in limits: men: ≤	28 units per week; wom	en ≤	21 units per week
Diabetes treatment	_	No diabetes Diet control		_	Oral control Insulin (with/without oral)
Steroids		No			Yes
21012111					
Pre-operative radiotherapy	0	No		0	Yes
Pre-operative chemotherapy	0	No		0	Yes
Extra-cardiac arteriopathy	0	No		0	Yes
Ischaemic heart disease	0	No		0	Yes
Hypertension	0	No		0	Treated or BP >140 / 90
Pulmonary disease	0	No			
	0	COPD / emph	ysema	0	Asthma
Neurological dysfunction	0	No		0	Yes
Height			cm		
Weight			kg		
ASA grade	0	ASA 1			
. Srt grade	0	ASA 2		_	ASA 4
	0	ASA 3		0	ASA 5

question titles coloured in **Egg Yolk Orange** denote mandatory fields in the UKNFR © BAPRAS & Dendrite Clinical Systems Ltd 2015

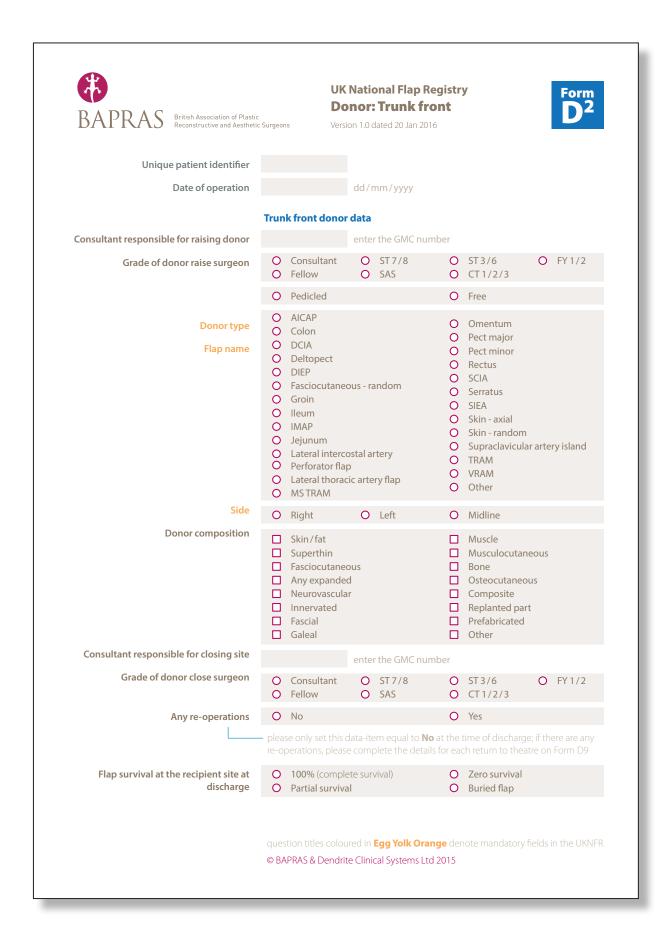






Unique patient identifier					
Date of operation			dd/mm/yyyy		
	Head	d & neck dono	r data		
Consultant responsible for raising donor			enter the GMC nur	nber	
Grade of donor raise surgeon	0	Consultant Fellow ST 7/8 SAS		0	ST 3/6 CT 1/2/3 FY 1/2
Donor type	0	Pedicled		0	Free
Flap name	0000	Ear Fasciocutaneo Forehead Galeal Masseter Nasolabial Nose	ous (random)	0 0 0 0	Platysma Scalp Skin (axial) Skin (random) STF/TPF Temporalis Other
Side	0	Right	O Left	0	Midline
Donor composition		Skin/fat Superthin Fasciocutaned Any expanded Neurovascula Innervated Fascial Galeal	b		Muscle Musculocutaneous Bone Osteocutaneous Composite Replanted part Prefabricated Other
Consultant responsible for closing site			enter the GMC nur	mber	
Grade of donor close surgeon	0	Consultant Fellow ST 7/8 SAS		0	ST 3/6 CT 1/2/3 FY 1/2
Any re-operations	– plea			o at the t	Yes time of discharge; if there are a
Flap survival at the recipient site at discharge	0	oerations, please 100% (comple Partial surviva	ete survival)	0	ch return to theatre on Form DS Zero survival Buried flap

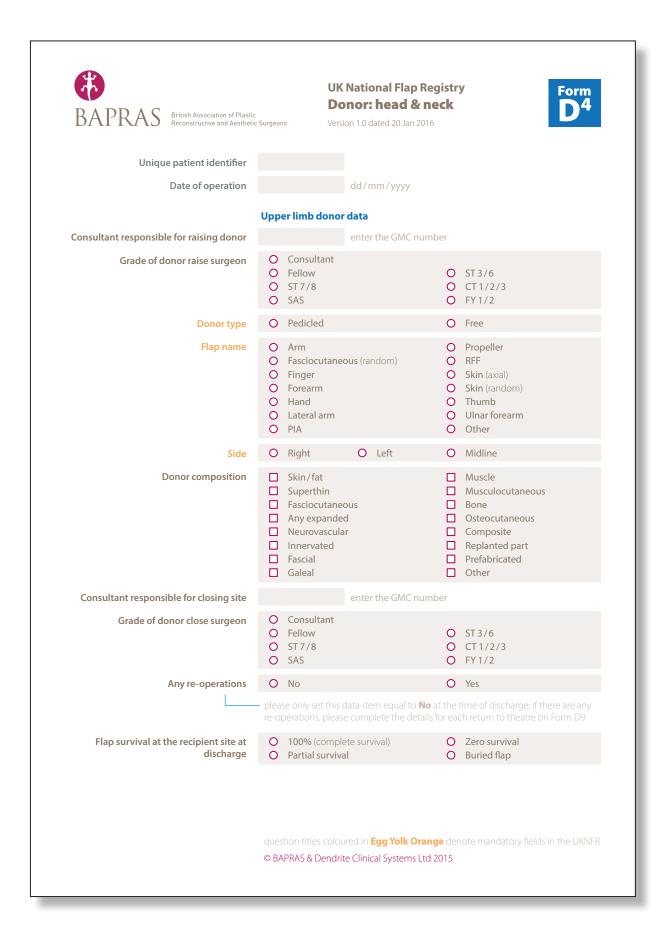






Unique patient identifier		
Date of operation	dd/mm/yyyy	
	Trunk back donor data	
Consultant responsible for raising donor	enter the GMC num	ber
Grade of donor raise surgeon	O Consultant O Fellow O ST 7/8 O SAS	O ST 3/6 O CT 1/2/3 O FY 1/2
Donor type	O Pedicled	O Free
Flap name	O Fasciocutaneous - random O Gluteus maximus O GAP O Lat dorsi O LICAP flap O Lateral thoracic artery flap O LICAP O PAP	O Parascap O Scapular O SGAP O Skin - axial O Skin - random O TDAP O Trapezius O Other
Side	O Right O Left	O Midline
Donor composition	Skin/fat Superthin Fasciocutaneous Any expanded Neurovascular Innervated Fascial Galeal	Muscle Musculocutaneous Bone Osteocutaneous Composite Replanted part Prefabricated Other
Consultant responsible for closing site	enter the GMC num	ber
Grade of donor close surgeon	O Consultant O Fellow O ST 7/8 O SAS	O ST3/6 O CT1/2/3 O FY1/2
Any re-operations	O No	O Yes
	 please only set this data-item equal to No re-operations, please complete the details 	
Flap survival at the recipient site at discharge	O 100% (complete survival) O Partial survival	O Zero survival O Buried flap







BAPRAS British Association of Plastic Reconstructive and Aesthetic								
Unique patient identifier			1.1.7	,				
Date of operation			dd/	mm/yyyy				
	Lowe	er limb donor						
Consultant responsible for raising donor	_	C 1		er the GMC num		ST 2 / 6	_	EV 1 / 2
Grade of donor raise surgeon		Consultant Fellow		ST 7/8 SAS	0	CT 1/2/3	J	FY 1/2
	0	Pedicled				Free		
Donor type Flap name	00000000	ALT Anteromedial Dorsalis pedis Fasciocutaneo Femoral bone Fibula Foot Gastroc Gracilis Hamstr adv Leg Medial planta MSAP PAP Peroneal arter	pus - I	random	0000000000000	Posterior thigh Propeller Rectus femoris Skin - axial Skin - random Sole of foot Soleus Sural artery island TFL TMG Toe Toe Thumb TUG Vastus lateralis Other	k	
Side	0	Right	0	Left	0	Midline		
Donor composition		Skin/fat Superthin Fasciocutaned Any expanded Neurovascula Innervated Fascial Galeal	d			Muscle Musculocutaneou Bone Osteocutaneous Composite Replanted part Prefabricated Other	us	
Consultant responsible for closing site			ente	er the GMC num	ber			
Grade of donor raise surgeon	0	Consultant Fellow		ST 7/8 SAS	0	ST 3/6 (CT 1/2/3	O	FY 1/2
Any re-operations	- plea:				at the	Yes time of discharge; if ch return to theatre		
Flap survival at the recipient site at discharge	0	100% (comple Partial surviva		rvival)	0	Zero survival Buried flap		

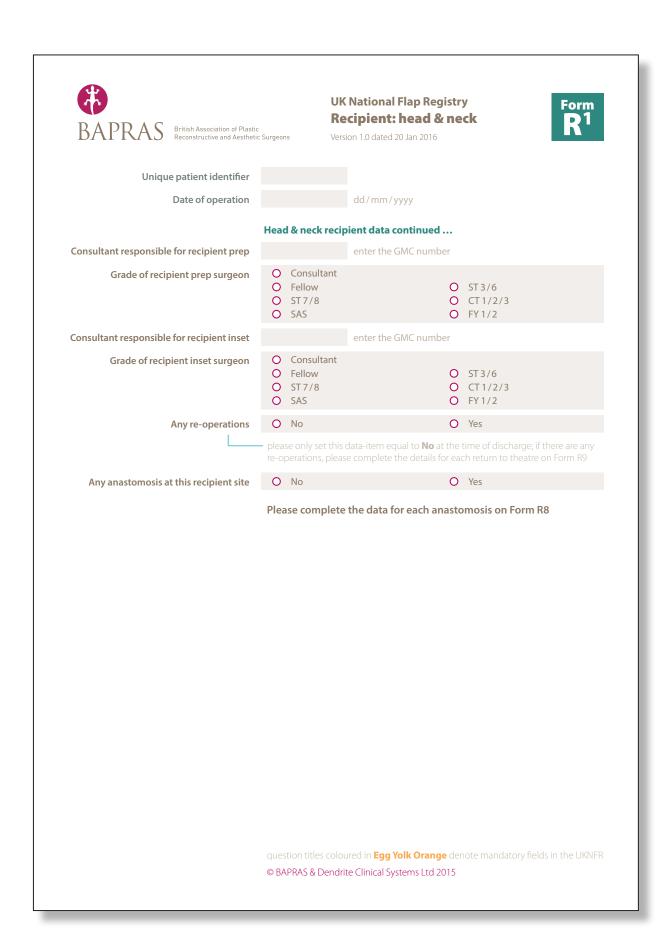


BAPRAS British Association of Plastic Reconstructive and Aesthetic	UK National Flap Registry Donor site re-operations Version 1.0 dated 20 Jan 2016
Unique patient identifier	
Date of operation	dd/mm/yyyy
	Donor site re-operations
	Please complete this form for each donor site re-operation
Date of donor site re-operation	dd/mm/yyyy
Donor re-operation	 ☐ Haematoma / seroma evacuation ☐ Graft ☐ Change of dressing ☐ Re-sutured ☐ Other
	question titles coloured in Egg Yolk Orange denote mandatory fields in the UKNFR © BAPRAS & Dendrite Clinical Systems Ltd 2015



Unique patient identifier					
Date of operation		dd/mm/yyyy			
	Head	d & neck recipient data			
Head & neck		External		Internal	
Head & neck external		Scalp / calvarium Base of skull Upper third of face		Mid third of face Lower third of face Neck	
Head & neck internal		Lip Tongue Floor of mouth Gingival / mandibular border Buccal		Mandible Nasopharynx Pharynx Maxilla Intracranial	
Head & neck recipient arteries	0	Fascial Lingual Superior thyroid External carotid	0	Transverse cervical Superficial temporal Other	
Head & neck recipient veins	0	External jugular Internal jugular Retromandibular Common facial	0	Lingual Cephalic Superficial temporal Other	
Side	0	Right O Left	0	Midline O	Biped
Recipient indication		Tumour immediate Tumour delayed Burn acute Burn secondary/delayed Trauma <72 hours Trauma 3-7 days Trauma >7 days Infection Exposed anatomy		Pressure sore Prior failed flap Craniofacial Facial palsy Congenital	
Infection details		Osteomyelitis Necrotising fasciitis	0	Other	
Exposed anatomy details		Tendon Nerve Vessel		Bone Other	
Tumour type		Breast Colorectal Gynaecological Sarcoma SCC		BCC MM Other skin Neuro oncology Other	

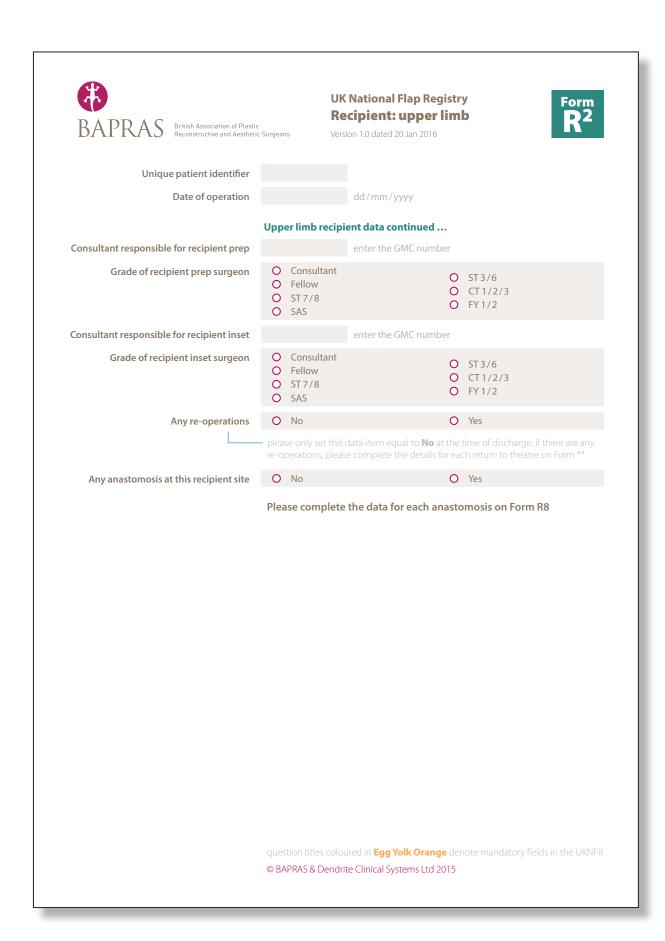






Unique patient identifier							
Date of operation			dd/mm/yyyy				
	Unne	er limb recipie	nt data				
Upper limb		Upper arm Elbow Forearm			Wrist Hand		
Upper limb recipient arteries	0 0	Axillary Brachial Radial			Ulnar Other		
Upper limb recipient veins	0 0	Axillary Basilic Cephalic		O	Radial VC Ulnar VC Other		
Side	0	Right	O Left	0	Midline	0	Bipedicle
Recipient indication		Tumour imme Tumour delaye Burn acute Burn secondar Trauma <72 h Trauma 3-7 da Trauma >7 day Infection Exposed anato	ed ry/delayed purs ys ys		Exposed prosthe Pressure sore Prior failed flap Craniofacial Facial palsy Congenital Risk reduction Radiation induction		
Infection details	0	Osteomyelitis Necrotising fa	sciitis	0	Other		
Exposed anatomy details		Tendon Nerve Vessel			Bone Other		
Tumour type		Breast Colorectal Gynaecologica Sarcoma SCC	al		BCC MM Other skin Neuro oncology Other	/	

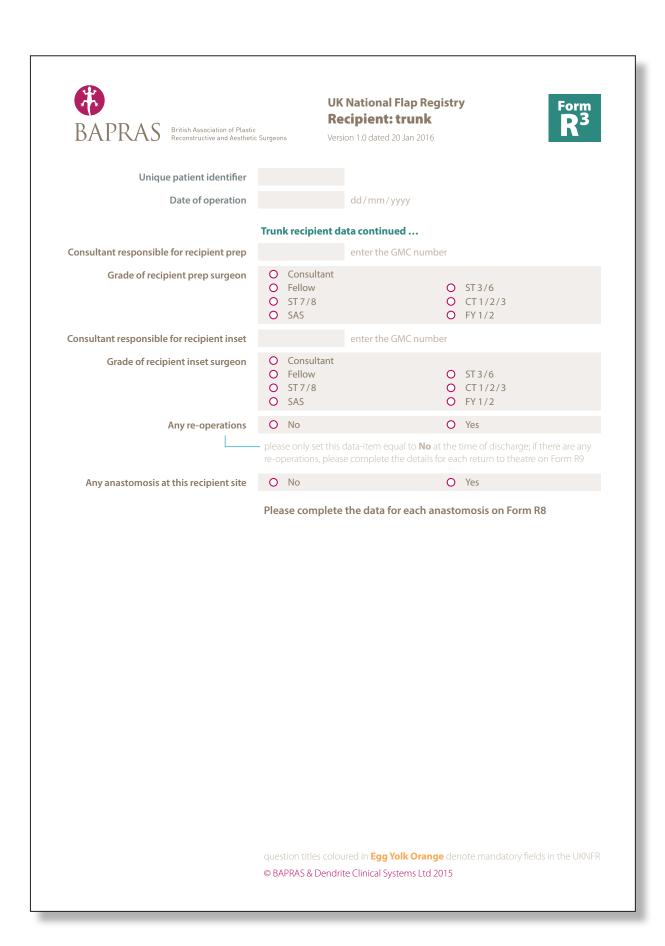






Unique patient identifier								
Date of operation			dd/r	nm/yyyy				
	Trun	k recipient dat	a					
Trunk		External anterio	or			External posterio	r	
Trunk external anterior		Sternum		Chest wall		Other		
Trunk external posterior		Spine		Buttock		Chest wall		Other
Trunk internal		Intrathoracic				Intraabdominal		
Trunk recipient arteries	0 0 0	Internal mamm Thoracodorsal Subscapular	-		Ö	Lateral thoracic Gluteal Other		
Trunk recipient veins	_	Internal mamm Thoracodorsal Lateral thoracio Circumflex scap	c		0	Cephalic Gluteal Other		
Side	0	Right	0	Left	0	Midline	0	Bipedicle
Recipient indication		Tumour immed Tumour delaye Burn acute Burn secondar Trauma <72 ho Trauma 3-7 day Trauma >7 day Infection Exposed anato	ed y/de ours ys	layed		Exposed prosthe Pressure sore Prior failed flap Craniofacial Facial palsy Congenital Risk reduction Radiation induce Other		
Infection details	0	Osteomyelitis Necrotising fas	ciitis		0	Other		
Exposed anatomy details		Tendon Nerve Vessel				Bone Other		
Tumour type		Breast Colorectal Gynaecologica Sarcoma SCC	ıl			BCC MM Other skin Neuro oncology Other		

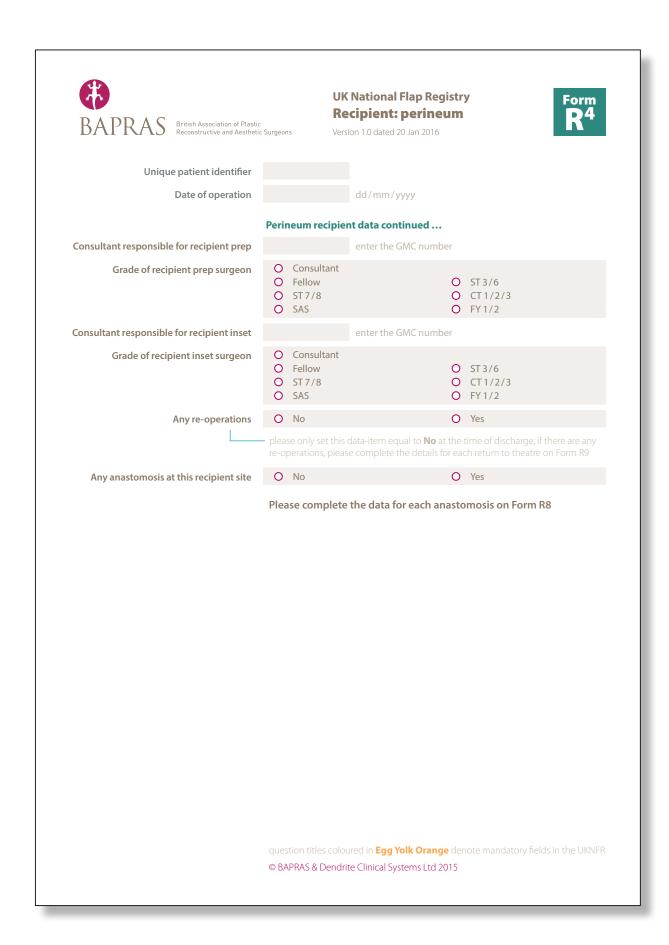






Unique patient identifier								
Date of operation			dd/r	mm/yyyy				
		neum recipie	nt data	a				
Perineum		External	_			Intra-pelvic	_	
Perineum external		Inguinal Scrotum		Penis Vulva		Vagina Perianal		Rectum Other
Perineum recipient arteries	0	Femoral Gluteal			0	Other		
Perineum recipient veins	0 0 0	Med/lateral Superior/inf DIEV				Long spahenou Other	us	
Side	0	Right	0	Left	0	Midline	0	Bipedicle
Recipient indication		Tumour imm Tumour dela Burn acute Burn second Trauma <72 Trauma 3-7 d Trauma >7 d Infection Exposed ana	yed ary/de hours lays ays	layed		Exposed prostl Pressure sore Prior failed flap Craniofacial Facial palsy Congenital Risk reduction Radiation indu Other)	
Infection details	0	Osteomyeliti Necrotising f			0	Other		
Exposed anatomy details		Tendon Nerve Vessel				Bone Other		
Tumour type		Breast Colorectal Gynaecologi Sarcoma SCC	cal			BCC MM Other skin Neuro oncolog Other	ıy	

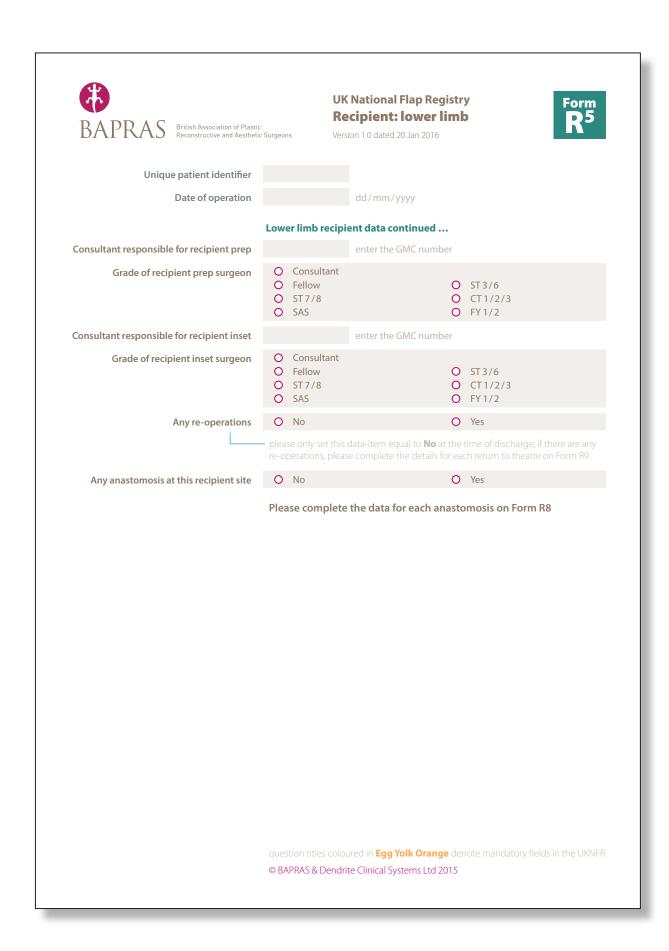






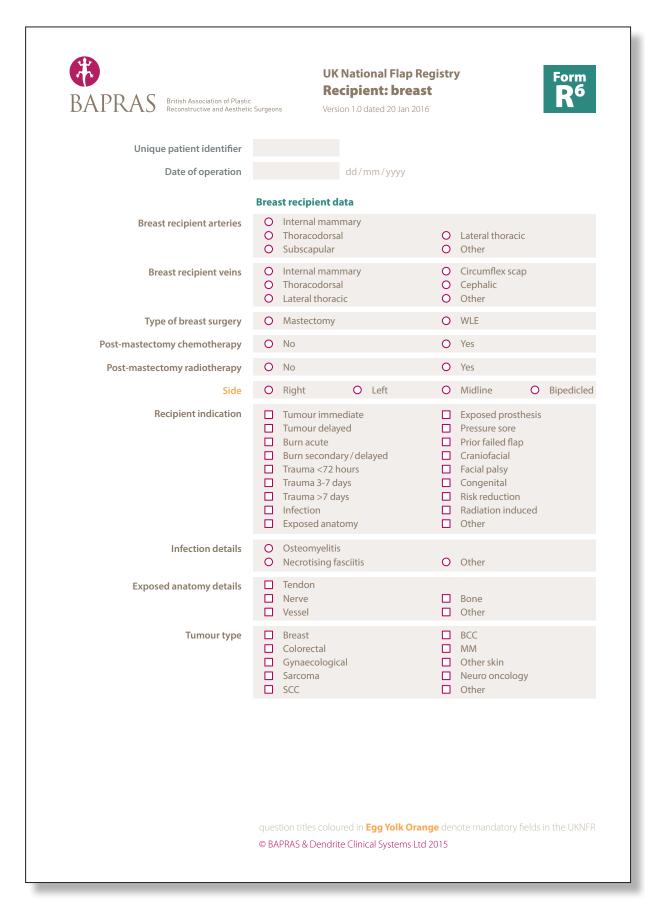
Unique patient identifier					
Date of operation		dd/mm/yyyy			
	Low	er limb recipient data			
Lower limb		Thigh Knee Lower leg		Ankle Foot	
Lower limb recipient arteries	0 0 0	Femoral Popliteal Posterior tibial	0	Anterior tibial Dorsalis pedis Other	
Lower limb recipient veins	0 0 0	External iliac Profunda femoris Femoral Popliteal Long saphenous Short saphenous	0 0	Deep calf veins Posterior tibial VC Anterior tibial VC Dorsalis pedis VC Other	
Side	0	Right O Left	0	Midline O	Bipedi
Recipient indication		Tumour immediate Tumour delayed Burn acute Burn secondary / delayed Trauma <72 hours Trauma 3-7 days Trauma >7 days Infection Exposed anatomy		Exposed prosthesis Pressure sore Prior failed flap Craniofacial Facial palsy Congenital Risk reduction Radiation induced Other	
Infection details	0	Osteomyelitis Necrotising fasciitis	0	Other	
Exposed anatomy details		Tendon Nerve Vessel		Bone Other	
Tumour type		Breast Colorectal Gynaecological Sarcoma SCC		BCC MM Other skin Neuro oncology Other	
	ques	ition titles coloured in Egg Yolk Ora	nge der	note mandatory fields i	n the Ul



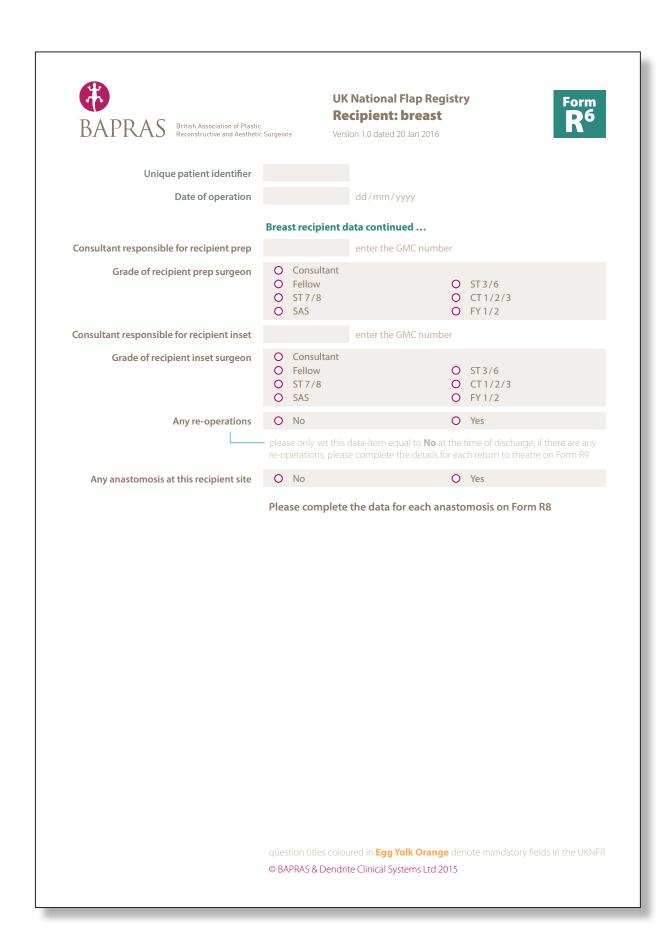


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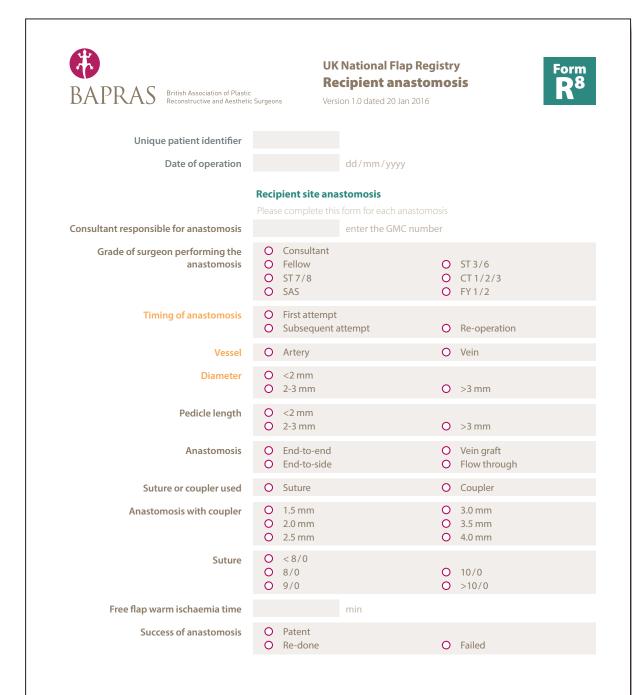




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BAPRAS British Association of Plastic Reconstructive and Aesthetic	UK National Flap Reg Recipient re-oper Surgeons Version 1.0 dated 20 Jan 2016	
Unique patient identifier		
Date of operation	dd/mm/yyyy	
	Recipient site re-operations	
Date of recipient site re-operation	Please complete this form for each re-opera dd/mm/yyyy	tion
Recipient re-operation	Haematoma / seroma evacuation Anastomosis redone (arterial) Anastomosis redone (venous) Flap repositioned Pedicle unkinked	☐ Debridement ☐ Amputation ☐ Exploration alone ☐ Sepsis/abscess
	☐ Pedicle diffilied ☐ Whole flap removed ☐ Part of flap removed ☐ Grafted	Fat necrosis Removal of implant/prosthes Other
		e denote mandatory fields in the UKN



BAPRAS British Association of Plastic Reconstructive and Aesthetic	: Surgeon	Dis	National Flap Reg s charge on 1.0 dated 20 Jan 2016	gistr	V
Unique patient identifier					
Date of operation			dd/mm/yyyy		
	Discl	harge			
Post-operative chemotherapy	0	None Planned		0	Given
Post-operative radiotherapy	0	None Planned		0	Given
Admission to ITU after procedure		No Yes (<24 hours	·)	0	Yes (>24 hours)
Type of admission to ITU	0	Planned		0	Unplanned
Patient status at discharge	0	Alive		0	Deceased
Date of discharge / death			dd/mm/yyyy		
Cause of death		Cardiovascula Sepsis Respiratory	r	_	Multi-organ failure PE Other
Any unplanned readmission to hospital	0	No		0	Yes
Date of unplanned readmission		mission to hosp is flap operatior		is ope	eration for a reason directly related
				je der	





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BAPRAS British Association of Plastic Reconstructive and Aesthetic Surgeons	UK National Flap Registry Follow up: breast recip Version 1.0 dated 20 Jan 2016	pients	Ì	Form
Unique patient identifier				
Date of follow up	dd/mm/yyyy			
Breast-Q	satisfaction with outcome	Disagree	Somewhat agree	Definitely agree
Having reconstruction is much better than the alternative of having no breast(s) $\frac{1}{2} \left(\frac{1}{2} \right) = \frac{1}{2} \left(\frac{1}{2} \right) \left(\frac{1}{2} \right)$		0	0	0
I would encourage other women to in my situation to have breast reconstruction surgery		0	0	0
	I would do it again	0	0	0
I have no regrets about having the surgery			0	0
Having this su	rgery changed my life for the better	0	0	0

The outcome perfectly matched my expectations

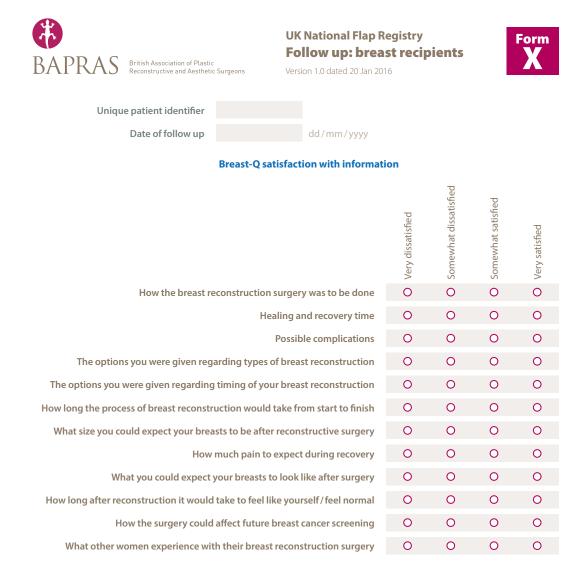
It turned out exactly as I had planned

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0

0



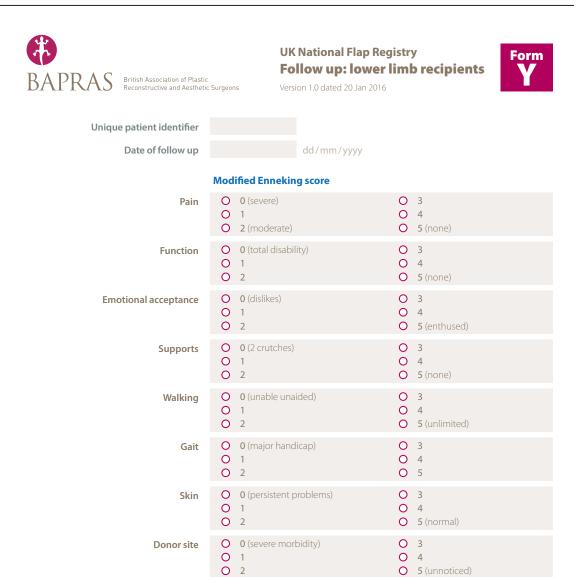


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O 5 (unnoticed)

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Appendices

Consent form

Email address:

Name of Patient

Mobile telephone number:

Name of Person taking consent

The following general consent form should be used in **Scotland**, **Northern Ireland** and the **Republic of Ireland**. For the collection of PROMs (patient reported outcome measures) for breast reconstruction patients (BREAST-Q) and lower limb reconstruction (Modified Enneking score), this form has to be used in all countries, as section 251 in England and Wales does not cover storage of e-mail addresses and mobile numbers.

UK National Flap Registry (UKNFR)

BAPRAS British Association of Plastic Reconstructive and Assistatic Surgeons	BADMS British Association of Oral and Maxillofacial Surgeons	ASSOCIATION OF BREAST SURGERY	BSSH The British Society for Sur,	gery of the Hand		
Patient Consent Form						
Patient's Full Name*: *please print name clearly		Hospital Name:				
NHS No:		Date of Birth:				
Consent for Data Collection		Initials				
I confirm that I have read the information will be stored and treated the Data Protection Act 1998 and all withdraw my consent at any time. I ushould wish to study my data they wunderstand that my personal details commercial or insurance organisation	d in a strictly confidential manne future users of this data will abi understand that if any other exte ill only have access to anonymis will never be used for commerc	r. My data will be stored de by the Act. I understa rnal or medical research sed data, which will not ic	in accordance with nd that I am free to organisation lentify me. I			
On this basis I agree to my personal collected and stored by The UK Nati						
I give permission for information abo National Statistics (ONS)	out me to be shared with the Dep	partment of Health (DH) a	and Office of			
I give permission to the UK National to ask about my recovery, current he Reported Outcome Measures). My contact details are:						

If you have a concern about any aspect of UKNFR, you should ask to speak to your surgeon or the audit staff who will do their best to answer your questions. If you remain unhappy and wish to complain formally, please contact BAPRAS 0207 8315161 or email: secretariat@bapras.org.uk

Date

Date

Signature

Signature

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Patient information leaflet

The following patient information sheet should be provided to patients in **Scotland**, **Northern Ireland** and the **Republic of Ireland**.

UK National Flap Registry (UKNFR)











We aim to collect information on the treatment outcome for every UK patient

Most surgical treatments for flap reconstructions are successful, but there is usually more than one treatment for the same condition and some are more successful than others. Unfortunately, the evidence, as reported by patients as to which treatment works best for an individual is not always available. Obviously, it would benefit all patients if we could correct this situation and the UK National Flap Registry (UKNFR) is setting out to do just that, by carrying out "clinical audits" of treatment.

To do these audits the UKNFR has to be able to contact patients, collecting information about their opinions on the different treatments' outcomes to find out which treatment works best. This will require your help and a great deal of extra effort by your surgeon.

Why we are only now able to do this for the first time?

The UK National Flap Registry (UKNFR) is the first of its kind in the world. It has grown from a collaboration between the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS, who are funding and running UKNFR), British Association of Head and Neck Oncologists (BAHNO), British Association of Oral and Maxillofacial Surgeons (BAOMS), Association of Breast Surgery (ABS) and British Society of Surgery of the Hand (BSSH). It is the brainchild of UK surgeons, like yours, who want to improve treatment for all patients worldwide. UKNFR is helping the UK lead the world in finding answers to which treatment works best for flap reconstructions in the body.

The methods

Like many successful studies before, it is essential to follow up large numbers of patients after treatment. The first step in this process requires every UK surgeon to accurately record data on the treatment of all their patients who have had flap reconstructions for cancer, injuries and infection.

Next, this data is transferred to the UKNFR, which acts like a library storing the patient information in a secure manner. Finally, when surgeons want to study the effectiveness of different treatments, they will sometimes seek approval from research ethics committees to contact patients and ask them questions about the results of their treatment.

Reasons for patient consent

But, before the UKNFR can keep your treatment information and contact you or the Department of Health (DH) to find out how you're doing, it needs your **consent**. This is where we need your help.

Your surgeon and the UKNFR would be extremely grateful if you would consent to keeping your name, contact details and medical treatment information in a secure manner, and to contact you in the future to ask you questions about your health status and your opinion on the outcomes of your reconstructive surgery.

We emphasise that your decision about whether or not to consent to the UKNFR keeping your information will not affect your treatment or your relationship with your surgeon in any way.

Patient confidentiality will be maintained

Before any research is conducted on your data all your personal information will be made **anonymous** or **coded** so that researchers cannot identify you. Research publications will **NOT** contain any patient's personal information.

All staff undertaking data collection will abide by the Data Protection Act 1998. Patient data will never be given or sold to any other person or organisation.

If you have a concern about any aspect of UKNFR, you should ask to speak to your surgeon or the audit staff who will do their best to answer your questions. If you remain unhappy and wish to complain formally, please contact BAPRAS 0207 8315161 or email: secretariat@bapras.org.uk



Patient information leaflet S251

The following patient information sheet should be provided to patients in **England and Wales**. Section 251 approval has been granted by the Secretary of State for Health and the Health Research Authority (HRA). Though formal written consent is not required, the patient should be informed that data is being collected and an option to opt out should be offered to the patient.

UK National Flap Registry (UKNFR)











The UK National Flap Registry aims to collect information on the results of surgery for every UK flap patient.

In flap reconstruction surgery some of your own tissue (called the flap) is moved from one part of the body to another. This is the treatment that your surgeon has discussed with you. Most flap reconstructions are successful, but often there are other surgical options. We need evidence from patients to show which treatment works best for them. The goal of the UK National Flap Registry (UKNFR) is to collect this evidence by bringing together details of the patient, their surgery, and aspects of their care. This is an example of clinical audit, a process by which the surgical team reviews treatments and outcomes with the aim of finding ways to improve care.

To do this the UKNFR has to be able to contact patients and collect information about their opinions on the results of the treatment they have had. As someone who has been given the option of flap surgery we would like you to help us to better understand which treatments work best in individual cases.

How is this done?

Clinical audit is a way for clinicians to look at how they care for patients. Audits look at what doctors should be doing, record how they are doing it, and ask how treatment can be improved. The information is strongest if a large numbers of patients can be followed up after treatment.

The first step in this process requires every UK surgeon to accurately record details of the treatment of all their patients who have had flap operations for different conditions including cancer, injuries and infection. Next, this data is transferred to the UKNFR, which acts like a library storing the patient information in a secure manner. Finally, when surgeons want to study the effects of different treatments they get permission from authorities to contact UKNFR patients and ask them questions about the process and results of their care.

Who is responsible for the Registry?

The UK National Flap Registry is the result of co-operation between groups of British specialist surgeons, helping the UK lead the world in finding answers to which treatments work best for flap reconstructions in the body. The British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS), who are funding and running UKNFR, are working with the British Association of Head and Neck Oncologists (BAHNO), the British Association of Oral and Maxillofacial Surgeons (BAOMS), and the Association of Breast Surgery (ABS) and the British Society of Surgery of the Hand (BSSH).

Your agreement to record your data

Your surgeon and the UKNFR have been given permission by the Health Research Authority and the Secretary of State for your name, NHS number, date of birth, and medical treatment information to be securely recorded. If you do not wish to participate in UKNFR, please inform your surgeon. Whether you choose to be part of the Registry or not, your treatment and your relationship with your surgeon will not be affected in any way.

Patient confidentiality will be maintained

Before any research is carried out using your data all your personal information will be made **anonymous** or **coded** so that researchers cannot identify you. Research publications will **NOT** contain any patient's personal information. All staff undertaking data collection will abide by the Data Protection Act 1998.

Patient data will never be given or sold to any other person or organisation. All records of your personal identifiable information, including your name, will be removed when these are no longer required, usually after a period of 3-5 years or in the event of death.

If you do not wish to participate or wish to opt out from the UK National Flap Registry

If you do not wish your personal and identifiable data to be entered on the database, please inform your surgeon. Your decision will be respected, and your choice will be recorded in the front of your medical notes. If you have changed your mind and wish to have your details removed from the registry, please contact either by email: secretariat@bapras.org.uk, or phone: 0207. 8315161 or in writing to:

UK National Flap Registry, at BAPRAS, Royal College of Surgeons of England, 35-43 Lincoln's Inn Fields, London WC2A 3PE

If you have a concern about any aspect of UKNFR, you should ask to speak to your surgeon or the audit staff who will do their best to answer your questions. If you remain unhappy and wish to complain formally or wish to see a copy of your information that is held on UKNFR, please contact BAPRAS by phone 0207 8315161 or email: secretariat@bapras.org.uk

Poster

This poster can be downloaded and placed in outpatient areas where patients for flap reconstruction are being seen.





Terms and conditions

All surgeons who register as users and their delegates have to consent to the attached terms and conditions prior to first data entry into the UK National Flap Registry.



UK National Flap Registry: Terms of use Version 4.0 dated 17 Mar 2015

Please read these terms and conditions carefully before using this site

The UK National Flap Registry

 $By using the UKNFR Website \ Database, you \ confirm that \ you \ accept \ these \ terms \ of \ use \ \& \ that \ you \ agree \ to \ comply \ with \ them.$

1. Terms of website use

- 1.1 These terms of use (together with the documents referred to in them) tell you the terms of use on which you may make use of the UK National Flap Registry ("UKNFR") website UKNFR.e-dendrite.com (the "UKNFR Website Database"), whether as a Surgeon/Clinician User or as an Other User.
- 1.2 Please read these terms of use carefully before you start to use the UKNFR Website Database, because these terms of use will apply to your use of the UKNFR Website Database. We recommend that you print a copy of this for future reference.
- 1.3 If you do not agree to these terms of use, you must not use the UKNFR Website Database.

We are The British Association of Plastic Reconstructive and Aesthetic Surgeons ("BAPRAS" and "we").

2. Definitions

2.1 In these terms of use the following words/terms have the following meanings:

"Affiliated National Associations" means the national associations which BAPRAS has agreed from time to time shall be affiliates to enable their members to contribute to the UKNFR Database.

"Delegated User" means any person who, from time to time, a Surgeon/Clinician User has authorised to enter data on the UKNFR Database on behalf of the Surgeon/Clinician User.

"Other User" means:

- any person who is not a Surgeon / Clinician User and who BAPRAS has agreed from time to time may have access to the UKNFR Website Database and some or all of the data held on the UKNFR Database ("Review Users"); and.
- any person employed or engaged by BAPRAS or any of the Affiliated National Associations who uses the UKNFR Website Database on behalf of BAPRAS or any of the Affiliated National Associations.

"Surgeon/Clinician User" means any surgeon or other clinician who registers to use the UKNFR Website Database for the purpose of data being added to the UKNFR Website Database about surgical procedures that he or she has carried out (with or without the participation of trainee surgeons or other clinicians), or for which he or she has otherwise been responsible.

"System Provider" means the provider of the platform for administering the Database and for all intents and purposes is Dendrite Clinical Systems Ltd.

"UKNFR Database" means the collection of systematically arranged data for the UKNFR accessible on the UKNFR Website Database.

"use" of the UKNFR Website Database includes accessing, browsing, registering to use and adding data to, or altering data on, the UKNFR Website Database.

3. Other applicable terms

- 3.1 These terms of use refer to the following additional terms, which also apply to your use of the UKNFR Website Database:
 - Our Privacy Policy, which sets out the terms on which we process any personal data we
 collect from you, or that you provide to us. By using the UKNFR Website Database, you
 consent to such processing.
 - Our Acceptable Use Policy, which sets out the permitted uses and prohibited uses of the UKNFR Website Database. When using the UKNFR Website Database, you must comply with this Acceptable Use Policy.

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Our Cookie Policy, which sets out information about the cookies on the UKNFR Website
Database.

4. Information about us

- 4.1 The UKNFR Website Database is a site owned and operated by us.
- 4.2 BAPRAS is a limited company registered in England and Wales under company number 2657454, is registered with charity number 1005353 and has its registered office at 35-43 Lincoln's Inn Fields, London WC2A 3PE, United Kingdom.
- 4.3 Our VAT number is 921 6446 32.

5. Changes to these terms

- 5.1 We may revise these terms of use at any time by amending this page.
- 5.2 Please check this page from time to time to take notice of any changes we made, because they are binding on you.

6. Changes to the UKNFR Website Database

- 6.1 We may update the UKNFR Website Database from time to time, and may change the content at any time, including the fields of data held on the UKNFR Database.
- 6.2 Please note that any of the content on the UKNFR Website Database may be out of date at any given time, and we are under no obligation to update it.
- 6.3 We do not guarantee that the UKNFR Website Database, or any content on it will be free from errors or

7. Accessing the UKNFR Website Database

- 7.1 The UKNFR Website Database is made available free of charge to Surgeon/Clinician Users.

 Surgeon/Clinician Users shall have no right to transfer, sublicense, or confer on any other person, the rights they have to use the UKNFR Website Database and such rights shall subsist only for the period covered by such Surgeon/Clinician Users' membership of BAPRAS or the relevant Affiliated National Association.
- 7.2 The UKNFR Website Database is also available for Other Users with the prior agreement of BAPRAS from time to time and on such additional terms, and with such limitations of access to data on the UKNFR Website Database, as BAPRAS may impose from time to time in its absolute discretion. Other Users shall have no right to transfer, sublicense, or confer on any other person, the rights they have to use the UKNFR Website Database and such rights shall subsist only for the period permitted by BAPRAS.
- 7.3 No-one else shall access or otherwise use the UKNFR Website Database without our prior written consent.
- 7.4 We shall have the right to refuse registration of any Surgeon/Clinician User or Other User and may suspend or terminate participation at any time or make continued participation conditional upon such terms as we may impose, and any Affiliated National Association may do the same in respect of any Surgeon/Clinician User who is a member of such Affiliated National Association.
- 7.5 If you print off, copy or download any part of the UKNFR Website Database in breach of these terms of use, your right to use the UKNFR Website Database will cease immediately and you must, at our option, return or destroy any copies of the materials you have made.
- 7.6 You must not use any part of the data or other content on the UKNFR Website Database for commercial purposes without obtaining a licence to do so from us or our licensors.
- 7.7 We do not guarantee that the UKNFR Website Database, or any data or other content on it, will always be available or be uninterrupted. Access to the UKNFR Website Database is permitted on a temporary basis. We may suspend, withdraw, discontinue or change all or any part of the UKNFR Website Database without notice. We will not be liable to you if for any reason the UKNFR Website Database is unavailable at any time or for any period.
- 7.8 You are responsible for making all arrangements necessary for you to have access to the UKNFR Website Database





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7.9 You are also responsible for ensuring that no-one other than you accesses the UKNFR Website Database through your internet connection.

8. Your account and password

- 8.1 If you choose, or you are provided with, a user identification code, password or any other piece of information as part of our security procedures, you must treat such information as confidential and keep it secure. You must not disclose it to any third party.
- 8.2 We have the right to disable any user identification code or password, whether chosen by you or allocated by us, at any time, if in our opinion you have failed to comply with any of the provisions of these terms of use.
- 8.3 You are also responsible for ensuring that no-one other than you accesses the UKNFR Website Database using your user identification code or password.
- 8.4 If you know or suspect that anyone other than you knows your user identification code or password, you must promptly notify us by email to secretariat@bapras.org.uk or by telephone to 0207 8315161.

9. Intellectual property rights

- 9.1 Although Surgeon/Clinician Users input their own data into the UKNFR Website Database and remain free to use that data, we are the owner or the licensee of all database rights and other intellectual property rights in the UKNFR Website Database, and in the UKNFR Database and other material published on it, except that each Affiliated National Association shall own the database rights in such parts of the UKNFR Database as relate to the Surgeon/Clinician Users who are.
 - 9.1.1 members of such Affiliated National Association; or
 - 9.1.2 who are not members of BAPRAS or any Affiliated National Association and whose surgical procedure activity is of the kind of surgical activity (for example by Specialty Advisory Committee (SAC) speciality) which falls within the scope of such Affiliated National Association.
- 9.2 Any data or other content you upload (or any Delegated User uploads on your behalf) to the UKNFR Website Database will be considered non-confidential and non-proprietary. Subject to our and any Affiliated National Association's database rights, you retain all of your ownership rights in your data and other content, but you are required to grant us and other users of the UKNFR Website Database a limited licence to use, store and copy that content and to distribute and make it available to third parties. The rights you license to us are described in paragraph 14 below (Use of your data that you are consenting to).
- 9.3 You shall not acquire any rights in the UKNFR Website Database or any part of it.
- 9.4 The UKNFR Website Database is protected by copyright laws and treaties around the world. All such rights are reserved but Surgeon / Clinician Users' use, outside the UKNFR Website Database, of the data they have themselves (or any Delegated User has on their behalf) input onto the UKNFR Website Database is not restricted by these terms of use.
- 9.5 We also have the right to disclose your identity to any third party who is claiming that any data or other content uploaded by you (or any Delegated User on your behalf) to the UKNFR Website Database constitutes a violation of their intellectual property rights, or of their right to privacy.
- 9.6 Our status as the owner of content on the UKNFR Website Database must always be acknowledged.
- 9.7 All copyright and other intellectual property rights in the content and design of the UKNFR Website Database and lay-out as well as names, trade marks and logos (other than Surgeon/Clinician Users' and Other Users' names, and Affiliated National Associations' names, trade marks and logos) are owned by System Provider and/or BAPRAS.

10. No reliance on information

- 10.1 The data and other content on the UKNFR Website Database is provided for general information only. It is not intended to amount to advice on which you should rely. You must obtain professional or specialist advice before taking, or refraining from, any action on the basis of the data or other content on the UKNFR Website Database.
- 10.2 We make no representations, warranties or guarantees, whether express or implied, that the data or other content on the UKNFR Website Database is accurate, complete or up-to-date.

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- 10.3 We will not be responsible, or liable to any third party, for the content or accuracy of any data or other content uploaded by or on behalf of you or any other user of the UKNFR Website Database.
- 10.4 The views expressed by other users on the UKNFR Website Database do not represent our views or values.

11. Limitation of our liability

- 11.1 Nothing in these terms of use excludes or limits our liability for death or personal injury arising from our negligence, or our fraud or fraudulent misrepresentation, or any other liability that cannot be excluded or limited by English law.
- 11.2 To the extent permitted by law, we exclude all conditions, warranties, representations or other terms which may apply to the UKNFR Website Database or any content on it, whether express or implied.
- 11.3 We will not be liable to you or any other user of the UKNFR Website Database or any data or other content on it for any loss or damage, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, even if foreseeable, arising under or in connection with:
 - use of, or inability to use, the UKNFR Website Database; or.
 - use of, or reliance on, any data or other content displayed on the UKNFR Website Database.
- 11.4 Please note that in particular, we will not be liable for:
 - loss of profits, sales, business, or revenue;
 - business interruption;
 - loss of anticipated savings;
 - loss of business opportunity, goodwill or reputation; or.
 - · any indirect or consequential loss or damage.
- 11.5 We will not be liable for any loss or damage caused by a virus, distributed denial-of-service attack, or other technologically harmful material that may infect your computer equipment, computer programs, data or other proprietary material due to your use of the UKNFR Website Database or to your downloading of any data or other content on it, or on any website linked to it.
- 11.6 We assume no responsibility for the content of websites linked on the UKNFR Website Database. Such links should not be interpreted as endorsement by us of those linked websites. We will not be liable for any loss or damage that may arise from your use of them.

12. Acceptable Use Policy

- 12.1 Surgeon/Clinician Users, Delegated Users and Other Users must comply with all the requirements of the following paragraphs of this paragraph 12, which comprise our "Acceptable Use Policy":
- 12.2 Data and other content may only be uploaded to the UKNFR Website Database by individuals who are registered users of the UKNFR Website Database.
- 12.3 If you are a Surgeon/Clinician User:
 - 12.3.1 when you upload (or a Delegated User uploads on your behalf) data or other content to the UKNFR Website Database you must ensure that such data or other content is:
 - $\hbox{a.} \quad \text{inserted into the relevant fields supplied in the UKNFR Website Database;} \\$
 - cross-checked against other local sources of data, such as operative logs or administrative data, to ensure case recording is as complete as is reasonably possible;
 - complete (including without limitation, so that there is uploaded to the UKNFR Website Database all the data required for the UKNFR Database in respect of each and every pedicled and / or free flap procedure that you have carried out (with or without the participation of trainee surgeons or other clinicians), or which you have otherwise been responsible for);
 - d. accurate
 - e. truthful and not in any way unlawful or fraudulent or having any unlawful or fraudulent purpose or effect; and
 - complies with any applicable laws, applicable regulatory requirements and applicable internal procedures.





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- 12.3.2 you must ensure the timely uploading to the UKNFR Website Database of data and other content required for the UKNFR Database in relation to each and every surgical procedure that you have carried out (with or without the participation of trainee surgeons or other clinicians), or which you have otherwise been responsible for; and
- 12.3.3 you must promptly advise the Audit / Outcomes Lead designated by BAPRAS from time to time, BAPRAS and any relevant Affiliated National Association of any change in circumstances affecting participation or reliability or completeness of the data or other content that is entered into the UKNFR Website Database in respect of any surgical procedure that you have carried out (with or without the participation of trainee surgeons or other clinicians), or which you have otherwise been responsible for.
- 12.4 Subject to the restrictions in our Acceptable Use Policy and the other provisions of these terms of use, each Surgeon/Clinician User is entitled to:
 - 12.4.1 extract or download for personal use for the purpose of audit, appraisal and revalidation, the data he or she (or a Delegated User on his or her behalf) has input into the UKNFR Website Database; and
 - 12.4.2 print off one copy, and may download extracts, of page(s) from the UKNFR Website Database which contain the data he or she (or a Delegated User on his or her behalf) has input into the UKNFR Website Database for his or her personal use only.
- 12.5 Other Users who are Review Users may use data or other content from the UKNFR Website Database only for review purposes expressly agreed by us, and only to the extent expressly agreed by us, in our absolute discretion from time to time and subject to the restrictions in our Acceptable Use Policy and the other provisions of these terms of use.

12.6 You must not:

- in any manner whatsoever modify the paper or digital copies of any data or other content, or any configuration or representation thereof, you have printed off or downloaded from the UKNFR Website Database, and you must not use any illustrations, photographs, video or audio sequences or any graphics separately from any accompanying text;.
- 12.6.2 save as approved by BAPRAS in its absolute discretion from time to time, publish or otherwise display for others to see any data or other content from the UKNFR Website Database, or any configuration or representation thereof,
- 12.6.3 reproduce, distribute, modify, supplement or split the contents or structure of the UKNFR Database, or any other part of the UKNFR Website Database;
- 12.6.4 take any step to seek to identify who (other than yourself) data or other content in the UKNFR Website Database relates to or to de-anonymise, or seek to de-anonymise, any of the data or other content in the UKNFR Website Database or to authorise anyone else to do so or to try to do so; or
- 12.6.5 set up any database which is derived from the UKNFR Database or any other part of the UKNFR Website Database.

12.7 You warrant that:

- 12.7.1 any data or other content uploaded to the UKNFR Website Database by you, or by a Delegated User on your behalf; and
- 12.7.2 your use of the UKNFR Website Database; will comply in all respects comply the requirements of our Acceptable Use Policy in this paragraph 12, and undertake that you will be liable to us for, and indemnify us against, any liabilities, losses, claims, proceedings, damages or expenses we suffer as a result of:
- 12.7.3 any breach of this warranty;
- 12.7.4 any breach of our Acceptable Use Policy by you, or by a Delegated User of yours; or
- 12.7.5 any inaccuracies in any data or other content uploaded by you, or by a Delegated User on your behalf, to the UKNFR Website Database, including (without limitation) where any such any liability, loss, claims, damages or expenses arise out of, or in connection with, any harm caused to any person in any way as a result of inaccuracy in such data or content or any such data or other content being uploaded without any required consent.

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12.8 Furthermore, and without limitation or prejudice to the other provisions of these terms of use, any deliberate manipulation of data uploaded to, or downloaded from, the UKNFR Website Database for the purpose of improperly impacting final outcomes is strictly forbidden and can be acted upon by BAPRAS or any relevant Affiliated National Association and reported to the General Medical Council or any other regulatory body with competent jurisdiction.

13. Removing data from the UKNFR Website Database

- 13.1 Subject to paragraph 13.3 below, we or any Affiliated National Association have the right to remove any data or other content you or any other person upload to the UKNFR Website Database if, in our opinion, such data or other content does not comply with the content standards set out in our Acceptable Use Policy.
- 13.2 Subject to paragraph 13.3 below, Surgeon/Clinician Users shall have the right at any time to remove from the UKNFR Website Database any or all of the data or other content entered by them or by any Delegated User for them.
- 13.3 However, Surgeon / Clinician Users must note that any data or other content removed under paragraph 13.1 or 13.2 will not be removed from, and we shall not have any obligation to seek or carry out any such removal from:
 - 13.3.1 any back up or other copy of the UKNFR Website Database, or any part of it, made before such removal: or
 - 13.3.2 any report, configuration or other representation of data or other content downloaded, uploaded, copied, printed or otherwise produced or exported from the UKNFR Website Database, or any part of it, before such removal.

14. Use of your data that you are consenting to

- 14.1 You agree to us or any Affiliated National Association using or disclosing any data or other content you upload (or any Delegated User uploads on your behalf) to the UKNFR Website Database or which is otherwise held on, or in relation to, the UKNFR Website Database for any of the purposes described or referred to in our Privacy Policy
- 14.2 If you are a Surgeon / Clinician User and you upload (or any Delegated User uploads on your behalf) data or other content to the UKNFR Website Database, you agree as follows and give the following permissions:
 - 14.2.1 you agree that restricted access (to an extent and on terms determined from time to time by BAPRAS in our absolute discretion) to the UKNFR Database will be made available to researchers in order to advance the science of flap surgery and other purposes approved from time to time by BAPRAS in our absolute discretion; and
 - 14.2.2 in addition to, and without limitation to the generality of, paragraph 14.1 above, you give permission for us and any Affiliated National Association to disclose your data and other content on the UKNFR Website Database (including, without limitation, personal information about you) to third parties in the following circumstances:
 - a. to notify the management of any hospital or other clinical facility at which:
 - you have carried out surgical procedures (with or without the participation of trainee surgeons or other clinicians); or
 - where surgical procedures you have otherwise been responsible for have been carried out,

of the results and other details or characteristics (either in relation to you alone, or relative to those of other Surgeon / Clinician Users) of surgical procedures you have carried out (with or without the participation of trainee surgeons or other clinicians) or for which you have otherwise been responsible;

 where BAPRAS, any Affiliated National Association or any of the relevant personnel of BAPRAS or any Affiliated National Association, believes that it, he or she is under a duty to disclose data or other content on the UKNFR Website Database (including, without limitation, personal information about you) in order to comply with any legal obligation;







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- where BAPRAS, any Affiliated National Association or any of the relevant personnel of BAPRAS or any Affiliated National Association, believes that it, he or she has an obligation to disclose data and other content on the UKNFR Website Database (including, without limitation, personal information about you):
 - i. to the General Medical Council;
 - ii. to any relevant professional organisation pursuant to a professional obligation
 - to any other regulatory body with competent authority applicable to you, BAPRAS or any Affiliated National Association; or
 - to any governmental body with competent authority applicable to you, BAPRAS or any Affiliated National Association,

time to time, including (without limitation) any disclosure for any such purpose of any data or content entered on the UKNFR Website Database by or on behalf of you;

15. Viruses

- 15.1 We do not guarantee that the UKNFR Website Database will be secure or free from bugs or viruses.
- 15.2 You are responsible for configuring your information technology, computer programmes and platform in order to access the UKNFR Website Database. You should use your own virus protection software.
- 15.3 You must not misuse the UKNFR Website Database by knowingly introducing viruses, trojans, worms, logic bombs or other material which is malicious or technologically harmful. You must not attempt to gain unauthorised access to the UKNFR Website Database, the server on which the UKNFR Website Database is stored or any server, computer or database connected to the UKNFR Website Database. You must not attack the UKNFR Website Database *via* a denial-of-service attack or a distributed denial-of service attack. By breaching this provision, you would commit a criminal offence under the Computer Misuse Act 1990. We will report any such breach to the relevant law enforcement authorities and we will co-operate with those authorities by disclosing your identity to them. In the event of such a breach, your right to use the UKNFR Website Database will cease immediately.

16. No linking to the UKNFR Website Database

- 16.1 You must not link to the UKNFR Website Database's home page in any circumstances whatsoever.
- 16.2 The UKNFR Website Database must not be framed on any other site, nor may you create a link to any part of the UKNFR Website Database.
- 16.3 If you wish to make any use of data or other content on the UKNFR Website Database other than that set out in these terms of use, please contact us by email to secretariat@bapras.org.uk.

17. Third party links and resources in the UKNFR Website Database

- 17.1 Where the UKNFR Website Database contains links to other sites and resources provided by third parties, these links are provided for your information only.
- 17.2 We have no control over the contents of those sites or resources.

18. Applicable law

These terms of use, their subject matter and any contract incorporating them, are governed by English law. You and we both agree to that the courts of England and Wales will have. exclusive jurisdiction.

19. Contact us

To contact us, please email to secretariat@bapras.org.uk.

Thank you for visiting the UKNFR Website Database.



The First UK National Flap Registry Report 2019

The first report from the United Kingdom National Flap Registry (UKNFR) is a testament to the team, who have brought the concept of the flap register to fruition. Flap surgery is often highly complicated and the pinnacle of surgical team care. A successful outcome is often life and/or limb saving for the patient and the UKNFR leads the world in assessment of outcomes, allowing national and international benchmarking of the most complex reconstructions in the surgical armamentarium. This and subsequent reports will improve the care of patients requiring reconstructive surgery.

Nigel Mercer ChM, FRCS, FRCPCH, FFFMLM President of the Federation of Surgical Specialty Associations

The UK First National Flap Registry Report is an extremely impressive achievement. Only by working together across multiple centres can we fully appreciate the success of autologous reconstruction and identify opportunities to improve and advance. This report is also a wonderful synthesis of both clinician and patient-reported outcomes. As we continue to innovate and improve reconstructive surgery techniques, this approach to collaborative outcomes measurement will most certainly lead the field. I wholeheartedly congratulate the UKNFR team and all the surgeons who contributed their outcomes.

Andrea Pusic
Chief, Plastic and Reconstructive Surgery
Director, Patient-Reported Outcomes, Value & Experience (PROVE) Center, Brigham Health
Joseph E Murray Professor of Surgery, Harvard Medical School



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