NHS

GIRFT
GETTING IT RIGHT FIRST TIME

Breast Surgery

GIRFT Programme National Specialty Report

by Fiona MacNeill, Clinical Lead
and Tracey Irvine, Senior Clinical Advisor

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GIRFT is delivered in partnership with the Royal National Orthopaedic Hospital NHS Trust, NHS England and NHS Improvement

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Foreword from Professor Tim Briggs, GIRFT Programme Chair

I am delighted to recommend this Getting It Right First Time review of breast surgery by Fiona MacNeill and Tracey Irvine.

Fiona and Tracey's report brings the GIRFT approach to their specialty, focusing on breast cancer, which forms the majority of the breast surgery workload. Together they have combined a data-led review of outcomes and costs with real insight into patients' experiences and what is or isn't working.

This report was developed just before the COVID-19 pandemic began to have huge implications for breast surgery, not least how to deliver surgery safely while addressing backlogs of operating, delayed reconstructions and the pausing of screening programmes. Fiona and Tracey's recommendations are crucial to the recovery of breast surgery in the NHS, helping to limit unnecessary hospital attendances and minimising unnecessary interventions.

I firmly believe that, with the support of clinicians and managers, this report can drive breast surgery services to not only recover from COVID-19, but to deliver substantial improvements for patient outcomes and experiences - as well as saving the NHS millions of pounds.

This report identifies many areas of unwarranted variation in breast surgery, including in the types of surgery available and in outcomes such as complications, revisions or re-excisions. Fiona and Tracey look at not only breast surgery for cancer, but also reconstructive surgery and breast surgery for non-cancer conditions. Almost a fifth of surgery on the breast is for conditions other than cancer, but this is sometimes an overlooked area. The outcomes of plastic surgery, an increasingly integral aspect of oncoplastic breast surgery, are also included in the report's findings.

They have also highlighted where there are currently gaps in the data and our understanding, such as the need to link data about cancer surgeries to the data on diagnoses and outcomes.

Having visited 129 breast surgery teams, their resulting evidence-based recommendations for change promise to make an immense difference to patients. If implemented, these recommendations would mean that patient choices about surgery are better informed and driven by what is most appropriate rather than what is available.

The recommendations will support improvements in referral pathways, breast assessment and cancer waits, meaning more patients should receive a definitive diagnosis or ruling out of cancer within 28 days of a referral, in line with the Faster Diagnosis Standard. These measures will help breast surgery services recover from the impact of COVID-19.

As with clinical leads before them, Fiona and Tracey have found numerous examples of outstanding practice and innovation on their deep dive visits. Some of these examples are included in this report, as well as – importantly – patients' stories. These examples are the result of the hard work of clinicians, managers and other staff, who were universally keen to engage with GIRFT and explore their data to deliver better care for their patients.

That is vital: GIRFT cannot succeed without the backing of clinicians, managers and all of us involved in delivering care. With that shoulder-to-shoulder support, GIRFT and the other Carter programmes are already demonstrating that transforming provider services and investing to save can bring huge gains in improving care for patients. My greatest hope is that they will continue to do so, to prompt solutions and improvements that make a greater difference for more patients.

Professor Tim Briggs *CBE*

GIRFT Programme Chair and National Director of Clinical Improvement for the NHS.

Professor Tim Briggs is a consultant orthopaedic surgeon at the Royal National Orthopaedic Hospital NHS Trust, where he is also Director of Strategy and External Affairs. He led the first review of orthopaedic surgery that became the pilot for the GIRFT programme, which he now chairs. Professor Briggs is also National Director of Clinical Improvement for the NHS.

Introduction from Fiona MacNeill and Tracey Irvine

Throughout the breast surgery visits we have conducted as part of the Getting It Right First Time (GIRFT) programme, we have been awestruck and humbled by how hard every member of every breast and plastic surgical team is working to provide patient-centred care in these challenging times for the NHS. This has been inspiring and energising for us both.

As expected, we have found wide variation in all aspects of breast surgery practice, but the breast and plastic surgery teams we have met have been universally keen to engage with GIRFT to explore their data, to better understand their services and discover what they can learn and improve, as well as good practice they can share and adopt.

This breast surgery report is unique in its scope and content as we have strived to demonstrate the long history of multidisciplinary working between breast and plastic surgery to improve patient care. Our findings and recommendations align not only with the NHS Long Term Plan but also with the quality improvement work already being done by our colleagues in breast and plastic surgery and the wider breast multidisciplinary teams.

All of our recommendations are designed to improve patient care and experience. However, the person at the heart of this – the breast surgery patient – has not been present in many of our visits. We are therefore very grateful to those patients who have given us feedback and allowed us to include their stories, thereby deeply enriching this report with the human drivers so often missing in quality improvement initiatives.

Our aim is to empower and enable our patients to have more choice and control about their own care. This includes through receiving understandable and meaningful quality data about local breast services. In turn, we would like to see patient feedback such as patient-reported outcome measures (PROMs) become part of daily practice, so that as we continue to develop and improve our services, patients remain the heart of everything we do.

Throughout the GIRFT process, we have benefited not only from the support of the GIRFT team – in particular, our project managers Zoe Price, Anne Clare and Caroline Ager – but also from colleagues and stakeholders across and beyond our specialty. We are very grateful for the input of – among many others – the Association of Breast Surgery (ABS)[1] and the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS),[2] Public Health England (PHE),[3] the IBRA Research Group,[4] the National Audit of Breast Cancer in Older Patients (NABCOP),[5] the National Cancer Registration and Analysis Service (NCRAS),[6] as a well as our multidisciplinary colleagues, the breast cancer charities and the patient groups. After publication, it is our intention to continue to work in partnership with all these groups to deliver on the recommendations and continue to strive to provide the very best care for breast surgery patients in England.

Finally, the GIRFT process has highlighted topics that require more focused research and data collection. We look forward to working with patients and stakeholders to expand our knowledge with the aim of supporting even better evidenced-based high-quality patient care.

Miss Fiona MacNeill

Clinical Lead Breast Surgery

Consultant breast surgeon, Royal Marsden NHS Foundation Trust.

Fiona has been a consultant breast surgeon since 1996 but now practices exclusively in oncoplastic breast surgery. She was chair of the Education and Training Committee and then president of the Association of Breast Surgery (ABS) of Great Britain and Ireland from 2015-2017 and is currently vice-president of the breast surgery division of the European Union of Medical Specialists (UEMS).

Miss Tracey Irvine

Senior Clinical Advisor Breast Surgery

Consultant oncoplastic breast surgeon, Royal Surrey County Hospital NHS Foundation Trust.

Tracey is an oncoplastic breast surgeon and was clinical director of the breast, skin and plastics unit in Surrey where she had experience of delivering quality breast care in a financially challenging environment.

1 *https://associationofbreastsurgery.org.uk/*
2 *www.bapras.org.uk/*
3 *www.gov.uk/government/organisations/public-health-england*
4 *ibrastudy.com*
5 *www.nabcop.org.uk/*
6 *www.gov.uk/guidance/national-cancer-registration-and-analysis-service-ncras*

Statements of support

Association of Breast Surgery

The Association of Breast Surgery welcomes the publication of this GIRFT report. The recommendations of this report will improve both experiences and outcomes for patients.

This report is the culmination of a huge amount of work by the GIRFT team, led by Fiona and Tracey, to analyse and understand how breast surgery services are being delivered in England and identify areas of unwarranted variation.

Breast surgery sees in excess of 55,000 new referrals per month, resulting in major challenges in both service delivery and meeting targets. This has been exacerbated by the COVID-19 pandemic. The recommendations in this report will help to streamline and speed up patient referrals and pathways, helping services to adapt to and recover from the pandemic and allowing us to deliver all treatments for patients in a timely way.

It is heartening to hear that Fiona and Tracey have had such an enthusiastic reception for their deep-dive visits and that they found so many examples of outstanding practice. This is a testament to the commitment and dedication of the breast surgery workforce. I have every confidence that we can continue to deliver improvements in the quality of treatment and care for patients.

Dr Julie Doughty
President, Association of Breast Surgery

British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS)

BAPRAS would like to congratulate GIRFT on this timely report, which is a significant contribution to the management of breast cancer.

We are delighted to be part of a constructive interspecialty collaboration, which we hope is reflected in this report and will develop further to the benefit of our patients.

Patients need reconstruction appropriate to their needs, which should not be limited by their locality. We are enthusiastic to continue and further develop our collaboration with our breast surgery colleagues in pursuit of autologous reconstruction being available for all women who would benefit from it.

We believe that his report is a major step forward in the pursuit of the GIRFT aim of uniform best practice available to all and would like to thank Fiona and Tracey for their notable achievement.

Ruth Waters
President, BAPRAS

Statements of support

Breast Cancer Now

Of the 46,000 people diagnosed with breast cancer in England each year, the vast majority will have breast surgery. We very much welcome the comprehensive and insightful work that Fiona and Tracey have led to highlight variation in an area that affects so many patients, and which presents a valuable opportunity to improve their outcomes and experience.

We are particularly concerned to see the variation between trusts in women having immediate, and 'free flap', breast reconstruction. It is vital that women who choose to have reconstruction have access to the right surgery, at the right time, for them. It is also disappointing that many CCGs continue to restrict the number of operations women may have to complete their reconstruction.

The coronavirus pandemic has had a huge impact on the issues covered by GIRFT, particularly breast reconstruction. It is vital that women whose reconstruction has been delayed are able to have their surgery as soon as possible. And while there is scope to improve referral and assessment processes we must ensure that any changes do not have unintended consequences, for example for younger women who can sometimes struggle to be diagnosed.

We look forward to working with the GIRFT team, ABS, BAPRAS and others on progressing the recommendations in the report.

Baroness Delyth Morgan
Chief executive, Breast Cancer Now

A report as comprehensive and complex as this takes months to plan and deliver. At the end of February 2020, we sent our completed report to stakeholders for comment. As feedback returned, it became apparent the UK was going to be significantly impacted by the coronavirus pandemic.

ABS issued prompt comprehensive guidance on prioritisation for de-escalation of breast services on 15 March 2020. By the time the UK-wide lockdown was announced on 23 March 2020, many units had stopped benign and reconstructive surgery and were prioritising their cancer services.

The impact on breast surgery services has varied across the country and each region had to develop solutions according to local pressures and resources. With the situation and guidance changing on an almost daily basis, all units had to adapt services at a pace never seen before. But what has been notable is the teamwork, innovation and flexibility that allowed safe patient-centred breast cancer care to continue.

Every step of the patient pathway had to be re-examined to ensure essential cancer care was delivered as safely as possible. Outpatient care underwent the most extensive changes, with many consultations becoming virtual rather than face-to-face. Widespread adoption of new technology allowed video consultations and ensured the continuation of multidisciplinary team meetings.

There was a marked decrease in cancer diagnoses and a change in case-mix because of reduced new patient referrals and cessation of the NHS Breast Screening Programme (NHSBSP), resulting in predominantly patient-detected cancers. Operating theatre capacity and workforce was reduced and surgery prioritised to higher risk breast cancers. To mitigate, in some regions cancer surgery was concentrated in dedicated 'COVID-protected' cancer hubs, often located in NHS England commissioned independent sector facilities.

The 31/62-day cancer targets remained throughout.

How GIRFT can support the COVID-19 recovery phase

It is clear the COVID-19 pandemic will have a longer-term impact on the delivery of breast surgery services.

New patient referrals, already an area that causes pressure for many of the teams we visited, will spike before a return to stability. There will be a backlog of operating for those with lower risk disease whose surgery was deferred. Those who have not been able to have immediate reconstruction during the pandemic may later wish to proceed with delayed reconstruction. In addition, non-cancer surgery such as risk-reducing mastectomies and reconstructive adjustments will need to resume.

We may not be able to operate at full capacity for some time, due to increased turnaround times because of coronavirus protocols in theatre and possibly reduced anaesthetic staff, some of whom have been redeployed to look after COVID-19 patients.

However, the response of teams across the country in these unprecedented times has shown how breast teams can adapt to change and continue to deliver high-quality care under difficult circumstances.

Now, more than ever, it is clear that breast surgery services must be of the highest quality with minimal unwarranted variation: we already know this is the safest and most efficient care possible. To that end, we believe there are three overarching areas where variation can and should be minimised, to protect patients, reduce the pressure on services and allow us to focus on those with greatest need.

1. Limiting unnecessary hospital attendances

Many of the recommendations in this report already focus on streamlining the patient pathway and minimising time in hospital with day case surgery, minimising returns to theatre (see our recommendations 3, 4 and 6, on pages 15-16) and patient-led follow up. A key GIRFT recommendation is review and refinement of the new patient referral process (recommendations 1 and 2): during the pandemic, many trusts started this process, introducing innovative measures to triage and support appropriate breast assessments as efficiently and safely as possible. We have already heard from trusts that this approach has been very popular with patients, not least because it means their appointment can often take place sooner.

The central point is simple: if there are suitable alternatives to hospital attendance, we should use them, both to protect patients and the hospital workforce. There is now a clear opportunity to do this.

2. Minimising unnecessary interventions

As full surgical services return, equity of access across the country remains paramount. Despite the inevitable variation in resource as we recover from the impact of COVID-19, it is essential that patients have access to the best and most appropriate oncoplastic techniques and reconstruction (recommendation 5). Theatre resource will always be at a premium so we must carefully consider selection of procedures to ensure patients do not undergo more surgery than is necessary (recommendations 6 and 8). That includes taking steps to reduce planned and unplanned readmissions, through applying surgical best practice. As well as benefiting individual patient experience, this will allow us to make more effective use of our resources for essential care.

3. Improving clinical coding and data capture

It is important as we move forward into the 'new normal' that we seize the opportunities afforded by the crisis to evaluate and adopt successful innovations and practice changes. Quality data will be key not only to understanding our progress but also to track the impact of COVID-19 on patterns of care and patient outcomes; that is the basis on which we can then plan services (see recommendations 11, 12 and 13).

Despite the many challenges posed by this pandemic, it has acted as a force for change. The breast surgical community has always led the way in quality patient-centred care; the recommendations in this report are designed to continue to help us do so and to deliver the best for breast surgery patients.

Executive summary

The Getting It Right First Time (GIRFT) programme has provided a unique opportunity to examine the delivery of breast surgery across the country. Drawing on the analytical resource available to us, and the GIRFT methodology of examining variation, we were able to bring together, for the first time, data about all breast surgery operations conducted in England – regardless of the specialty under which the patient was admitted. We have then used that rich data to inform our deep-dive visits to 129 breast surgery teams, providing a powerful context for discussions about current practice, pressures and priorities. The findings of this work are summarised in this report, along with our recommendations for further improving the provision of breast surgery in England.

Focused on breast cancer

The report focuses on surgery related to breast cancer, which forms the majority of the specialty's workload. It looks at the overall pathway from referral, through access to different options for cancer surgery (mastectomy or wide local excision, sometimes referred to as breast conserving surgery), to reconstruction and any subsequent surgery – including planned adjustments. As will become clear, we have found significant variation between trusts in practice and in access to some types of surgery. This is something that many have previously suspected; our data demonstrates the scale of that variation.

We have also seen numerous examples of outstanding practice: of innovation, of patients benefiting from real choice and being given thoughtful, caring support through what is an incredibly difficult experience for them. We have met trusts that successfully minimised unplanned readmissions and reduced the length of time patients have to stay in hospital – both indicators of a better patient experience. We have also been repeatedly impressed by the commitment to working as a breast oncoplastic team, combining the expertise and skills of breast and plastic surgeons, radiologists, oncologists and pathologists, nurses and care assistants, all striving to deliver a high quality service and better outcomes for their patients. Some of these examples are included as case studies in our report.

The gap in our understanding

Unfortunately, beyond what trusts, patients and representative groups have told us, we cannot say with certainty whether this apparent excellence results in better outcomes for cancer patients, because at present, data about the surgery provided is not consistently linked with data about cancer diagnosis and outcome. Through Hospital Episode Statistics (HES), we can see what surgery was undertaken, but cannot see what other cancer therapies were provided and how this might have impacted on surgery outcomes and vice versa. Above all, we cannot understand the impact of surgery on cancer outcomes including local recurrence, an important quality measure for surgery. This is a significant gap in our understanding and we strongly support the work that is underway to better align HES data about procedures and episodes with information from the National Cancer Registration and Analysis Service (NCRAS) about patients.

Optimising referral pathways

One area where we were able to use NCRAS data was in relation to referrals to breast clinics – and the data underlined the message we repeatedly heard from trusts: that referrals have been consistently increasing. Between April 2015 and March 2018, the total number of new referrals to breast clinics increased by around 20%, from around 42,000 to almost 50,000 a month.

Despite this consistent increase in breast referrals, the number of patients diagnosed with breast cancer has barely increased. This is likely to be because the highest increases in referrals have been among younger people at low risk of cancer – particularly women under 40 years of age, who now account for over 20,000 referrals a quarter.

These lower-risk people still need to be assessed and reassured they do not have cancer, but they do not need to experience the stress of an urgent cancer pathway. We have therefore suggested that alternative mechanisms for managing lower risk referrals need to be urgently explored, that will allow continuing access to rapid breast diagnosis as required but crucially also ensure sustainable future provision of breast services.

Targeting those at greatest risk

Meanwhile, because referrals from the age groups at higher risk of cancer (over 60 years of age) are not increasing at the same rate, this indicates that more work needs to be done to target these groups – as well as those in other harder to reach at-risk groups – with more relevant/specific breast cancer awareness information.

It is very reassuring to note that breast cancer diagnosis is already comfortably ahead of the NHS Long Term Plan target of diagnosing 75% of all cancers at stage 1 or 2 by 2028; already, over 90% of breast cancers are diagnosed at stage 1 or 2.

The impact of COVID-19

As our report neared completion, the COVID-19 pandemic hit, and the response showed the adaptability of NHS breast surgery care. Perhaps the area which saw the greatest transformation, however, was in relation to the management of new patient referrals. It is imperative that we move quickly to evaluate the benefits of some of the service changes introduced in the time of crisis to see if they can be adopted more widely. When it comes to managing referrals, we believe there is a real opportunity to do so.

With that in our mind, one of the three core recommendations of our report is:

Ensure that new breast referral and assessment pathways are timely and centred around the individual with the aim of providing the best outcomes and experience.

Alongside this, we recognise the need for greater nuance within public health messaging, so that there is a deeper understanding of breast health, alongside promoting better awareness of breast cancer in harder to reach risk groups.

Ensuring equity of access to breast-conserving surgery

Our focus in the report then moves beyond the 95% of women referred who do not have cancer, and begins to look in detail at the surgical care and treatment provided to those with cancer. It is here that we identified some of the most extensive variation, both in terms of what treatments are offered and how they are provided.

The first crucial surgical decision is whether to treat cancer via mastectomy or wide local excision (WLE), which conserves the breast. Our data and deep-dive visits indicate that most breast multidisciplinary teams (MDTs) do currently support breast conservation where possible. However, the ongoing variation in WLE rates suggests there is an opportunity to increase the use of WLE at some trusts. This is a complex discussion, which is beyond the scope of the GIRFT data analysis and report, but was explored extensively during deep-dive visits. Our prime concern is that some of the variation identified may relate to a lack of availability of oncoplastic conservation techniques. So part one of our second core recommendation is:

Ensure equity of access to oncoplastic surgery to support safe breast conservation.

A strong case for more day surgery

Increasingly, breast conservation surgery is provided as day surgery, with over 70% of breast excisions in cancer patients conducted as day surgery – allowing patients to recover at home. At some providers, the proportion is higher still, with very positive feedback from patients.

The British Association of Day Surgery has recommended that 95% of such excisions could be conducted as day surgery. Though clearly this must be considered with the patient's welfare and circumstances in mind, GIRFT analysis suggests that if 95% of breast cancer excisions were to be conducted as day surgery there would be a notional financial benefit of around £2.9 million a year – invaluable given the cost pressures resulting from the COVID-19 pandemic.

There are greater improvements still to be made by increasing the proportion of patients who have a mastectomy as day surgery. Nationally, just under 20% of mastectomies with no immediate reconstruction were conducted as day case. However, we found that the rates varied widely, from 0% to 78.28% across trusts. While eight providers conducted more than 60% of mastectomies as day cases, almost half conducted 10% or less. This appears to be an opportunity for significant change.

Breast reconstruction: reducing variations in rates, techniques and timely availability

Any woman offered mastectomy should also have timely access to the breast reconstruction most appropriate for her needs. However, our data found that the proportion of women undergoing immediate breast reconstruction varied between trusts from 3% to 75%. Some of this variation is explainable: for example, rates at the higher end of the range are the result of some trusts providing immediate breast reconstruction for the whole region. It is also important to acknowledge that not all patients choose reconstruction. Nonetheless, the variation seems sufficiently wide such that factors other than patient choice need to be considered.

Rates at the lower end of the range suggest that one factor may be lack of timely access (i.e. within cancer wait standards) locally, or in a network, to a patient's preferred method of reconstruction. This requires further exploration to identify opportunities for improvement.

Broadly, there are two types of reconstruction: implant-based, and autologous reconstruction. In trusts with an onsite free flap service, 45% of immediate reconstructions are autologous/free flap and 55% are implant-based. Where no free flap service is available onsite, about 30% are autologous, of which two-thirds are outsourced free flap reconstructions and 70% are implant-based.

Our concern is that this variation in technique utilisation is the consequence of inequity in access: at providers with the full range of reconstruction options on site, patients make different choices regarding reconstruction type. In areas where there is no free flap service, most women undergo implant-based reconstruction.

We believe women should have access to the most appropriate reconstruction for them in timeframes that support the cancer wait standards, so part two of our second core recommendation is:

Ensure equity of access to breast reconstruction to reduce variation in immediate reconstruction rates and utilisation of free flap reconstruction techniques.

While there is not an ideal immediate breast reconstruction rate, we see no reason why all trusts wouldn't be able to achieve a rate of 25% (broadly 1 in 4 patients having a mastectomy also having an immediate reconstruction).

Minimising unnecessary surgery

For many patients, reconstruction is multi-staged with a number of planned adjustments/refinements to optimise breast appearance. However, we found wide variation in the average number of adjustment operations conducted in different trusts – from 0.4 to 3.0 for implant-based reconstruction, with a nationwide average of 1.6 adjustment operations, and 0.0 to 3.2 for free flap reconstruction, with a nationwide average of 1.3.

We also found that, within five years of their initial reconstruction (implant or autologous), 5-7% of women have a further reconstruction, on the same breast but using a different method, suggesting complete failure of the first reconstruction. Nationwide, the unplanned implant removal rate within one year of surgery is 7% - higher than the best practice target of 5% (at 90 days) set in 2012. Overall, this picture suggests that breast reconstruction surgery outcomes can be improved.

In addition, we found that the number of patients who had a simultaneous bilateral mastectomy varied widely between trusts, from just under 2% to up to 18%, with a national average of 8.5%. There are some patients who need a bilateral mastectomy for medical reasons; for example, around 4% have cancer in both breasts and others with cancer on one side also carry a gene mutation which increases their risk of developing cancer in the other breast, so want both breasts removed to reduce this risk. A very small number choose to have both breasts removed to achieve a flat and balanced chest wall.

However, the variation in double mastectomy rates (when the patient has cancer in one breast only) between trusts suggests that the decision for bilateral mastectomy is being driven by factors other than treatment and/or risk reduction. In particular, where trusts had higher rates of bilateral mastectomy, this seemed to be linked to having an immediate breast reconstruction: this suggests achieving reconstruction symmetry is a major driver for the removal of the other breast. This appears to be particularly true for implant-based reconstruction, where symmetry may be more difficult to achieve with implant reconstruction on one breast.

It seems likely that this variation in reconstruction adjustments, bilateral mastectomy rates and outcomes reflects different reconstruction practices: in some cases, this may be related to the limited availability of all reconstruction techniques and/or not fully understanding or aligning with patient requirements. Multiple adjustments may also be driven by unrealistic expectations about the aesthetic results that can be delivered; this is a communication issue, with the surgery team needing to be sensitive to patient preferences and goals but open about the limitations and likely outcomes for each technique for that patient. Either way, this variation results in increased demand on surgical resource and – more importantly – a prolonged surgical journey for the patient.

With this in mind, our third core recommendation is:

Ensure that no patients undergo more surgery than is necessary.

Minimising re-excision and returns to theatre for complications

The principle of ensuring that no patients undergo more surgery than is necessary is also fundamental to improving the patient experience for breast conservation surgery. Minimising repeat surgery following WLE for cancer is highly desirable for patients and providers. However, the variation in repeat surgery after WLE between providers is extensive, suggesting significant differences in local breast MDT practice. Notably, in 13 trusts, the re-excision rate was over 25% - meaning 1 in 4 patients had a repeat excision, compared to the national average of just under 1 in 5 (19%). By contrast, at eight trusts, fewer than 1 in 8 patients had repeat surgery. Re-excision rates in the USA fell to 12.3% in 2017, following the introduction of the American Society of Breast Surgeons (ASBrS) best practice toolbox with a target of 10%. We would strongly encourage a similar national MDT focus on reducing re-excisions after breast conservation surgery in the UK.

Ensuring that no patients undergo more surgery than is necessary is also central to minimising unplanned readmissions and returns to theatre for complications after any type of breast surgery. Complications can have a devastating impact on the treatment pathway and patient experience, and it is essential they occur as rarely as possible.

Avoiding unnecessary breast surgery for conditions other than cancer

Additionally, ensuring that no patients undergo more surgery than is necessary is particularly relevant for excisional surgery for benign/normal conditions, where we found substantial variation in the amounts conducted at different trusts, from 12-60% with a national average of about 30%. Some of this variation is explainable by local data capture issues that need to be addressed, but if all providers followed the ABS guidelines regarding the management of benign and normal breast conditions, the volume of diagnostic and breast excision surgery could be substantially reduced.

Finally, this same recommendation applies to the surgical treatment of mastitis – a condition that can and should be managed in the community or outpatient department, but that still results in more than 2,000 surgical procedures a year.

We believe there are clear opportunities to reduce unnecessary surgery in all of these areas and have identified actions to that effect.

The case for aesthetic breast surgery for congenital, developmental and acquired anomalies

Having identified areas of unnecessary surgery, we have also looked at a subset of breast surgery which is becoming harder to access: aesthetic breast surgery for congenital, developmental and acquired anomalies. This broad category includes various procedures, which have been deemed of 'limited clinical value', with predictable consequences for the patients.

In 2008/09, the procedures now bracketed as being of limited clinical value accounted for 7.78% of all breast surgery admissions; by 2017/18 that proportion had dropped to 2.84%. The total number of admissions for surgery for a congenital breast problem has dropped from 1,342 a year to 506; this is surgery that can make a huge difference to physical and mental wellbeing of teenagers/young adults. In 2008/09, 2,671 breast surgery operations were conducted on males with a non-cancer diagnosis; in 2017/18, there were 1,105. The major factor in this decrease is a drop in the volume of gynaecomastia surgery – again, something that has the potential to make a huge difference to the lives of those affected.

While it will undoubtedly be necessary to make difficult decisions about priorities as we emerge from the COVID-19 pandemic, we remain concerned that the designation of procedures as being of limited clinical value risks ignoring the needs of vulnerable patients. Further, once a procedure is in this category, clinical commissioning groups are able to set their own policies in relation to it; this appears to have resulted in regional variation in access. We believe that such variation is unwarranted and would like to see clear, evidence-based guidelines applied consistently and fairly to all individuals seeking surgery for congenital, developmental and acquired anomalies, across the country.

Data: an asset and a challenge

As has been stated above, the ability to bring together for the first time data about all breast surgery has been central to our approach and we want to use the data we have gathered as a baseline for the future. We have therefore begun discussions about adding some of the reliable and consistent HES-derived quality indicators to the Model Hospital to enable

trusts to monitor their own performance. We are also very pleased that work is already underway to improve the links between HES and NCRAS data, so that we can better understand the connection between surgery and cancer outcomes.

We recognise that the quality of any such data is dependent on the initial input. We have identified various aspects of data capture and clinical coding where current data entry leads to a misleading picture of clinical practice.

For example, when we initially looked at re-excision rates – a metric breast surgeons regard as a key performance indicator under the NHS Breast Screening Programme – we found that nine providers reported a re-excision rate of over 34%, effectively more than 1 in 3 patients. Following deep-dive discussions, it emerged that in some trusts locally determined data capture methods meant diagnostic radiology-guided (excision) biopsies could not be distinguished from therapeutic surgical excisions, so the initial therapeutic surgical excision appeared to be a re-excision. When we adjusted the data, no provider had a re-excision rate of over 33% and the national mean re-excision rate dropped from 21% to 18.75%.

It is with this in mind that we make several recommendations about clinical coding and data capture and – with patient safety in mind – about making participation in national registries for both implants and flap reconstruction mandatory and ensuring the data entered is complete.

Consistent, standardised and accurate clinical coding and data capture is essential to reflect true breast surgery activity and complexity and allow meaningful comparisons between trusts: it will also support better tariffing. As a specialty, we work closely with – and rely on – the skills of oncology, radiology and plastic surgery teams: improved data can help us better understand the demands we place on these other specialties, and on our own colleagues; it can also help us identify trends and patterns in clinical practice. This not only feeds in to monitoring our workload and performance today but also to help shape our workforce and optimise training in the future. GIRFT will support further work to develop a directory of clinical codes that will better reflect modern breast surgery.

With more than 100,000 breast operations conducted each year, each having a huge impact on people's lives, our specialty needs to be organised as effectively as possible to provide the best possible care. We hope the recommendations here – rooted in data, and the experiences of patients and breast teams we have met – can help do this.

Recommendations

In addition to the recommendations outlined below, we expect all teams to have reviewed their GIRFT breast surgery data pack and visit reports to:

- understand how they compare with national activity and outcome data;
- explore why their data may demonstrate variation; and
- take appropriate steps to ensure that their clinical coding and general data capture (e.g. appropriate use of relevant treatment function codes (TFCs)) reflects their service.

It is also anticipated breast surgery teams will have registered with the Model Hospital data platform (model.nhs.uk) and be able to monitor their activity and outcomes for key clinical metrics. Examples may include (but are not limited to): breast reconstruction rates and bilateral mastectomy rates. For index procedures: outpatient attendances at 1 and 5 years, day surgery rates and length of stay, as well as unplanned return to theatres within 30 days of surgery and implant removal rates at 12 months.

We have used GIRFT Hospital Episode Statistics (HES) derived national rates as benchmarks for activity and outcomes wherever possible. Quality standards from other sources are clearly indicated. Below outlines the supporting actions, target timescales and owners for each of our recommendations.

Recommendation	Actions	Owners	Timescale
Core Recommendation **1. Ensure that new breast patient referral and assessment pathways are timely and centred around the individual with the aim of providing the best outcomes and experience.**	**a** Provide primary care support and guidance to allow best use of the access pathway.	Trusts / commissioners / Cancer Alliances	For immediate action
	b Ensure that access and assessment pathways are evidence-based, risk-adapted and standardised to support safety and cost efficiency.	Trusts / commissioners/ Cancer Alliances	For immediate action
	c Redesign and pilot breast clinic access (referral) and assessment pathways to further reduce barriers to early diagnosis, support the Faster Diagnosis Standard and allow patient choice. Ensure new ways of working are audited.	Trusts / commissioners / Cancer Alliances	For immediate action
	d GIRFT to work with specialty associations and Cancer Alliances to identify the workforce requirements associated with pathway redesign.	GIRFT to work with specialty associations and Cancer Alliances	For immediate action
	e Ensure that breast MDTs have a link to a plastic surgeon.	Trusts / commissioners / Cancer Alliances	For immediate action
2. Support better self-management through public health messaging at both national and local levels which emphasises breast health and targets breast cancer awareness messages at those at greatest risk.	**a** Ensure that public health messaging focuses on harder to reach groups (e.g. older age, BAME) in regard to breast health and awareness to encourage early healthcare engagement for any breast issues.	GIRFT to work with breast cancer charities, patient groups and primary care	For completion within 24 months of publication of the GIRFT report
	b Support and promote breast health awareness in the younger age groups.	GIRFT to work with breast cancer charities, patient groups and primary care	For completion within 24 months of publication of the GIRFT report
	c Align and collaborate with other health education initiatives aimed at supporting better understanding of women's and men's health.	GIRFT	For completion within 24 months of publication
	d Develop educational tools and materials to support public health messaging as outlined in the NHS Long Term Plan.	Primary care, NHS England and NHS Improvement, with support from relevant specialty associations	For completion within 24 months of publication of the GIRFT report

Recommendation	Actions	Owners	Timescale
3. Reduce unnecessary outpatient attendances for follow-up.	**a** Trusts to complete or implement the introduction of personalised stratified follow-up.	Trusts / commissioners	For completion within 12 months of publication of the GIRFT report
	b All trusts to have robust, up-to-date and highly digital Remote Monitoring Systems for patients on a personalised stratified follow-up pathway with 'call and recall' and 'right-results' systems or capabilities.	Trusts	For completion within 12 months of publication of the GIRFT report
4. Ensure that no breast surgery patients stay in hospital longer than is medically necessary.	**a** Increase day surgery rates for key index procedures to meet or exceed BADS target of 95% for simple breast excision and 75% for both oncoplastic excisions and mastectomy.	Trusts	For completion within 12 months of publication of the GIRFT report
	b Reduce median* and long length of inpatient stay for breast reconstruction by, for example, introducing enhanced recovery programmes with the aim of enabling patients to return home sooner. **In regard to implant-based reconstruction, the GIRFT benchmark is a median of two days, with less than 20% of patients at three days or more. In regard to free flap reconstruction, the GIRFT benchmark median is six days, with less than 20% of patients staying seven or more days.*	Trusts	For completion within 12 months of publication of the GIRFT report
	c Trusts to consider day case surgery for selected patients undergoing mastectomy and implant-based reconstruction, if deemed appropriate for the patient.	Trusts	For completion within 12 months of publication of the GIRFT report
Core Recommendation **5.** Ensure equity of access to: • oncoplastic surgery to support safe breast conservation; and • breast reconstruction, with the aim of reducing variations in immediate reconstruction rates and variable access to free flap econstruction techniques. (Breast MDTs should have a link to a plastic surgeon).	**a** Establish oncoplastic MDTs in every breast and plastic surgery unit (virtual/real).	Trusts / commissioners	For immediate action
	b MDTs to support breast conservation regardless of age whenever safe and desirable. They could for example consider using: • primary systemic therapies to support conservation when clinically indicated. • oncoplastic breast conservation when appropriate. Where access is not available on site, alternative providers must be offered through oncoplastic networks.	Trusts	For immediate action
	c Trusts to provide access to all index methods of reconstruction, (following NICE guideline NG101) and outsourcing reconstruction where necessary.	Trusts	For immediate action
	d ICS/STPs to work with oncoplastic MDTs to examine facilitators and barriers to immediate reconstruction and free flap reconstruction.	ICS/STPs	For immediate action
	e ICS/STPs to conduct needs assessments and plan capacity between breast and local plastic surgery units with the aim of: • achieving an immediate breast reconstruction rate of 25% (GIRFT national rate), whether performed onsite and/or outsourced • ensuring at least 30% (GIRFT national rate) of immediate breast reconstructions are free flap.	ICS/STPs	For immediate action

Recommendation	Actions	Owners	Timescale
6. Reduce unplanned readmissions and returns to theatre.	**a** Oncoplastic surgery teams to ensure 30- and 90-day unplanned admissions and return to theatres rates are within the median quartile (GIRFT national benchmark).	Oncoplastic surgery teams within trusts	For completion within 12 months of publication of the GIRFT report
	b Oncoplastic surgery teams to ensure unplanned implant removal rates at 1 year are 7.5% or below (GIRFT national benchmark). (The target is 5% or less in accordance with the oncoplastic guidelines.	Oncoplastic surgery teams within trusts	For completion within 12 months of publication of the GIRFT report
	c Plastic surgery teams to reduce unplanned free flap return to theatres to UKNFR rates of 7%.	Plastic surgery teams	For completion within 12 months of publication of the GIRFT report
7. Incorporate PROMs for all oncoplastic, reconstructive and related surgery as well as for aesthetic breast surgery.	**a** Trusts to consider the adoption of the BreastQ questionnaire, or similar, as a standardised means of gathering PROM data.	Trusts	For completion within 12 months of publication of the GIRFT report
Core Recommendation **8. Ensure that no patients undergo more surgery than is necessary.**	**a** Reduce excisional surgery rates for benign/normal conditions to 25% or less of total excisional surgery (GIRFT national rate) by following ABS guidelines and GIRFT best practice exemplars.	Trusts	For immediate action
	b Reduce repeat surgery after wide excision for cancer, aiming towards repeat surgery rates of 10% or less (as recommended by the American Society of Breast Surgeons).	Trusts	For immediate action
	c Minimise adjustment and revision surgery, following ABS, BAPRAS and Breast Cancer Now 'Guidance for the Commissioning of Oncoplastic Breast Surgery'.	Specialty associations	For immediate action
	d Limit bilateral mastectomy for unilateral cancer to when clinically indicated and ensure ABS guidelines and NICE guideline CG164 Familial breast cancer are followed. There must be clear documentation regarding the rationale and benefits (e.g. symmetry) and more specially: • all trusts must provide clear information to patients with unilateral breast cancer to support shared decision making regarding the benefits and risks of bilateral mastectomy +/-reconstruction • all requests or recommendations for bilateral mastectomy (for unilateral cancer) and immediate breast reconstruction must undergo MDT review.	Trusts	For immediate action

Recommendation	Actions	Owners	Timescale
9. Reduce admissions/ surgery for mastitis to 1% or less of admissions captured under the OPCS codes for excisional breast surgery.	**a** MDTs to develop a plan to reduce their admissions for non-surgery related breast infections and breast interventions.	Trusts and primary care	For completion within 12 months of publication of the GIRFT report
	b MDTs to work with local healthcare providers, A&E departments and on call surgery teams to reduce the need for emergency hospital admissions for non life-threatening breast infections.	Trusts and primary care	For completion within 12 months of publication of the GIRFT report
	c Specialty associations to develop a best practice pathway for the management of non-surgical breast infections which reflects the NICE guideline CG37 Postnatal care up to 8 weeks after birth.	Specialty associations	For completion within 24 months of publication of the GIRFT report
10. Reduce inequity in access to aesthetic breast surgery for congenital, developmental and acquired anomalies.	**a** Commissioning criteria for aesthetic breast surgery for congenital, developmental and acquired anomalies to be consistent, and applied consistently.	Commissioners	For completion within 24 months of publication of the GIRFT report
11. Improve the consistency and accuracy of data capture in HES.	**a** Trusts to capture at least 95% of admissions for (oncoplastic) breast surgery using TFC 103 or TFC160.	Trusts	For completion within 12 months of publication of the GIRFT report
	b Trusts to capture at least 95% of breast excision procedures under the appropriate breast surgery or radiology TFC.	Trusts	For completion within 12 months of publication of the GIRFT report
	c Specialty associations, coding bodies and others to work together to identify a solution that enables trusts to capture at least 95% of outpatient attendances for (oncoplastic) breast surgery using TFC103.	Specialty associations, coding bodies and others	For completion within 24 months of publication of the GIRFT report
	d NHS Digital to develop means of accurately recording and coding cross-disciplinary/multi-disciplinary surgery, for example by allowing the use of multiple appropriate TFCs for a single procedure.	NHS Digital	For completion within 24 months of publication of the GIRFT report
	e GIRFT to work with specialty associations and NHS Digital to develop guidance on standardising the use of OPCS and ICD codes with particular regard to oncoplastic reconstructive surgery, where necessary.	GIRFT, specialty associations, NHS Digital	For completion within 24 months of publication of the GIRFT report
12. Ensure that HES and NCRAS patient level data is linked to support outcome monitoring.	**a** GIRFT and NHS England to work together to continue to link NCRAS and HES data, to enable better case mix adjusted comparison of breast conservation, repeat surgery rates and the impact on local recurrence rates.	GIRFT and NHS England	For completion within 24 months of publication of the GIRFT report

Recommendation	Actions	Owners	Timescale
13. Improve the consistency and accuracy of data capture in the BCIR and UKNFR with the aim of 95% completeness within three months of surgery.	**a** BCIR and UKNFR data submission to become mandatory for all providers who use breast devices/flaps, including data about surgical meshes used in breast surgery.	Trusts / commissioners	For completion within 12 months of publication of the GIRFT report
	b GIRFT to work with NHS Digital and others to consider options to improve data capture processes	NHS Digital	For completion within 24 months of publication of the GIRFT report
	c Specialty associations to work with trusts and commissioners to develop a framework to allow the safe introduction of new devices and techniques – 'No innovation without evaluation'.	Specialty associations, trusts, commissioners	For completion within 24 months of publication of the GIRFT report
	d GIRFT to explore how BCIR and UKNFR data can be linked to HES and Spend Comparison Service, to avoid duplication and enrich data collection on outcomes.	GIRFT	For completion within 24 months of publication of the GIRFT report
	e CQC to support GIRFT in ensuring that providers capture and enter at least 95% of data into the breast implant and flap registries.	CQC	For completion within 24 months of publication of the GIRFT report
14. Enable improved procurement of devices and consumables through cost and pricing transparency, aggregation and consolidation, and by sharing best practice.	**a** Use sources of procurement data, such as Spend Comparison Service and relevant clinical data, to identify optimum value for money procurement choices, considering both outcomes and cost/price.	GIRFT	Within 24 months of publication of the GIRFT report
	b Identify opportunities for improved value for money, including the development of benchmarks and specifications. Locate sources of best practice and procurement excellence, identifying factors that lead to the most favourable procurement outcomes.	GIRFT	Within 24 months of publication of the GIRFT report
	c Use Category Towers to benchmark and evaluate products and seek to rationalise and aggregate demand with other trusts to secure lower prices and supply chain costs. At least 80% of NHS spend in breast surgery to be channelled through NHS Supply Chain, and market dominance issues addressed.	Trusts, commissioners, GIRFT	Within 24 months of publication of the GIRFT report
15. Reduce litigation costs by application of the GIRFT programme's five-point plan.	**a** Clinicians and trust management to assess their benchmarked position compared to the national average when reviewing the estimated litigation cost per breast surgery admission. (Trusts will receive this information in the GIRFT 'Litigation data pack').	Trusts (clinicians and trust management)	For immediate action
	b Clinicians and trust management to discuss with the legal department or claims handler the claims submitted to NHS Resolution included in the data set to confirm correct coding to that department. Inform NHS Resolution of any claims which are not coded correctly to the appropriate specialty via *CNST.Helpline@resolution.nhs.uk*	Trusts (clinicians and trust management)	Upon completion of 15a

Recommendation	Actions	Owners	Timescale
15. (continued) Reduce litigation costs by application of the GIRFT Programme's five-point plan.	**c** Once claims have been verified clinicians and trust management to further review claims in detail including expert witness statements, panel firm reports and counsel advice as well as medical records to determine where patient care or documentation could be improved. If the legal department or claims handler needs additional assistance with this, each trusts panel firm should be able to provide support	Trusts (clinicians and trust management)	Upon completion of 15b
	d Claims should be triangulated with learning themes from complaints, inquests, and serious untoward incidents (SUI)/ serious incidents (SI) / patient safety incidents (PSI) and where a claim has not already been reviewed as SUI/SI/PSI we would recommend that this is carried out to ensure no opportunity for learning is missed. The findings from this learning should be shared with all front-line clinical staff in a structured format at departmental/directorate meetings (including Multidisciplinary Team meetings, Morbidity and Mortality meetings where appropriate).		Upon completion of 15c
	e Where trusts are outside the top quartile of trusts for litigation costs per activity, GIRFT will be asking national clinical leads and regional hubs to follow up and support trusts in the steps taken to learn from claims. They will also be able to share with trusts examples of good practice where it would be of benefit.	GIRFT	Ongoing
16. Identify breast surgery clinical negligence claims at a national level to allow early detection of variation in breast surgery.	**a** NHS Resolution, supported by GIRFT, to categorise clinical negligence claims related to the specialty of breast surgery to enable these claims to be differentiated from general surgery and improve taxonomy of claims so that surgery of the breast can be easily identified when carried out by other specialties outside of breast surgery.	NHS Resolution, supported by GIRFT	For immediate action as part of the review of NHS Resolution's clinical coding of claims and core system review supported by GIRFT.
17. Align breast surgery workforce recommendations to the NHS People Plan	**a** Oncoplastic breast and plastic surgeons to practice at the top of their licence which includes: • all WTE oncoplastic breast surgeons to be allocated at least two, and ideally three operating sessions a week. • trusts to address over-reliance/utilisation of oncoplastic breast surgeons to support non-surgical activities.	Trusts	For completion within 24 months of publication of the GIRFT report
	b Ensure training for breast and plastic surgery trainees is fit for purpose.	HEE, the GMC and Royal Colleges	For completion within 24 months of publication of the GIRFT report
	c Address the shortage of trained microvascular plastic surgeons, so that free flap reconstructions are available more widely and equitably.	Specialty associations, working with HEE and the GMC	For completion within 24 months of publication of the GIRFT report
	d Specialty associations to work with the GMC to develop a road map for the further development of training in oncoplastic breast surgery.	Specialty associations to work with the GMC	For completion within 24 months of publication of the GIRFT report

Statements of principle

Statements of principle which relate to the core recommendations have been included in the report at appropriate points to set the tone of the evidence discussed.

What is breast surgery?

Breast surgery refers to a range of surgical procedures on the breast – the majority of which are related to the treatment of breast cancer. It includes the removal of cancerous tissue via wide local excision (WLE) or mastectomy, with or without reconstruction, plus a range of operations for non-cancer conditions. Breast surgery teams also play a core role in the assessment of breast problems and the diagnosis of breast cancer.

Specialist breast surgery has evolved over the last 25 years, driven by the introduction of the NHS Breast Screening Programme in 1987 and the need for specialist surgeons to treat early breast cancer in a dedicated multidisciplinary team (MDT) of surgeons, radiologists, pathologists, oncologists, specialist nurses and many other supporting staff.

Hospital Episode Statistics (HES) data analysed by the GIRFT team has shown that about 60% of NHS admissions for surgery on the breast are **directly** related to primary breast cancer treatment.

Breast cancer

Breast cancer is the most common female cancer, accounting for around 15% of all newly diagnosed cancers in the UK.[7] About one in eight women are diagnosed with breast cancer during their lifetime[8] plus a small number of men. Figures from Cancer Research UK show that between 2014 and 2016, about 55,000 women and 400 men a year were diagnosed with breast cancer in the UK, equivalent to around 150 people a day.[9]

Approximately 60% of cancers are diagnosed as a result of GP referrals; a further 30% are diagnosed as a result of the NHS Breast Screening Programme (NHS BSP) and a further 4-5% through emergency departments. Projections suggest that by 2035, there will be 71,000 new breast cancer cases in the UK each year.[10]

Breast cancer incidence increases steadily with age; over 25% of breast cancers are diagnosed in people over 75 years of age and fewer than 10% in those under 50.

Surgery for breast cancer

Surgery on the breast for breast cancer can involve:

- removal of part of the breast, known as wide local excision (WLE) or lumpectomy, or more broadly breast conservation surgery. This is usually recommended for smaller cancers or larger volume breasts; or
- removal of the whole breast, known as mastectomy. This is usually required for larger cancers, multi-centric disease or small volume breasts. It can be performed with or without reconstruction.

Breast surgery is often termed oncoplastic breast surgery to highlight that modern specialist surgery not only safely removes the cancer but also applies plastic surgery techniques to maintain the breast appearance. For example, oncoplastic breast conservation uses breast reduction techniques to reshape and re-volume one or both breasts after large-volume partial breast removal (therapeutic mammoplasty). Oncoplastic surgery can range from very simple manoeuvres, such as hiding scars, to full breast reconstruction, that may take multiple operations over a period of time.

Breast reconstruction involves replacing the breast either by the use of an internally placed silicone/saline breast implant, or by transplanting some of the patient's own tissue from one part of the body to another (known as an autologous flap), or by combination of flap and implant. It can be conducted at the same time as the mastectomy (immediate reconstruction) or at any later time (delayed reconstruction).

When a transplanted flap is disconnected from its original blood supply and reconnected to different blood vessels closer to the breast, this is known as free flap reconstruction. Free flap surgery is highly specialised; it is usually performed by specialist microvascular plastic surgeons. The most common approach is to use spare tissue on the abdomen (this is known as a DIEP flap). Sometimes both a flap of tissue from the back (latissimus dorsi flap) and an implant are used together; however, use of this reconstruction technique is declining.

A range of factors influence both the type of cancer surgery and type of reconstruction advised: these include the cancer stage of the patient and their treatment requirements (especially the need for radiotherapy, which has a detrimental effect on tissue), as well as patient body shape and preferences.

Surgery on the breast for breast cancer is often performed simultaneously with surgery to the axilla (armpit). Axillary surgery

[7] *www.cancerresearchuk.org/about-cancer/breast-cancer/about*
[8] *www.nhs.uk/conditions/breast-cancer/*
[9] *See www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer*
[10] *See www.cancerresearchuk.org/about-us/cancer-news/press-release/2017-02-03-womens-cancer-rates-rising-faster-than-mens*

is either to remove a small number of lymph nodes to find out if cancer is present (sentinel lymph node biopsy – SLNB) or to remove cancerous lymph nodes (axillary lymph node dissection – ALND).

Breast surgery not directly related to cancer removal

- Nearly 17% of all breast surgery admissions are to complete a planned programme of reconstruction or adjust previous oncoplastic surgeries: this can include balancing surgery to the opposite breast.
- About 13% are to excise normal or benign (non-cancerous) breast tissue. This can be for many reasons; the list below is in order of volume of activity:
  - surgery to remove known benign lumps, lesions and tissues such as fibroadenoma, hamartoma and pseudoangiomatous stromal hyperplasia (PASH). It is regarded as highly desirable to minimise this type of surgery. The Association of Breast Surgeons (ABS) has produced clinical guidelines to support best practice;[11]
  - surgery to remove breast tissue for diagnostic purposes, where the tissue turns out to be benign. The need for this type of surgery is now minimal, thanks to overall improvements in breast assessment and the increasing use of modern diagnostic radiology techniques, such as vacuum-assisted biopsies and excisions performed in the radiology outpatient department (VAB/VAE);
  - surgery to correct breast overgrowth in males and females resulting from congenital or medical conditions.
- Just over 2.5% of admissions for breast surgery are to treat breast infections and drain abscesses (usually related to breastfeeding or smoking).
- Less than 1% are to correct congenital breast underdevelopment in females.
- Less than 0.5% are to change a person's gender. This is usually mastectomy for female to male gender reassignment. This type of surgery is commissioned by NHS Specialised Commissioning.
- About 6% of admissions for breast surgery are for other reasons that do not fall into the above categories.

Almost all breast surgery is elective; the only emergency activity is for breast infection (which mostly involves non-surgical treatment) and for complications following breast surgery.

Who receives breast surgery?

While the majority of breast surgery is conducted on women over the age of 50 with breast cancer, the specialty also supports surgery outside this broad demographic group.

Gender

98% of breast surgery is conducted on females – the majority for breast cancer.

About 2% of surgery is on males, mostly for the treatment of breast cancer or breast overgrowth (gynaecomastia). Small volumes of breast surgery take place on trans males (born as female sex) for gender reassignment breast surgery.

Age

For women with cancer, age varies according to the type of operation, for example:

- for mastectomy with no reconstruction, the average (mean) age is 65 years;
- for mastectomy with immediate or delayed reconstruction, the average age is 51 and 52 years respectively – over a decade younger than for mastectomy with no reconstruction;

In short, women who have a breast reconstruction are in general younger than those who have a mastectomy with no reconstruction. This is likely to be a result of both patient choice and clinical guidance: reconstruction is a more complex operation with more potential complications (as will be examined further in this report).

The recent National Audit of Breast Cancer in Older Patients (NABCOP) has found that women over 70 are less likely to receive surgery (regarded as the most effective form of cure) for the same cancer than women aged between 50 and 69, even if they are of similar fitness.[12] Our questionnaire showed that only 16 trusts had a dedicated pathway for the frail older person (typically an older sub group of those over 70).

Less than 1% of breast surgery is carried out on young people under the age of 18.

[11] *See https://associationofbreastsurgery.org.uk/media/64950/abs-summary-statement-fibroadenomas-v1.pdf*
[12] *See www.nabcop.org.uk/reports/nabcop-2019-annual-report/*

Ethnicity

According to 2015 PHE data, 7% of people with newly diagnosed breast cancer were from a black, Asian or minority ethnic (BAME) background. HES data, based on trust submissions, also gives information on ethnicity by breast cancer operation; the average percentage of women who receive mastectomy (with or without a reconstruction) and identify themselves as BAME is between 7 and 8%. This suggests that a person's ethnicity has no effect on the treatment recommendations they receive or choices they are offered.

Breast surgery providers

In England, there are about 130 breast surgery units[13] – usually at least one in each hospital trust. However, service mergers and closures mean the number varies from year to year. There are about 70 plastic surgery units, but only around 40 that conduct significant volumes of surgery on the breast; only two of these are in trusts which do not also have a breast surgery unit.[14]

Almost all NHS breast surgery is conducted in NHS hospitals; unlike other surgical specialties, very little NHS commissioned breast surgery is undertaken in the independent (private) sector. However, some trusts do use private sector partners to help conduct breast diagnostic activity; this is, in general, to help the trusts meet the target of providing a diagnosis within two weeks for all patients referred from primary care.

Who performs breast surgery?

Breast surgery is usually performed by surgeons who exclusively specialise in the management of breast cancer and other breast conditions in both women and men. Breast surgeons (in the majority from the specialty of general surgery, but also from plastic surgery) perform surgery on the breast for a range of conditions, but mainly for breast cancer. Breast surgeons conduct the majority of oncoplastic and reconstruction surgery. Plastic surgeons (with a special interest in breast surgery) mainly perform highly specialised breast reconstruction, usually in collaboration with a breast surgeon. In some units, plastic surgeons also perform the cancer surgery as well as correction of congenital anomalies. There is also a growing role for interventional radiology procedures within breast surgery.

Breast and plastic surgeons now typically work together as oncoplastic breast surgery teams within the wider MDT to provide patients access to a wide range of skills and expertise that will allow patients to maintain their appearance after breast surgery.

Cosmetic breast surgery

Cosmetic breast surgery is when surgery is used to change the breast appearance for personal preference, rather than because of a medical condition or indication as above (termed aesthetic breast surgery). Cosmetic breast surgery utilises the same surgical techniques used in breast oncoplastic and reconstruction surgery and subsequent adjustment/balancing surgery, such as breast augmentation with implants and/or fat (lipofilling) and breast reduction/uplifts.

Very little cosmetic breast surgery is provided on the NHS.

It is hard to establish data about the volume of cosmetic breast surgery conducted privately in the UK; around 12,000 such operations are performed each year by members of the British Association of Aesthetic Plastic Surgeons (BAAPS), but it is believed that many more are undertaken by non-members.[16]

[13] *The exact number of units changed multiple times during the period of our analysis, deep-dive visits and the production of this report. However, it remained close to 130 at all times, hence our use of 'about 130'.*

[14] *It has been difficult to ascertain the number of plastic surgery units that offer oncoplastic reconstructive breast surgery. We have sought to identify these through examining HES breast surgery volumes captured under the treatment function code for plastic surgery (TFC 100) as well as the type of breast procedures performed. To enable more useful comparison between plastic surgery units that offer breast surgery, we chose to suppress data relating to providers that conducted fewer than 100 plastic surgery operations on the breast between 2015 and 2018. With those removed, there are about 40 units that provide regular plastic surgery on the breast.*

[15] *There is one trust where the CCG commissions specialist breast reconstruction in the private sector.*

[16] *See British Association of Aesthetic Plastic Surgeons Annual Audit 2019 https://baaps.org.uk/media/press_releases/1708/cosmetic_surgery_stats_number_of_surgeries_remains_stable_amid_calls_for_greater_regulation_of_quick_fix_solutions*

Breast surgery activity

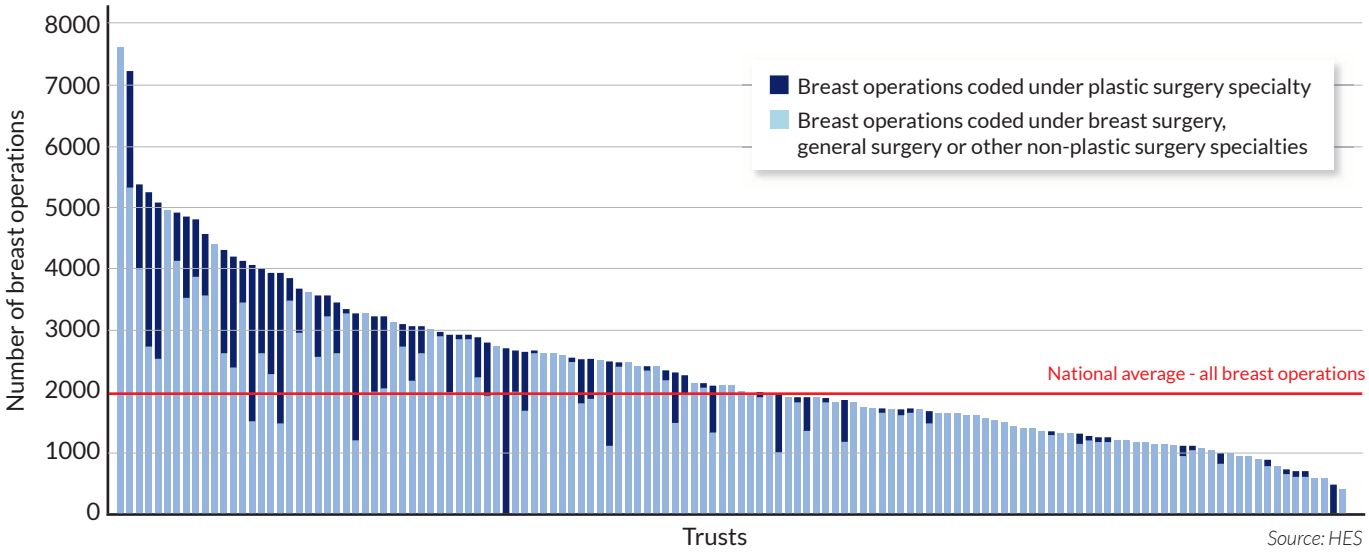
Breast surgery remains the mainstay of breast cancer treatment, with over 90% of cancers undergoing surgery. Consequently, breast surgery has very high volumes of activity.

Using data from HES that covers all breast surgery operations, whether the admission was recorded under plastic surgery, breast surgery, general surgery or any other specialty, we have established that there were 102,000 breast operations each year between April 2015 and March 2018 (annualised over the three years studied.)

By bringing data about all breast surgery operations together regardless of the specialty the patient was admitted under, we have been able to provide a more complete picture of breast surgery activity than has previously been available.

Figure 1 shows the total number of breast operations conducted at each trust in England over the three-year period April 2015-March 2018. The two busiest trusts conducted over 7,000 operations over this three year-period, and there were a dozen providers who conducted under 1,000.

Figure 1: Number of breast operations by trust, April 2015-March 2018



An operation may include one or more procedures. An operation coded with a bilateral code in the same episode of admission is counted as two operations. Specialty defined based on treatment function code (TFC).

The two trusts where all the operations were coded under plastic surgery are plastics-only units with no onsite breast surgeons.

The three-year average (mean) number of breast surgery operations per provider is about 2,200, annualised to 733. However, most breast units do not have on-site plastics units; if operations recorded under plastic surgery are removed from the figures, the three-year average is about 2,000, annualised to 654, with a range of 182 to 2,500. This provides a more useful comparison of activity levels across the approx. 130 specialist breast surgery units.

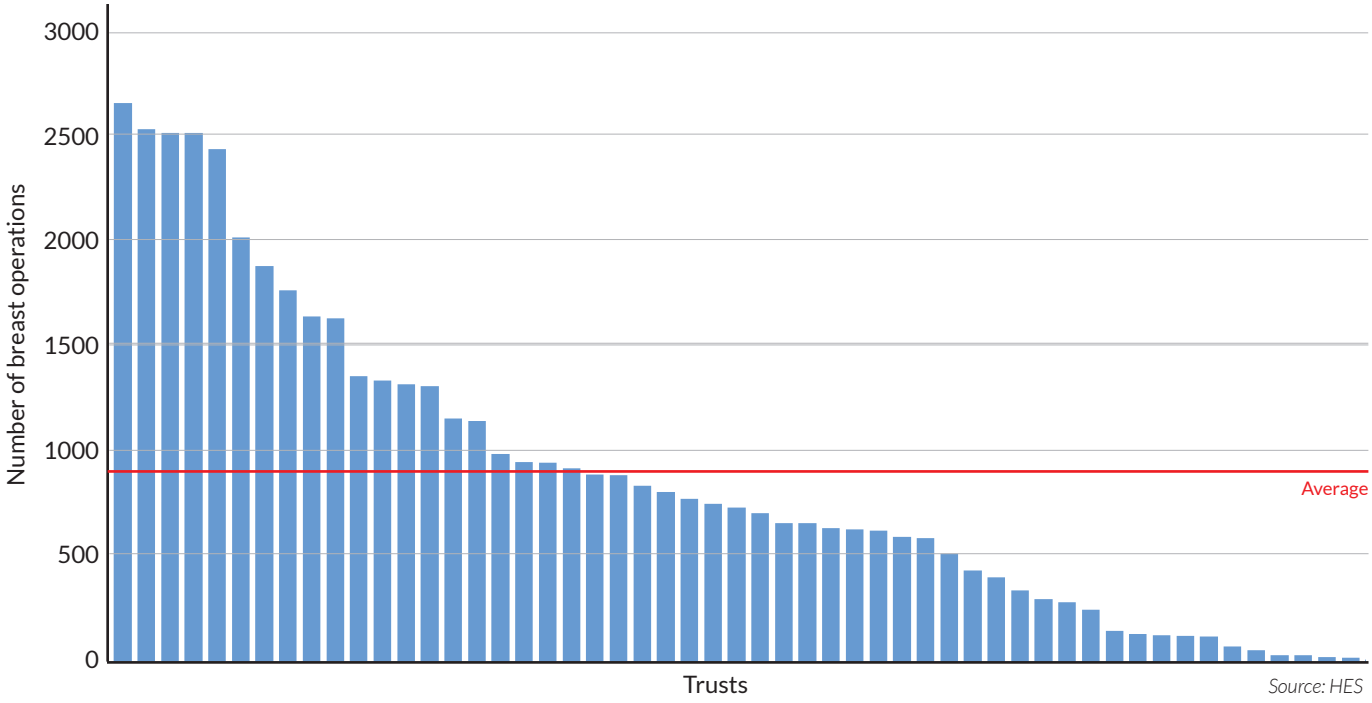
Volumes of admissions are slightly lower than volumes of operations, as a patient may have more than one operation in a single episode of care (for example, if the patient has operations on each breast simultaneously, this may be counted as two operations for the purposes of recording activity and workload.) This is important when assessing productivity, business planning and for resource allocation.

Plastic and breast specialty activity

Of the 102,000 operations a year, about 85% were performed by specialist breast/general surgeons and 15% (11,500) by specialist plastic surgeons. However, the variation in plastic breast surgery activity between trusts is steep, with a long tail of very small volume providers. By contrast, in trusts with a large regional plastic surgery unit, the plastic surgery team's share of the overall breast surgery workload can exceed 50%. This is because the plastics unit draws in referrals for breast reconstruction and other complex breast surgery from around the region. The HES data we analysed demonstrates that plastic surgeons conduct just under a third of all immediate breast reconstructions (27%) but the majority (over 60%) of delayed reconstructions.

Among the 40 units that provide regular plastic surgery on the breast, the annualised volume of operations each year is about 395. Once again, there is a wide range from 40 to 886 operations per year.

Figure 2: Volume of breast operations coded under plastic surgery (TFC160) by trust, April 2015-March 2018 (trusts with more than 100 such operations only)



An operation may include one or more procedures. An operation coded with a bilateral code in the same episode of admission is counted as two operations. Specialty defined based on treatment function code (TFC).

Plastic surgery on the breast accounts for about 5% of the total plastic specialty surgery workload.[17]

However, a count of operations performed is a very simplistic measure of activity, as it makes no allowance for the type or complexity of procedures being conducted. A simple excision for a benign lump may take less than an hour; a full mastectomy and free flap reconstruction may take a whole day. As plastic surgery operations on the breast are typically complex, major operations, the average plastic surgery operation would take longer than the average breast operation overall. HES data demonstrates that nearly 17% of the plastic surgery breast workload is free flap surgery (equating to about 2000 operations each year.) This activity provides a useful benchmark to assess data completeness in the self-reported UK National Flap Registry (UKNFR).

[17] *There is a separate GIRFT workstream examining plastic surgery which will result in a national report. In this report, we look in detail at all surgery on the breast, regardless of the specialty title of the surgeon.*

About our analysis

In analysing breast surgery as part of the GIRFT process, we have reviewed HES data between April 2015 and March 2018 relating to **every** admission for an operation or intervention on the breast regardless of whether the patient was under the care of breast surgery, plastic surgery or any other specialty. We identified these using the relevant ICD10[18] diagnosis codes and OPCS-4 codes.[19] This means that, for the first time, we have been able to provide an overview of the totality of breast surgery in England.

By reviewing every admission for breast surgery, we have been able to build a fuller understanding of variations in activity and service configurations, access to specialist surgery, as well as patterns of surgical care and surgery outcomes. For the first time, we have been able to obtain information on surgery for benign conditions, non-surgical breast infections, gender reassignment and surgery for congenital breast problems, as well as to better understand the volume of adjustment surgery post reconstruction/oncoplastic conservation.

A single admission can of course involve multiple procedures, which is not always discernible from the data, However, where a patient was admitted for bilateral surgery, we have captured that as two operations to better reflect the activity.

We chose to look at data across a three-year period to smooth out any yearly fluctuations in workload resulting from the NHS Breast Screening Programme (NHSBSP) three-year cycle. Where data is presented from a different timeframe, this is stated in the report.

The core issues we have examined include:

- length of stay (LOS) for all key procedures;
- day case rates for breast excisions and mastectomy;
- the amount of readjustment surgery after immediate and delayed breast reconstruction by technique;
- readmissions and complications within 30 days and 90 days of surgery – both for all causes and for breast-specific complications;
- rates of unplanned removal of breast implants; and
- follow-up outpatient attendances for each key index procedure.

There are several areas of breast surgery for conditions other than cancer that have never been nationally audited, including:

- admissions and interventions for non-surgery related breast infection, mainly surgery for lactational abscesses;
- breast surgery for congenital/developmental issues; and
- gender reassignment surgery.

These have been examined through the GIRFT process and key findings are included in this report. However, risk reduction surgery for women identified as being at increased risk of breast cancer has not been examined in depth in this report. It is important that trusts know their outcomes for these patients. These can be seen in Table 3 on page 54 (readmissions for adjustments) and Table 7 on page 70 (readmissions for complications).

Other sources of data

In addition to our core data, we have considered data about breast cancer surgery and treatment from a range of other sources. These include:

- the National Audit of Breast Cancer in Older Patients (NABCOP), which collates a large amount of data about the care pathways and outcomes for older women (70+) with breast cancer compared to those in the 50-69 age group;[20]
- the NHS Breast Screening Programme (NHSBSP). It publishes an annual audit, which focuses on the diagnostic and assessment process of the NHSBSP as well as selected aspects of breast cancer surgery;[21]
- the National Mastectomy and Breast Reconstruction Audit (NMBRA), which between 2008 and 2011 gathered data on reconstruction, based on trust returns and patient reported outcome measures (PROMs);[22]
- the UK National Flap Registry (UKNFR)[23] and the Breast and Cosmetic Implant Registry (BCIR)[24], which collect data on these two types of reconstruction, including some self-reported outcomes; and
- several cancer charities that collate and publish data about breast cancer screening, diagnosis and treatment.

[18] *ICD10 refers to the 10th revision of the International Statistical Classification of Diseases and Related Health Problems https://icd.who.int/browse10/2016/en*

[19] *OPCS is an abbreviation of Office of Population Censuses and Surveys, a forerunner of the Office for National Statistics. It introduced a classification of surgical operations and procedures; version 4 of this remains in use today. See www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/opcs_classification_of_interventions_and_procedures.asp?shownav=1*

[20] *See www.nabcop.org.uk/reports/nabcop-2019-annual-report/*

[21] *See www.gov.uk/health-and-social-care/population-screening-programmes-breast*

[22] *See www.rcseng.ac.uk/library-and-publications/rcs-publications/docs/mastectomy-breast-4/*

[23] *See https://uknfr.e-dendrite.com/*

[24] *See https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry*

Gaps in our analysis

We have not been able to access data about the cancer diagnoses that led to the surgery. We can see, from HES data, whether a procedure has been undertaken on a patient with cancer, but we do not know what type of cancer that patient had or how advanced the cancer was. We also do not know whether they had radiotherapy, chemotherapy or any other adjuvant treatment as well as surgery.

These gaps are significant because they affect our understanding of treatment decisions and provide important context for outcomes. For example, patients with larger tumours are more likely to require mastectomy rather than a wide local excision; therefore, having this information would add a further dimension to an analysis of variation in mastectomy rates.

The National Cancer Registration and Analysis Service (NCRAS)[25] holds some such data and discussions have begun regarding making it available to improve future analysis.

[25] *See www.gov.uk/guidance/national-cancer-registration-and-analysis-service-ncras*

Findings and recommendations

Breast surgery outpatient care

Statement of principle

Access to breast surgery outpatient care should be timely and centred around the individual with the aim of providing the best outcomes and experience.

Improving the management of referrals

Every year, breast surgery teams in England deal with more than half a million new outpatient referrals, the largest number of new two-week referrals for any cancer-focused specialty apart from dermatology. The number of referrals is increasing: even over the last three years (2015-2018), the total number of new referrals to breast clinics has increased by around 20%, from around 42,000 to almost 50,000 a month.

Over 95% of breast patients referred from GPs follow the two-week cancer access pathways either for suspected cancer (urgent) or breast symptoms. In breast surgery, there is no longer any easy mechanism for GPs to make routine referrals for other reasons, such as gynaecomastia and other symptoms that are not of concern which may require routine review.

Currently, around 55,000 new cases of breast cancer are diagnosed in England each year. Approximately 60% of cancers are diagnosed as a result of GP referrals – meaning that the 50,000 referrals result in around 2,500 diagnoses a month. A further 30% are diagnosed as a result of the NHS Breast Screening Programme (BSP) and a further 4-5% through emergency departments.[26]

Changes to practice during COVID-19

The GIRFT review took place prior to COVID-19, but we have nonetheless noted encouraging changes to practice during this time, particularly in relation to the management of new patient referrals. This corresponds to the recommendations outlined in this chapter and is one of our three core recommendations in the report.

At the start of the pandemic, the rapid uptake of technology to support safe prioritisation of referrals using virtual or telephone consultations, as well as the overnight reorganisation of breast outpatient processes to provide a COVID-19 safe breast assessment service, was remarkable. For example, during the most acute phase of the first wave of the crisis, some units triaged all referrals by telephone, to assess the potential risk of cancer and COVID-19, and so balance the need for face-to-face consultation and appropriate assessment.

It is important we maintain and continue to embed these changes when the crisis eases as, not only do they align with the spirit of the GIRFT report recommendations, they also support the delivery of the 28 Faster Diagnosis Standard as well as the goals and ambitions of the NHS Long Term Plan. Further, it is likely that we will experience additional diagnostic service pressures simply to manage the backlog of new referrals and undiagnosed cancers among patients who were not seen due to the focus on COVID-19. It is imperative that we continue to innovate and further enhance the use of technology to firmly integrate telemedicine into new patient referral and assessment pathways, as recommended in the pages that follow.

In addition, it is clear that in response to COVID-19 most units took the clinically pragmatic decision to diverge from NICE guidance on referral and triage in cases where cancer risk was lowest and defer referrals for breast pain only for three months or more. It is essential that data from this major practice change is audited, to provide information that will guide future improvements for patients and the service.

[26] *These are all broad figures; specific detail can be seen in figures 3-6 below.*

Cancer access standards in breast surgery

To support earlier cancer diagnosis, access standards were introduced in England in 2000 as part of the NHS Cancer Plan.[27] These include seeing all urgent referrals for suspected cancer within two calendar weeks – often referred to as the 'two week wait (2WW)'. In 2008, the access standards for breast referrals were updated, meaning that breast surgery teams are required to see all patients referred by their GP for a breast symptom within two weeks as well, even if cancer was not initially suspected. This parallel standard for symptomatic breast referrals is not replicated in any other specialty.

The access standards have proven very successful in delivering rapid breast diagnosis by streamlining service configuration and assessment pathways for all breast conditions but particularly in breast cancer. Over 90% of breast cancers are diagnosed at stage 1 or 2;[28] the NHS Long Term Plan set the aim of diagnosing 75% of all cancers at stage 1 or 2 by 2028.

In 2015, the Independent Cancer Taskforce recommended replacing the 2WW with a new Faster Diagnosis Standard (FDS) to ensure that the time from referral to a diagnosis is no more than 28 days as this better supports all referrals, both whether for suspected cancer or for other conditions. This recommendation was further endorsed by the interim report of the NHS Medical Director's Clinical Review of Standards,[29] and the 28 Day FDS was included in the NHS Standard Contract for 2020/21. We understand that the intent is that the 28 Day FDS would supersede the 2WW, though this would require changes in legislation.[30] There are further changes proposed as part of the clinical review.[31]

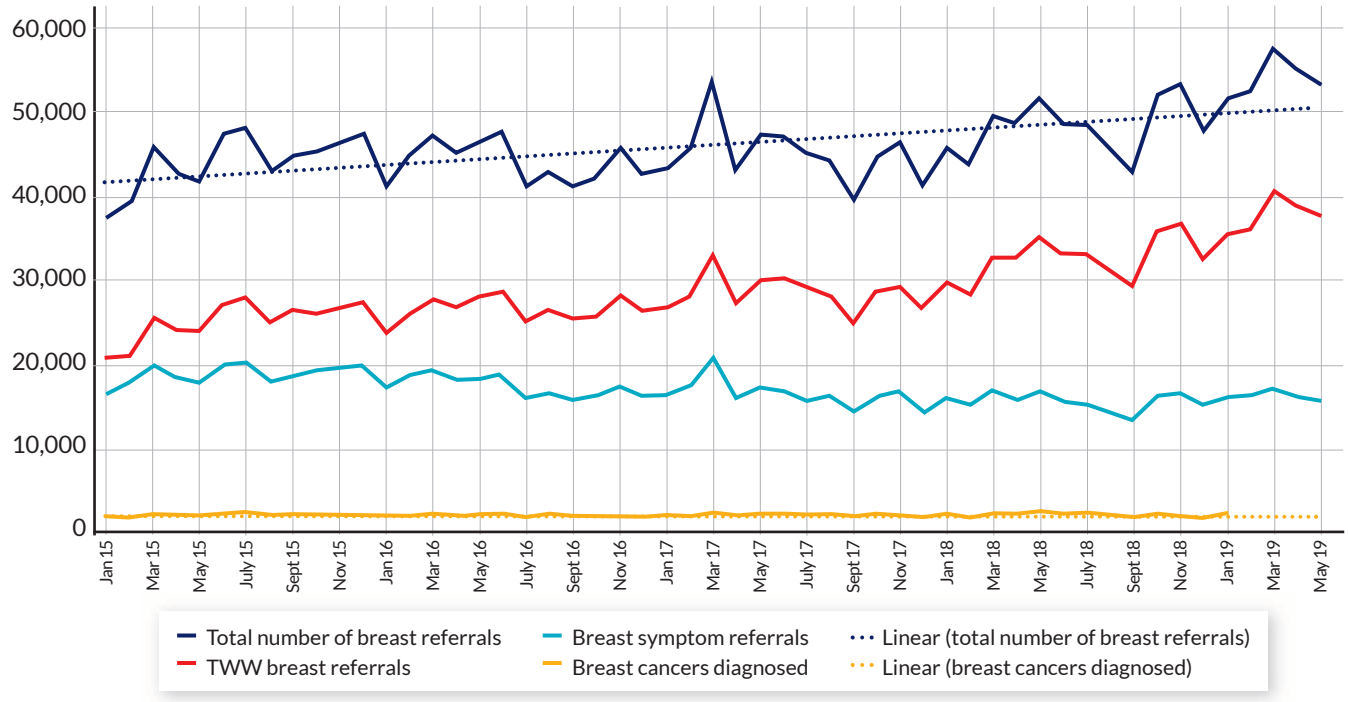
We fully support this focus on rapid diagnosis for all breast patients, rather than on the time to first appointment. However, because the 28 FDS will continue to apply to all breast referrals – via both the suspected cancer and symptomatic pathways – breast surgery will be expected to meet the 28-day standard for over half a million new breast referrals each year.

Managing increasing numbers of referrals

There is no doubt, from our deep-dive visits, that meeting the requirement to see all patients within two weeks has been the single biggest challenge facing breast surgery teams.

As Figure 3 below shows, over the last three years (2015-2018), the total number of referrals to breast clinics has increased to almost 50,000 a month. This is an increase of almost 20%.

Figure 3: Breast referrals and diagnoses in England, January 2015-May 2019



Source: National Cancer Registration and Analysis Service, Public Health England, July 2019. From Cancer Waiting Times data provided by NHS England.

[27] *The NHS Cancer Plan (2000): A plan for investment, a plan for reform*

[28] *See www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer/diagnosis-and-treatment#ref-1*

[29] *See www.england.nhs.uk/clinically-led-review-nhs-access-standards/*

[30] *See www.england.nhs.uk/cancer/early-diagnosis/#faster*

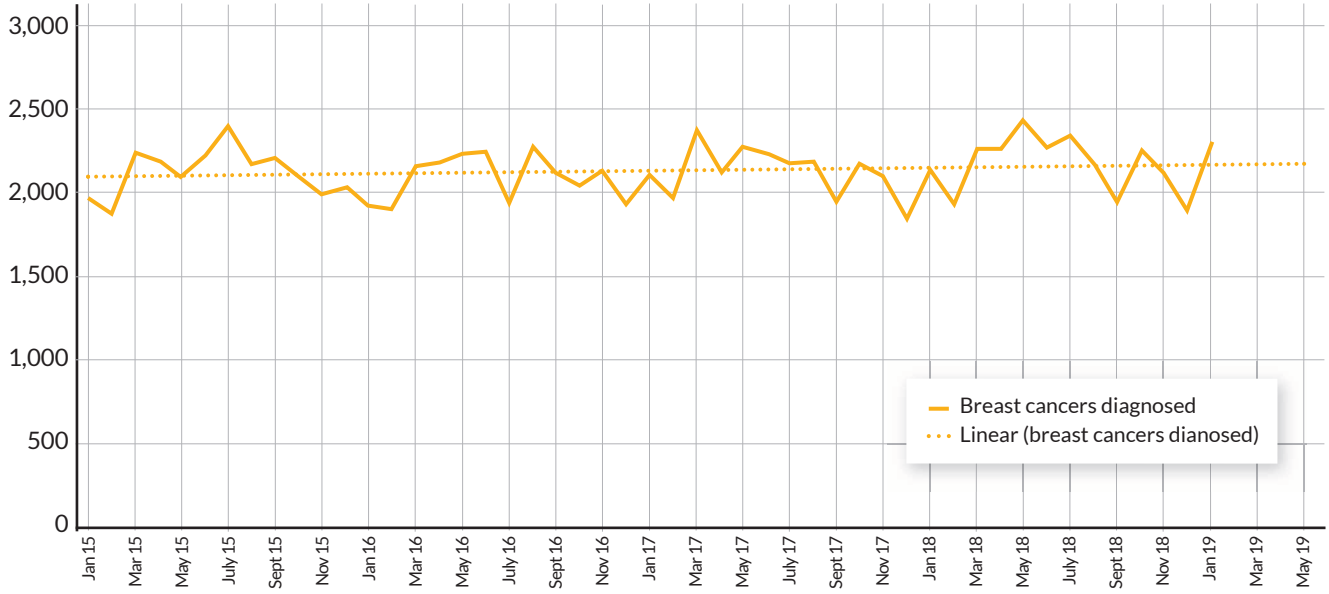
[31] *See www.england.nhs.uk/cancer/early-diagnosis/clinical-review-of-standards/*

While the exact number varies from month to month, the underlying trend shows a steady increase in total volumes of referrals. However, it can also be seen that, regardless of the fact everyone referred is expected to be seen within two weeks, volumes referred through the symptomatic pathway are declining and referrals through the urgent cancer pathway are increasing. This suggests that, despite the existence of established guidelines from NICE in relation to referrals for suspected breast cancer, there remains a degree of confusion regarding which referral pathway to follow. (It could of course be argued that, given the majority of patients referred must be seen within two weeks under either referral pathway, it is largely immaterial which referral pathway is triggered by primary care.)

Earlier cancer diagnosis and access pathways

As Figure 4 shows, the 20% increase in referral numbers over the last five years has not been mirrored by a similar rise in cancer diagnosis.

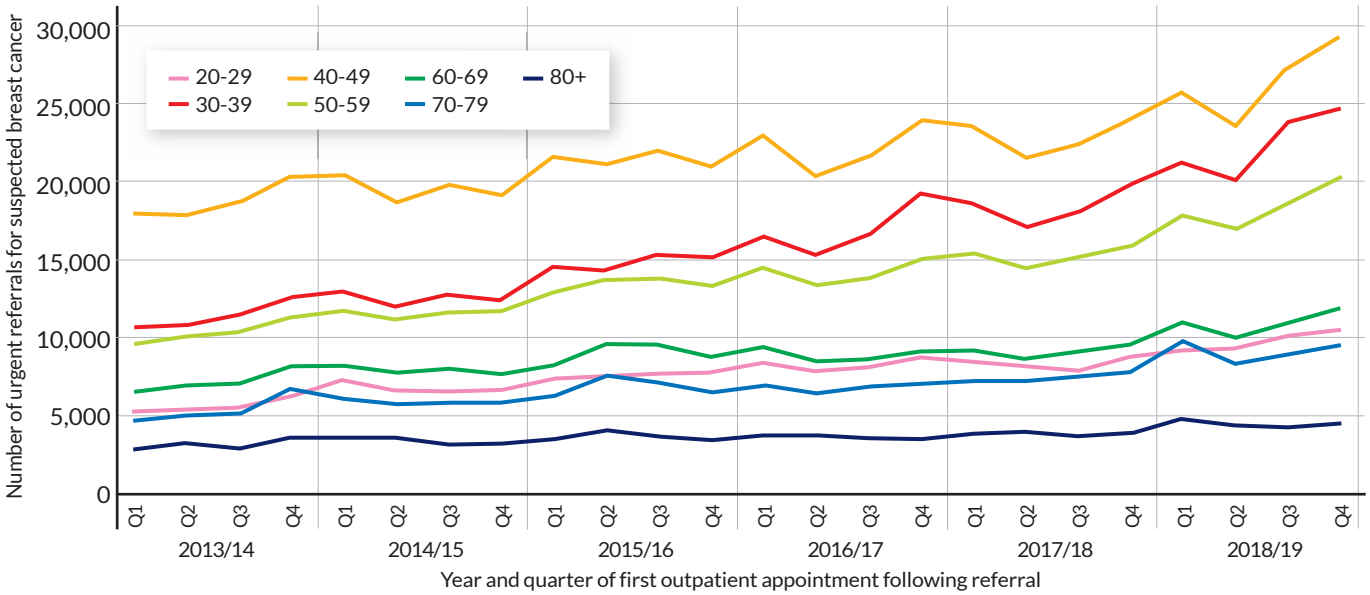
Figure 4: Number of breast cancers diagnosed from all breast referrals, January 2015-May 2019 (expanded from Figure 3 above)



Source: National Cancer Registration and Analysis Service, Public Health England, July 2019. From Cancer Waiting Times data provided by NHS England.

The main reason for this is because the highest increases in referrals have been among younger people at low risk of cancer – particularly women under 40 years of age, who now account for over 20,000 referrals a quarter. This can be seen in Figure 5, provided by NCRAS for GIRFT. By contrast, referrals from the age groups at higher risk of cancer (over 60 years of age) are not increasing at the same rate.

Figure 5: Breast referral volumes by age, April 2013-March 2019



Source: National Cancer Registration and Analysis Service (NCRAS), Public Health England, March 2019.

At present, most providers do manage to see most referrals for both suspected cancer and other breast symptoms within the target time. However, they have told us that doing so requires them to allocate a significant share of finite resources to seeing new breast referrals – the overwhelming majority of whom do not have cancer. One of the consequences of doing so is that they end up diverting resources away from people with cancer.

Despite huge efforts across every provider in England, with many scheduling additional clinics on a weekly basis simply to manage new referrals, in the last year the national standard of seeing 93% of all patients referred within two weeks has been missed with increasing frequency. Units have typically managed to see 85-90% of referrals within the two-week window – still the majority, but consistently below target levels.[33] Even those providers that were meeting the current access standard consistently told us that they felt they were at constant risk of not maintaining their performance.

The sheer volume of patients that providers are having to see in this short timeframe is placing an unsustainable strain on the system. Further, we heard that it is also leading to unnecessary levels of stress and anxiety amongst some patients, who perceive themselves to be suspected of having cancer, even though their age and symptoms make this extremely unlikely.

An opportunity to improve the referral process

It is very clear that the access standards in place in England must remain, as these are vital. They are recognised by clinicians in other countries that do not have such standards, including Scotland, as invaluable in delivering patient-centred care.

To ensure breast diagnostic teams can reliably meet the new 28-day FDS, we would like to take the opportunity to further streamline breast clinic referrals and access as well as standardise the assessment process. At the same time, changes need to be introduced that ensure we are providing more targeted support and assessment to patients with benign and normal conditions. This dual approach will benefit all breast patients, both new and existing, by releasing clinicians from spending such a high proportion of their time in assessment clinics, meaning they can dedicate more time to the care of patients with cancer.

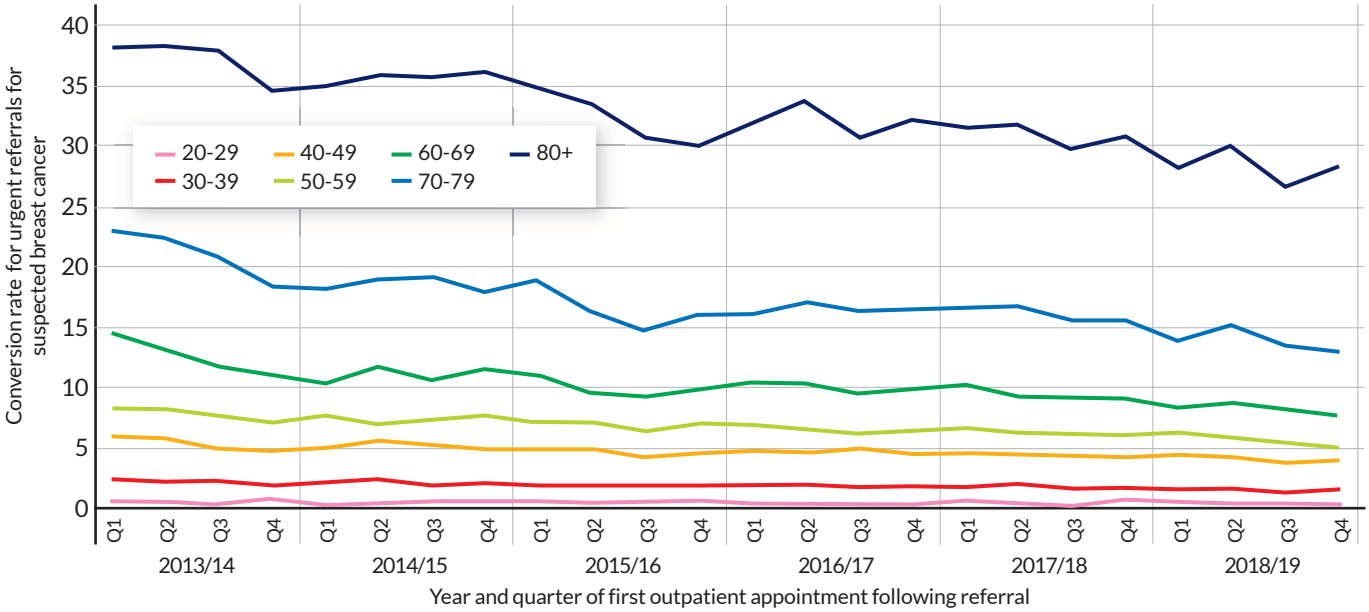
This is very much in line with the messages we heard in our deep-dive visits, where almost without exception, clinical teams wanted to simplify breast clinic access and standardise the assessment process to improve patient care. Based on the data, the feedback from providers and some of the innovative approaches already being adopted, we have identified a range of ways that should help to reduce the number of patients referred for urgent diagnosis, while providing a better service to all.

Improving support for GPs and primary care

We heard that the current dual-pathway 2WW referral process is leading to confusion amongst referrers. Further, when younger women are referred on what appears to be a cancer pathway, it is leading to unintended stress and anxiety. As Figure 6 shows, the proportion of younger women who have been referred and are then diagnosed with cancer remains very low. The growth in referrals of 30-49 year olds (shown in Figure 5 above) has not been matched by an increased conversion rate.

[33] *Full data available at www.england.nhs.uk/statistics/statistical-work-areas/cancer-waiting-times/*

Figure 6: Conversion rate of cancer diagnosis from all breast referrals by age, April 2013-March 2019



Source: National Cancer Registration and Analysis Service (NCRAS), Public Health England, March 2019.

These lower-risk people still need to be assessed and reassured they do not have cancer, but they do not need to experience the stress of an urgent cancer pathway. We believe there is a major opportunity to work with primary care and CGGs to simplify and optimise rapid breast clinic access pathways to better support patient care. We are aware, for instance, that in some areas, GPs must navigate multiple different referral pathways and triaging algorithms for symptomatic/urgent referrals; these could usefully be replaced by a single 28 day FDS breast referral pathway for suspected cancer, along with a second referral pathway specifically for other non-cancer related breast referrals such as gynaecomastia, family history assessment, transfer of follow up care etc.

CASE STUDY

Supporting assessment by GPs

Sherwood Forest Hospitals NHS Foundation Trust

Building on a pilot scheme developed by its neighbouring trust, the breast MDT at Sherwood Forest Hospitals NHS Foundation Trust has transformed the management of referrals across the East Midlands by implementing a comprehensive mastalgia (breast pain) pathway involving primary and secondary care.

Patients with breast pain are first assessed in primary care. If there are any signs or symptoms of potential cancer, they are referred to the hospital breast clinic. Those without signs of cancer then undergo a robust familial risk assessment, in the primary care setting. This assessment is based on NICE guidelines using the FaHRAS risk assessment software. Patients who are at population risk can be reassured and their breast pain managed within the primary care setting. Where, due to familial or other reasons the patient may be at higher risk, they are referred to an appropriate family history/genetic risk assessment clinic within secondary care.

This structured, consistent approach has been endorsed regionally and beyond by the East Midlands Expert Clinical Advisory Group (ECAG), the ABS and the East Midlands Primary Care Transformation Group. As well as reducing demand on secondary care services, it has helped to support best practice and address unmet needs by introducing a robust mechanism for identifying individuals at increased risk of familial breast cancer.

The full pathway is included as an example at Appendix B of this report.

Standardising assessment pathways

Once patients are referred from primary care, they can be managed more effectively using standardised assessment protocols stratified by age which is the most important predictive determinant of cancer risk. For example, in some units, women over 40 years can go straight to imaging, following an assessment process that effectively replicates the protocols used in the highly efficient NHS Breast Screening Programme.

In 2010, the ABS published *Best practice diagnostic guidelines for patients presenting with breast symptoms*;[34] this helped to define the appropriate breast tests for a variety of clinical situations. However, we found that breast assessment pathways, especially where cancer is not suspected, are variable across England. We believe it would be beneficial to establish a standardised evidence-based breast symptomatic diagnostic pathway – along the lines of the protocol-driven NHSBSP assessments – to ensure equality and consistency.

We are also aware that historically, payments to trusts were linked to clinic appointments – which led to some unnecessary complexities in pathways. The outpatient/diagnostic tariffs for 2020/21 have changed substantially; this should help to limit any unintended financial disincentives to best practice.

Introducing open access

Open access models are commonly used in follow-up after cancer treatment. However, during our deep dive visits, one or two innovative providers discussed the desirability of piloting open access breast assessment clinics. This would help avoid the situation that some clinicians described during deep dives, where some patients report feeling almost pressurised to attend a breast clinic within two weeks simply to help trusts meet their targets.

Maintaining the 'one-stop' standard

When patients are referred for either suspected breast cancer or breast symptoms, the optimal approach is a one-stop diagnostic service. In this approach, once referred to the hospital, patients are typically assessed by the breast diagnostic team made up of surgeons, advanced nurse practitioners, breast physicians, radiologists/radiographers and pathologists. Although traditionally everyone referred will have a clinical examination (CE) at the outset of the breast assessment process, for the vast majority of women who do not have cancer, CE has a low discriminatory value: consequently most women (90%), especially those over 40 also have either a mammogram and/or a breast ultrasound.

For the small number of people where imaging reveals a breast change, a biopsy is also required to exclude or confirm cancer. Together, these stages are known as a triple assessment. An audit conducted at The Royal Marsden NHS Foundation Trust found that about 10% of all patients referred will require a biopsy (i.e. the full triple assessment). However, the proportion of people undergoing biopsies is dependent on referral patterns, and patient demographics, especially age: at the Royal Surrey NHS Foundation Trust, 12.5% of under those of 50 and 19% of those over 70 required a biopsy, reflecting the fact than breast changes are more likely to be a cancer in the older age groups.

At the end of the one-stop clinic, most people can be offered a diagnosis. The overwhelming majority – at least 95% – do not have cancer, so can be reassured that no further action is required. However, a small proportion will require extra tests such as breast MRI, CT scans, and/or further biopsies, especially if a cancer is suspected or diagnosed.

This one-stop rapid diagnostic approach used for breast referrals is the model for other suspected cancers and complex diagnoses. We understand that clinicians in other countries regard it as an exemplar of diagnostic care and seek to emulate it.

In our questionnaire, we asked trusts how often they provide a full one-stop service. Responses indicated that in over 30% of cases, trusts have diluted the service in a bid to maintain the access standard in the face of increasing demand. Instead of the desirable one-stop service, some have introduced a system where the patient has their initial appointment within the target access standard of two weeks, but is then required to return for subsequent appointments for tests that previously were (and ideally would be) done on the same day. This not only inconveniences the patients and creates additional work for the provider; it also adds clinical risk to the whole assessment process.

[34] *Association of Breast Surgery (2010) Best practice diagnostic guidelines for patients presenting with breast symptoms. PDF available at www.evidence.nhs.uk/document?id=2013590&returnUrl=search%3Fq%3Dhc11%26sp%3Don&q=hc11*

Further research

While we believe that the one-stop, triple assessment model represents a high-quality, reliable and efficient service, especially for those with cancer (or suspected cancer), it should be open to change and continued evidence-based evolution to ensure future best practice and sustainability.

In particular, there is an urgent need to modernise and streamline breast assessment to better support the majority who do not have cancer, for example by evaluating the utility of (pre-imaging) history taking and clinical examination, evaluating the utility of breast ultrasound and biopsies in low risk individuals and identifying people who do not require any breast tests.

It will be essential to audit the effectiveness and safety of new assessment models.

As expectations of care continue to grow, the views of those referred, especially those without disease, remain important. It would be of benefit to understand where digital technologies could play a greater role in the referral and assessment process and to explore differences in views between different age and demographic groups.

Focusing on public health

We need to promote breast **health** awareness, so that we empower people to manage their breast health effectively. There are two particular concerns that emerged from our deep-dive visits and data analysis:

- a growing number of younger women who have a breast problem or concern, are entering a cancer referral pathway, even though their likelihood of having cancer is very low;
- among the over 60s, who have higher cancer conversion rates, there has only been a modest increase in referrals.

Both concerns indicate that there may be a gap in public understanding of the ages at which women are at greatest risk of breast cancer. They also create additional issues; for instance, younger women may be highly stressed by being placed on a cancer pathway, while in an ageing population, we appear not to be reaching older at-risk women sufficiently with current public health initiatives. More work needs to be done to target age groups at higher risk of cancer (over 60 years of age) – as well as those in other harder to reach at-risk groups – with more relevant/specific breast cancer awareness information.

We also need to explore mechanisms other than a cancer referral pathway to support younger women worried about their breasts. For example, it is normal for the breast to change throughout the menstrual cycle, and whilst period pain is accepted as a normal part of the monthly female cycle, breast pain, also a normal symptom of the monthly cycle, is interpreted as a sign of cancer and is one of the most common causes for referral and unnecessary tests. We know that organisations such as Breast Cancer Now do include such messaging on their website; while this is clearly important, these organisations primarily exist to support those with, or who are concerned that they might have, breast cancer. Our view is that this information needs to be more widely available, outside of discussions or concerns around cancer. Tools such as the RM Partners breast pain video, where a GP provides information about breast pain and possible causes other than cancer, can be a great asset.[35]

Information about how the breasts can be affected during the menstrual cycle could be usefully incorporated into the growing number of period tracking apps that are available. We are also keen to explore how we can work with organisations such as charities to raise breast health awareness.

The huge spikes in referrals following national public health campaigns such as Be Clear on Cancer, and following high-profile women being diagnosed with breast cancer, serve to demonstrate how effective such campaigns can be. We believe they should be harnessed not only for breast cancer awareness, but for breast health awareness. In our deep-dive visits, we also met trusts that have introduced highly targeted local public health campaigns, in particular for addressing hard-to-reach groups.

[35] *Available at https://youtu.be/v0FkthTQggc*

CASE STUDY

Increasing breast health awareness among hard-to-reach groups

St Helens and Knowsley Teaching Hospitals NHS Trust and University Hospitals of North Midlands NHS Trust

Breast cancer is considered a taboo among people belonging to certain ethnic minority groups and this may prevent women with breast symptoms from seeking medical advice. These women often present with locally advanced breast cancer at a young age. One of the contributing factors for the late presentation is the lack of breast awareness. Aware of this issue, consultants from two different trusts – St Helens and Knowsley Teaching Hospitals NHS Trust and University Hospitals of North Midlands – independently identified a need to reach out to these women and raise awareness.

The approach taken was similar: the trusts chose to approach women from socio-economic deprived areas and arrange sessions at a place where women would congregate to worship or attend communal activities.

Breast cancer awareness sessions were conducted in collaboration with the local primary care providers and the local screening programme. The first events were in Manchester (Cheadle) and in Stoke-on-Trent. These sessions covered information on breast symptoms and screening, self-examination and support groups. Information was provided in different languages and a particular emphasis was made on the importance of self-examination and that early breast cancer has excellent prognosis. A young breast cancer survivor from the same community shared her treatment experience at one of the events and encouraged women to teach their daughters to examine themselves.

Women who attended the awareness session found it extremely helpful and the local GPs were also very impressed. Through the GIRFT programme, the two teams were put in contact and now plan to work together to conduct similar sessions in other areas.

Putting patients in control

Finally, we want to work with willing providers and healthcare 'innovators' to pilot novel referral and assessment pathways, exploring the use of technology to support education at the point of contact, so putting the individual firmly in control of their access to breast services.

One such example is the work of the RM Partners[36] early diagnosis group (with GIRFT support) in developing a simplified referral form. This referral form was approved for use by the NHS England London Clinical Advisory Group during the COVID-19 pandemic. It is included as Appendix A to this report.

In addition, RM Partners is exploring how to support the 28-day FDS by streamlining the assessment process. The plan is to explore two distinct age-stratified assessment pathways based on current triple assessment patterns:

- Because all women **over 40** who are referred will usually have imaging as part of their assessment, this group are sent to imaging first (mammogram and/or ultrasound, as required) and the subsequent clinical assessment would then follow a model similar to that used in the NHS Breast Screening Programme, including clinical examination as required or if there is non-concordance.
- Women **under 40** will follow one of two routes:
  - those with breast pain only (who are at very low risk of breast cancer) would initially be redirected to digital information and educational resources around breast health – including details on the normality of breast pain – before initiating any secondary care referrals and so triggering the requirement for a diagnosis within the 28 day FDS;
  - those with other breast problems would be seen for CE with further imaging assessment (e.g. ultrasound) determined by symptoms.

This approach promises a better patient experience, with more streamlined and risk appropriate assessment pathways. It would also facilitate faster diagnosis for all.

Such models are in development and need to be applied selectively and in consultation with patients. However, they potentially offer patients more choice and control over their care and treatment.

[34] *RM Partners is the West London Cancer Alliance, hosted by The Royal Marsden NHS Foundation Trust. https://rmpartners.nhs.uk/*

The primary aim of our recommendations is not to reduce the total number of referrals – systems are now in place to manage large volumes of referrals – but to redesign breast clinic access around the individual, especially those at low risk of cancer, by providing targeted information and advice to empower future self-management where appropriate.

In addition, we recommend streamlining the assessment process (through innovation and evaluation of different assessment models) to support the 28 day FDS for all referrals.

Such changes will increase the specialty's capacity to meet the 28 day FDS.

Recommendation	Actions	Owners	Timescale
Core Recommendation **1.** Ensure that new breast patient referral and assessment pathways are timely and centred around the individual with the aim of providing the best outcomes and experience.	**a** Provide primary care support and guidance to allow best use of the access pathway.	Trusts / commissioners / Cancer Alliances	For immediate action
	b Ensure that access and assessment pathways are evidence-based, risk-adapted and standardised to support safety and cost efficiency.	Trusts / commissioners/ Cancer Alliances	For immediate action
	c Redesign and pilot breast clinic access (referral) and assessment pathways to further reduce barriers to early diagnosis, support the Faster Diagnosis Standard and allow patient choice. Ensure new ways of working are audited.	Trusts / commissioners / Cancer Alliances	For immediate action
	d GIRFT to work with specialty associations and Cancer Alliances to identify the workforce requirements associated with pathway redesign.	GIRFT to work with specialty associations and Cancer Alliances	For immediate action
	e Ensure that breast MDTs have a link to a plastic surgeon.	Trusts / commissioners / Cancer Alliances	For immediate action
2. Support better self-management through public health messaging at both national and local levels which emphasises breast health and targets breast cancer awareness messages at those at greatest risk.	**a** Ensure that public health messaging focuses on harder to reach groups (e.g. older age, BAME) in regard to breast health and awareness to encourage early healthcare engagement for any breast issues.	GIRFT to work with breast cancer charities, patient groups and primary care	For completion within 24 months of publication of the GIRFT report
	b Support and promote breast health awareness in the younger age groups.	GIRFT to work with breast cancer charities, patient groups and primary care	For completion within 24 months of publication of the GIRFT report
	c Align and collaborate with other health education initiatives aimed at supporting better understanding of women's and men's health.	GIRFT	For completion within 24 months of publication
	d Develop educational tools and materials to support public health messaging as outlined in the NHS Long Term Plan.	Primary care, NHS England and NHS Improvement, with support from relevant specialty associations	For completion within 24 months of publication of the GIRFT report

Reducing unnecessary follow-up outpatient attendances

The majority of new breast referrals are discharged after the rapid diagnostic clinic assessment confirms all is well. This means the majority of other outpatient appointments are for follow-up after cancer or breast reconstruction surgery.

In total, over the three-year period from April 2014 to March 2017, the NHS provided more than 400,000 outpatient appointments to people within a year of their breast excision.

However, this covered a range of procedures, from excision of a benign lesion to cancer surgery. The national average number of follow-up appointment after a benign excision is 1.77, but the need for any follow-up after this sort of surgery should be minimal.

Excisions for cancer have on average 4.1 follow-up attendances in the first year after surgery and an average of 7.03 over five years. But there was considerable variation between trusts, with the average number of follow-up appointments ranging from 3.1 to 13.9.

The tables below show follow-up data from two trusts with similar numbers of admissions – one with a low average number of follow-up appointments and the other at high end of the spectrum. (To clarify, these are not follow-up appointments based on the admissions above; the number of admissions is used simply as an indicator of overall surgical workload, to facilitate the comparison in follow-up activity.)

Table 1a: Trust A - Comparison of follow-up activity between two trusts with similar admission levels

Metric	Source/ Period	Breast excisions	Mastectomy	Mastectomy and immediate reconstruction		
				Implant-only	Implant+flap	Autologous
No. of admissions	HES Apr 2014-March 2017	730	150	50	29	2
Outpatient follow-up						
Average number of outpatient attendances within breast surgery, plastic surgery or general surgery within 5 years of the index procedure	HES Apr 2009-March 2012	3.86	7.81	12.57	15.43	N/A

Source: HES

Table 1b: Trust B - Comparison of follow-up activity between two trusts with similar admission levels

Metric	Source/ Period	Breast excisions	Mastectomy	Mastectomy and immediate reconstruction		
				Implant-only	Implant+flap	Autologous
No. of admissions	HES Apr 2014-March 2017	657	174	92	6	27
Outpatient follow-up						
Average number of outpatient attendances within breast surgery, plastic surgery or general surgery within 5 years of the index procedure	HES Apr 2009-March 2012	13.44	22.84	27.64	N/A	31.60

Source: HES

The concern emerging from deep-dive visits is that this variation is not always driven by patient need or choice, but rather by provider practice.

The NHS Long Term Plan set out a proposed model of follow-up care across all cancers.

'After treatment, patients will move to a follow-up pathway that suits their needs, and ensures they can get rapid access to clinical support where they are worried that their cancer may have recurred.'[37]

It further specifically stated that such an approach 'should be established in all trusts for breast cancer in 2019'. In support of this, in April 2020 NHS England and NHS Improvement published a handbook to help local health and care systems implement personalised stratified follow-up pathways for cancer patients.[38] This reiterated that breast cancer should be in the first wave of the move towards personalised, stratified follow-up for the majority of patients.

Many breast cancer services have already adopted such a model, typically supported by regular breast imaging (usually for five years after cancer treatment). However, for personalised, stratified follow-up to be effective, it is essential that:

1. patients are given sufficient information about 'red flag' indicators of cancer relapse, possible treatment side-effects, and the signs and symptoms of secondary breast cancer so that they know when to raise concerns. This can be provided as part of a written care plan, as recommended in NICE guideline NG101 Early and locally advanced breast cancer: diagnosis and management.[39]
2. trusts have sufficient flexibility and capacity in their outpatient services so that cancer patients with concerns can be swiftly accommodated and holistic needs assessments provided: one provider guarantees appointments within five working days of the patient raising concerns.
3. trusts have robust, up-to-date and digital Remote Monitoring Systems for patients on a personalised stratified follow-up pathway with 'call and recall' and 'right-results' systems (comparable with the NHSBSP) for the yearly surveillance mammograms and MRIs. In addition, these systems must be able to support virtual MDTs to review and update treatment plans based on new research and drugs. The patients can then be contacted and offered the latest treatments.

The NHS England and NHS Improvement handbook provides further guidance on principles, protocols and enablers of personalised stratified follow-up.

Providers have told us that moving to a personalised stratified follow-up model has released sufficient clinic capacity to allow a more thorough and detailed review of patients concerned about treatment side-effects or cancer recurrence.

It is important that trusts are given the practical and financial support needed to move to more flexible models of outpatient care. The set-up process, technology and change in team working is complex and daunting: consequently, some trusts have struggled to find the time and resources to evolve their follow-up services. One productive approach to addressing these challenges is through Cancer Alliances, who are able to pool resources and expertise to make personalised stratified follow-up work on a regional level.

There have also been issues with tariffs, with trusts concerned that they could lose out financially if they reduced face-to-face outpatient appointment numbers. It is hoped that recent changes to tariffs will address this.[40] It is now imperative that these changes are clearly and consistently communicated to trusts, so that these concerns can be allayed.

We know there is currently a drive across the NHS to rethink outpatient care, in line with the commitments made in the NHS Long Term Plan. We believe there is an opportunity to align with the work of the Outpatients Transformation Programme to share best practice and address barriers to change.

[37] *The NHS Long Term Plan (2019) para 3.65 www.longtermplan.nhs.uk/*

[38] *NHS England and NHS Improvement (2020) Implementing Personalised Stratified Follow Up Pathways www.england.nhs.uk/wp-content/uploads/2020/04/cancer-stratified-follow-up-handbook-v1-march-2020.pdf*

[39] *See NICE (2018) NG101 Early and locally advanced breast cancer: diagnosis and management section 1.13 www.nice.org.uk/guidance/ng101/chapter/Recommendations#followup*

[40] *See 2019/20 National Tariff Payment System https://improvement.nhs.uk/documents/4980/1920_National_Tariff_Payment_System.pdf paragraphs 95-96*

CASE STUDY

Personalised stratified follow-up

Manchester University NHS Foundation Trust

Manchester University NHS Foundation Trust (MFT) has worked with MacMillan Cancer Support to introduce a personalised stratified follow-up model for breast cancer patients following breast cancer treatment.

In MFT the service is known as BREAMO (an abbreviation of Breast Moving On) and combines all aspects of aftercare, in relation to monitoring cancer outcomes and patients' general wellbeing. If patients become concerned about their breast health, telephone triage allows rapid re-access.

Since BREAMO was piloted in 2016, it has proved extremely successful. Over 1,300 patients have taken part and 98% have stated they now feel they can move on. BREAMO has resulted in a reduced number of face-to-face follow-up appointments – freeing up around 400 consultant appointments a year to focus on new patient referrals. Patients report improved self-confidence, satisfaction with managing their own health and enhanced quality of life. Primary care healthcare professionals also feel more empowered to manage people living with cancer.

The Pennine Acute Hospitals NHS Trust, another large provider of breast care in Manchester, has adopted a similar scheme with outcomes consistent with those described above.

Recommendation	Actions	Owners	Timescale
3. Reduce unnecessary outpatient attendances for follow-up.	**a** Trusts to complete or implement the introduction of personalised stratified follow-up.	Trusts / commissioners	For completion within 12 months of publication of the GIRFT report
	b All trusts to have robust, up-to-date and highly digital Remote Monitoring Systems for patients on a personalised stratified follow-up pathway with 'call and recall' and 'right-results' systems or capabilities.	Trusts	For completion within 12 months of publication of the GIRFT report

Increasing the use of day surgery and reducing length of stay

Statement of principle

No breast surgery patient should stay in hospital longer than is medically necessary.

Only a minority of breast surgery procedures require long stays in hospital; many operations can be completed and patients discharged within a day, as long as they have sufficient support available. This includes the majority of breast excisions, including those for cancer, as well as mastectomies and, in a handful of innovative units, some immediate implant-based reconstructions.

For excisions, there is already a strong trend towards day surgery. Nationally, over 70% of breast excisions in cancer patients are conducted as day surgery, rising to 92.85% in non-cancer patients.

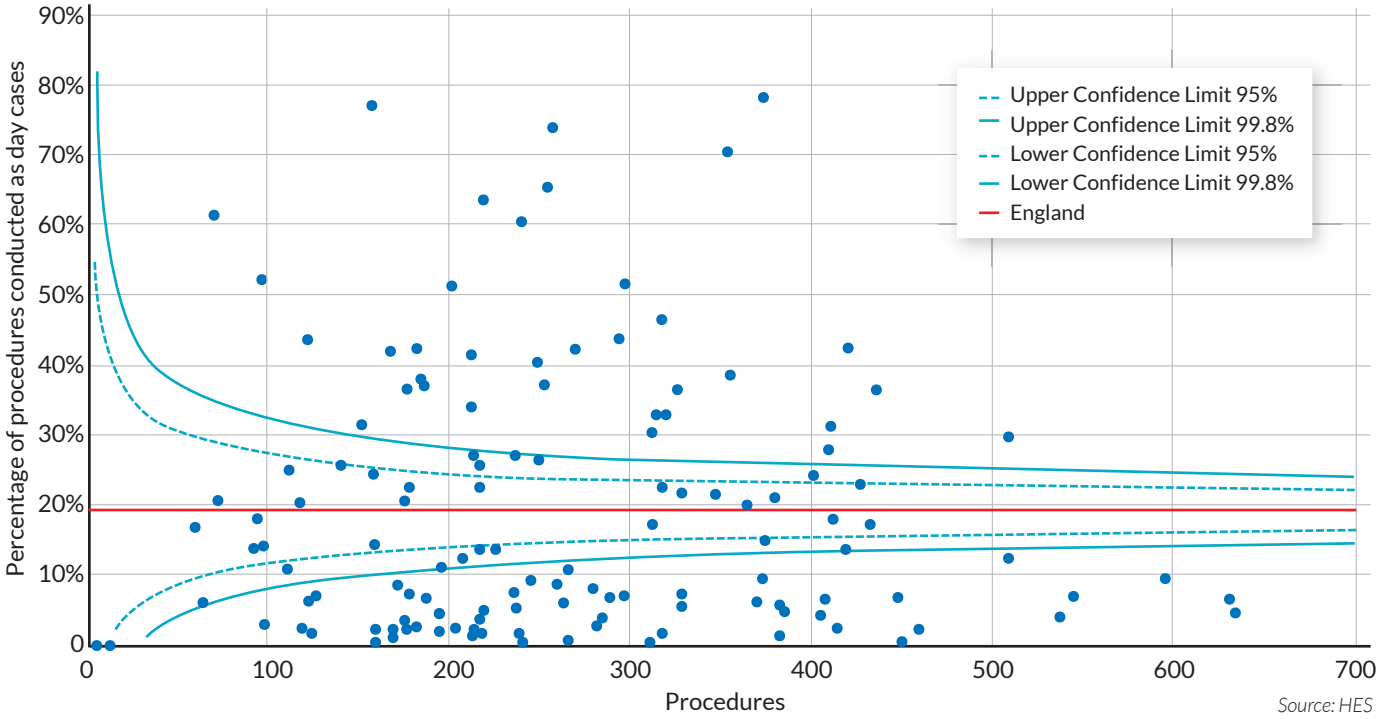
The British Association of Day Surgery (BADS) recommends that 95% of breast excisions could be conducted as day cases.[41] This includes excisions which also involve axillary surgery. We believe there is an opportunity for all providers to reach this rate.

To achieve this, providers with lower rates may need to address admissions and discharge procedures, ensuring that they are aligned with the goal of day surgery. During our deep-dive visits to units with higher day case rates, the breast care nurses observed that patient selection, early information and education about the benefits of day surgery, with management of expectations, was key to improving day case rates.

Day surgery mastectomy

While the majority of excisions are now conducted as day cases, for mastectomies the picture is much more varied. The national average (mean) day case rate for mastectomy with no immediate reconstruction was 19.13%. However, as Figure 7 demonstrates, the rates varied widely, from 0% to 78.28% across trusts.

Figure 7: Percentage of mastectomies with no immediate reconstruction conducted as day cases, 1 April 2015-31 Mar 2018



Source: HES

[41] *British Association of Day Surgery (2019) – Directory of Procedures (6th edition) available at: https://daysurgeryuk.net/en/shop/directory/bads-directory-of-procedures-6th-edition*

Just eight providers conducted more than 60% of mastectomies as day cases; almost half conducted 10% or less as day cases. This latter group includes the five providers that carry out the highest volumes of mastectomies with no reconstruction.

Some of this variation will be a result of data capture issues. However, the degree of variation strongly suggests a divergence in practice between providers; it would appear that those with rates under 10% only rarely consider carrying out the procedure as a day case.

BADS recommends that up to 75% of mastectomies, including mastectomies where there is also an axillary procedure, could be conducted as day cases.[42] Only three providers currently appear to be reaching this level – but they are experiencing no detriment to patient care as evidenced in the deep dive data pack complication metrics.

While 100% day case rates would not be achievable – some patients need to stay in for medical or social reasons – there is a major opportunity for change here. Unlike with excisions, where most teams now appear prepared to conduct the procedure as day cases, there would need to be a shift in culture and practice to conduct more mastectomies as day surgery. This would involve the whole team; not only the surgical and anaesthetic team but also nursing, preoperative assessment teams and administrative staff. BADS has recently published updated guidance for the use of day case pathways for all types of breast surgery, including many oncoplastic and reconstructive procedures; this can be a useful place to start.[43]

CASE STUDY

Day surgery as default

Bolton NHS Foundation Trust

At Bolton NHS Foundation Trust, the majority of non-reconstructive breast surgery takes place on a well-established day case pathway. The pathway was introduced in 2013 for wide local excisions (WLE); now over 90% of WLEs are conducted as day surgery, as well as over 70% of mastectomies. The approach has consistently received positive feedback from patients.

The pathway involves the entire multidisciplinary team (MDT) from HCAs to surgeons and anaesthetists. Once a patient is identified as needing surgery, they are informed it is likely to be undertaken as a day case. The pre-operative appointments provide detailed information about planned discharge and physiotherapy; patients are even fitted with a post-mastectomy bra and prosthesis pre-operatively.

To improve post-operative pain control and decrease post-operative nausea, interpectoral nerve blocks are used and surgeons are encouraged to use drains for reconstructions only. There is a dedicated four-bed bay on the ward for day cases, and the nurse looking after the day case patients should not also be looking after inpatients or emergency admissions. This enables the nursing staff to prioritise preparing day case patients for home. Patients are encouraged to start walking around the ward by the second hour after surgery, and within three hours the majority can be discharged.

There is then a well-established comprehensive post-operative support service, where concerned patients can contact the breast team directly, for review by specialist nurses the same day.

Reconstruction as day surgery – the future?

A further opportunity lies in conducting some immediate implant-based breast reconstruction as day surgery. Any reconstruction of course increases the complexity of the operation so, with current techniques, only a small proportion of patients undergoing implant-based reconstruction can be considered for day surgery.

However, we did find a small number of pioneering breast surgery teams conducting day case breast reconstruction. These included teams at The Royal Wolverhampton NHS Trust, Milton Keynes University Hospital and the Countess of Chester Hospital to name just a few. The volumes are low (usually less than 10% of implant-based reconstructions) and focused almost exclusively on patients having pre-pectoral fixed volume implant-based reconstruction. We have encouraged these units to link and share experiences with the aim of developing a standard operating procedure or toolkit that may be useful for other units considering moving towards day case reconstruction for selected patients.

[42] *British Association of Day Surgery (2019) – Directory of Procedures (6th edition) available at: https://daysurgeryuk.net/en/shop/directory/bads-directory-of-procedures-6th-edition*

[43] *See British Association of Day Surgery (2020) - Day Case Breast Surgery, available at: https://daysurgeryuk.net/en/shop/handbooks/day-case-breast-surgery/*

Minimising length of stay following breast reconstruction

There is also an opportunity to reduce overall length of stay for reconstructive procedures.

The table below shows the national average (median) length of stay (LoS) in hospital following three common breast surgery procedures, with the national lower and upper quartile length of stay. Stay in hospital over the upper quartile is deemed a long LoS.

Table 2: Length of stay for three breast reconstruction operations, April 2015-March 2018

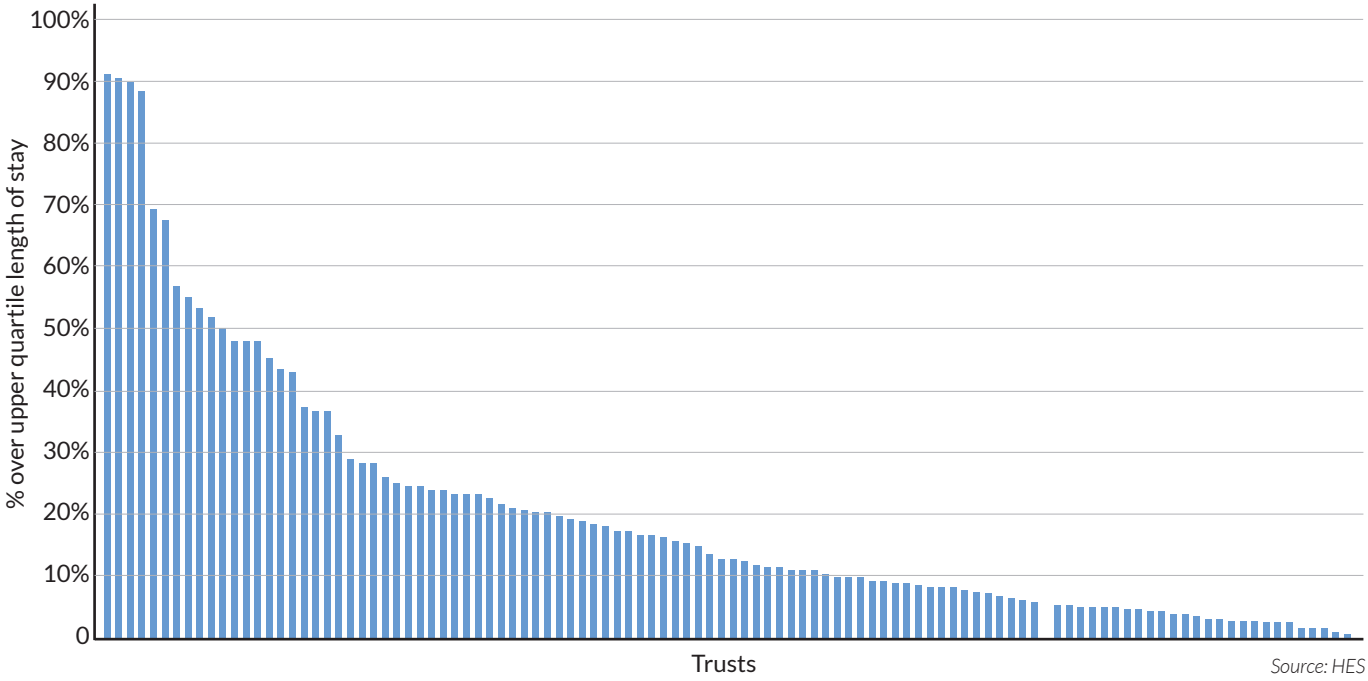
Procedure	Lower quartile LoS	National average LoS	Upper quartile LoS
Mastectomy, no immediate reconstruction	1 day	1 day	2 days +
Mastectomy with implant-only reconstruction	1 day	2 days	3 days +
Mastectomy with free flap reconstruction	5 days	6 days	7 days +

Source: HES

Immediate implant-only reconstruction

For immediate implant-only reconstruction nationally, just under 20% of patients have a long LoS (more than three days). But when looked at by trust (Figure 8), there is marked variation in the proportion of patients that have a long LoS: the majority of trusts have fewer than 20% of patients having a long LoS, but at six providers more than 60% of patients stay in hospital for more than three days for the same procedure.

Figure 8: Percentage of patients who have a long LoS following mastectomy and immediate implant-only reconstruction, April 2015-March 2018



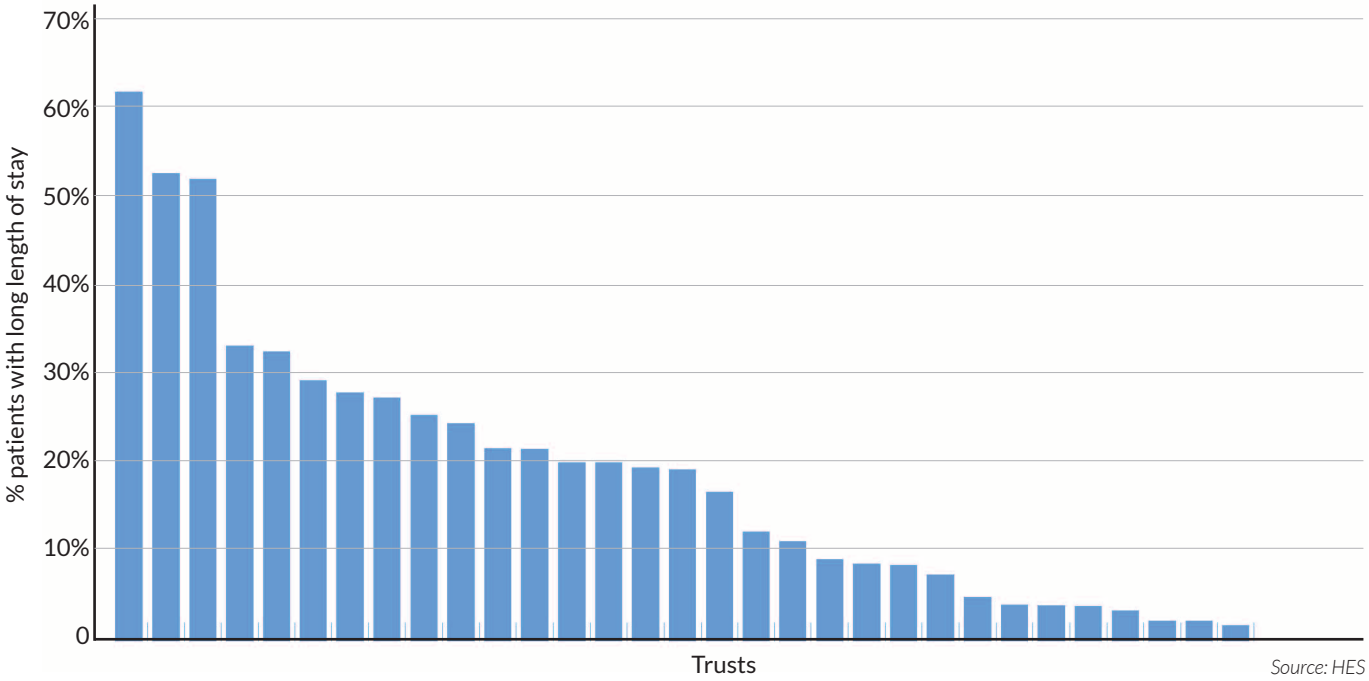
Source: HES

Trusts with fewer than 10 operations in the denominator have not been displayed on the chart.
Long length of stay is defined by the national upper quartile length of stay for patients undergoing the procedure during the time period.
The national upper quartile length of stay was seven days for mastectomy and immediate free flap construction.

Immediate free flap reconstruction

For immediate free flap reconstruction nationally, just over 17% of patients have a long LoS (more than seven days). But, as for implant-only reconstruction, when looked at by trust (Figure 9) there is marked variation in the proportion of patients that have a long LoS.

Figure 9: Percentage of patients who have a long LoS following mastectomy and immediate free flap reconstruction, April 2015-March 2018[44]



Source: HES

Trusts with fewer than 10 operations in the denominator have not been displayed on the chart.
Long length of stay is defined by the national upper quartile length of stay for patients undergoing the procedure during the time period.
The national upper quartile length of stay was seven days for mastectomy and immediateimplant reconstruction.

Shorter length of stay is not associated with higher complications or readmissions

GIRFT data analysis found that units with shorter stays did not show adverse complication rates such as higher readmissions or returns to theatre. While there are invariably some patients who will need to stay in hospital for longer for any procedure – perhaps because of a co-morbid condition, which necessitates additional monitoring, or because of a complication during surgery – these exceptions did not account for the variation we saw in length of stay. The variation is sufficiently extensive to indicate that some providers have not adopted recommended guidelines on enhanced recovery or developed a short stay ethos; their longer LoS is simply a matter of established practice.

[44] *There are fewer columns in figure 9 than figure 8, because free flap reconstruction is available at fewer providers than implant reconstruction.*

CASE STUDY

Lowering length of stay for free flap breast reconstruction

Queen Victoria Hospital NHS Foundation Trust

The multidisciplinary breast reconstruction team at Queen Victoria Hospital NHS Foundation Trust has worked hard to develop an Enhanced Recovery After Surgery (ERAS) pathway for free flap breast reconstruction patients. Patients having unilateral or bilateral, immediate or delayed breast reconstructions all follow the same ERAS pathway, no matter what type of flap reconstruction is being used.

During 2019-20, the QVH team performed 355 free-flap breast reconstructions for 294 women. 44% of these cases were immediate reconstructions, performed at the same time as mastectomies. During this period, the mean length of stay for QVH free-flap breast reconstruction patients was 3.6 nights – down from a trust average of five nights before the introduction of ERAS and substantially lower than the national average length of stay of six nights following a free flap reconstruction. In 18% of cases, patients were discharged after just two nights in hospital.

Crucially, outcomes have remained very good throughout: the total failure rate was just 0.6%, well below national averages. With focused pre-operative education, and an active post-operative recovery regime, patient feedback is extremely positive.

Learning from deep dives

During deep-dive visits, we asked providers about their discharge planning practices for immediate breast reconstruction. At one higher-volume free flap provider, the standard practice is that patients remain in hospital for up to seven days simply so the breast surgery team can retain the bed for the next patient. The unit felt this was the only way they could continue to provide high volumes of immediate reconstruction for the region: this is undesirable for patients, providers and the wider NHS. The clinical team expressed deep frustration at their inability to alter the situation despite many attempts.

In a different unit, the reconstruction surgeons were less experienced and preferred to 'watch over' their patients – again leading to longer LoS. In another service, patients were kept in hospital until the drains were removed, as there was no community nursing support which could allow this to be done after patients had been discharged.

Taken as a whole, these explanations for long LoS related to logistical and/or process issues rather than patient factors. This indicates they are all addressable, with appropriate support and help.

Reducing length of stay in breast reconstruction

We believe there is a good opportunity to improve long LoS in breast reconstruction: allowing the majority of patients to be discharged sooner and also freeing up resources. Trusts may wish to compare practices with their peers and neighbours, to identify quick wins; this is also a topic that other GIRFT workstreams have looked at and recommended simple, practical changes to provider policies that can shorten length of stay.

Further, our benchmark data suggests there is good scope for substantially reducing overall LoS, not just long LoS for immediate reconstruction. However, in the first instance, it is reasonable to set the long LoS standard as no more than 20% of patients should stay longer than three days for immediate implant-based reconstruction and seven days for free flap reconstruction, with a target of two days and six days respectively. These targets should be reduced further in time and this can be monitored on the Model Hospital platform.

Recommendation	Actions	Owners	Timescale
4. Ensure that no breast surgery patients stay in hospital longer than is medically necessary.	**a** Increase day surgery rates for key index procedures to meet or exceed BADS target of 95% for simple breast excision and 75% for both oncoplastic excisions and mastectomy.	Trusts	For completion within 12 months of publication of the GIRFT report
	b Reduce median* and long length of inpatient stay for breast reconstruction by, for example, introducing enhanced recovery programmes with the aim of enabling patients to return home sooner. **In regard to implant-based reconstruction, the GIRFT benchmark is a median of two days, with less than 20% of patients at three days or more. In regard to free flap reconstruction, the GIRFT benchmark median is six days, with less than 20% of patients staying seven or more days.*	Trusts	For completion within 12 months of publication of the GIRFT report
	c Trusts to consider day case surgery for selected patients undergoing mastectomy and implant-based reconstruction, if deemed appropriate for the patient.	Trusts	For completion within 12 months of publication of the GIRFT report

Improving breast surgery patient outcomes and experience

Maximising safe breast conservation

Statement of principle

Patients should have access to the full range of oncoplastic breast conservation techniques to support the best cancer and aesthetic outcomes.

As noted earlier, there are two fundamental approaches to surgery for breast cancer: wide local excision (WLE), which allows the breast to be conserved, and mastectomy. It is not always oncologically safe to conserve the breast. However, when employed appropriately, both methods are equally effective at treating cancer.

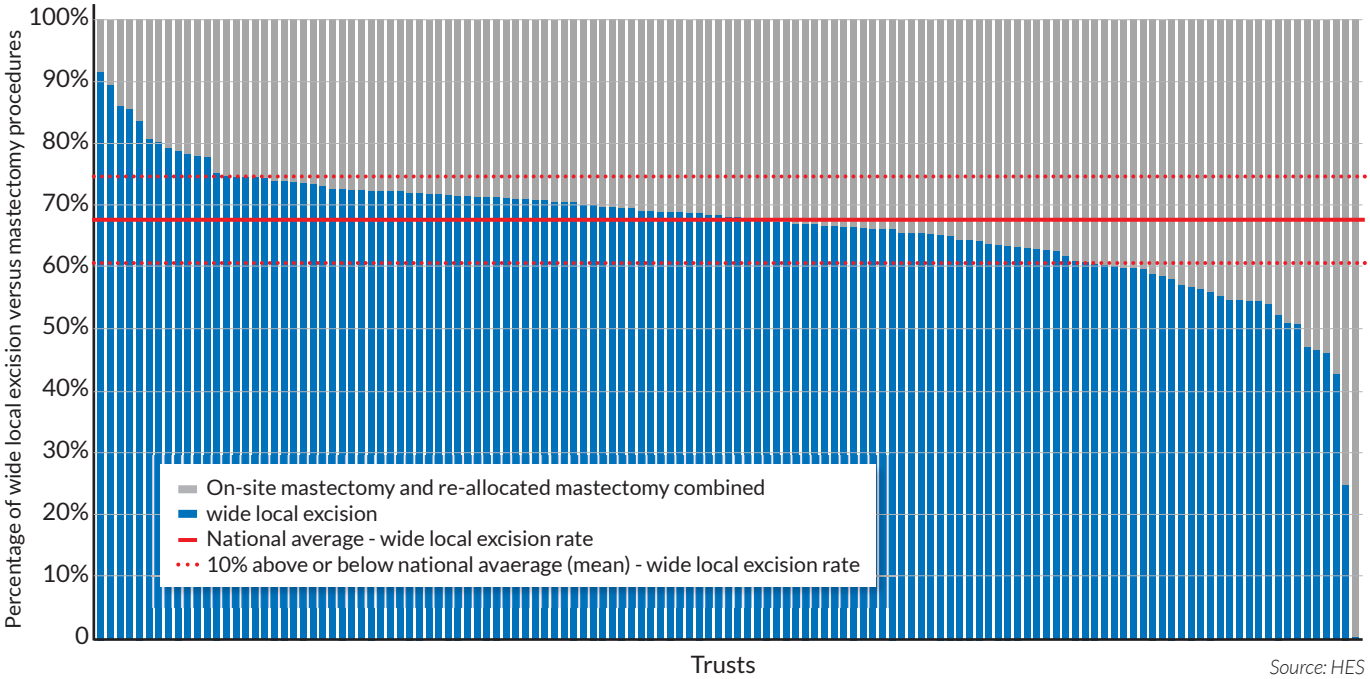
Breast conservation has several aesthetic and psychological benefits compared to mastectomy and as a result is increasingly regarded as the default position where it is safe and clinically appropriate. Consequently, clinicians should offer breast-conserving surgery – i.e. WLE, rather than a mastectomy – whenever it is oncologically safe and aesthetically feasible.

However, the prime guiding factor in whether to opt for breast-conserving surgery or mastectomy should be patient choice; we see it is essential that patients have a ***genuine*** choice, that is not restricted by local resources, and that they are given sufficient balanced information to make an informed choice about what is best for them. Previous research has shown that surgeon and team views and preferences towards or against a mastectomy can exert a strong influence on the patient's decision-making.

Examining variation in breast conservation rates

At a national level, between April 2015 and March 2018, 68.5% of breast cancer patients who underwent breast cancer surgery received a WLE as their first operation

Figure 10: First surgery method for breast cancer patients by trust, April 2015-March 2018



Source: HES

The available data shows variation in breast conservation rates from a broad norm (+/-10% from the national average). However, the extent of variation is narrower than most other surgery metrics we reviewed. If we exclude providers of a regional or tertiary immediate breast reconstruction service (who therefore have inflated mastectomy rates) this variation is less pronounced. This suggests most breast MDTs are supporting breast conservation wherever appropriate.

Access to oncoplastic breast conservation surgery

The need for mastectomy is likely to decline over the next decade, as MDTs:

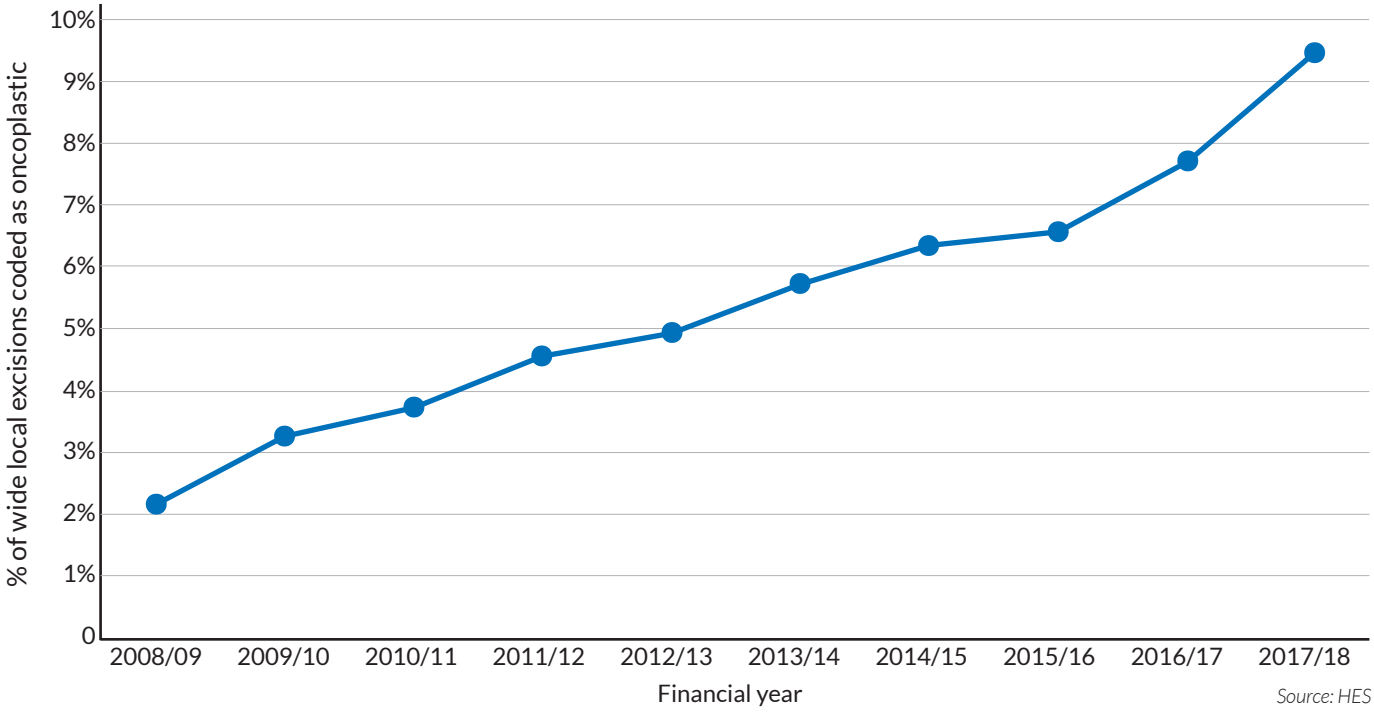
- continue to improve and provide the information and decision-making tools to allow patients to make an informed choice regarding conservation and mastectomy;
- maximise the appropriate use of anticancer drugs before surgery (neoadjuvant therapy), to reduce the size of the cancer which in turn facilitates conservation;[45] and
- provide equity of access to modern oncoplastic conservation surgery techniques.

Some studies have shown that chemotherapy before surgery can eradicate up to 70% of cancers in some patients. The use of, and access to, neoadjuvant chemotherapy (NACT) and risk-adapted conservation surgery was not considered in this report as we did not have access to the necessary cancer data to examine it.[46]

Modern oncoplastic conservation uses plastic surgery techniques such as breast reduction and/or uplift to allow the removal of larger or multiple areas of cancer so conserving the breast and providing a good aesthetic result (therapeutic mammoplasty).

Figure 11 below shows that the percentage of WLEs that also contain an oncoplastic code (such as the B31 codes – other plastic operations on breast) is steadily and consistently increasing. But this is likely to be an underestimate of the true incidence of oncoplastic breast conservation surgery, as many units we visited felt the HES data did not reflect their true oncoplastic conservation rates. This was usually because they did not capture oncoplastic conservation under the relevant mammoplasty OPCS codes.

Figure 11: Percentage of WLEs coded as oncoplastic by year, April 2008-March 2018



Source: HES

[45] *For further information on this, see NICE (2018) NG101 Early and locally advanced breast cancer: diagnosis and management section 1.11 Primary systemic therapy www.nice.org.uk/guidance/ng101/chapter/Recommendations#primary-systemic-therapy*

[46] *This is an important area for further analysis in the future, once there are more established links between HES and NCRAS data.*

However, not every unit we visited had the necessary skill mix to provide a full range of oncoplastic techniques. About 20 units had no recorded breast conservation/WLE procedures coded as oncoplastic; at the other end of the scale, 20 units recorded over 10% of their WLE as therapeutic mammoplasties, with four units achieving over 30%. This lack of skills means that not all women who could achieve safe breast conservation using oncoplastic techniques are offered it as an option. Many may even be unaware of this option.

Providers need to know and monitor their conservation and mastectomy rates, and be able to compare rates with other providers with similar patient demographics and cancer stages. This will be possible through the Model Hospital in the future.

Crucially, providers must ensure that patients do not miss out on the option of breast-conserving surgery as a result of a lack of access to oncoplastic conservation techniques.

Improving breast reconstruction access and choice

Statement of principle

Every woman should have access to the right reconstruction, for her, at the right time.

Breast reconstruction: background

In guidance published in 2018, NICE recommended that breast reconstruction should be offered to all patients having a mastectomy and that all options should be discussed. Table 1 of the guidance acknowledges that *'Not all hospitals or surgeons can offer all procedures. Travel to a different hospital may be needed for a specific option.'* [47]

Reconstruction is most commonly offered immediately, as part of the same operation as the mastectomy. However, in a smaller number of women, the mastectomy and reconstruction may be separated by months or years. The decision on whether to have a reconstruction (either immediate or delayed) depends on patient preference and a complex interplay between patient and cancer-specific factors, such as co-morbidities and cancer treatment plans, particularly the need for radiotherapy after mastectomy.

Most reconstructions also involve at least one, and often several, further operations to achieve the desired aesthetic result.

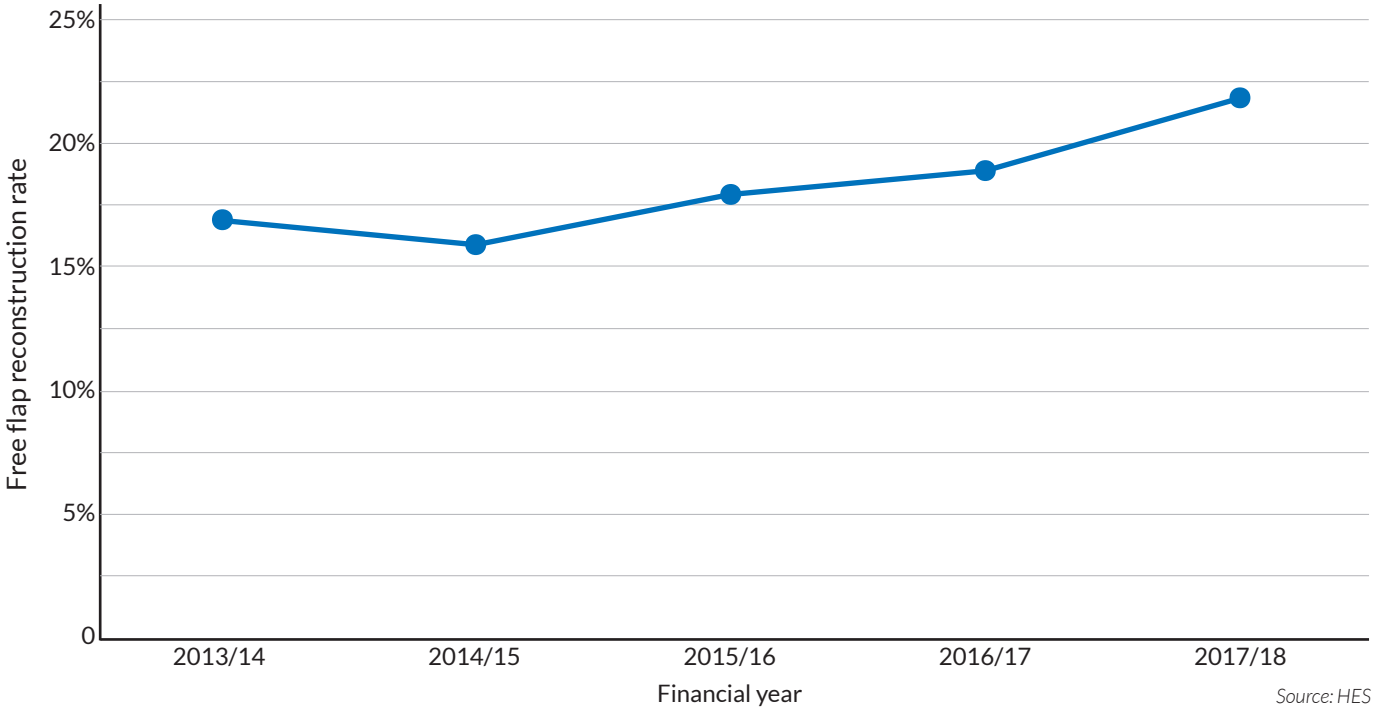
As noted earlier, there are a number of different techniques used in breast reconstruction which can be broadly categorised as implant-based or autologous (either pedicled flap or free flap).

There is no ideal reconstruction technique: the advantages and disadvantages of each method need to be carefully weighed up for each woman's requirements including cancer treatments, body habitus and desired aesthetic outcomes.

More than 1 in 5 reconstructions now use the free flap method – demonstrating a steady increase over the last five years. The use of pedicled autologous flaps, especially LD flaps, is declining due to improvements in implants and free-flap techniques.

[47] *See www.nice.org.uk/guidance/ng101/chapter/Recommendations#breast-reconstruction. See also NICE (2012) Interventional Procedures Guidance 417 Breast reconstruction using lipomodelling after breast cancer treatment www.nice.org.uk/guidance/ipg417/*

Figure 12: Proportion of reconstructions using free flap method, April 2013-March 2018



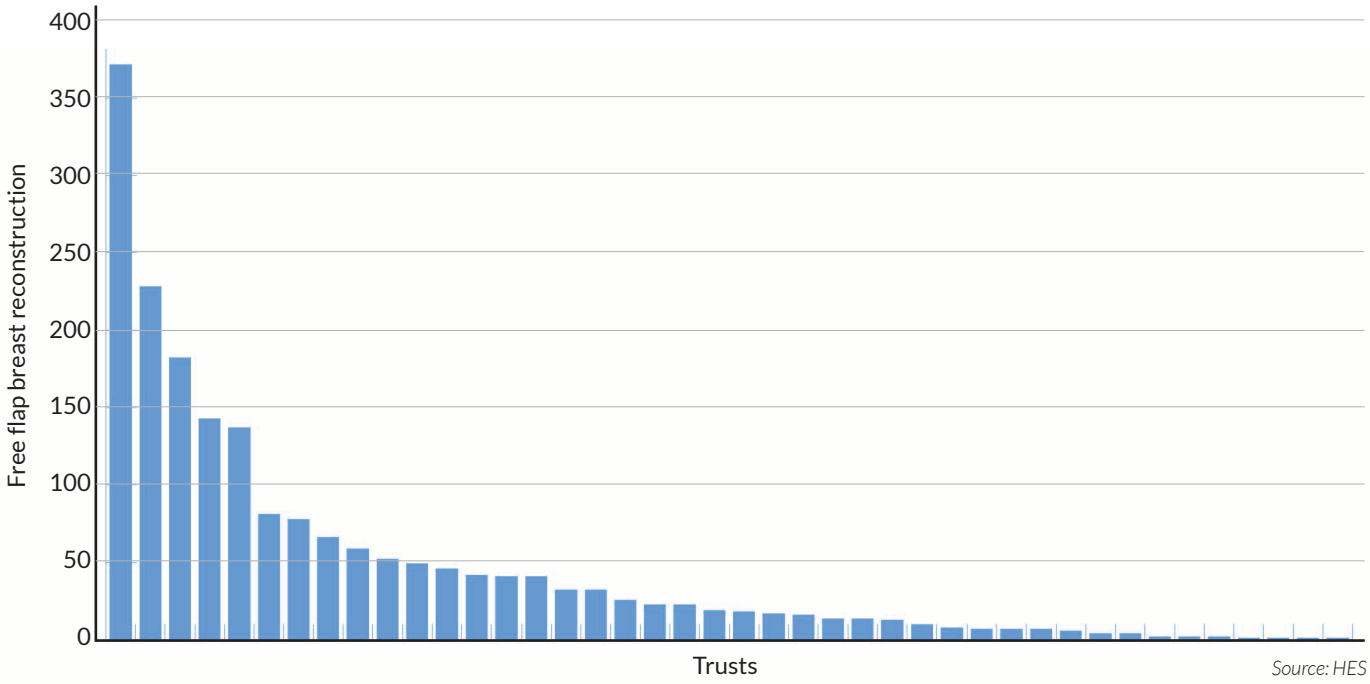
Source: HES

However, not all reconstruction options are available in every trust. While many breast surgery units have oncoplastic breast surgeons who can offer both implant-based and pedicled flap reconstructions, the majority of free flap reconstructions in the UK are done by plastic surgeons, who are also experienced in providing the other techniques.

Between 2015 and 2018, there were about 2,000 free flap reconstructions conducted each year, of which 650-700 were immediate and the rest were delayed These represent about 17% of the total breast-related plastic surgery workload.

To establish where free flap surgery is provided, we sought to identify a list of all units that have an on-site plastics unit offering a free flap reconstructive service; however, such a list proved hard to find. From other HES data, we believe that there are 40 trusts in the UK who offer free flap reconstruction. The chart below shows the number of free flap reconstructions undertaken over the three-year period at these trusts.

Figure 13: Free flap reconstruction volumes by trust, April 2015-March 2018



As most trusts cannot offer free flap reconstruction, patients may need to consider travelling to a different trust for free flap surgery or to access the full range of reconstructive options as recommended by NICE.

The decision-making process for reconstruction is invariably complex and each individual patient's preferences and circumstances need to be taken into account. However, as a basic principle, lack of timely access to a full range of surgical methods should not be a barrier to the decision to have an immediate reconstruction using the optimal technique for any individual. Through our deep-dive visits and data analysis, we sought to examine whether there is equity of access to reconstruction and to all available methods.

Immediate reconstruction rates

Nationally, 27% of women who have a single mastectomy for cancer have an immediate reconstruction, an increase from 21% recorded a decade ago (2008-9) by the National Mastectomy and Breast Reconstruction Audit (NMBRA).[48]

In England, there is no standard for immediate breast reconstruction rate, as reconstruction is not desired by every patient and remains a very personal choice. However, NHS Scotland has set a national target that 25% of patients should receive an immediate reconstruction following mastectomy.[49]

NICE guidance is clear that women should be offered immediate reconstruction following a mastectomy in most cases, but there should be no pressure on them to accept the offer. They should also be able to select, with the input of the oncoplastic team, from all methods of reconstruction appropriate for them.

Clearly, fully informed patient choice is essential for a procedure that carries risks but without more detailed and routinely used PROMs that cover the decision-making process, we cannot understand the complex interplay between the triple drivers of clinician preference, informed patient choice and/or timely access on immediate reconstruction rates. This is one of the reasons we strongly recommend that PROMs should be embedded into all oncoplastic breast surgery and plastic surgery units and used routinely across all breast surgery (including non-cancer surgery).

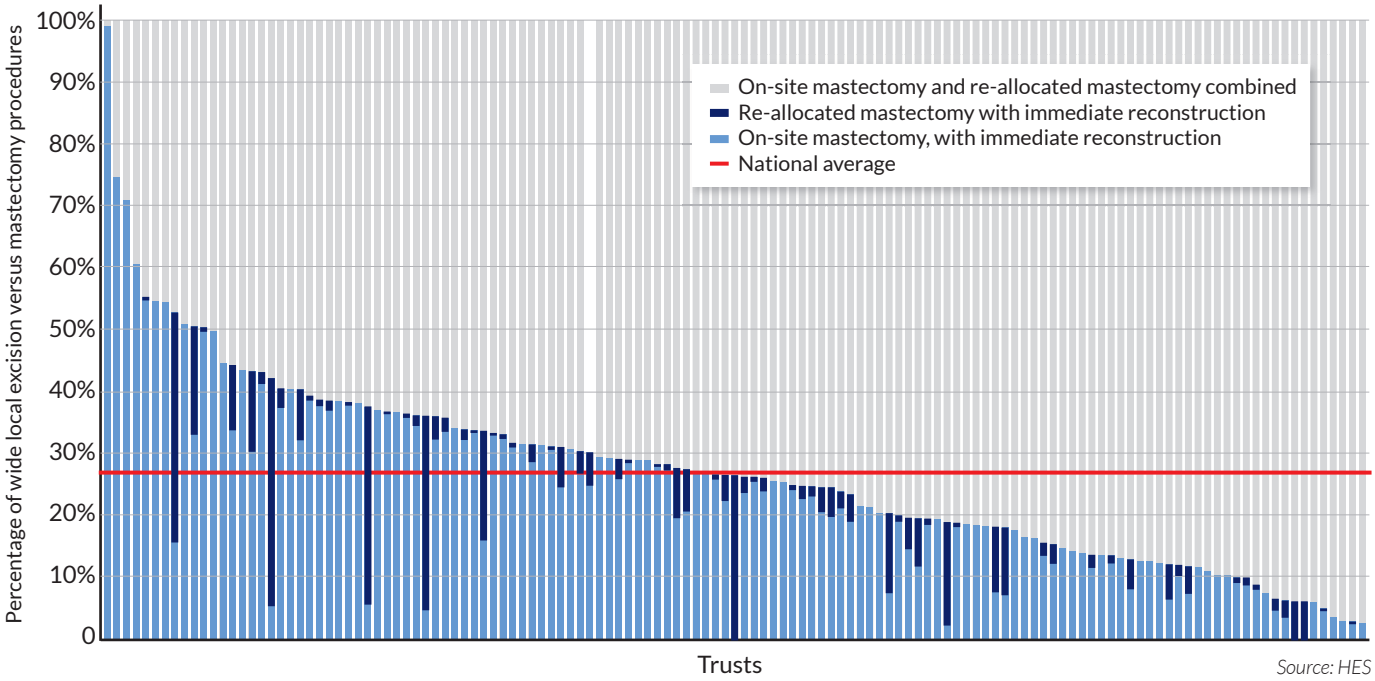
At present, PROMs are not routinely collected for breast surgery. There are a number of well-validated questionnaires created by different organisations and used in different trusts. For example, the UK National Flap Registry (UKNFR), a voluntary data collection based on submissions from breast plastic surgery teams themselves, uses the BreastQ questionnaire. However, to date there has been no consistency in the use of PROMs.

[48] *See www.rcseng.ac.uk/library-and-publications/rcs-publications/docs/mastectomy-breast-4/ pg 9*
[49] *See www.isdscotland.org/Health-Topics/Quality-Indicators/Publications/2019-04-09/2019-04-09-Breast-QPI-Report.pdf pg 26*

Variations in immediate breast reconstruction rates

As Figure 14 shows, there is wide variation in the immediate reconstruction rates between trusts.

Figure 14: Proportion of patients who have an immediate reconstruction following mastectomy, by trust, April 2015-March 2018



Source: HES

Excluding the two standalone plastic surgery units, whose patients are referred specifically for reconstruction (seen at the left-hand edge of the chart), the immediate reconstruction rates ranged from 3% to 75%.

Some, but not all, of the units with high immediate reconstruction rates have plastic surgical services on site and therefore have a higher proportion of reconstructions overall. This is because they not only provide reconstruction for on-site patients but may also act as tertiary referral centres for patients coming from other trusts who cannot offer the full range of options.

The available data does not include any reasons why a patient did not choose an immediate reconstruction. There are various possible explanations: the patient may have other significant competing health risks (co-morbidities); they may simply wish to defer reconstruction till a later date, enabling them to recover from the mastectomy and other cancer treatments first. In some cases, the patient may wait because they are not able to have a reconstruction by their preferred method immediately.

Regardless of the reasons, the sheer scale of the variation shown in Figure 14 suggests that this is not purely a result of patient choice and/or case mix, but rather is affected by other factors such as local service configurations and workforce skills, policies, pathways, MDT preferences and importantly, access.

While there is not an ideal IBR rate, we see no reason why all trusts wouldn't be able to achieve a 25% (broadly 1 in 4 patients having a mastectomy) immediate reconstruction rate.

Outsourced reconstructions

As is shown in Figure 14, at some providers all (or almost all) reconstructions are outsourced to another trust: this is regarded as best practice if reconstruction is not available locally.

However, it is not clear from HES data where this takes place, as HES allows the procedure to be allocated to only one consultant; the other is therefore 'invisible' in the data.

We have sought to identify where reconstructions have been outsourced to another provider to help with our understanding of the reconstruction options available at each trust. We therefore looked at all reconstructions admitted under the plastic surgery TFC 160 and 'reallocated' them if the last breast OPD attend was recorded under TFC103 at another hospital.

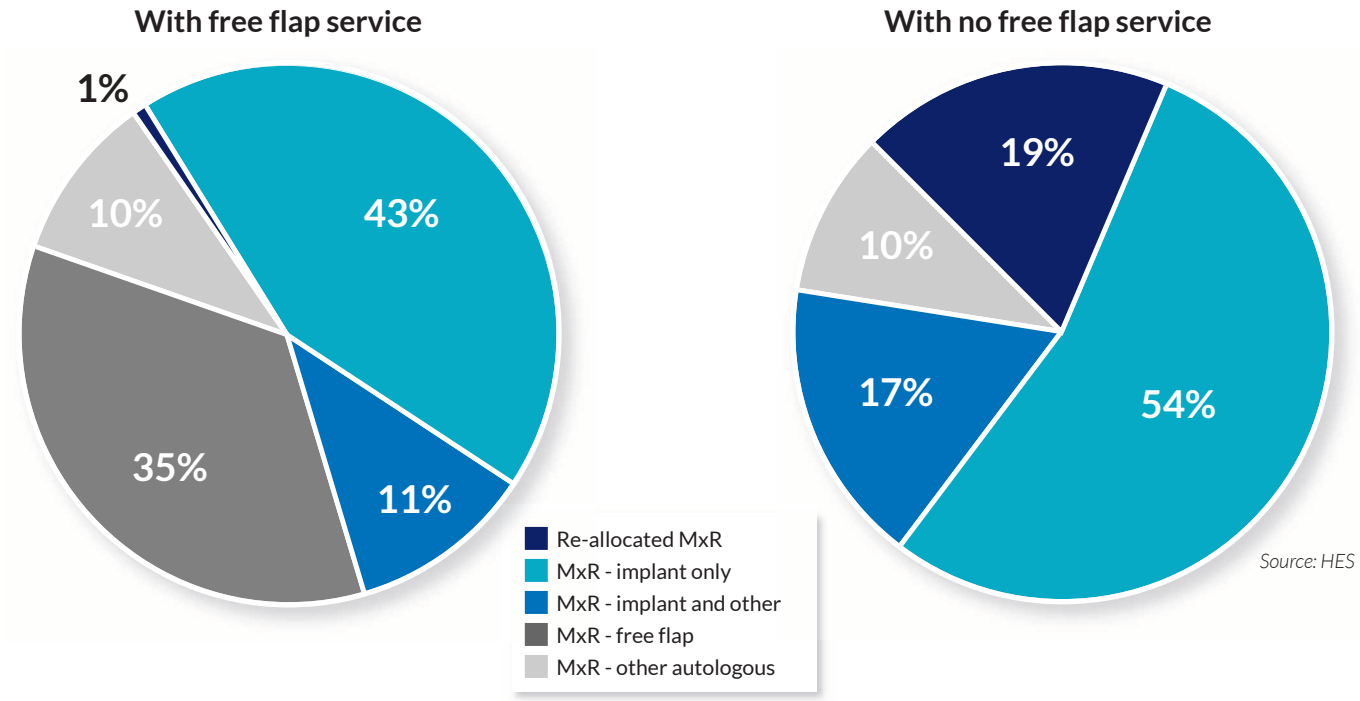
We identified that around 355 outsourced reconstructions are carried out annually, almost 10% of the total reconstruction workload. While this is likely to be an underestimate, due to variable capture of breast surgery OPD attends under TFC103 as discussed later in the report, the majority of trusts we visited felt that the number of these outsourced reconstructions broadly reflected the number of patients that had opted for a reconstruction off-site.

Addressing variation in reconstruction by type

As stated above, the ideal scenario is that all women undergoing a mastectomy have the option of accessing the most appropriate type of reconstruction, in a timely manner, as part of their initial cancer surgery.

To examine whether the full range of options are available to all women, we compared the types of reconstruction that were provided in trusts which have a free flap service (indicating a comprehensive plastic surgery service) – shown in Figure 15 on the left – with the types provided in trusts with no free flap service (indicating a limited plastic surgery or breast surgery only services), shown on the right.

Figure 15: Reconstruction type for patients undergoing mastectomy with immediate reconstruction as their first surgery in trusts with a free flap service, April 2015-March 2018



In trusts with an onsite free flap service, 45% of immediate reconstructions are autologous/free flap and 55% are implant-based. Where no free flap service is available onsite, about 30% are autologous of which two-thirds are outsourced free flaps and 70% are implant-based. This indicates that at providers with the full range of reconstruction options on site, patients make different choices regarding reconstruction type compared to patients in trusts where there is a more limited range of options.

As set out above, NICE guidance is clear that if a trust doesn't offer the patient's preferred option, travel to a different hospital should be recommended. A well-networked referral process is therefore required to allow patients who want an autologous or free flap reconstruction to have one. However, the data suggests there is a marked disparity in access to free flap surgery.

Some of this variation of course reflects patient choice, the type of cancer and co-morbidities. There may also be some socio-demographic factors. But when we compared reconstruction types and free flap rates among neighbouring trusts with broadly similar populations in socio-demographic terms, there was still marked variation between reconstruction type between the trusts which have an on-site free flap service and those that don't.

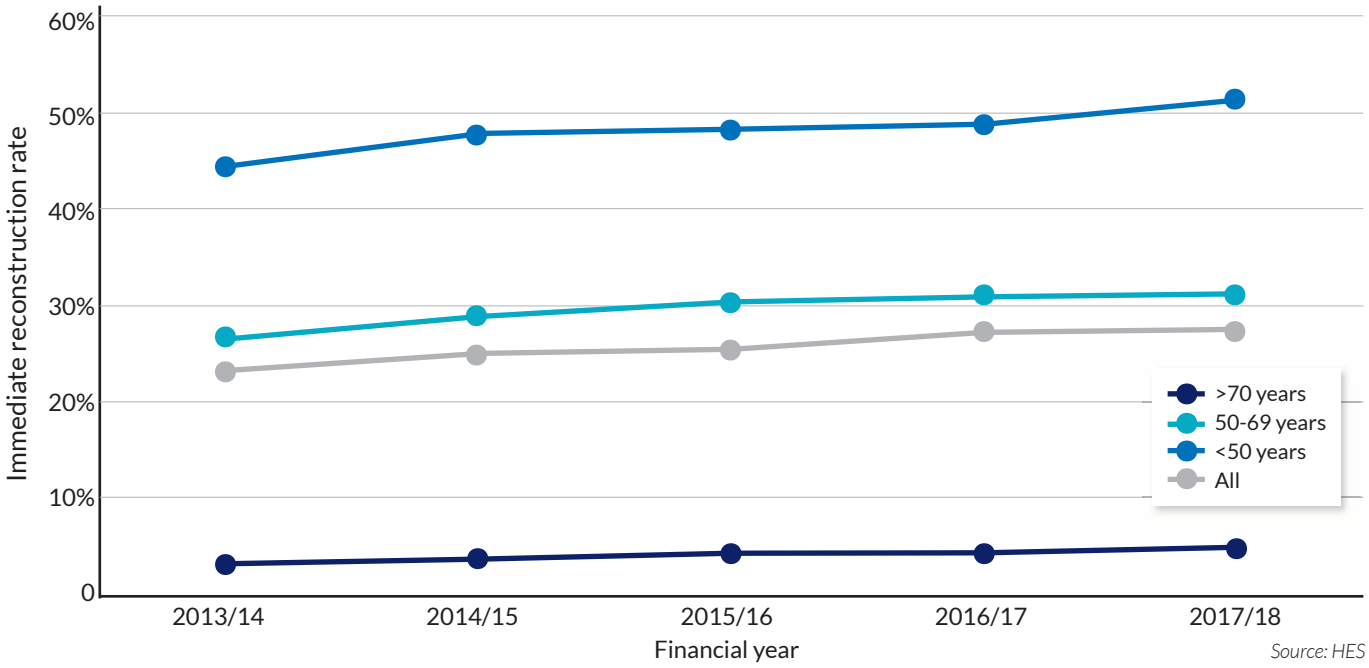
In our deep-dive visits, we saw multiple examples of trusts that were 30 minutes or less apart but had different reconstruction rates and different ratios of autologous/free flaps and implant reconstruction techniques. This is likely to reflect multiple factors including local service issues impacting on smooth and timely access to free flaps as well as surgeon preferences, rather than just patient choice.

Overall, the data around reconstruction types suggests there remains inequity in access to free flap reconstruction. Patients in a trust which has its own free flap service are far more likely to receive a free flap reconstruction than patients in areas without such a service. Where there is a true choice of all methods, up to 50% of women choose free flap reconstruction. In areas where there is no free flap service, most women accept the alternative of implant-based reconstruction.

Examining reconstruction by age

Almost since breast reconstructions were first introduced, they have been more common in younger than older age groups. As Figure 16 shows, around half of women under 50 have an immediate reconstruction following mastectomy, compared to under 10% of women over 70.

Figure 16: Immediate reconstruction rate by age group, April 2013 - March 2018



Source: HES

This is not purely for aesthetic reasons; some older patients, especially those with other health problems, choose not to have a reconstruction to avoid the need for further surgery and so that their initial recovery time may be shorter.

However, in an ageing population, with a growing proportion of people living longer and having different expectations of what 'old age' should be like, it is likely that a growing number of women over 70 will want immediate reconstruction. Indeed, over the last five years, there has already been a small increase in the proportion of women over 70 that have an immediate reconstruction – albeit at a slower rate than for the under 50s. Commissioners and providers need to be aware of this trend.

We also looked at the type of reconstruction by patient age. While there are similar rates of implant-only reconstruction in all age groups, among the over 70s 'other autologous' reconstructions – such as pedicled flaps – were three times more common than free flap surgery. This was a major difference with the other age groups, where free flap surgery was roughly twice as common as other autologous methods.

The fact there may be increasing demand for autologous reconstruction among older but fit women may need to be considered in commissioning decisions.

Minimising adjustment surgery after breast reconstruction

Statement of principle

Oncoplastic conservation and breast reconstruction techniques and pathways should be optimised to minimise the need for adjustment or second stage surgery.

Following a breast reconstruction – using any method – there is often a need for planned second stage or adjustment surgery. For example, an implant-based reconstruction may start with the use of a temporary 'expander' under the skin following mastectomy; this would then be replaced by the main implant in a second procedure, with a third operation to construct a nipple. Lipofilling (fat transfer), to smooth out unevenness or tissue gaps, is also a common reason for a planned return to theatre.

However, in other instances, further surgery is required because of surgical or radiation complications or because the outcomes have not met patient expectations.

Nationally, on average, a patient will have at least one adjustment operation in the five years after an immediate reconstruction. However, we found wide variation in the average number of adjustment operations conducted in different trusts – from 0.4 to 3.0 for implant-based reconstruction, with a nationwide average of 1.6 adjustment operations, and 0.0 to 3.2 for free flap reconstruction, with a nationwide average of 1.3.

Research by Breast Cancer Now found that some CCGs limit the number of follow-up operations that are permitted as part of a single reconstruction.[50] In response, the ABS, BAPRAS and Breast Cancer Now produced guidance for CCGs in relation to commissioning oncoplastic breast surgery, including reconstruction.[51] This addressed the issue of adjustment/second stage surgery, making clear that services should be commissioned in such a way as to ensure that patients can obtain an outcome that they are satisfied with.

In deep-dive visits, many units told us that, despite the publication of this guidance, CCGs are restricting the number of operations available and/or access to balancing surgery on the other breast, or prescribing the type of surgery that can be carried out. This commissioning variation is unacceptable and as such we would encourage CCGs to adopt the guidance.

However, both from a patient perspective and a clinical perspective, it is clearly desirable that adjustment surgery is minimal. For patients, each further adjustment means an additional trip to hospital and additional recovery and inconvenience. It makes it harder for them to 'move on' from their cancer. For clinicians and providers, it is only logical that achieving the patient's desired outcomes sooner and with fewer trips to theatre and the outpatient department is a better use of resources.

Oncoplastic surgeons should aim to minimise the need for adjustment surgery. The focus should be on the patient aesthetic requirements and recognising that different patients will have different priorities. Some will want and need further surgery to optimise the aesthetic outcome; others may prefer to limit revisions.

Separate from the deep-dive visits, we were also alerted by a patient to a different issue around commissioning: the unintended impact of changes in CCG commissioning policies. This is explored below. Our view is simple: once a woman embarks on a reconstruction programme, changes in CCG policies should not then leave her unable to complete the process.

[50] *Breast Cancer Now (2018) - Rebuilding my body: Breast reconstruction in England https://breastcancernow.org/sites/default/files/public/rebuilding_my_body_report_june_2018.pdf*

[51] *Breast Cancer Now, ABS, BAPRAS (2018) Guidance for the commissioning of Oncoplastic Breast Surgery https://breastcancernow.org/sites/default/files/public/guidance_for_the_commissioning_of_oncoplastic_breast_surgery_-_ccg_guidelines_2018.pdf*

CASE STUDY

Patient stories: the impact of restricted commissioning

Following advice and informed discussion with her clinician, a patient with breast cancer decided to have a free flap reconstruction using a DIEP flap. This was intentionally delayed for clinical reasons while she underwent other treatment.

Once her treatment was complete, however, her request for reconstruction was turned down, as the local CCG had stopped funding delayed reconstruction using the DIEP method.

Instead, the trust was only able to offer her an implant-based reconstruction, which she did not want and was not the best option in her case. To have a free flap reconstruction, she would have to arrange the reconstruction privately and fund it herself.

Rates, types and volumes of adjustment surgery after reconstruction

We examined the rates of readmissions for adjustments following immediate breast reconstruction by reconstruction type, broadly categorised into implant-based or autologous (usually DIEP free flap). This covered readmissions within five years of the reconstruction (but at least 90 days after the original surgery to avoid capturing readmissions for complications).

Table 3: Readmission rate for adjustments following immediate breast reconstruction between April 2010 and March 2013

	Free flap			Implant-based		
	Unilateral	Bilateral for cancer	Bilateral for risk reduction	Unilateral	Bilateral for cancer	Bilateral for risk reduction
Average no. subsequent procedures within 5 years of (but at least 90 days after) index procedure	1.34	1.60	1.76	1.64	1.77	1.92

Source: HES

Table 4: Number of admissions and main type of adjustment procedures following immediate breast reconstruction between April 2010 and March 2013

Free flap (2186 procedures)	
Number of admissions for adjustment procedures	3113
Nipple reconstruction	2050
Lipofill	1211
Mastopexy and reduction mammoplasty	522
Conversion to another reconstruction	6%

Implant-based (5109 procedures)	
Number of admissions for adjustment procedures	8554
Implant revisions	6431
Nipple reconstruction	2191
Lipofill	1651
Conversion to autologous	5-7%

Please note that one admission may be for an operation that may contain multiple adjustment procedures

Source: HES

Nationally, free flap reconstruction appears to have slightly lower rates of adjustment surgery compared to implant-based reconstruction.

Patients who have free flap reconstructions are most commonly readmitted for nipple reconstruction while the most common reason for readmission among those who had implant-based reconstructions was for implant revisions – usually the exchange of an expander implant to a fixed volume implant. Newer implant-based reconstruction techniques allow the use of fixed volume implants from the outset; once these are more widespread, readmissions may reduce.

Lipofilling is the second most common adjustment procedure. It is typically used to address unevenness following breast surgery.

Approximately 20% of patients undergoing mastectomy and immediate reconstruction now receive lipofilling within five years of their initial operation (17.85% for patient undergoing implant only reconstruction, and 23.74% for patients undergoing free flap reconstruction). While only 1.5% of patients undergoing breast excisions have subsequent lipofilling, because almost 37,000 patients per year receive excisions, this impacts on a high number of patients.

The rates of lipofilling are surprising, especially after breast conservation. They suggest that some surgeons may be using it as a standard corrective measure after a generous WLE, rather than carrying out an oncoplastic conservation procedure. Lipofilling is an invaluable technique to support better aesthetic outcomes which carries limited surgical risks and side effects and can be undertaken as a day case procedure under local anaesthetic. However, as with any surgical procedure, use needs to be appropriate and relevant steps taken to minimise risks and side-effects.

It is also interesting to note that our data suggests bilateral mastectomy and reconstruction for (usually unilateral) cancer seems to be associated with more subsequent adjustment surgery, rather than less. The rationale often given for removal and reconstruction of the other healthy breast at the same time as the cancer mastectomy and reconstruction is to allow better symmetry; our data does not support that rationale.

Nationally, free flap reconstruction appears to have slightly lower rates of adjustment surgery compared to implant-based reconstruction for unilateral, bilateral and risk reduction reconstructions.

For both implant and autologous immediate reconstruction, the highest volume of adjustment surgery is after bilateral mastectomy and immediate reconstruction for risk reduction, usually in cancer gene mutation carriers. This may indicate a mismatch between patient expectation and the realities of what aesthetic results can be achieved, no matter how well executed the surgery.

Conversion to an alternative reconstruction

Within five years of their initial reconstruction, 5-7% of women have a further reconstruction on the same breast using a different method. The rates are broadly similar for both autologous and implant-based reconstruction.

Conversion of the initial reconstruction can be for many reasons and HES data does not give an explanation. Some conversions may be planned: for example, we know of some units where, if radiotherapy is predicted, an implant is recommended as a temporary measure before providing a definitive free flap reconstruction (immediate delayed reconstruction).

Another less valid reason for offering a temporary implant is when immediate planned free flap reconstruction cannot take place within a suitable timeframe. This not only masks an underlying access problem; it also means the patient is subjected to an unnecessary extra procedure which increases the total time for a patient to complete their reconstruction pathway and the cost of the overall reconstruction.

However, the majority of conversions are likely to be unplanned and represent a failure of the primary reconstruction.

We would welcome coding refinements that enable more detailed data to be captured within HES about return to theatre, to allow us (and all surgeons) to better understand all of these issues. Patient level linkage with NCRAS data and the use of radiotherapy may also provide further insights into conversions and subsequent adjustment.

However, the data as it stands emphasises the need for women to be appropriately advised about the likely volume of repeat surgery that may be required to achieve the desired aesthetic outcome. It is also imperative that MDTs are consistent in the information they give women about realistic expectations regarding what is possible aesthetically from the outset.

Finally, it reinforces the need for the right operation for the right patient at the right time and the need for equity of access at the time of mastectomy to all forms of reconstruction.

Reconstruction and patient choice

Overall, the data we have examined relating to reconstruction suggests that, at present, there is not equity of access across the NHS.

- There is considerable variation in initial reconstruction rates, perhaps indicating different policies at different trusts.
- There is considerable variation in reconstruction type: where all types are available, around a third of women have a free flap reconstruction. In trusts which do not have a free flap service, this drops to under 1 in 5.

Our concern is that in areas where there is no free flap service, women are more likely to receive implant-based reconstruction, or another method that may not be clinically or aesthetically best for them.

Our deep dive discussions offered some potential reasons for this. Firstly, it is possible that patients are offered a full choice and simply choose the method that appears most convenient to them – the one that can be arranged soonest, can be provided locally, or involves the fewest appointments.

Some providers suggested that surgeons may be discouraged from referring patients to free flap services over concerns regarding timeliness and ensuring that patients receive their first procedure within 31 days. For patients with complex pathways, the added involvement of a free flap service – potentially in another trust – can mean the target is missed.

We are also aware that some tertiary referral services have had to restrict their services geographically to deal with backlogs.

We did see, however, many examples of plastic and breast surgeons working together to overcome these barriers and provide a service that offered all the options. Joint/parallel clinics and/or oncoplastic multidisciplinary teams (MDTs) in these units facilitated discussion and offered timely assessment for surgery. However, less than half the units we visited had such oncoplastic MDTs; of those that did, only half had invited a plastic surgeon to be part of the MDT.

Another possible approach is for the plastic teams to introduce an immediate reconstruction rota. Under this model, instead of patients being referred for surgery to a particular consultant, they are simply allocated to the next available list and that surgeon for their clinic assessment. This helps to ensure access to timely reconstruction, rather than requiring patients to wait to see a particular surgeon. The approach is used to good effect at hospitals such as the Queen Victoria Hospital at East Grinstead – though it should be acknowledged that some patients may prefer to wait to be operated on by a surgeon they already know.

Reducing unplanned readmissions and returns to theatre for complications

Statement of principle

Unplanned readmissions and return to theatres for complications should be minimised.

As breast surgery is surface surgery that doesn't breach a major cavity such as the chest or abdomen, it has low readmissions and unplanned/emergency return to theatre rates for complications in comparison with other surgical specialties. There are numerous providers that report consistently low rates for returns, often as a result of fairly straightforward changes to practice; those at the other end of the spectrum could valuably learn from their high-performing peers.

For WLE, mastectomy, mastectomy with immediate reconstruction and delayed reconstruction, we reviewed HES data on readmissions and returns to theatres within 30 and 90 days[52] and used these two metrics as a surrogate measure for major complications.

The ICD (diagnosis) codes used in HES offer some explanations as to the reasons for readmissions, and the OPCS (procedure) codes for any return to theatre. The volume of ICD and OPCS codes that may represent a complication is huge and application is not standardised, but we chose some more specific ICD and OPCS intervention codes that could be used as surrogate measures of surgery quality.

[52] *It should be noted that HES data does not record all returns to theatre on the day of surgery; it is therefore likely that the true numbers for return to theatre are higher than documented.*

These were:

- haematoma rates within 30 and 90 days;
- unplanned implant removal within a year of the initial surgery; and
- attention/revision to microvascular anastomosis (the connection between the transferred veins or arteries and the existing tissue) etc during admission or within 30 or 90 days.

While we have sought to compare readmission rates, we would note that it was clear at some visits that readmissions were captured in different ways. For example, in some trusts with surgery ambulatory units, an attendance for wound review – which could represent excellent clinical care – was captured as an admission.

Consistent clinical coding and capture of attendances and admissions would be useful so these key quality measures can be better monitored and used for comparison between providers.

Minimising readmissions/returns to theatre for bleeding and haematoma

Because the breast and axilla have a rich blood supply, surgery to both can lead to a risk of post-operative bleeding, resulting in the development of large collections of blood (haematoma) in the armpit or breast cavities. The most common method of dealing with these is a second operation to stop the bleeding and evacuate the blood. The risk of haematoma can be minimised by adhering to surgical best practice.

Return to theatre for haematoma is covered by a limited number of ICD and OPCS codes so it is comparatively straightforward to establish the rates. This makes it a useful surrogate quality measure for the surgery/anaesthetic/perioperative team. Using HES data, we identified haematoma rates following four main breast surgery procedures.

Table 5: Haematoma rates following four main breast surgery procedures

Procedure	National average	Lowest haematoma rate	Highest haematoma rate
WLE	1.6%	0.4%	6%
Mastectomy only	5.2%	0.6%	13%
Mastectomy with immediate implant-based reconstruction	4.6%	0.7%	14.3%
Mastectomy with immediate autologous reconstruction	8.4%	1.7%	16.3%

Source: HES

As the table shows, there was wide variation between the best performers (lowest haematoma rates) and the worst. While causes of haematoma are multifactorial, we believe there is an opportunity to reduce haematoma rates by following surgical best practice. For patients and providers alike, this would be highly beneficial.

Co-morbidities and complication rates

The frequency and severity of complications in all specialties are influenced by patient-related factors such as age, deprivation, smoking and other health conditions (co-morbidities) such as obesity, diabetes and use of blood-thinning drugs.

In breast surgery, complications are also related to extent of cancer (stage) and extent of surgery (for example, mastectomy is associated with more complications than simple excision surgery, and breast reconstruction is associated with more complications than mastectomy). Understanding the casemix is therefore important when comparing complication rates between providers.[53]

While our data allowed comparison of deprivation and co-morbidities with the England mean, it is clear that there is still variation in complication rates, unrelated to deprivation and co-morbidities.

Some units told us they had comparatively higher rates of complications after reconstructions because they had more permissive policies in terms of providing reconstruction patients with higher co-morbidities. We looked at whether variation in complication rates appeared to reflect the levels of deprivation and co-morbidities by trust; there was no clear trend.

[53] *Levels of deprivation and poor health provide important context for providers when they are comparing GIRFT HES data on day case rates, length of stay, surgery complications and quality indicators with other trusts. For a trust with large volumes of highly deprived patients with multiple health problems, an average rate of day case or complications is an achievement. A trust with mainly affluent, healthy patients should achieve higher day case rates and better outcomes with less complications.*

Minimising readmissions/returns to theatre for unplanned implant removal

There is always a risk that immediate mastectomy and implant-based reconstructions can result in complications (usually wound healing problems or infections) such that the implant may have to be removed. However, good patient selection and meticulous surgical care should minimise the need for unplanned implant removal.

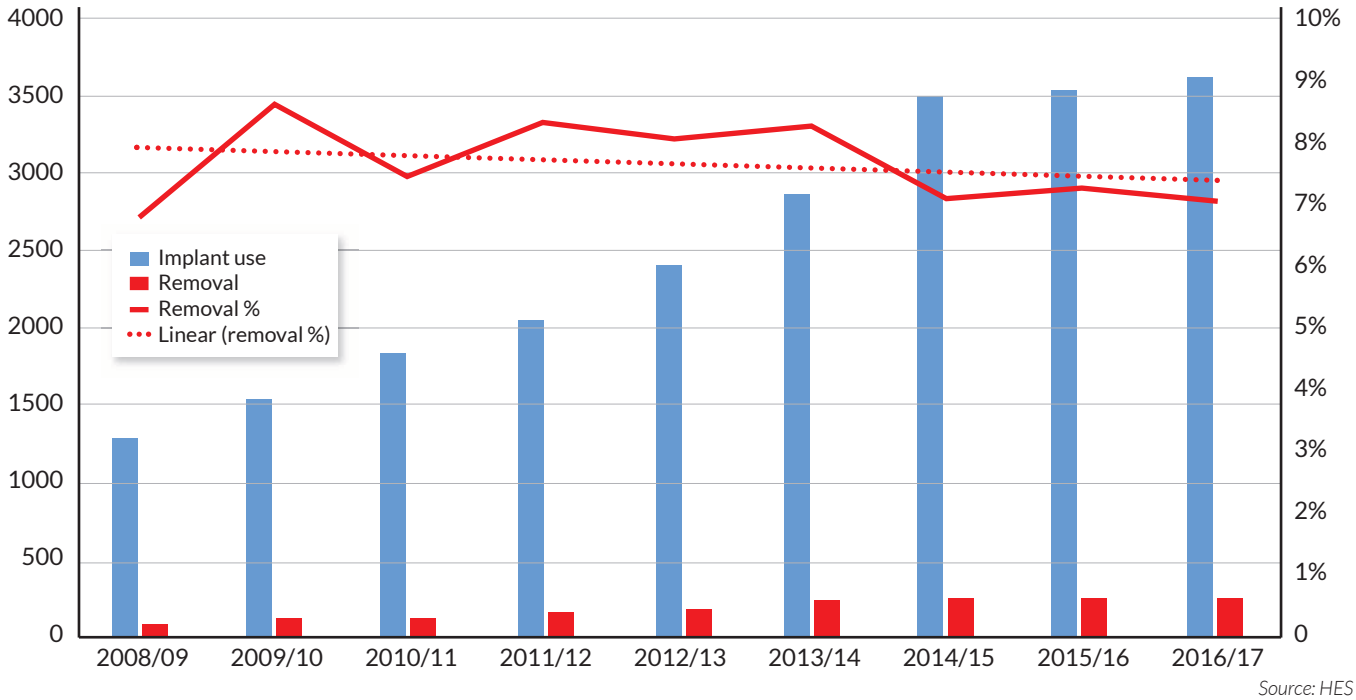
When the NMBRA examined this issue over a decade ago, it found that that 9% of patients who had an immediate implant-based breast reconstruction (for cancer only) reported implant loss.[54] For delayed reconstructions, the figure was 7%.

In 2012, ABS/BAPRAS published best practice guidelines for oncoplastic breast reconstruction, which set quality targets based on the NMBRA findings: *'Complications leading to implant loss should occur in less than 5% of cases at 3 months.'*

We looked at HES data for 2014-17 and found that 7.14% of patients had their implants removed within a year of receiving an implant-only reconstruction after mastectomy for any reason (risk reduction, cancer etc.). It is not easy to ascertain a reason for implant removal using HES data; however, this metric was based on the OPCS code for implant removal with no other OPCS codes recorded under the same operation, which suggests that these removals were not part of planned adjustments or revisions.

This rate of 7% represents a modest decrease compared to ten years ago, as the linear trend in Figure 17 shows. Further, the actual number of removals has decreased in the last three years, even as the use of implants has continued to increase.

Figure 17: Implant use and removal rate, April 2008-March 2017

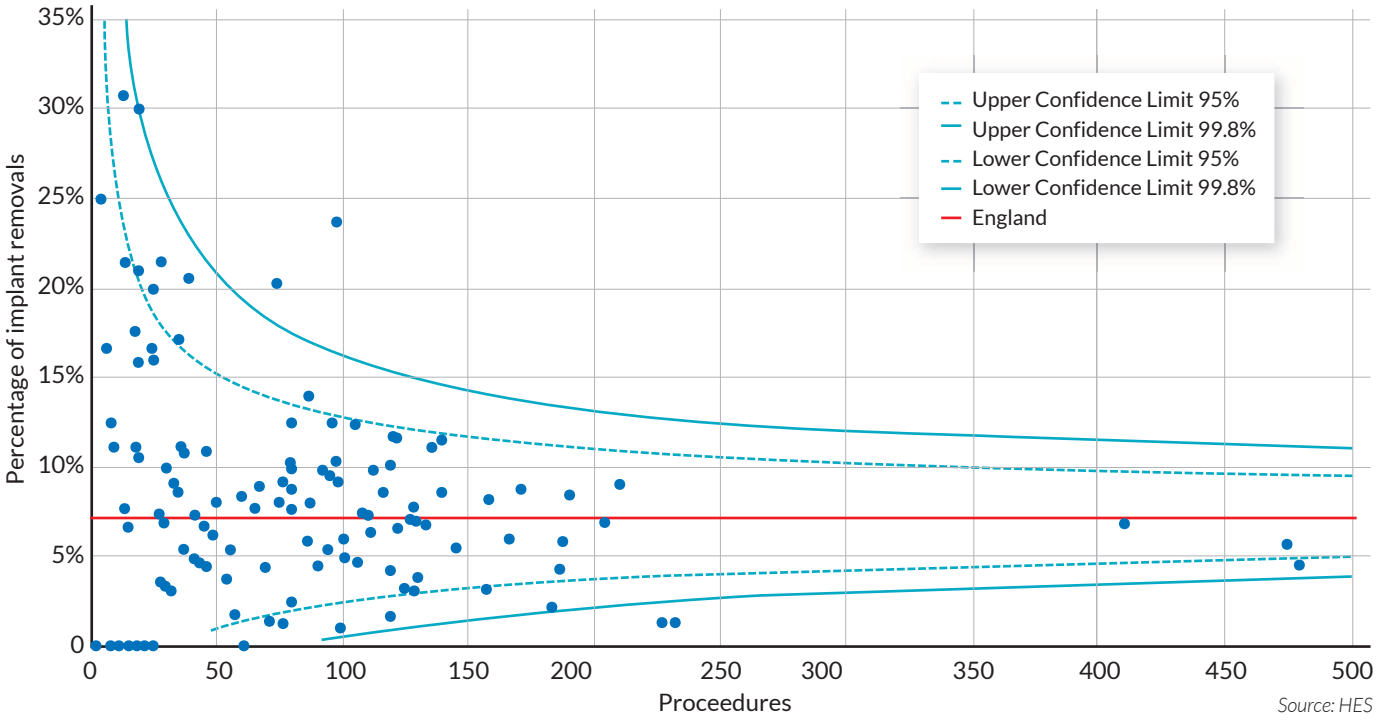


Source: HES

However, the nationwide unplanned implant removal rate of 7% is higher than desirable and is still higher than the 2012 best practice target of 5% (at 90 days). Further, as Figure 18 shows, there is considerable variation between trusts.

[54] *See www.rcseng.ac.uk/library-and-publications/rcs-publications/docs/mastectomy-breast-4/*

Figure 18: Percentage of unplanned implant removals within one year of mastectomy and implant-only reconstruction, by trust, April 2014-March 2017



Source: HES

Most trusts had a rate close to the national average. However, there were ten trusts where more than 20% of patients had their implants removed. These were all trusts who conducted fewer than 100 procedures over the three-year period.

We also looked at unplanned implant removal rates for patients undergoing mastectomy and other implant-based immediate reconstruction; these were similar to the rates for implant-only reconstructions.

By contrast, 40 trusts had unplanned removal rates below the best practice target of 5% – including the trust conducting the highest number of implant-only reconstructions. Of these, 20 had a rate under 2% – effectively meaning that less than 1 in 50 women needs to return to theatre for this reason.

We believe there is no reason why other providers cannot improve their unplanned implant removal rates to the best practice target of 5% or less.

It should be noted that other surgical specialties that use 'implants' (for example, joint replacement) have implant removal rates of less than 1%. This is the result of decades of monitoring outcomes using the National Joint Registry with peer review, focused training and the widespread adoption of good practice resulting in steady marginal gains and improvements.

These approaches now need to be applied more rigorously within breast surgery.

CASE STUDY

Reducing implant loss rates

Royal Devon and Exeter NHS Foundation Trust

The breast oncoplastic team at the Royal Devon & Exeter Hospital was able to reduce its three-month unplanned implant removal rate from 14% to 0% by limiting implant surgery to a small group of dedicated surgeons and implementing a novel, evidence based intervention bundle, including more than 25 protocol changes.[55]

[55] *Knight, H.J., et al. (2020) Significantly reducing implant loss rates in immediate implant-based breast reconstruction: A protocol and completed audit of quality assurance. Journal of Plastic, Reconstructive and Aesthetic Surgery 2020, 000, 1-7 https://pubmed.ncbi.nlm.nih.gov/32008945/*

Minimising readmissions/returns to theatre following free flap reconstruction

A key quality measure following free flap reconstructions is the return to theatre rate. Such returns occur either due to concern about the viability of the microvascular anastomosis or because of partial/complete flap loss.

Data about such returns is difficult to obtain in HES, due to the variety of codes used to capture this activity. Return to theatre 'take backs' usually occur within the index admission and may even be on the day of surgery. There is no robust system on HES to know if two procedures on the same date are separate operations at different times, or part of the same multi-procedure index operation.

We looked at a number of codes to try to obtain the return to theatre rate. HES data suggests that 6.16% of all free flap reconstructions result in a return to theatre. This was supported by data recently published by the UKNFR, which showed a very similar take back rate of 7% for free flap reconstructions.[56] This suggests HES is a reliable data source for future Model Hospital monitoring and interunit comparisons.

We could not identify a HES data point that could be used to measure free flap loss rates; however, UKNFR identified a rate of about 2.5%.

Published studies suggest that, internationally, flap loss rates are typically between 1 and 4%, with partial flap loss rates of up to 40%.[57] There is very little published data about returns to theatre.[58]

Total costs of reconstruction

A wide range of factors affect access to all forms of reconstruction, but we have heard that price may play a part. In particular, it has been suggested that some commissioners are less keen to commission free flap surgery – where the basic procedure cost is generally deemed to be substantially higher than an implant-based reconstruction. Free flap reconstruction takes longer than implant-based and may involve two consultants – a breast surgeon and a plastic surgeon – rather than the whole procedure, from mastectomy to implant-based reconstruction, being conducted by a single surgeon.

It is simplistic to think that the price of an operation relates to the actual procedure alone. The entire pathway must be taken into account, including likely planned and unplanned readmissions and further surgery.

When we looked into this further, it quickly became clear that no consistent information was available on the actual costs of the whole reconstruction pathway, or of the difference in costs between different types of reconstruction, because patient level cost data is not yet available. At present, Healthcare Resource Groups (HRGs) are a relatively crude method to determine fair reimbursements for services delivered by providers.

Calculating total costs for reconstruction

We asked GIRFT analysts to calculate estimated total costs for implant-based and free flap reconstructions. For simplicity, we only considered unilateral reconstruction for this illustrative comparison.

The analysts gathered data about the number of unilateral reconstructions carried out over the three-year period from April 2010 to March 2013. The tariff that was payable at the time was used to calculate a total cost. This total was divided by the number of operations to provide an average (mean) cost per operation.

Over the three-year period, there were 1,456 free flap reconstructions, at a total cost of £9.4m and an average cost of £6,458 for the initial operation. There were 3,309 implant-based reconstructions, at a total cost of £12.65m and an average cost of £3,824 for the initial operation.

From procedure cost to pathway cost

For both implant-based and free flap reconstruction, the analysts then gathered data about emergency readmissions within 30 days of the operation, further breast surgery within five years and outpatient attendances (in agreed specialties) within five years. Again, a total cost was calculated based on relevant tariffs, then divided by the number of operations, to create an average cost (including readmissions and follow-up) for the entire pathway.

[56] *See BAPRAS (2019) First UK National Flap Registry Report www.bapras.org.uk/docs/default-source/default-document-library/uknfr-first-report-4-dec-2019.pdf?sfvrsn=2*

[57] *Patel, NG., Ramakrishnan, V., Microsurgical Tissue Transfer in Breast Reconstruction. Clinics in Plastic Surgery 2017 Apr; 44(2):345-359. www.ncbi.nlm.nih.gov/pubmed/28340667*

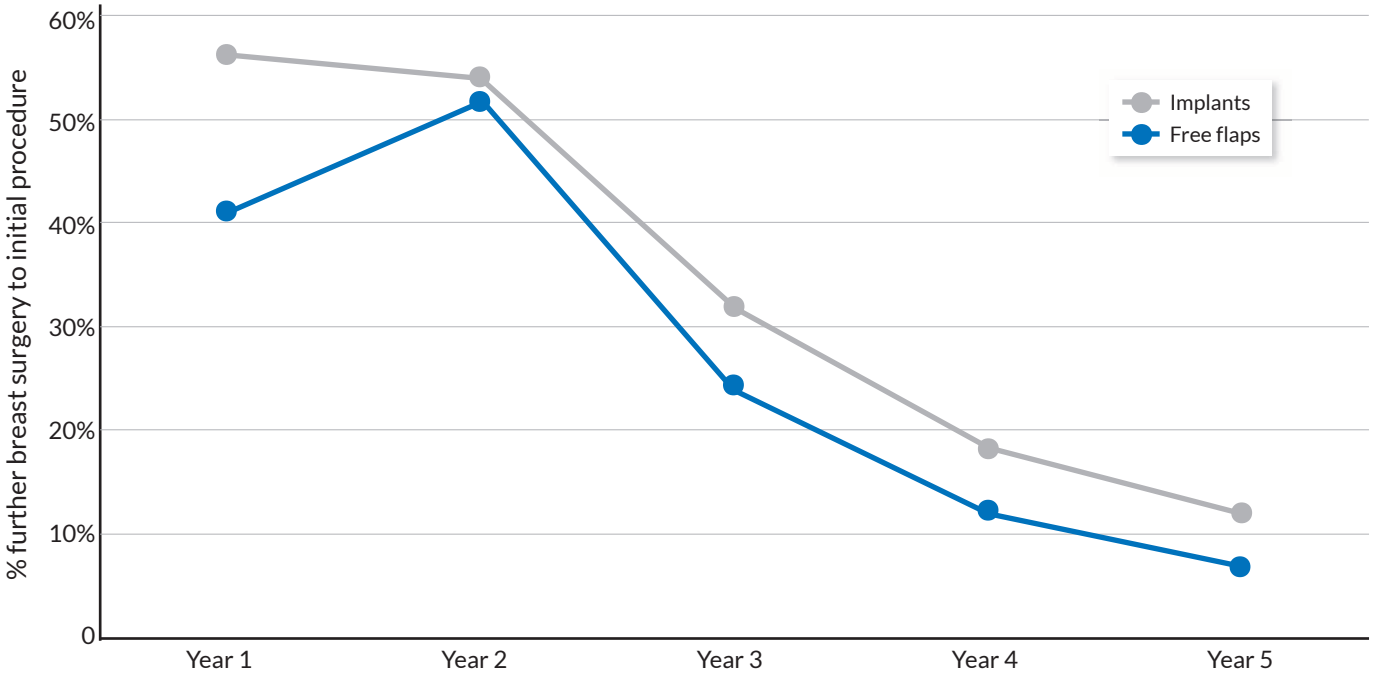
[58] *See www.plasticsurgery.org/documents/medical-professionals/quality-resources/guidelines/guideline-2017-autologous-breast-reconstruction.pdf*

The data showed that the emergency readmission rates were very similar for the two methods; however, there were higher rates of further surgery and outpatient attendances following implant-based reconstruction. As a result, the average follow-up cost for a free flap reconstruction was £4,321 and for an implant-based reconstruction £6,355.

Aside from costs, the need for further surgery has a significant impact on patients, both in terms of the risk associated with any surgery and the convenience of having to attend multiple further operations, and on provider workload. Figure 19 below shows the percentage of patients who had further surgery in the five years after their reconstruction; some patients will have had more than one further operation over this time.

As can be seen, in every year, the percentage was higher for implant-based reconstruction than for free flap. As the total number of implant-based reconstructions was also higher, this amounts to a far greater number of additional operations over the five-year period.

Figure 19: Proportion of patients requiring further breast surgery following reconstruction between April 2010 and March 2013, by reconstruction method



Source: HES

Our analysis found that the average pathway cost over five years for a free flap reconstruction of £10,779. For implant-based reconstructions, the average was £10,180.

Put another way, while a free flap reconstruction costs 41% more than an implant-based reconstruction if we look at the initial procedure only, when the whole pathway is considered, the cost difference is just £600.

Table 6: Cost comparison for reconstruction pathways following unilateral breast surgery

	Free flaps			Implants			Variation in average cost***	
	Activity	Total Cost****	Average costs/ initial proc****	Activity	Total Cost****	Average costs/ initial proc****		
Initial procedure (unilateral only)*	**1,456**	**£9,402,878**	**£6,458**	**3,309**	**£12,653,926**	**£3,824**	**£2,634**	**41%**
Any cause emergency readmission in 30 days	136	£351,865	£242	261	£555,083	£168	£74	31%
Further breast surgery within 5 years**	1,992	£3,408,904	£2,341	5,715	£13,886,974	£4,197	-£1,855	-79%
Outpatient attend/proc within 5 years ***	29,340	£2,530,852	£1,738	72,080	£6,587,999	£1,991	-£253	-15%
Subtotal cost of follow-up care		**£6,291,621**	**£4,321**		**£21,030,056**	**£6,356**	**-£2,035**	**-47%**
Total cost per initial procedure	**1,456**	**£15,694,499**	**£10,779**	**3,309**	**£33,683,982**	**£10,180**	**£599**	**6%**

Source: HES

* Initial procedure between April 2010 and March 2013
** further breast surgery based on defined list of procedures
*** outpatients in agreed specialties
**** cost = tariff for the year activity took place, adjusted for average MFF of all associated activity

We were told by some plastic surgery units that the current tariff for free flap surgery does not cover the costs incurred; this may be because certain procedures are not assigned to the most appropriate HRG. This is a particular issue for trusts that accept referrals for reconstruction only from other units, as the reconstruction losses cannot be compensated for by gains from the overall cancer treatment pathway which takes place in another trust. While some trusts have managed to negotiate tariffs locally with commissioners, this is an issue which should be addressed nationally as several units told us they have had to restrict access to free flap reconstruction, apparently because of cost recovery issues.

Finally, to keep our data as current as possible, we only looked at contact with the breast surgery team in the first five years from the reconstruction. However, as our data shows, the majority of patients who have a reconstruction are under the age of 70. We know that implants are likely to require further revision throughout the patient's life, for reasons such as ageing and/or rupture of implants, encapsulation or displacement. As a result, we can be confident that the total cost of implant-based reconstruction is likely to increase beyond the costs incurred in the first five years to account for these further revisions.

It is important that surgeons and commissioners are aware of the ongoing financial and patient costs of different reconstruction methods, so that they can be adequately funded. We believe that, to inform longer-term funding decisions, more in-depth analysis is required to provide a more accurate picture of the true costs of breast reconstructions.

Recommendation	Actions	Owners	Timescale
Core Recommendation **5.** Ensure equity of access to: • oncoplastic surgery to support safe breast conservation; and • breast reconstruction, with the aim of reducing variations in immediate reconstruction rates and variable access to free flap econstruction techniques. (Breast MDTs should have a link to a plastic surgeon).	**a** Establish oncoplastic MDTs in every breast and plastic surgery unit (virtual/real).	Trusts / commissioners	For immediate action
	b MDTs to support breast conservation regardless of age whenever safe and desirable. They could for example consider using: • primary systemic therapies to support conservation when clinically indicated. • oncoplastic breast conservation when appropriate. Where access is not available on site, alternative providers must be offered through oncoplastic networks.	Trusts	For immediate action
	c Trusts to provide access to all index methods of reconstruction, (following NICE guideline NG101) and outsourcing reconstruction where necessary.	Trusts	For immediate action
	d ICS/STPs to work with oncoplastic MDTs to examine facilitators and barriers to immediate reconstruction and free flap reconstruction.	ICS/STPs	For immediate action
	e ICS/STPs to conduct needs assessments and plan capacity between breast and local plastic surgery units with the aim of: • achieving an immediate breast reconstruction rate of 25% (GIRFT national rate), whether performed onsite and/or outsourced • ensuring at least 30% (GIRFT national rate) of immediate breast reconstructions are free flap.	ICS/STPs	For immediate action

Recommendation	Actions	Owners	Timescale
6. Reduce unplanned readmissions and returns to theatre.	**a** Oncoplastic surgery teams to ensure 30- and 90-day unplanned admissions and return to theatres rates are within the median quartile (GIRFT national benchmark).	Oncoplastic surgery teams within trusts	For completion within 12 months of publication of the GIRFT report
	b Oncoplastic surgery teams to ensure unplanned implant removal rates at 1 year are 7.5% or below (GIRFT national benchmark). (The target is 5% or less in accordance with the oncoplastic guidelines.	Oncoplastic surgery teams within trusts	For completion within 12 months of publication of the GIRFT report
	c Plastic surgery teams to reduce unplanned free flap return to theatres to UKNFR rates of 7%.	Plastic surgery teams	For completion within 12 months of publication of the GIRFT report
7. Incorporate PROMs for all oncoplastic, reconstructive and related surgery as well as for aesthetic breast surgery.	**a** Trusts to consider the adoption of the BreastQ questionnaire, or similar, as a standardised means of gathering PROM data.	Trusts	For completion within 12 months of publication of the GIRFT report

Reducing unwarranted surgery on the breast

Statement of principle

No patient should undergo more surgery than is necessary.

As a general principle, reducing the need for surgery as well as the volume of surgery is highly desirable for patient, provider and the wider NHS. Surgery usually requires hospital admission and general anaesthetic and carries with it the risk of chronic pain, permanent scars and other shorter-term complications, such as infection or bleeding that requires further surgery to control.

During the GIRFT process, we gathered data about a range of breast surgery activity and found substantial variation between trusts in their rates of:

- surgery for benign and normal breast conditions;
- repeat surgery after breast excision for cancer; and
- bilateral mastectomy for cancer.

We explore each of these areas below but, taken as a whole, this variation suggests that at some providers a substantial amount of unwarranted (or unnecessary) surgery is being conducted. As units are facing growing workloads for diagnosis and cancer surgery, unnecessary operations should be minimised – both for provider workloads and the benefit of patients. With that aim in mind, we have identified best practice exemplars and, in discussion with key stakeholders including ABS, BAPRAS and patient charities, will set best practice targets for future monitoring on the Model Hospital platform.

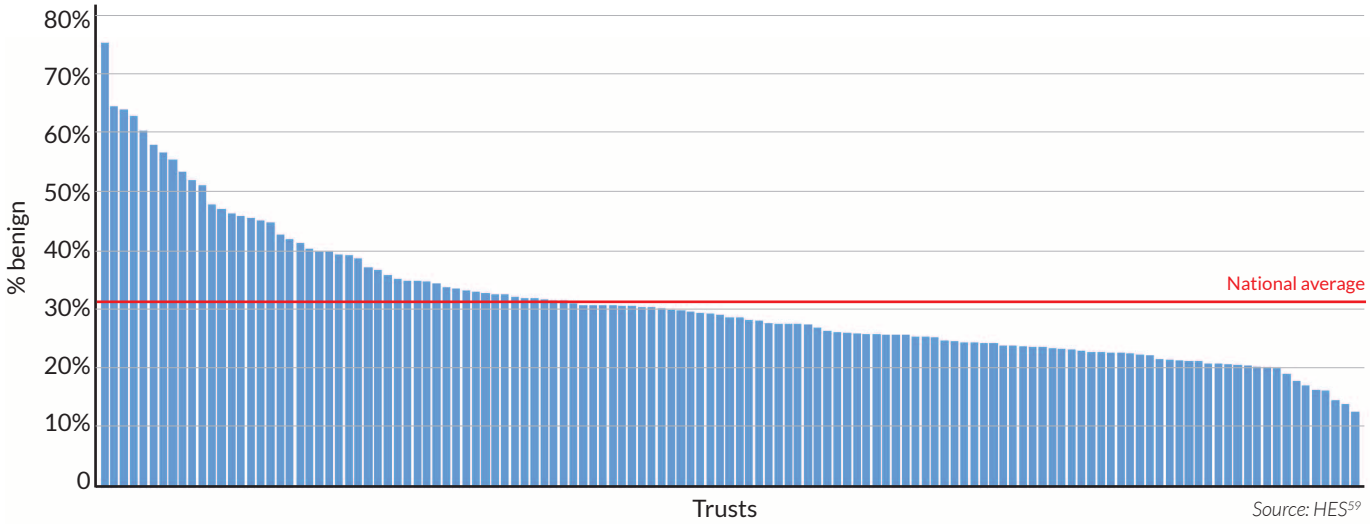
Reducing breast excisions for benign/normal conditions

Statement of principle

Breast excision surgery for benign or normal conditions should be minimal.

The majority of surgery which removes part of the breast (breast excision) is performed as wide local excision to remove cancer. However, nationally just under a third of breast excisions are for non-cancer reasons and as Figure 20 shows, there is considerable variation between providers in the percentage of excisions performed for non-cancer reasons.

Figure 20: Percentage of breast excisions for non-cancer diagnosis, by trust, April 2015-March 2018



[59] *Excludes standalone plastics units as they do not routinely conduct breast excisions. Breast excision is defined as any operation to remove breast tissue that is not a mastectomy. It must be a patient's first admission for a breast excision. For the purposes of the analysis, benign refers to excisions that were not for invasive, DCIS or B3 lesions; diagnosis is determined post-surgery.*

Around two-thirds of providers sit on or below the national mean here, indicating that the mean itself is strongly affected by a small number of providers with the highest proportion of excisions for a non-cancer diagnosis. Over the period under consideration, 11 providers recorded more excisions for non-cancer diagnosis than they did for cancer. During deep dives, we discovered that some providers are using the code for breast excision for vacuum-assisted biopsies. This is essentially part of the diagnostic process and not a surgical excision. We believe this accounts for some of the variation, but nonetheless believe there is a substantial opportunity to reduce excision rates for benign or normal conditions.

There are several types of excision on benign or normal breast conditions where rates could be reduced if providers adhered to good practice guidelines. These are:

- repeat excision surgery after cancer WLE, where the final excision reveals benign tissue only. Such repeat excisions should be as low as possible (see next section);
- diagnostic breast excisions. Modern techniques and working practices, such as good MDT working with guideline-based radiological assessment, including the use of image-guided vacuum-assisted biopsy/excision (VAB/VAE), should virtually eliminate the need for diagnostic surgery;[60] and
- primary breast excision of benign/normal breast lumps, such as fibroadenomas, hamartomas and PASH lesions, or excision surgery of the nipple milk ducts such as major duct excisions, microdochectomy etc.

If all providers followed the breast assessment protocols[61] and guidelines produced by the ABS regarding the appropriate management of benign and normal conditions, the volume of diagnostic and primary breast excision surgery could be substantially reduced.

As noted above, one of the main ways to reduce breast excision surgery for benign or normal conditions is through the use of VAB and VAE. We are that aware some units do not yet have access to vacuum systems; this is something that should be addressed as soon as possible for the benefit of patients.

However, this desirable change in practice needs to be reflected in appropriate data capture and tariffs. Firstly, complex radiology procedures (e.g. complex breast biopsy/excision) need to be recorded using the interventional radiology specialty treatment function code (TFC) 811 rather than the diagnostic radiology TFC 812. In addition, interventional radiology procedures should not be captured as day cases but more appropriately as OPD procedures: this will help to limit confusion with a surgery admission for breast excision. We are aware that appropriate tariffs now exist to encourage accurate clinical coding;[62] we encourage providers to use them.

It should be noted that benign or normal conditions that do not require surgery (such as fibroadenomas) also do not require VAE.

Minimising repeat surgery following WLE for cancer

Statement of principle

Repeat surgery following WLE for cancer should be as low as possible, while supporting safe breast conservation and delivering a good cosmetic outcome.

Wide local excision (WLE) is regarded as the default surgical recommendation for early breast cancer that meets the relevant clinical criteria. It removes the cancer while maintaining the appearance of the breast. However, to be oncologically successful, WLE requires the edges of the tissue removed (margins) to be clear of cancer. Some patients will then require further treatment (involving radiotherapy and drugs) to reduce the chance of recurrence.

After the initial WLE, some women require a second (very occasionally a third) operation to ensure there are clear margins. This may either be a repeat excision of the margins (so still conserving the breast) or mastectomy.

Though some second surgery is inevitable when providing breast-conserving treatments, repeat surgery is stressful and inconvenient for patients. The appearance of the breast is more difficult to maintain after repeat excision surgery, while a mastectomy will often also mean reconstruction is required. Repeat surgery also increases providers' workloads and costs.[63]

[60] *See e.g. https://associationofbreastsurgery.org.uk/media/64791/breast-screening-v2.pdf*

[61] *See e.g. https://associationofbreastsurgery.org.uk/media/65098/breast-surgery-v4.pdf*

[62] *See www.crbard.com/vae/resources/NHS-Coding/01-Coding-Advice-for-Vacuum-Assisted-Excision.pdf*

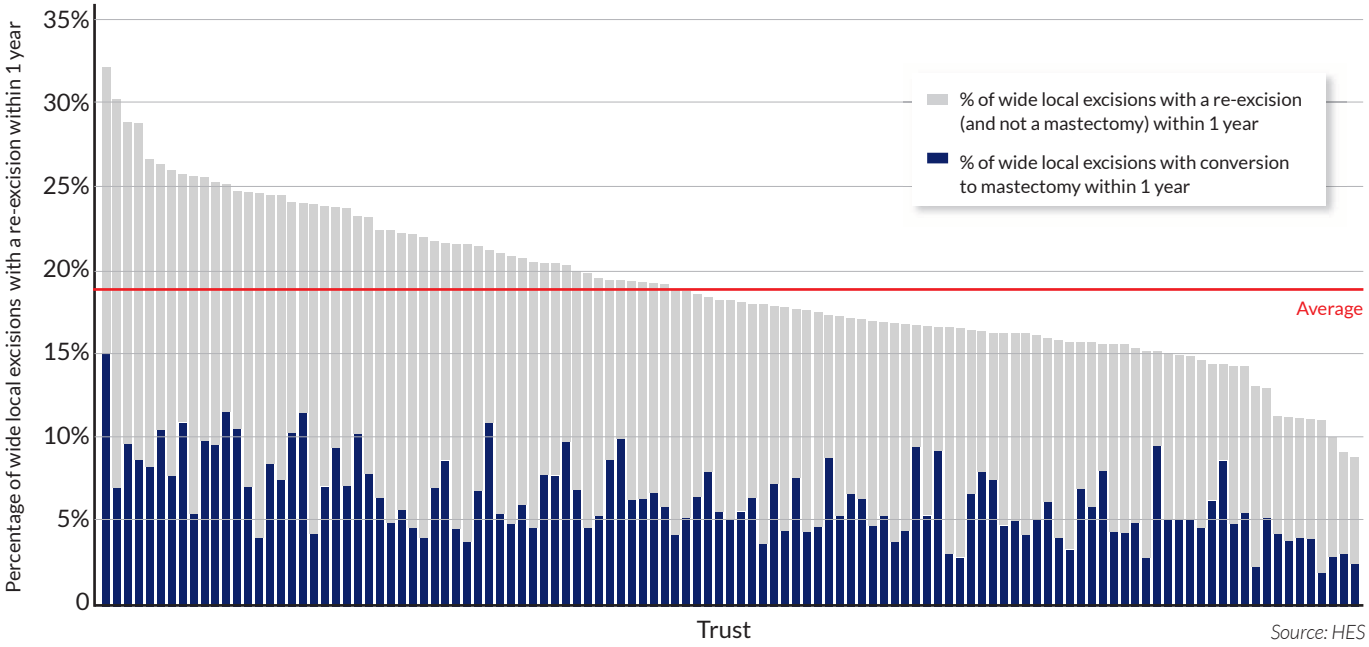
[63] *See Grant, Y., Al-Khudairi, R., St John, E., et al – Patient-level costs in margin re-excision for breast-conserving surgery British Journal of Surgery March 2019;106(4):384-394. https://bjssjournals.onlinelibrary.wiley.com/doi/abs/10.1002/bjs.11050*

It is therefore desirable that repeat surgery rates are as low as possible.

However, there is a fine balance to achieve between re-excision rates and optimal cancer outcomes, conservation rates and cosmesis. If repeat surgery rates are inappropriately suppressed, this could result in increased local recurrence rates, which may impact on overall survival. Low re-excision rates could also indicate that the initial surgery recommendation is over-cautious, with more patients being offered mastectomy rather than breast-conserving surgery, or larger volumes of breast tissue being removed in the first excision, which in turns impacts on the appearance of the breast and patient satisfaction.

We looked at overall repeat surgery rates between providers and found extensive variation.

Figure 21: Proportion of cancer patients undergoing repeat surgery within 1 year of WLE, either as re-excision or mastectomy, by trust, April 2014-March 2017[64]



Source: HES

For patients who had a WLE between April 2014 and March 2017, the overall repeat surgery rate within a year was just under 19%. This is a reduction of about 2% since the last major audit a decade ago and similar to the BCCOM audit in 2006[65] – though it should be noted that the methodologies of these three audits are not directly comparable.

It is encouraging that overall repeat surgery rates have not increased over this period, in which WLE rates (as a proportion of first surgery for breast cancer) have increased from 60% to 70% over the same time.

However, the variation in repeat surgery after WLE between providers is extensive, suggesting significant differences in local practice. Notably, in 13 trusts, the re-excision rate was over 25% - meaning 1 in 4 patients had a repeat excision, compared to the national average of just under 1 in 5. By contrast, at eight trusts, fewer than 1 in 8 patients had repeat surgery.

The majority of re-excisions will be as a margin shave, so still conserve the breast. However, a percentage of re-excisions will be as mastectomy. Figure 21 also shows the proportion of patients who, after having a WLE, had a full mastectomy on the same breast within a year. The conversion of initial WLE to mastectomy ranged from 2.54% to 34.48%. Even allowing for a degree of patient choice, the variation is broader than we would have expected.

Our re-excision data is similar to the national re-excision rate in the US before 2014. However, this dropped to 12.3% in 2017,[66] following the introduction of a best practice toolbox[67] and the American Society of Breast Surgeons (ASBrS) setting an 'accountability' re-excision target of 10% (the first ever published for excisions by a professional organisation). Surgeons performing more than 100 WLE a year met this target.

[64] *The data here is for patients whose initial excision was between 2014 and 2017; therefore, the re-excision took place between 2015 and 2018, the main period under examination as part of the GIRFT process.*

[65] *See Jeevan, R., Cromwell, D., Trivella, M., et al (2012) Reoperation rates after breast conserving surgery for breast cancer among women in England: retrospective study of hospital episode statistics. BMJ 2012 www.bmj.com/content/345/bmj.e4505*

[66] *See Landercasper, J., Borgert, A., Fayanju, O., et al (2019) Factors Associated with Reoperation in Breast-Conserving Surgery for Cancer: A Prospective Study of American Society of Breast Surgeon Members. Annals of Surgical Oncology 2019; 26(10): 3321–3336. doi: 10.1245/s10434-019-07547-w*

[67] *Landercasper, J., Attai, D., Atisha, D., et al. (2015) Toolbox to Reduce Lumpectomy Reoperations and Improve Cosmetic Outcome in Breast Cancer Patients: The American Society of Breast Surgeons Consensus Conference. Annals of Surgical Oncology 2015 Oct; 22(10):3174-83 www.ncbi.nlm.nih.gov/pmc/articles/PMC4550635/*

This would appear to suggest that best practice approaches can help reduce re-excision; indeed, institutional repeat surgery rates of less than 4% have been reported using frozen section margin analysis.[67] While this specific technique may not be realistically deliverable across a whole nation, it indicates that low re-excision rates are possible. Intraoperative margin assessment to reduce re-operation rates on receipt of the final pathology a few days after surgery is an area of considerable research and innovation at present.

Importantly, however, most re-excision rate studies did not include cancer and aesthetic outcomes. Currently, the relationship between WLE and need for repeat surgery on local recurrence rates and survival is very difficult to measure and monitor as there is no data link between breast surgery procedures (held in HES) and the data about specific cancer characteristics (held in NCRAS). In the longer term, we hope that linkage of HES and NCRAS data may make it possible to study this.

Without such data, and with the risks identified of setting targets for repeat surgery, we would not recommend a specific target or rate for repeat surgery.

Strategies to reduce repeat surgery rates

Drawing on the ASBrS toolbox, there appear to be a number of strategies involving the whole breast MDT that can help reduce repeat surgery rates. These include:

- improving the accuracy of the MDT's diagnostic assessment of disease extent and presence/extent of micro-calcification and DCIS (usually non-calcifying);
- improving the accuracy and appropriate use of localisation;
- use of oncoplastic WLE (see above), to allow larger specimen excisions without compromising the breast appearance;
- considering primary systemic therapy where appropriate;
- adopting simple intraoperative margin assessment (margin shaves, specimen x-rays, accurate margin labelling and operation note recording, etc); and
- using the MDT to decide, on an individual basis, whether repeat surgery is necessary.

Following the introduction of the 2015 ABS consensus statement which redefined what width of margin is acceptable,[69] plus the increased use of oncoplastic WLE and primary chemotherapy, we believe there should be a significant reduction in repeat surgery rates over the next few years. This should be visible through the Model Hospital platform, which will include HES data about repeat surgery (including excision or mastectomy), based on the GIRFT methodology.

By drawing on this data and seeing how they compare to others, breast MDTs will be able to better understand and refine their criteria for breast excision and repeat surgery.

CASE STUDY

Reducing repeat surgery rates

East Suffolk and North Essex NHS Foundation Trust

At Colchester Hospital (part of the East Suffolk and North Essex NHS Foundation Trust), an internal review of practice found that there was a significant difference in the re-operation rate between surgeons. Those that conducted WLE using the four-quadrant cavity shaving approach had a far lower reoperation rate than the surgeons that did not use this method.

After presenting data that showed this difference, it was agreed that all surgeons would use the four-quadrant cavity shaving method. When the audit was repeated the following year, the reoperation rate was consistently lower across the team – and well below the national average – with the only exception being a locum.

[68] *Boughey, J., Hieken, T., Jakub, J., et al (2014) Impact of analysis of frozen-section margin on reoperation rates in women undergoing lumpectomy for breast cancer: evaluation of the National Surgical Quality Improvement Program data Surgery 2014 Jul;156(1):190-7. https://pubmed.ncbi.nlm.nih.gov/24929768/*

[69] *Association of Breast Surgery (2015) Margin Width in Breast Conservation Surgery https://associationofbreastsurgery.org.uk/media/64245/final-margins-consensus-statement.pdf*

Limiting unnecessary bilateral mastectomy

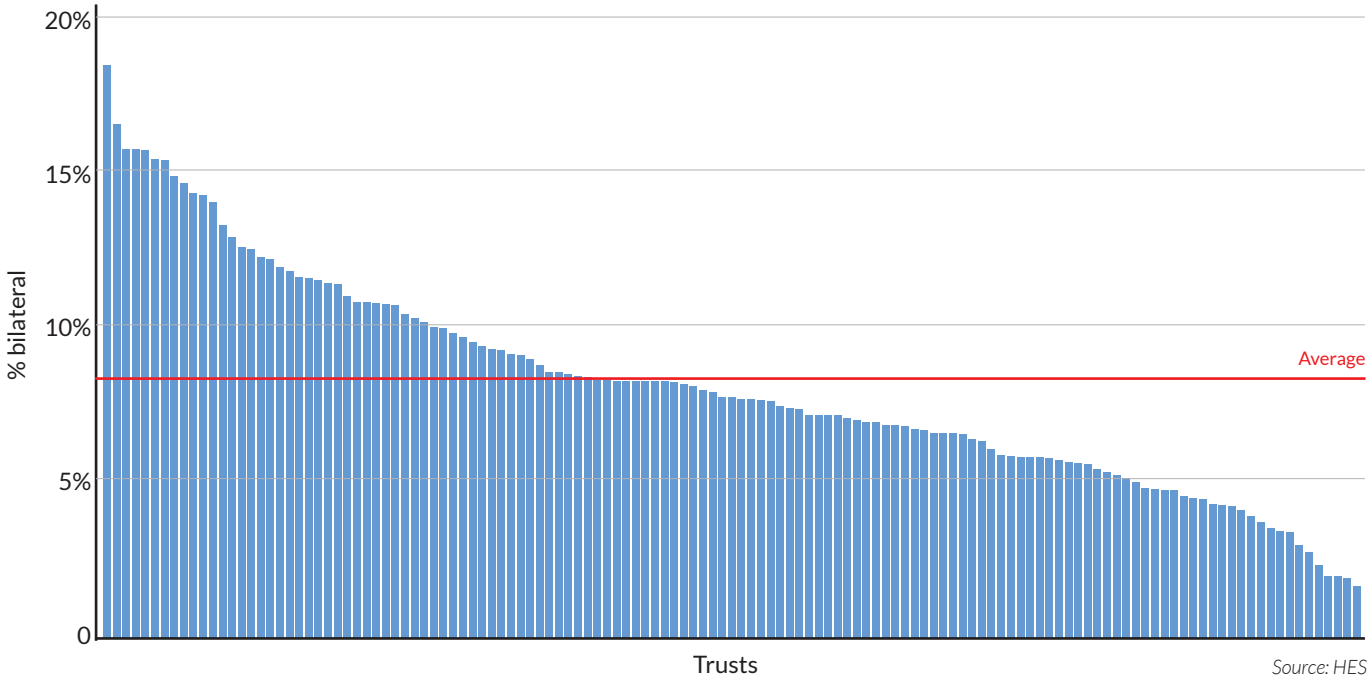
Statement of principle

Bilateral mastectomy should only be performed when clinically indicated in line with national guidance.

This section does not refer to women without cancer having bilateral mastectomy for risk reduction.[70]

Nationally each year, using HES data from April 2015 to March 2018, 8.5% of NHS patients with breast cancer who required a mastectomy had simultaneous bilateral breast removal ('double mastectomy'). As can be seen in Figure 22 there was substantial variation between trusts ranging from 1.7% to 18.4%.

Figure 22: Percentage of cancer patients undergoing bilateral simultaneous mastectomy, by trust, April 2015 to March 2018 [71]



Simultaneous bilateral breast cancer is uncommon; generous estimates based on published data suggest simultaneous bilateral breast cancer occurs in about 4% of newly diagnosed patients.[72]

This suggests that many of the bilateral mastectomies undertaken in England are for reasons other than bilateral cancer. We know that, both in the UK and USA, there is an increasing trend in women with unilateral cancer towards removal of the opposite healthy breast.[73]

[70] *The NICE guideline CG164 Familial breast cancer covers these issues and includes specific recommendations on risk-reducing breast or ovarian surgery for people with a personal history of breast cancer (recommendations 1.7.55 to 1.7.66). See www.nice.org.uk/guidance/cg164/chapter/Recommendations#risk-reduction-and-treatment-strategies*

[71] *GIRFT data does not include women who had risk-reducing bilateral mastectomy because they carry a 'cancer gene'.*

[72] *Kheirelseid, E.A.H., Jumustafa, H., Miller, N. et al. (2011) Bilateral breast cancer: analysis of incidence, outcome, survival and disease characteristics. Breast Cancer Research and Treatment 126, 131–140 (2011). https://doi.org/10.1007/s10549-010-1057-y*

[73] *See Neuburger, J., MacNeill, F., Jeevan, R., van der Meulen, J., Cromwell, D. (2013) Trends in the use of bilateral mastectomy in England from 2002 to 2011: retrospective analysis of hospital episode statistics. BMJ Open. 2013 Aug 1;3(8). https://bmjopen.bmj.com/content/3/8/e003179 .*

While acknowledging the range of complex factors in what is a very personal decision, we understand that there are three broad reasons why patients opt for a bilateral mastectomy for unilateral cancer:

1. **To reduce the risk of developing further cancer**

   A small number of women carry an abnormal gene or have an unexplained high-risk family history that significantly increases the risk of developing another breast cancer. Once this is identified, it presents a strong case for bilateral mastectomy.

   However, a growing number of women request bilateral mastectomy (usually simultaneous) when there is only cancer in one breast, in the belief that this will reduce the risk of recurrence or the development of further potentially life-threatening cancer in the other breast. In the majority of cases, this is clinically inaccurate; their risk-reduction is at best minimal and for most, non-existent. Existing studies don't support the perception that removing the second cancer-free breast will improve cancer outcomes or the risk of needing more chemotherapy, which are usually decided by the prognosis of the index cancer.

2. **To achieve symmetry of the appearance of the chest wall or breasts.**

   Symmetry is an important and generally desirable outcome in breast surgery; for some women it is easier to achieve chest wall or breast symmetry through a double mastectomy +/- a double reconstruction.

   Whereas 26% of patients having a single mastectomy for cancer opt for an immediate reconstruction, nearly half (47%) of those who have a bilateral mastectomy have an immediate bilateral reconstruction, of which 75% are implant- based – where it is easier to achieve symmetry. This suggests that reconstruction symmetry is an important driver in bilateral mastectomy.

   However, it should also be noted that there are also some patients who do not want a reconstruction, for whom a single mastectomy would leave them very unbalanced: they request removal of the other healthy breast to achieve a flat symmetrical chest wall.

3. **To avoid breast screening on the other breast.**

   This is typically among women whose breast cancer was not detected through standard imaging, so they have lost confidence in the screening process.

While there are clinically justifiable reasons for removal of the opposite healthy breast, there is growing concern within the breast surgery specialty that some patients are undergoing double mastectomy either because they/their clinicians overestimate the risk reduction benefits or to enable immediate bilateral reconstruction.

A bilateral mastectomy, in particular with reconstruction, carries greater risks than a single mastectomy; effectively, it's double the amount of surgery, a longer time under anaesthetic and potentially a more prolonged recovery and more scope for complications.

Table 7 below provides a summary of readmissions for complications following mastectomy and reconstruction between April 2014 and March 2018. For all but one measure (haematoma rates following free flap reconstruction), the readmission rate was substantially higher following bilateral reconstruction.

Table 7: Readmissions for complications following mastectomy and reconstruction, 2014-2018

Readmissions	Mx	Implant			Free flap		
		Bilateral	Unilateral	Risk reducing	Bilateral	Unilateral	Risk reducing
% haematoma (30 days)	5%	6%	4.5%	4.5%	8.5%	9%	8.6%
% ER any cause (90 days)	9%	14%	11%	12.5%	15%	11%	15%
% complications (90 days)	11%	28%	21%	22%	31%	21%	25%
% wound complication (180 days)	10%	21%	15%	18%	30%	24%	24%
% unplanned implant removal (1 yr)	-	8.6%	7.2%	5.4%	-	-	-

Source: HES

Bilateral surgery also requires significantly more resources, both in terms of staffing and theatre time. To limit time under anaesthetic (a risk factor for recovery), bilateral surgery may be carried out by two consultants and their teams. Bilateral surgery also requires longer stays in hospital and, from the patient perspective, there are other factors related to decisional regret and irreversible changes in body image and sexuality.

There is no correct bilateral mastectomy +/-IBR rate, but good practice dictates the need for surgery to the opposite breast should be minimised by following best practice guidelines.

Though it may be easier to achieve symmetry in the short term by conducting a bilateral mastectomy and reconstruction, offering an alternative reconstruction technique can deliver symmetry by operating on the affected breast only.

The ASBrS recommends shared decision-making in relation to bilateral (or contralateral) mastectomy, so that patients are fully informed of the risks and benefits of potentially unnecessary surgery.[74] Where possible, decisions regarding the simultaneous removal and reconstruction of the opposite breast must be deferred. In the UK, ABS recommends formal risk assessment (if relevant) and multidisciplinary team (MDT) discussion.[75] Family history patients should be treated in line with the NICE guideline (CG164) on familial breast cancer.

During deep-dive visits, we noted that breast surgery teams who undertake MDT review of all requests for bilateral mastectomy tend to have lower bilateral mastectomy rates, as they will only support the operation if relevant risk or other clinical criteria are met (as described above). We were also told that some CCGs will only support removal of the other breast for risk-reducing purposes and only if linked to a predicted risk of 25% or above of the patient developing a new breast cancer.

We recommend that providers need to monitor bilateral mastectomy for unilateral cancer and clearly document the rationale (symmetry, avoid screening, risk reduction etc). Any risk reduction value (or not) must be clearly conveyed to the patient and documented in writing so there are no misunderstandings. Discussion by the MDT of all requests for bilateral mastectomy (with or without reconstruction), with the outcomes documented, will support best practice.

Admissions and surgery for non-surgery related breast infection

Statement of principle

Admission for non-surgery related breast infection should be avoided where possible.

Breast infection accounts for about 2.5% (ranging from 0.5% to 7.5%) of all breast surgery admissions and about 1.2% (0.3% - 5%) of all breast 'excisions' (either as radiology or surgery drainage). Roughly a quarter of those admitted have (radiology) aspiration and the rest a more formal surgical incision and drainage.

The most common cause of non-surgically related breast infection is mastitis. Approximately 80% of cases are lactational-related and associated with breastfeeding. Non-lactational mastitis (often termed periductal mastitis) can be associated with smoking and other poorly defined and understood causes.

If not managed appropriately, simple mastitis can progress to abscess formation with permanent breast damage and, in a small number of cases, potentially life-threatening sepsis.

Mastitis can, and should, be effectively managed in primary care. In its guideline CG37 *Postnatal care up to 8 weeks after birth*, NICE provides specific recommendations on this.[76] Even if mastitis progresses to an abscess, the overwhelming majority of patients can and should be managed in breast / radiology outpatient settings. Admissions – typically emergency hospital admission, via the on-call general surgery team, for urgent surgical drainage by non-specialist surgeons or radiological aspiration in the breast unit the next day – represent a missed opportunity to diagnose and treat the condition earlier.

[74] *Boughey, J., Attai, D., Chen, S., et al (2016) Contralateral Prophylactic Mastectomy (CPM) Consensus Statement from the American Society of Breast Surgeons: Data on CPM Outcomes and Risks. Annals of Surgical Oncology DOI 10.1245/s10434-016-5443-5 Available at: https://associationofbreastsurgery.org.uk/media/1421/contralateral-prophylactic-mastctomy-consensus-stamte-from-the-american-society-of-breast-surgeons-data-on-cpm-outcomes-and-risks.pdf*

[75] *See https://associationofbreastsurgery.org.uk/media/64790/cancer-surgery-v2.pdf*

[76] *See NICE (2015) CG37 Postnatal care up to 8 weeks after birth paragraphs 1.3.34 to 37 www.nice.org.uk/guidance/cg37/chapter/1-Recommendations#infant-feeding*

Where mastitis has been diagnosed in older non-lactational women or in younger lactational women not responding to first line antibiotics, the patient should be reviewed in a breast clinic. This is because inflammatory breast cancer can present with symptoms suggestive of mastitis.

While 2.5% of admissions and 1.2% of breast excisions is a small proportion of breast activity, this represents more than 2,000 women and around 1,700 potentially avoidable admissions every year, for a condition that can and should be managed in the community or outpatient department.

We found wide variation between trusts in admissions and excision for breast infection. Individual trust volumes may be influenced by having large on-site maternity services, higher levels of deprivation in the catchment areas and rates of smoking, diabetes and obesity. Some women may choose to present to emergency departments, rather than use other community-based services.

However, there is also variation in admission and excision/drainage rates between trusts with similar demographics and levels of deprivation, suggesting there is considerable scope for improvement in the management of non-surgery related breast infection.

In the GIRFT questionnaire, we asked trusts if they have a formal breast infection pathway. 99 of the 132 respondents answered the question; 49 said the pathway is based on initial assessment by the on-call general surgery team, followed by discharge home, with an informal process for referral to the breast surgery team. This was the most popular answer. Most pathways also include, if required, access to suction needle abscess drainage in the outpatient department.

Over the last decade, HES data demonstrates there has been a modest 14% reduction in admissions for breast infection. This suggests more focused efforts are required to improve the management of breast infections and reduce these mostly unnecessary admissions.

While it may be difficult for the breast surgery team to influence factors such as deprivation, smoking, obesity and diabetes, breast services are well placed to lead local health initiatives, through engaging with all relevant healthcare providers including community and primary care, maternity/midwifery services, emergency departments and general surgery.

To facilitate an improvement in the management of non-surgery breast infections, breast surgery and radiology teams need to ensure they develop and promote to the wider healthcare community a simple and clear breast infection management guideline, as well as provide easy, open and rapid access to the breast/radiology service as required. The pathway needs to be communicated effectively with primary care and all emergency departments – so avoiding admissions for all non life-threatening breast infections.

CASE STUDY

Managing infection to minimise admission for breast abscesses

York Teaching Hospital NHS Foundation Trust

Following the introduction of the surgical assessment unit at the York Teaching Hospital NHS Foundation Trust, new protocols were developed for the management of women with presumed breast infection. These were designed to be used by the general surgeons as well as the breast surgeons. The protocols include clear instructions on who to refer for imaging and what imaging to request. They also help ensure that slots are available daily for imaging to occur.

This access to early radiological intervention helps diagnose the condition promptly and removes the need for patients to be reviewed by a breast surgeon, avoiding unnecessary delays in the patient pathway. Infections can then be managed in the most appropriate way. It has resulted in the trust having one of the lowest rates of admission for breast abscess in England.

Recommendation	Actions	Owners	Timescale
Core Recommendation **8.** Ensure that no patients undergo more surgery than is necessary.	**a** Reduce excisional surgery rates for benign/normal conditions to 25% or less of total excisional surgery (GIRFT national rate) by following ABS guidelines and GIRFT best practice exemplars.	Trusts	For immediate action
	b Reduce repeat surgery after wide excision for cancer, aiming towards repeat surgery rates of 10% or less (as recommended by the American Society of Breast Surgeons).	Trusts	For immediate action
	c Minimise adjustment and revision surgery, following ABS, BAPRAS and Breast Cancer Now 'Guidance for the Commissioning of Oncoplastic Breast Surgery'.	Specialty associations	For immediate action
	d Limit bilateral mastectomy for unilateral cancer to when clinically indicated and ensure ABS guidelines and NICE guideline CG164 Familial breast cancer are followed. There must be clear documentation regarding the rationale and benefits (e.g. symmetry) and more specially: • all trusts must provide clear information to patients with unilateral breast cancer to support shared decision making regarding the benefits and risks of bilateral mastectomy +/-reconstruction • all requests or recommendations for bilateral mastectomy (for unilateral cancer) and immediate breast reconstruction must undergo MDT review.	Trusts	For immediate action
9. Reduce admissions/ surgery for mastitis to 1% or less of admissions captured under the OPCS codes for excisional breast surgery.	**a** MDTs to develop a plan to reduce their admissions for non-surgery related breast infections and breast interventions.	Trusts and primary care	For completion within 12 months of publication of the GIRFT report
	b MDTs to work with local healthcare providers, A&E departments and on call surgery teams to reduce the need for emergency hospital admissions for non life-threatening breast infections.	Trusts and primary care	For completion within 12 months of publication of the GIRFT report
	c Specialty associations to develop a best practice pathway for the management of non-surgical breast infections which reflects the NICE guideline CG37 Postnatal care up to 8 weeks after birth.	Specialty associations	For completion within 24 months of publication of the GIRFT report

Access to aesthetic breast surgery

Statement of principle

There should be equality of access for aesthetic breast surgery for congenital, developmental and acquired anomalies.

The difference between cosmetic and aesthetic breast surgery

Cosmetic breast surgery can be defined as when surgical procedures are used to alter the breast appearance for personal preference. However, if these same procedures are required to support recovery from or reduce the risk of breast cancer, or indicated for a recognised medical problem such as gender dysphoria, failure of breast development, or overgrowth of the male breast because of cancer treatments, they are better termed aesthetic breast surgery procedures.

This is a subtle but important distinction: cosmetic breast procedures cannot and should not be routinely funded by the NHS, but breast surgery procedures for aesthetic purposes can and should be. At an individual patient level, the value of aesthetic breast surgery to correct a medical condition is often considerable, particularly in terms of the patient's overall psychological wellbeing and quality of life. This is demonstrated by the fact that corrective aesthetic breast surgery has been clearly acknowledged as essential to facilitate high-quality recovery and survivorship after breast cancer surgery.

However, for other equally well-recognised medical conditions, the use of the same or similar breast surgery techniques for corrective aesthetic purposes are commonly banded under the umbrella term 'procedures of low clinical value' (PoLCV).[77] This means access to corrective aesthetic surgery for these other medical conditions is dependent on local CCG policies and guidelines. With budgets stretched, such procedures can then appear as easy targets to be cut or severely restricted.

Aesthetic breast surgery for gender dysphoria (reassignment)

Gender reassignment surgery on the breast for gender dysphoria, a recognised medical condition,[78] is commissioned directly by NHS England Specialised Commissioning. In December 2019, NHS England published a new service specification and designated eight units to provide mastectomy and related chest reconstruction.[79]

Gender reassignment breast surgery is performed as part of a programme of care to change the appearance of a person's physical anatomy and sexual organs to match their sense of gender identity.

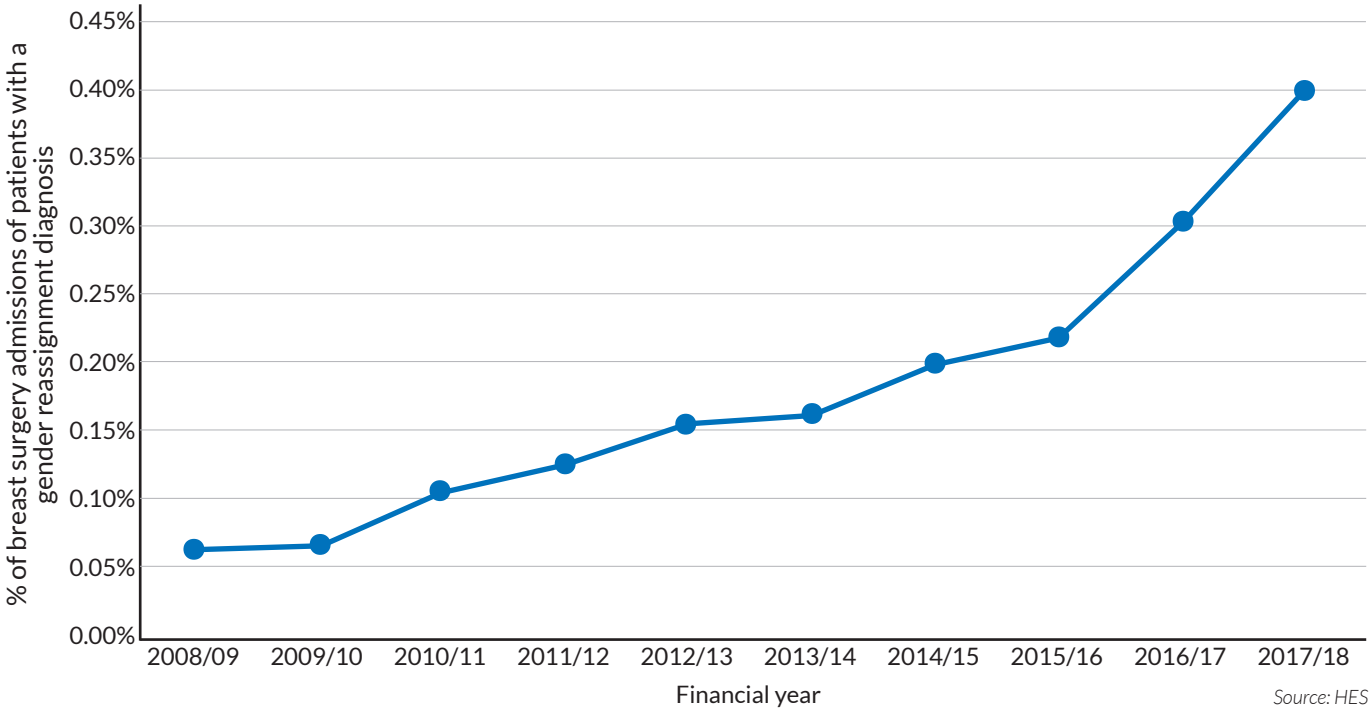
Over the last decade, the volume and percentage of all breast surgery admissions for gender reassignment has increased from 0.06% (53 admissions) in 2008/09 to 0.40% (355 admissions) in 2017/18.

[77] *These are sometimes referred to as procedures of limited clinical effectiveness.*

[78] *Gender dysphoria is a condition where a person experiences discomfort or distress because there's a mismatch between their biological sex – which is assigned at birth, depending on the appearance of the genitals – and gender identity, the gender that a person 'identifies' with or feels themselves to be. It is sometimes known as gender incongruence. Some people with gender dysphoria have a strong and persistent desire to live according to their gender identity, rather than their biological sex. These people are sometimes called transsexual or trans people. Some trans people have treatment to make their physical appearance more consistent with their gender identity.*

[79] *See www.england.nhs.uk/wp-content/uploads/2019/12/nhs-england-service-specification-gender-identity-surgical-services.pdf*

Figure 23: Percentage of breast surgery admissions for patients with a gender reassignment diagnosis, by financial year



Source: HES

As can be seen, the increase accelerated from 2013, when Specialised Commissioning took on responsibility for commissioning gender reassignment surgery.

In the time period April 2015 – March 2018, there were just over 600 admissions for gender reassignment breast surgery. Gender reassignment usually requires simultaneous surgery on both breasts, so the number of operations undertaken is likely to be over 1,200.

The main procedures were mastectomy or breast excisions. Nearly 90% were in persons whose gender was recorded as male (trans males).[80] The range of masculinising breast surgery procedures approved under Specialised Commissioning is comprehensive and includes all breast surgery procedures commonly used to change the breast appearance.

The high percentage of male, compared to female admissions, is due to the fact that Specialised Commissioning funds masculinising breast surgery (usually mastectomy and any related chest reconstruction) for males who were female at birth. However, augmentation mammoplasty for women who were male at birth (trans women) is not funded. This may be because trans women are often treated with female hormones, which also allow natural breast development, so feminising breast surgery may be less commonly required.

Over the last five years, gender dysphoria clinics have seen a 240% increase in referrals; waiting lists for initial consultations are now over two years long.[81] How this will translate into surgery activity is unknown, but based on trends over the last decade, it seems likely there will be substantial increases in demand for reassignment surgery over the next decade. From October 2019, NHS England will fund up to 1,000 cases per year, distributed between the units that have successfully met the tender criteria.

Between April 2015 and March 2018, seven trusts had more than ten gender reassignment admissions for breast surgery. However, four of these are the main breast surgery gender reassignment providers, with admissions ranging from 33 to 80 each year. These surgery providers are dispersed unevenly across the country; most, but not all, are geographically close to one of the eight specialist NHS gender identity clinics.[82]

[80] *When admitted to a hospital, a person who is gender incongruent is normally registered under the gender they identify with, rather than the sex they were born with. A trans man is a biological female, who identifies with the male gender; a trans woman is a biological male, who identifies with the female gender.*

[81] *Torjesen, I. (2018) Trans health needs more and better services: increasing capacity, expertise, and integration. BMJ 2018; 362 https://doi.org/10.1136/bmj.k3371*

[82] *www.nhs.uk/live-well/healthy-body/how-to-find-an-nhs-gender-identity-clinic/*

In 2018, NHS England published new (surgical) service specifications for adult gender dysphoria services, formed through a process of extensive stakeholder engagement and public consultation. These are comprehensive and include clear requirements for surgery providers to demonstrate MDT working, expertise and competence. They recommend that gender reassignment surgery should be undertaken only in providers where the MDT performs over 20 cases each year.

We strongly support the service specifications recommendations and the need to establish a mechanism to ensure compliance and to review outcomes. The recommended outcomes measures and quality indicators align with those that GIRFT will be recommending for all breast surgery.

Aesthetic breast surgery for other medical conditions

Corrective aesthetic breast surgery, including augmentation, mammoplasty and mastopexy, can be used to address:

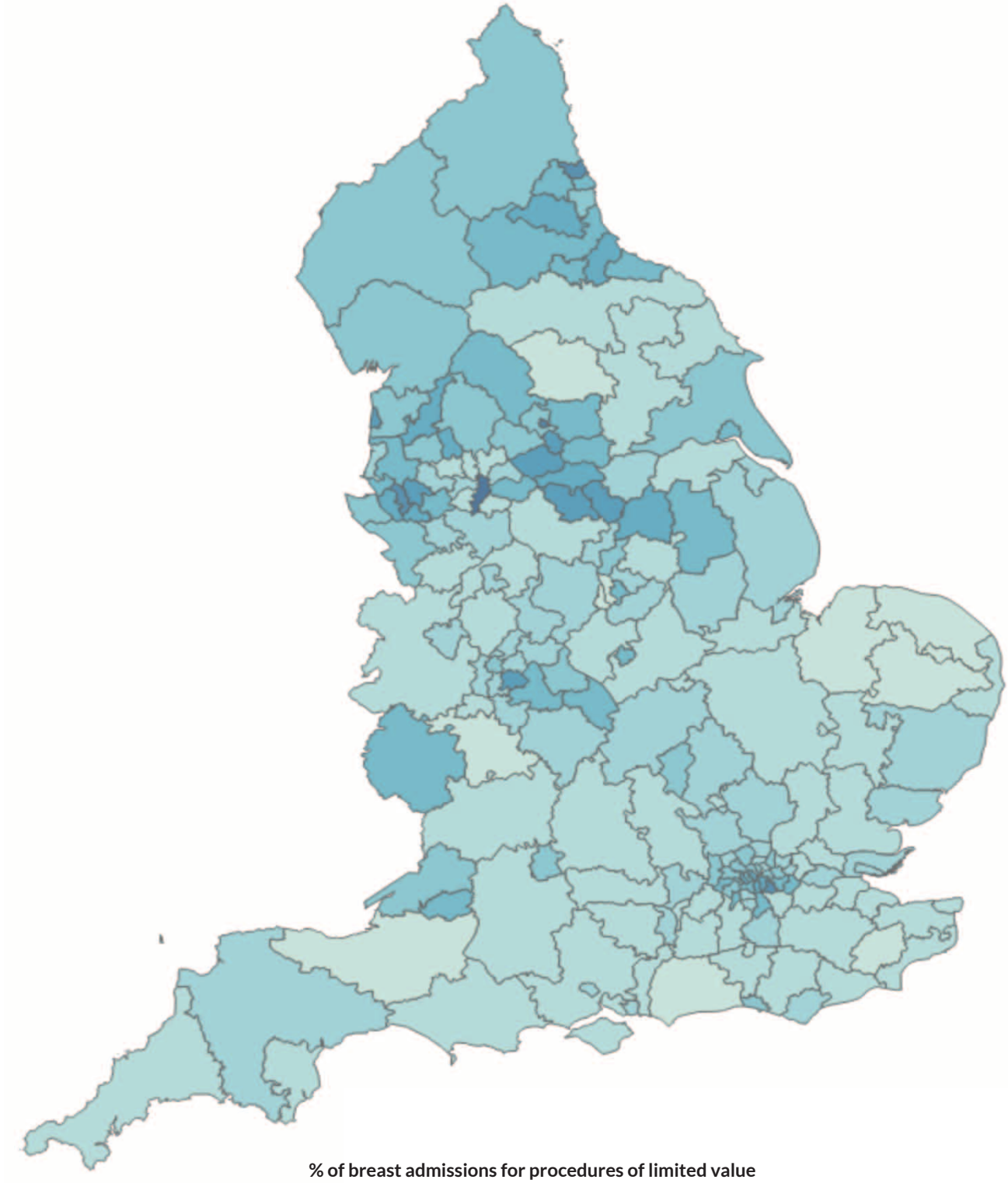
- congenital breast developmental problems, resulting in minimal breast growth or significant breast asymmetry;
- breast overgrowth in females, known as developmental hyperplasia; and
- breast overgrowth in males (gynaecomastia) caused by medical conditions or treatment for prostate cancer.

However, at present, the common surgical procedures for these indications have been labelled procedures of limited clinical value.

The number of individuals seeking these procedures is small but, because of the designation that they are of limited value, CCGs are able to choose if and how they commission this surgery. Some CCGs don't offer them at all and, in the others, patients must meet strict criteria to have surgery funded.

The impact of this can be seen in the map at Figure 24, which shows that over the three-year period between 2015-17, there was considerable local variation in access to these procedures. At one CCG, nearly 10% of all breast surgery admissions were for such procedures; at another, they accounted for less than 1% of admissions. In essence, this means patients in some areas are ten times more likely to be able to access this kind of surgery than in others.

Figure 24: Percentage of breast surgery admissions that were for procedures of limited clinical value, by CCG, April 2015-March 2018



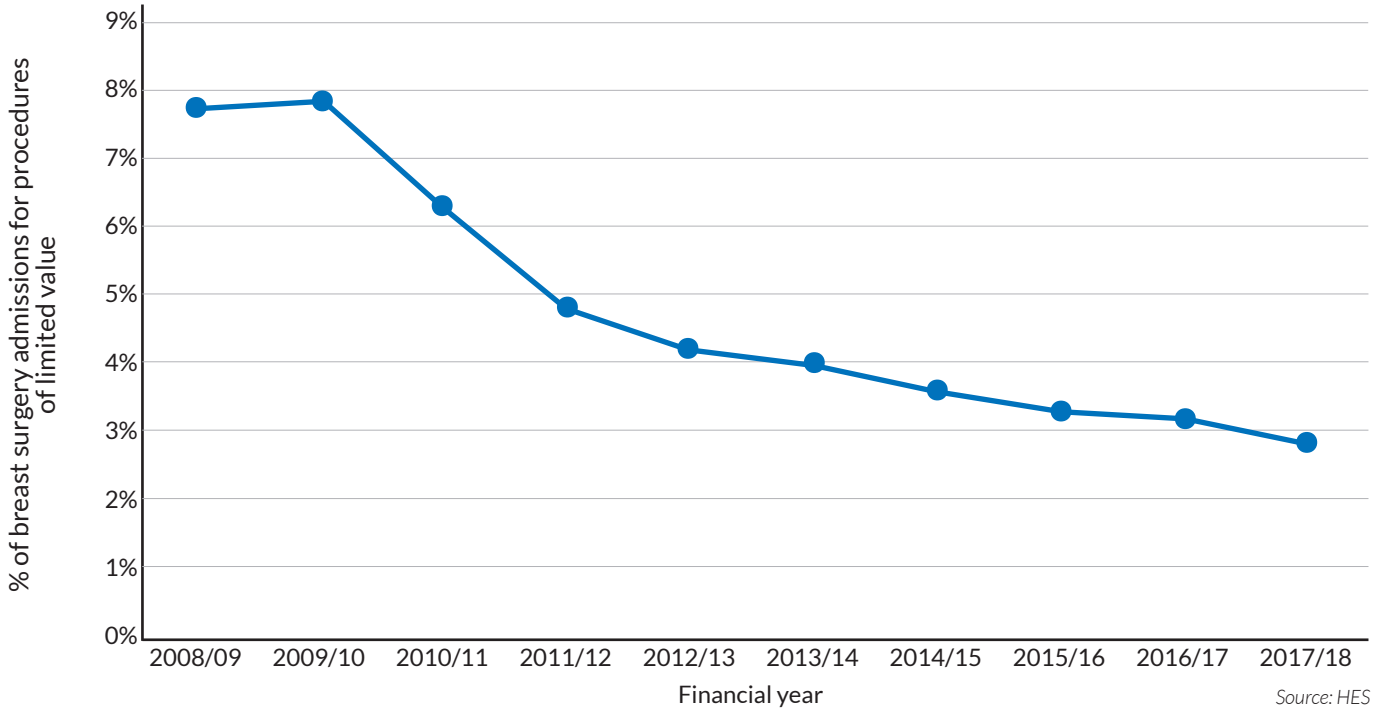
Source: HES

In our deep-dive visits, we heard from trusts who serve a number of CCGs with different eligibility criteria. Put simply, this means it is possible that if two patients in the same clinic required the same so-called procedure of limited clinical value, one may get funding and the other may not, purely based on where they live.

Clinicians may recommend an operation, but have to submit an individual funding request (IFR) and not know if it will be funded until after the IFR request has been assessed. This raises patient expectations, creates considerable administrative work for the clinicians and can create unnecessary tensions between clinical staff and patients.

In addition to the geographic variation in access to these procedures, national data indicates that access is reducing over time. In 2008/09, the procedures now bracketed as being of limited clinical value accounted for 7.78% of all breast surgery admissions, but by 2017/18 that proportion had dropped to 2.84%. There is no reason to believe the incidence of the medical conditions requiring treatment is declining with time.

Figure 25: Breast surgery admissions for procedures of limited clinical value by financial year[83]



Source: HES

Overall, therefore, it seems that it is becoming harder for patients with certain medical conditions to access corrective aesthetic breast surgery. The underlying reasons why some medical conditions attract support and funding for corrective aesthetic and not others are opaque, but may be the result of confusion over what is cosmetic breast surgery (for personal preference) and what is aesthetic breast surgery (for medical indications). Alternatively, it may simply be a consequence of lack of advocacy or lobbying for conditions experienced by a small minority of generally younger adults.

At best, the term 'procedure of limited clinical value' is insensitive and ignores the distress caused by the underlying medical condition. At worst, it appears to permit discriminatory application of arbitrary policies, at the expense of a minority of vulnerable individuals.

Congenital breast developmental problems

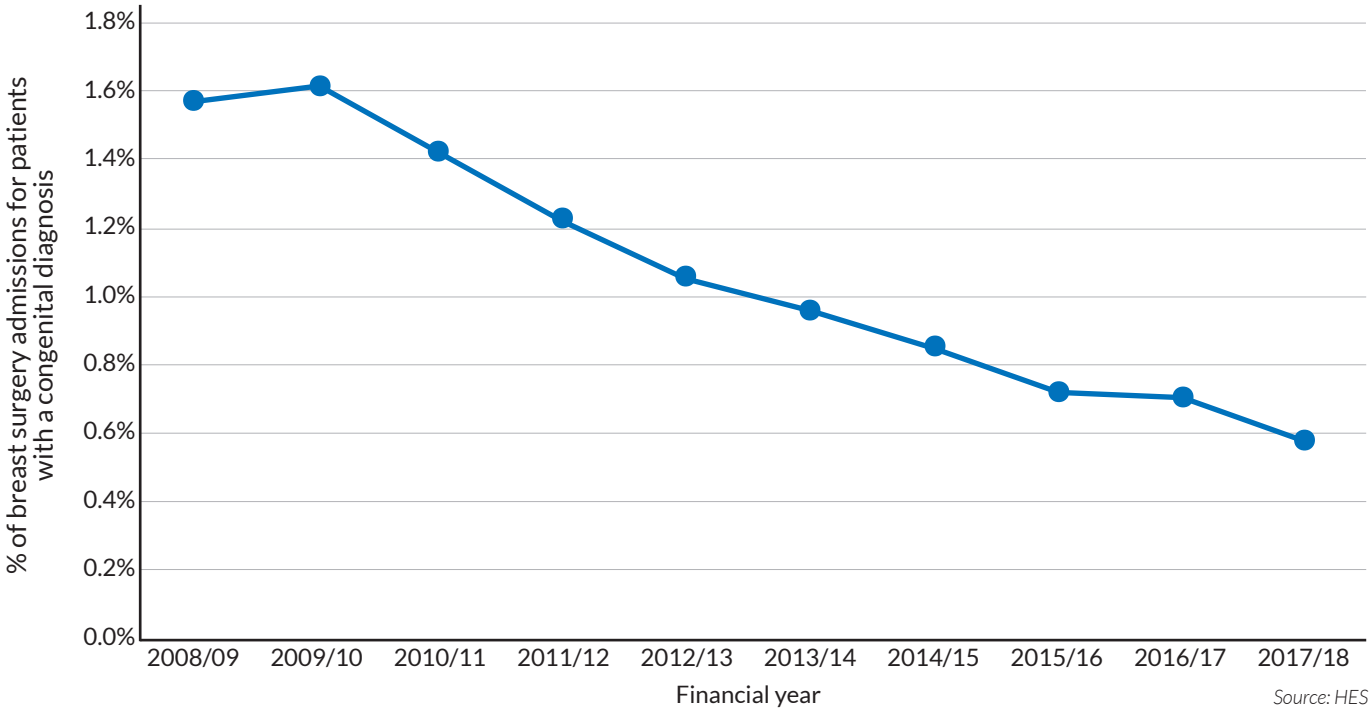
Congenital breast conditions include a wide range of rare conditions where a young person's breast, underlying chest wall or whole shoulder girdle /arm does not develop normally. Problems become apparent at puberty, usually in the teenage years.

[83] *For this data analysis, we have defined 'Procedures of limited clinical value' as the sum of operations conducted for patients meeting at least one of the following criteria: admissions where the patient has a congenital diagnosis, non-cancer patients undergoing a bilateral mammoplasty, males with a non-cancer diagnosis.*

Failure of normal breast development in a young woman can have a major psychological effect, impacting on quality of life, social integration and long-term mental health. The corrective breast surgical procedures undertaken to mitigate congenital developmental problems are varied but commonly include augmentation, mammoplasty and lipofilling.

Over the last decade, the total number of admissions for surgery for a congenital breast problem has dropped from 1,342 a year to 506; this meant that the percentage of all breast surgery admissions for girls with a congenital breast problem diagnosis dropped from 1.6% to 0.6%.

Figure 26: Percentage of breast surgery admissions for patients with a congenital diagnosis, by financial year



Source: HES

Overall, we found considerable variation between trusts in the delivery of corrective breast development surgery. Around 50 trusts conducted fewer than five procedures over the three-year period. By contrast, 14 trusts conducted at least 40 over the same timespan. This is not surprising: as corrective aesthetic breast surgery is bespoke and tailored to the individual patients' needs it is preferable that it should be conducted by surgeons with a super-specialist interest. Best practice dictates this type of surgery should be concentrated in units with sufficient expertise and experience to ensure good outcomes with low complications and satisfied patients.

We noted that in one or two trusts with large paediatric surgery units (who may treat patients up to 21 years of age), corrective breast surgery can be carried out as part of a package of other corrective surgeries that may be associated with the underlying congenital problem.

When we reviewed CCG policies, surgery for congenital breast developmental problems was usually listed as an exception to the procedures of limited clinical value policy, with surgeons advised to make individual funding requests (IFR) where necessary. However, the decline in the rate of such surgery suggests that in reality severe funding restriction is taking place, with thresholds for IFR increasing.

This impression was reinforced by the number of clinicians who told us during deep dives they either no longer accepted patients without IFR already in place, or were increasingly reluctant to apply for IFR as the process was time-consuming and all too often did not result in the funding being granted. Without such applications, CCGs have no record of the need or demand for corrective aesthetic surgery for congenital developmental problems. Clinicians commented that they feel CCG criteria vary in an arbitrary manner and are generally becoming more restrictive. Sadly, in the midst of this, it appears the needs of vulnerable young patients are overlooked.

CASE STUDY

Patient stories: restricted access to corrective aesthetic breast surgery

A 38-year old woman presented with a misshapen and painful breast. On investigation, the implant which had been inserted by the NHS when she was 17, for left-sided amastia (failure of the breast to grow), was leaking and had come to end of its life. Implants do not last forever so this outcome would have been known when the implant was inserted.

The optimal solution was to replace the implant with a new one and perform corrective aesthetic surgery to match her opposite breast, but a change in commissioning policies meant this type of surgery was now regarded as cosmetic and no longer routinely funded: she was advised that the NHS would support implant removal, but not replacement and corrective aesthetic surgery.

Two requests for funding were made, but both were unsuccessful. As the woman is unable to fund the surgery privately, she has chosen at present to keep the leaking implant, rather than being left with stretched, empty breast skin on her chest wall.

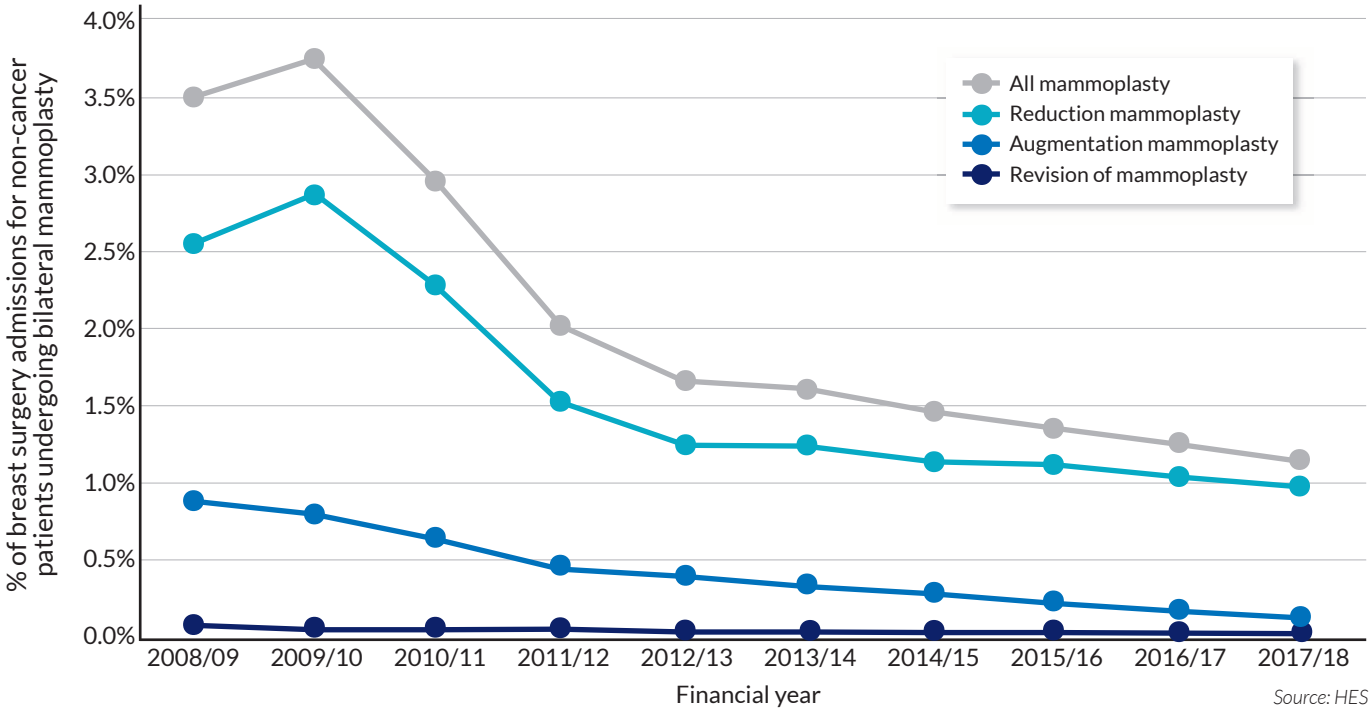
Surgery for breast overgrowth in females (breast hypertrophy/hyperplasia)

A small number of pubertal girls and women experience extreme breast overgrowth, to the extent that the disproportionate size can cause a wide range of physical and mental health problems because of back pain and/or difficulties with day-to-day activities.

This massive breast enlargement can be corrected by a bilateral reduction mammoplasty, and there is a substantial body of evidence to show that this surgery improves symptoms such as back and neck pain.[84]

However, in almost all areas of England, this kind of breast surgery is not routinely commissioned. It is no surprise therefore to see the marked decrease in admissions over the last decade for reduction mammoplasty for non-cancer patients.

Figure 27: Percentage of all breast surgery admissions for bilateral mammoplasty procedures in non-cancer patients, 2008/09 – 2017/18



Source: HES

[84] *See e.g. Jones SA and Bain JR (2001) Review of data describing outcomes that are used to assess changes in quality of life after reduction mammaplasty. Plastic and Reconstructive Surgery 2001 Jul;108(1):62-7. https://pubmed.ncbi.nlm.nih.gov/11420505/*

In total, this amounted to a reduction from 2,979 such procedures in 2008/09 to 988 in 2017/18.

Reduction mammoplasties are typically covered under CCG guidelines for procedures of limited clinical value, with various criteria – such as cup size, BMI, volume of tissue to be removed – defining when funding can be given. GPs or surgical teams need to submit IFRs and during deep-dive visits, we heard that bilateral mammoplasty for extreme overgrowth was the procedure of limited clinical value most likely to be funded, if criteria are met. However, as with surgery for congenital development conditions, clinicians felt that the thresholds of acceptance of IFR varied between CCGs – a view that the data above appears to support.

We strongly believe that where women meet the CCG criteria or have particular need, they should be able to access bilateral mammoplasty and urge CCGs and others to monitor this area closely to ensure that women who do meet the criteria are not disadvantaged.

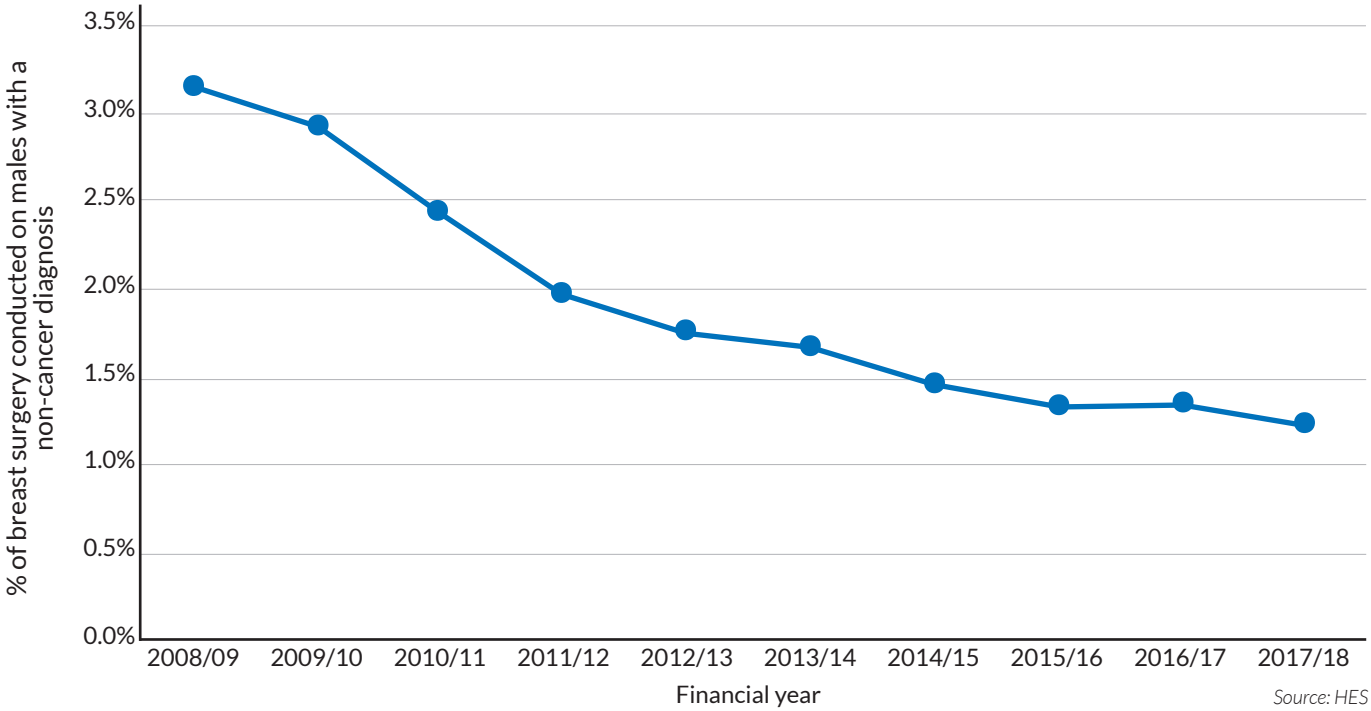
Surgery for breast overgrowth in males (gynaecomastia)

The most common reason that a man requires breast surgery (excluding breast cancer) is overgrowth of the breast (gynaecomastia). Gynaecomastia is most commonly the result of obesity and/or age. However, for a few men, breast enlargement occurs as a result of medical conditions or drug treatments for prostate cancer that cause imbalances in testosterone level. Such men, like women, can benefit enormously from corrective breast surgery and this is usually breast reduction (mammoplasty) surgery.

Breast surgery gynaecomastia accounted for 1,450 admissions between April 2015 and March 2018 – equivalent to about 480 a year. Of these, about 10% were in young men under the age of 18.

Overall, the number of breast surgery operations conducted on males with a non-cancer diagnosis decreased by 60% from 2008/09 to 2017/18. In 2008/09, 2,671 such operations were carried out – amounting to 3.1% of all breast surgery procedures; in 2017/18, there were 1,105 equivalent to 1.25% of all breast surgery. The major factor in this decrease is a drop in the volume of gynaecomastia surgery.

Figure 28: Percentage of all breast surgery procedures conducted on males with a non-cancer diagnosis



Source: HES

Male breast reduction will be considered via IFR if the local CCG criteria (BMI, degree of gynaecomastia, whether the patient has stopped taking gynaecomastia-promoting drugs and whether any underlying hormonal imbalances have been treated etc) are met. However, it seems that here too over the last decade CCG policies have become more restrictive with numbers eligible for surgery dropping. Further, there are major regional differences in IFR thresholds, similar to that seen for female breast reduction for a medical condition.

Procedures of limited clinical value: our evidence and our concerns

Taken as a whole, the data related to breast surgery procedures deemed to be of limited clinical value raises significant concerns:

1. that across the country as a whole, it is becoming harder for individuals to access aesthetic breast surgery despite having a recognised medical condition; and
2. that there is considerable national variation in access to aesthetic breast surgery for a medical condition.

We disagree with the assertion that these operations are of limited clinical value. Surgery for a congenital condition can make an immense difference to a young woman's, or young man's, confidence and quality of life. Clearly, there need to be gateways and caveats to such surgery, but at present, it appears that the barriers to receiving surgery are greater in some areas than in others.

In this context, it is striking to note how NHS Specialised Commissioning has facilitated greater access to gender reassignment surgery for gender dysphoria – even though some of the surgical procedures involved are the same as those used to treat e.g. congenital breast developmental issues.

We see it as both inconsistent and illogical that a procedure can be deemed of limited clinical value for one group of patients or medical condition, but acceptable for another, where there is no substantial difference in the surgical outcomes.

Clear criteria exist for commissioning breast reduction surgery – as set out in the 2018 *Evidence-Based Interventions: Guidance for Clinical Commissioning Groups (CCGs)*.[85] However, it is apparent from our visits that these guidelines are not uniformly being adhered to.

Clear, evidence-based guidelines should be applied consistently and fairly to **all** individuals seeking surgery for congenital, developmental and acquired anomalies across the country.

Recommendation	Actions	Owners	Timescale
10. Reduce inequity in access to aesthetic breast surgery for congenital, developmental and acquired anomalies.	**a** Commissioning criteria for aesthetic breast surgery for congenital, developmental and acquired anomalies to be consistent, and applied consistently.	Commissioners	For completion within 24 months of publication of the GIRFT report

[85] *Available at www.england.nhs.uk/publication/evidence-based-interventions-guidance-for-clinical-commissioning-groups-ccgs/*

Achieving excellence in breast surgery

Statement of principle

Timely, accurate and comparative clinical data improves patient care.

The GIRFT process has underlined how much high-quality breast surgery is provided by the NHS in England.

Through our deep-dive visits, we have met hundreds of committed breast MDT members and learned about innovative approaches that improve the patient experience, use resources effectively and deliver positive outcomes.

By bringing together data on all breast surgery, we have also gained a greater insight into the total workload than has previously not been possible, and been able to identify where there is variation in practice and outcomes.

A clinical team cannot improve what they do unless they know how they compare against their peers, current standards and best practice. The GIRFT process has identified areas where existing data is insufficient to enable this and areas where the ways that data is captured are inconsistent. This risks undermining clinician confidence and the value of comparative analysis.

In this section, we recommend changes to data recording that will improve data accuracy and reliability. We know from the data capture and clinical coding teams we have met that they are willing to assist in this process and to work with clinicians to ensure that data accurately reflects the work being undertaken.

Standardising trust-level data capture for breast surgery

As has been the case in many other specialties, the GIRFT process has revealed various issues with the data currently recorded around breast surgery. In general, breast surgery is well served by HES, as breast surgery is mainly elective, planned surgery. This means that patients usually have a clear and accurate diagnosis on admission (captured using ICD codes)[86] and admissions are usually for a specific intervention (using OPCS code[87]). As a result, both diagnosis and interventions are very well captured on HES by the clinical coding teams.

HES also holds important data about the process of care, such as outpatient attendances, admissions, ward occupancy and theatre usage. However, this data is usually captured by administrative clerks who are 'behind the scenes', distant from daily clinical practice and managerial oversight. Almost inevitably, there are then differences in data capture between trusts – which in turn may result in significant variations between trusts in terms of apparent activity and outcomes.

For example, within HES, some clinical specialties have a specific treatment function code (TFC)[88] that can be applied when recording all treatment under that specialty. For breast surgery, the TFC is 103. The appropriate use of the TFC becomes important when looking at volumes of specialty activity for surgery interventions and outpatient attendances.

However, the application of a TFC is at provider discretion. Some providers capture breast surgery interventions and outpatient department attendances under either the TFC for general surgery (TFC100) or for plastic surgery (TFC160), because the activity took place under the care of a surgeon whose specialty title was general surgeon or plastic surgeon. This means that the breast-related activity these surgeons undertake is not identifiable within the more generic and all-encompassing TFCs of general or plastic surgery.

We recommend that the breast surgery TFC code 103 should be used for ALL surgical activity related to the breast, rather than the general surgery code.

The exception should be vacuum-assisted biopsies and excisions, which should be recorded using the appropriate TFC for interventional or diagnostic radiology (TFC811 and 812 respectively).

[86] *ICD is the International Classification of Diseases. See www.datadictionary.nhs.uk/data_dictionary/data_field_notes/i/icd-10_code_de.asp?shownav=1 During the data gathering and analysis for the report, version 10 was in use. Version 11 has now been released.*

[87] *OPCS is an abbreviation of Office of Population Censuses and Surveys, a forerunner of the Office for National Statistics. It introduced a classification of surgical operations and procedures; version 4 of this remains in use today. See www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/opcs_classification_of_interventions_and_procedures.asp?shownav=1*

[88] *See www.datadictionary.nhs.uk/data_dictionary/attributes/t/tran/treatment_function_code_de.asp*

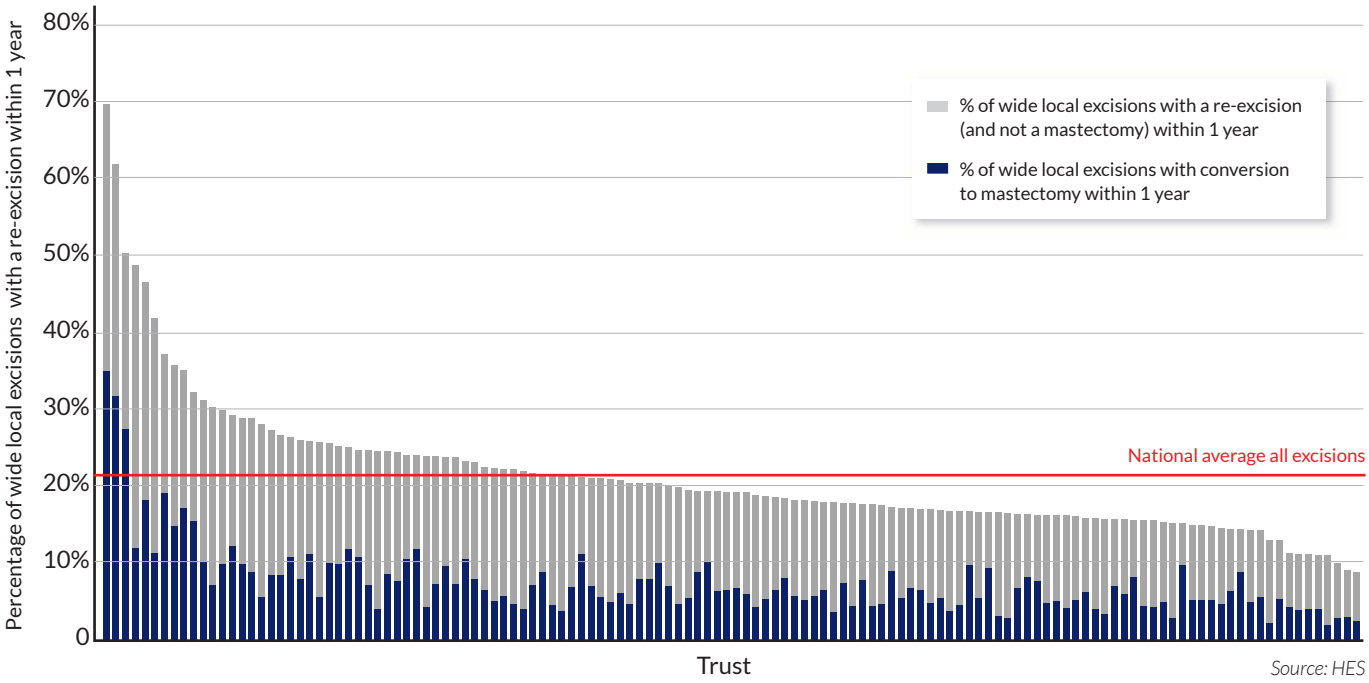
Illustrating the consequences of inconsistent TFC assignment

Because TFC codes are not yet used consistently or reliably, at present any admission for breast excision surgery is usually assumed to be for an operation. However, we know that in some trusts up to 30% of excision admissions are for radiology procedures. This potentially skews any analysis of breast excision data.

This can be clearly demonstrated when looking at re-excision rates – a metric breast surgeons regard as a key performance indicator under the NHS Breast Screening Programme. If the biopsy to diagnose the cancer is recorded as an admission, and thus appears as a first 'operation' in the data, then the actual therapeutic operation will appear to be a re-excision – meaning the trust's re-excision rate will appear much higher than it actually is.

The impact of this can be seen in the below graphs showing the range of re-excision rates across England – before and after we adjusted for radiology admissions.

Figure 29A: Unadjusted re-excision rate within 1 year of a WLE, by trust, April 2014-March 2017

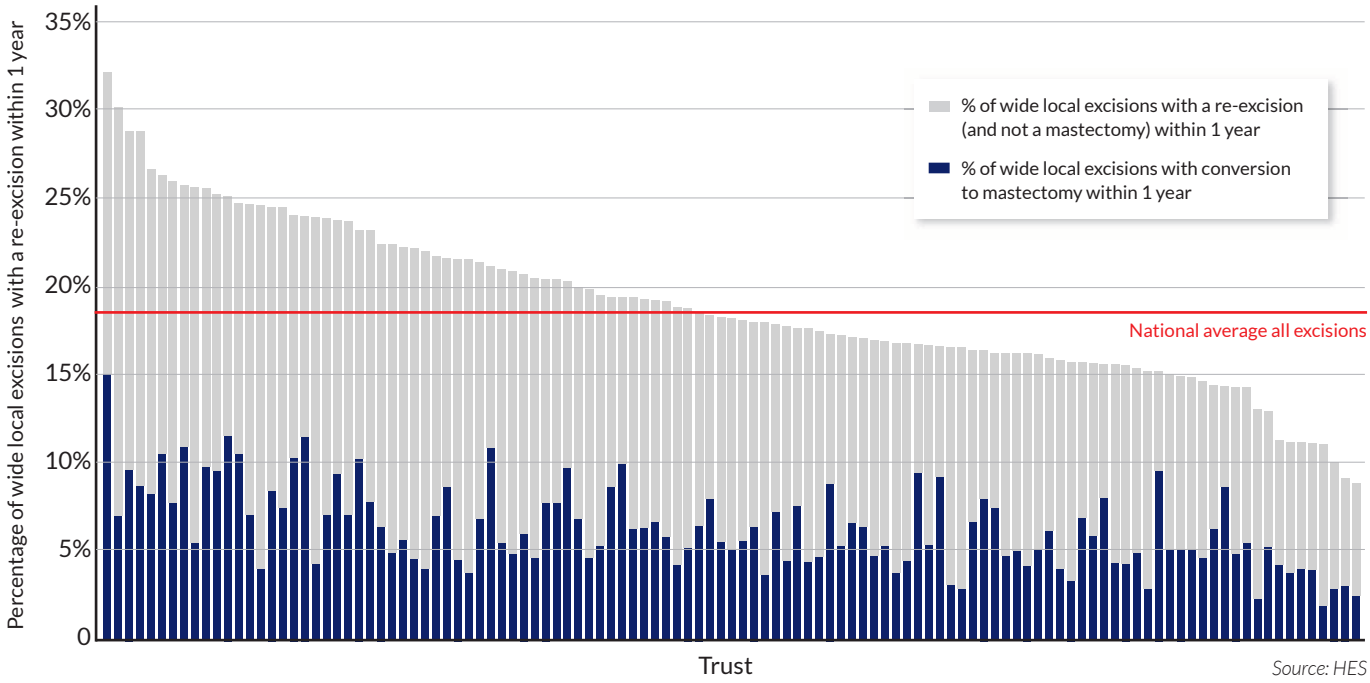


Source: HES

In this unadjusted version, nine providers reported a re-excision rate of over 34% - effectively more than 1 in 3 patients – raising the national mean to over 21%.

In the adjusted version below, with radiology admissions removed, no provider had a re-excision rate of over 33% and the national mean was 18.75%.

Figure 29B: Adjusted re-excision rate within 1 year of a WLE, by trust, April 2014-March 2017



Source: HES

It is highly likely that in the next decade the use of vacuum-assisted excision will increase substantially; for example, it may supplant surgery as the primary method of removal of early impalpable screen-detected cancers. The shifting pattern of workload needs to be appropriately tariffed rather than being recorded as day case admissions. As noted earlier, suitable tariffs[89] do exist but at present these do not appear to be widely known.

Improving the consistency and accuracy of data capture

As well as improving the utilisation of TFC103, to enable us to examine volumes and outcome data accurately, we also need to ensure that:

1. the usage of ICD and OPCS codes is standardised and reflects modern breast surgical diagnoses and practice;
2. HES patient level data is linked to the NCRAS database; and
3. implant and flap registries are fully populated.

More broadly, beyond clinical coding – which is undertaken by dedicated and highly-trained teams of coders working to agreed standards – we believe there is a need to standardise the way general administrative patient data, such as ethnicity, age, date of admission/discharge, is captured by clerical staff within HES. While there is currently a significant focus on increasing standardisation in breast surgery clinical coding, at present there is little, if any, standard guidance on capturing this important patient administration data. We believe this is an issue which is likely to affect all specialties, not just breast surgery.

The need to standardise the usage of OPCS and ICD codes

Neither OPCS nor ICD codes have kept pace with the development of new surgical techniques in oncoplastic and reconstructive breast surgery over the last 25 years – though recent changes in ICD-11 and OPCS version 4.9 are a positive step. Nonetheless, this makes comparison of volume and outcome data difficult.

For example, breast conservation is performed for 68% of cancer patients. We know, from deep dives and our own experience, that there is an increasing use of oncoplastic techniques to support this, but as yet this work is not being captured within HES. This is a result of two factors:

- lack of use of existing mammoplasty OPCS codes for oncoplastic purposes; and
- lack of codes to reflect the complexity and range of oncoplastic surgery, particularly reconstruction.

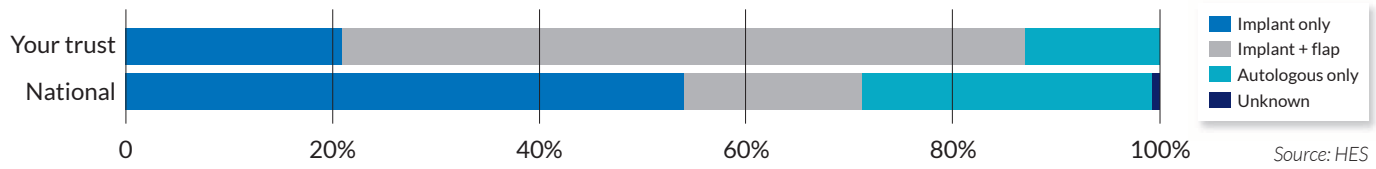
[89] *See www.crbard.com/vae/resources/NHS-Coding/01-Coding-Advice-for-Vacuum-Assisted-Excision.pdf*

Many of the units we visited felt that the volume of oncoplastic conservation surgery we could see in their data was an underestimate of their activity. Oncoplastic conservation surgery is more complex and time-consuming than simple breast wide local excision (WLE). It is therefore essential that we can capture this breast conservation case mix accurately, especially when comparing outcomes.

We have also learned through our deep-dive visits that new reconstructive techniques are coded differently across trusts. For example, at some trusts, implant-plus meshes (either animal-based or manufactured) and implant-plus dermal sling reconstructions are coded as pure implant reconstructions; in others, they are coded as implant with flap reconstructions. This makes it impossible to compare outcomes for similar procedures.

This can be seen in the charts below, provided to trusts as part of their pre-visit data pack.

Figure 30A: Comparison of trust-specific reconstruction type (as coded in HES) with national average, Trust A, April 2014-March 2017

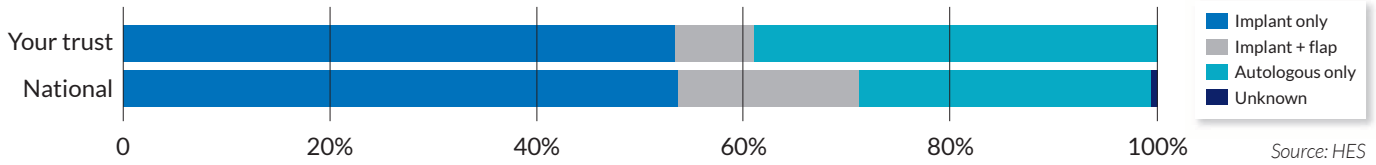


Source: HES

Trust A appeared, based on its HES coding, to be conducting a far higher proportion of implant + flap-based reconstructions than the national average.

Using the same measure, Trust B appeared to be doing a far higher proportion of implant-only reconstructions.

Figure 30B: Comparison of trust-specific reconstruction type (as coded in HES) with national average, Trust B, April 2014-March 2017



Source: HES

When we discussed this during deep dive visits, it became clear that both trusts used similar techniques for implant-based reconstruction; the variation was in clinical coding practice.

Current OPCS coding also doesn't reflect the increased complexity of microvascular flap reconstruction with the development of bi-pedicled flaps and dual flap reconstructive techniques.

On a positive note, the Breast Expert Working Group (EWG) of the National Casemix Office (NHS Digital) is working well and has representatives from ABS, BAPRAS and the British Society of Radiologists (BSBR). The Breast EWG has successfully managed to incorporate new oncoplastic codes into the latest version of OPCS, which will be available soon. For example, different types of meshes or ADMs will have separate codes. The EWG is now in the process of designing appropriate Healthcare Resource Groups (HRGs) for breast procedures to ensure equitable reimbursements. This is very much a work in progress and over the next few years, the Breast EWG will continue to work collaboratively with the Clinical Classification Service to bring in new procedural codes to reflect the complexity of modern breast clinical practice.

In the interim, it is important that available codes are used appropriately and consistently to enable analysis and comparison. We would encourage ABS, BAPRAS and others to consider issuing guidance on which codes should be used in what circumstances, so that clinical coding can be increasingly standardised.

Linking surgical activity and outcomes with cancer data

Finally, the crucial gap in analysis of breast surgery is that at present it is not possible to link surgical activity data with cancer data. This means we cannot yet understand whether patients in different trusts with the same specific cancer receive the same treatments and schedules. This in turn means we have little or no national information about the long-term cancer outcomes of breast cancer surgery, and how other cancer treatments may impact on surgery recommendations, surgery outcomes or even cancer outcomes, particularly with regards to local recurrence rates.

One way to capture this invaluable information at a national level could be through better use of, and linkage between, data registries. GIRFT is working closely with NCRAS to develop links with HES data to support the collection of more outcome focused data.

Improving the use of breast surgery registries

There are two main national registries relating to breast surgery that record some patient outcomes:

- the UK National Flap Registry (UKNFR);[90] and
- the Breast and Cosmetic Implant Registry (BCIR).[91]

Submitting data to these is not currently mandatory, but the BCIR – hosted and managed by NHS Digital – is on the Schedule of Approved Collections. This is part of the NHS Standard Contract and means that trusts could potentially be penalised for not submitting data. The overwhelming majority of trusts do now submit data to the BCIR, but most private sector providers of breast reconstructive, aesthetic and cosmetic surgery do not.

The BCIR was set up in the aftermath of major safety concerns about certain types of breast implants. Implants are usually manufactured from silicone or a combination of silicone and saline: in 1999, Trilucent implants (soya bean gel) were withdrawn for safety reasons; ten years later Poly Implant Prothèse (PIP) implants were also withdrawn, when it became apparent that they had been manufactured from non-medical grade silicone. Women who had these implants were then advised to receive corrective surgery. In the UK, about 45,000 women with Trilucent gel implants and 47,000 with PIP implants were affected.

However, there was then a major challenge in identifying the women with these implants so that they could be offered revision surgery. This led to the creation of the BCIR in 2016. Its aim is to collect details on every implant inserted in England both in the NHS and in the private sector, for any reason, so that in the event of a product recall or other safety concern relating to a specific type of implant, affected women could be traced and contacted. The registry dataset was also designed to allow the identification of possible trends and complications relating to specific implants.

The importance of being able to identify which patients have had a specific implant has been underlined again over the last couple of years as concerns have emerged regarding a rare (1 in 24,000) form of cancer called Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL).[92] The cause of this cancer is not yet understood but it may be a combination of factors including an individual's genetic susceptibility and interaction with the surface of the implant, especially textured implants. Much research is ongoing.

First Do No Harm

Shortly before our report was finalised, "First Do No Harm", the report of the Independent Medicines and Medical Devices Safety Review led by Baroness Cumberlege was published.[93] This focused on ways to address avoidable harm by dealing more robustly and promptly with patient safety concerns related to the use of devices and medicines. The report did not examine PIP implants in detail, but cited them as a further illustration of the issues the Review team had encountered – and the patient stories the team heard.

It identified a recurring issue: the fact that "the system does not know, so neither do we" the number of patients treated with different devices or medicines – let alone their location or condition.

The Independent Medicines and Medical Devices Safety Review made nine recommendations for change. In relation to our report, the most relevant was recommendation 7:

[90] *See https://hscn.e-dendrite.com/csp/bapras/frontpages/index.html*

[91] *See https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry*

[92] *See www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl*

[93] *The Independent Medicines and Medical Devices Safety Review (2020) First Do No Harm www.immdsreview.org.uk/Report.html*

A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures.

Improving data quality in the BCIR

We fully endorse this recommendation as it relates to breast surgery and the existing registries. However, our examination of the registry data – and the way it is collected – has highlighted some important issues that should be considered in the development of a database, as recommended by The Independent Medicines and Medical Devices Safety Review.

A primary concern that emerged regarding the quality of the BCIR data recorded was the fact that there is no process of validation around recording specific details of the implants used such as serial numbers, catalogue reference numbers and lot numbers. Currently, details are simply typed in as part of a data set that – according to feedback during the deep dives – many providers find unwieldy. With long serial numbers, the risk of manual error is potentially high.

This raises the concern that, in the event of another implant safety issue and product recall, the BCIR would not be able to identify accurately all the individuals to be contacted. To address the situation, changes need to be made to the way the BCIR is used.

Firstly, instead of relying on manual error, the BCIR should be supported to incorporate an efficient implant-tracking mechanism, both to link patients with implants and to track device performance with clinical outcomes over time. A scanning system in theatres, such as Scan4Safety, where implant bar codes are scanned and recorded at the point of surgical insertion, would offer a more reliable approach to implant tracking, down to Unique Identifier (UID) level. This would improve both the accuracy and completeness of BCIR data and make it possible to link patients with UIDs in the event of a safety issue, so simplifying any potential recalls. We understand that NHSX is exploring what can be done more systematically to develop prospective recording of all surgical implants; however, at present the available funding for the BCIR is focused simply on day-to-day maintenance and management, rather than having the scope to add invaluable new functionality.

Further, to enable the broader goal of assessing performance over time, BCIR data then needs to be better linked with HES. This would mean that implants can be associated with specific operative techniques or clinical indications, and outcomes that are recorded in HES such as repeat surgery or implant loss.

Once such processes and linkages are in place, we believe that the BCIR should also be used to record data about other devices (such as surgical meshes) used in breast surgery. This would again align with the recommendations of The Independent Medicines and Medical Devices Safety Review.

The UK National Flap Registry

The UK National Flap Registry (UKNFR) was set up in 2015 by a team led by consultant plastic surgeons Anita Hazari (audit lead) and Richard Cole (design lead). It is funded by BAPRAS and is a collaboration between five surgical specialty associations: BAPRAS, ABS, the British Association of Head & Neck Oncologists (BAHNO), the British Association of Oral and Maxillofacial Surgeons (BAOMS) and the British Society for Surgery of the Hand (BSSH). It aims to collect information about all major free and pedicled flap operations carried out in the UK (including in private healthcare) and, through that, to assess the quality of care provided for patients.

The UKNFR is based on self-reported data and submission is not mandatory, but it is already one of the largest collections of data on free flap surgery in the world and provides a wealth of information.

In December 2019, the UKNFR published its first national report, drawing on data from 5,688 procedures from almost 100 units.[94] This includes flap operations on all areas of the body, not just the breast; however, of the 5,021 records comprising the group for the main analysis, 50.1% were breast operations.

The report provided national averages for key performance indicators such as case mix, age demographics, length of stay, flap success and return to theatre, listed broadly according to anatomically reconstructed areas.

[94] *See BAPRAS (2019) First UK National Flap Registry Report www.bapras.org.uk/docs/default-source/default-document-library/uknfr-first-report-4-dec-2019.pdf?sfvrsn=2*

The UKNFR report found that the unplanned reoperation rate for the recipient site in breast surgery was 7% - lower than for the other areas of the body. The flap 'survival rate' was also highest for breast surgery, at 97%.

Surgeons entering data have a 'surgeon dashboard' at login, which gives real-time audit of their practice. This is useful for annual appraisal and revalidation.

The report also referred to the BreastQ questionnaire, sent electronically by UKNFR to breast reconstruction patients at six and 18 months after surgery to gather patient-reported outcome measures (PROMs). This found that after six months 72.5% of patients were satisfied with their breast reconstruction; the number of responses after 18 months were not yet sufficient to report.

We see the UKNFR as a significant asset to breast surgery. Its value will be enhanced if participation and data collection is maximised, so we recommend that it should be added to the Schedule of Approved Collections. Similar to the BCIR, we also recommend that the UKNFR is linked to HES to support data collection and provide outcomes data.

Incorporating breast surgery quality indicators into the Model Hospital

The data gathered and methodology adopted as part of the GIRFT process means that, for the first time, we have been able to establish national and trust level comparative outcomes for breast excisions, mastectomies and reconstructive procedures for both cancer and non-cancer patients. These outcome metrics enable comparison between units. They will also allow future standard setting to reflect evidence or best practice: this will drive up quality, reduce unwanted variation and support more efficient delivery of care.

The quality indicators we have developed, based on HES data, provide trusts with an average level of performance or adhere to evidence-based national guidelines that should be achievable for all. We have found through our visits that these quality indicators appear reliable and relevant to providers. We therefore recommend that some of the reliable and consistent HES derived quality indicators should be added to the Model Hospital. This would enable individual providers to make contemporaneous and ongoing comparisons of activity and outcomes with their peers. It would also provide a means of evaluating the impact of new techniques and adoption of new protocols, guideline recommendations or research findings.

Our aim is the development of a suite of unit and consultant level quality metrics, which will be defined in consultation with ABS and BAPRAS.

Ideally, such measures would be available not just at a unit level, but also for individual surgeons within the team. This anonymised data would then inform individual performance management and professional development.

Outcome metrics of course need to be interpreted in the context of patient and cancer demographics.

Patient-reported outcome measures (PROMs)

HES-derived quality outcomes are important for the delivery of high-quality care, but patient reported outcomes are even more important, especially regarding their experiences and outcome of aesthetic reconstructive surgery for which there are no reliable, cost-effective objective aesthetic evaluation tools.

As noted above, PROMs are not routinely collected for breast surgery – so in relation to data, we reiterate our earlier recommendation that PROMs should be incorporated for all oncoplastic, reconstructive and related surgery as well as for aesthetic breast surgery.

Recommendation	Actions	Owners	Timescale
11. Improve the consistency and accuracy of data capture in HES.	**a** Trusts to capture at least 95% of admissions for (oncoplastic) breast surgery using TFC 103 or TFC160.	Trusts	For completion within 12 months of publication of the GIRFT report
	b Trusts to capture at least 95% of breast excision procedures under the appropriate breast surgery or radiology TFC.	Trusts	For completion within 12 months of publication of the GIRFT report
	c Specialty associations, coding bodies and others to work together to identify a solution that enables trusts to capture at least 95% of outpatient attendances for (oncoplastic) breast surgery using TFC103.	Specialty associations, coding bodies and others	For completion within 24 months of publication of the GIRFT report
	d NHS Digital to develop means of accurately recording and coding cross-disciplinary/multi-disciplinary surgery, for example by allowing the use of multiple appropriate TFCs for a single procedure.	NHS Digital	For completion within 24 months of publication of the GIRFT report
	e GIRFT to work with specialty associations and NHS Digital to develop guidance on standardising the use of OPCS and ICD codes with particular regard to oncoplastic reconstructive surgery, where necessary.	GIRFT, specialty associations, NHS Digital	For completion within 24 months of publication of the GIRFT report
12. Ensure that HES and NCRAS patient level data is linked to support outcome monitoring.	**a** GIRFT and NHS England to work together to continue to link NCRAS and HES data, to enable better case mix adjusted comparison of breast conservation, repeat surgery rates and the impact on local recurrence rates.	GIRFT and NHS England	For completion within 24 months of publication of the GIRFT report
13. Improve the consistency and accuracy of data capture in the BCIR and UKNFR with the aim of 95% completeness within three months of surgery.	**a** BCIR and UKNFR data submission to become mandatory for all providers who use breast devices/flaps, including data about surgical meshes used in breast surgery.	Trusts / commissioners	For completion within 12 months of publication of the GIRFT report
	b GIRFT to work with NHS Digital and others to consider options to improve data capture processes.	NHS Digital	For completion within 24 months of publication of the GIRFT report
	c Specialty associations to work with trusts and commissioners to develop a framework to allow the safe introduction of new devices and techniques – 'No innovation without evaluation'.	Specialty associations, trusts, commissioners	For completion within 24 months of publication of the GIRFT report
	d GIRFT to explore how BCIR and UKNFR data can be linked to HES and Spend Comparison Service, to avoid duplication and enrich data collection on outcomes.	GIRFT	For completion within 24 months of publication of the GIRFT report
	e CQC to support GIRFT in ensuring that providers capture and enter at least 95% of data into the breast implant and flap registries.	CQC	For completion within 24 months of publication of the GIRFT report

Improving procurement

Procurement of medical devices used in breast surgery is not just about securing the best prices for the NHS; it is also about ensuring products are safe and deliver the best outcomes for patients. Over recent years, there has been a growing catalogue of failures with medical devices where the evidence for their use has been found to be weak and patients have suffered the consequences. As described earlier this report in relation to the development of the BCIR, this has affected breast surgery with the Trilucent and PIP implant recalls. Evidence-based procurement can play an important role in preventing such issues and enabling the introduction of a culture of 'no innovation without evaluation' but, at present, the available data limits this.

In 2016, NHS Improvement mandated all NHS trusts to submit their monthly purchase order data to a central database – the Purchase Price Index & Benchmarking data tool (PPIB). This was the first time a single national dataset of procurement information had been established for the NHS. Since then, the GIRFT procurement team has been analysing procurement data to better understand the variation in products and brands used and prices paid across NHS trusts. This report used the PPIB tool in its analysis of trust procurement data, prior to the tool being replaced by the Spend Comparison Service.

It has become clear that variation in the choice of product, device and brands is market-led, supported and driven by clinician enthusiasm to improve patient care and outcomes. As First Do No Harm made clear, this is an issue that extends beyond breast surgery.

Compared to the requirements for the introduction of new medicines, regulations concerning the evidence required on both efficacy and safety of new devices are considerably less stringent. Within Europe, regulations require manufacturers to obtain a CE mark of quality for a new device. However, for the CE mark to be given, the amount of safety evidence required is usually small. In many cases, new medical devices are introduced with weak or non-existent evidence regarding safety or clinical effectiveness and adverse events are not routinely collected. The report of the Independent Medicines and Medical Devices Safety Review highlighted this and recommended a more active role for the Medicines and Healthcare products Regulatory Agency (MHRA) in relation to adverse event reporting and medical device regulation. Such a role would include pre-market regulation and post-market surveillance.

Evidence of device effectiveness, comparative outcome data and longer-term complications accumulates slowly, highlighting some of the difficulties patients and clinicians face when deciding which device is best for them. There is an urgent need to provide a more robust and consistent framework for the introduction of new devices and surgical procedures/techniques, that will also collect clinical efficacy evidence, including from device manufacturers, to facilitate innovation and progress while protecting patients. The Beyond Compliance system, which gathers information about the use of new or modified implants in orthopaedics to support their safe introduction, is an example of one such framework.[95] However, as the NHS Digital team managing the BCIR has made clear, the issue that has limited such important patient safety initiatives is establishing a secure funding stream.

Variation in device and product usage not only compromises patient safety, it also adds significant costs to the NHS Supply Chain, as every brand used requires inventories and NHS purchasing leverage is compromised. Addressing the variation will not only improve safety and efficacy but also provide the opportunity to secure better deals and improved value for money for trusts.

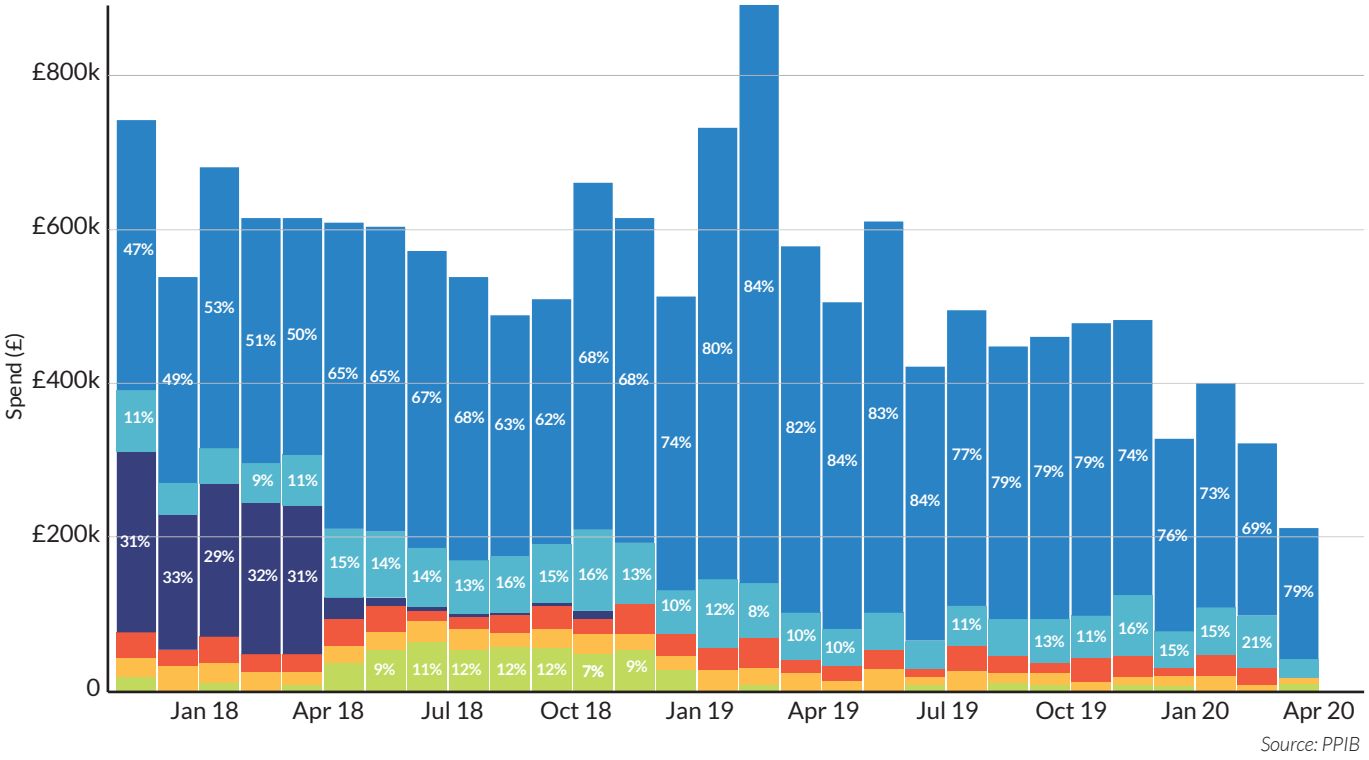
To help, GIRFT has established a programme to root out unwarranted variation in procurement, improve the evidence-base to enable better decision-making, accelerate adoption of new proven technologies, and improve overall value for money by reducing supply chain costs.

[95] *See www.beyondcompliance.org.uk/Home.aspx*

Breast surgery procurement data

PPIB data reveals that in 2018 and 2019 the NHS in England spent about £7m on breast implants every year. This purchases around 3,000 implants a year for immediate breast reconstruction, with the remainder being purchased for revision and adjustment surgery. One supplier now consistently accounts for over 75% of all NHS purchases each month (Figure 31).

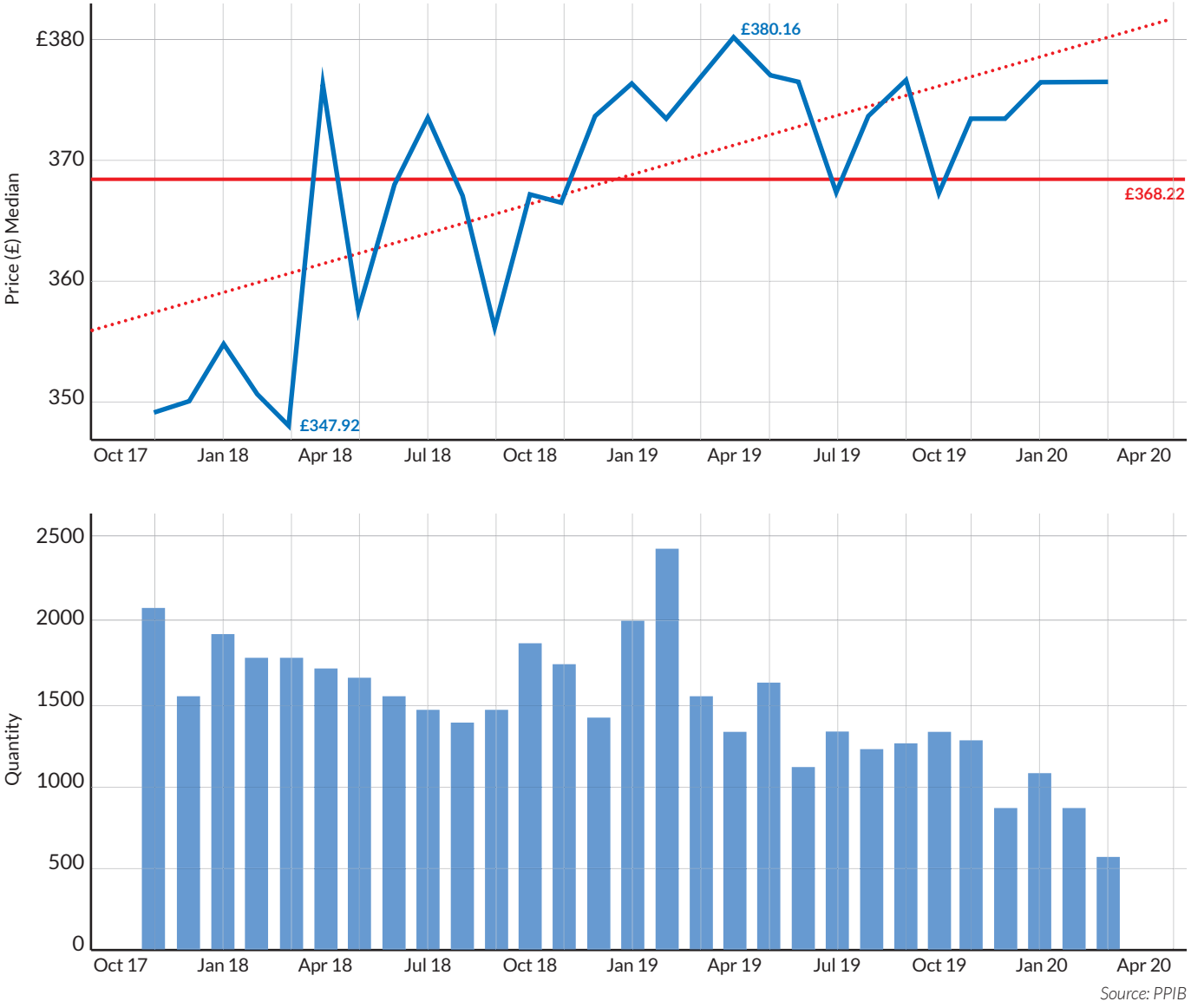
Figure 31: Monthly NHS breast implant expenditure, by supplier, January 2018- April 2020



Source: PPIB

Such reliance on a diminishing number of manufacturers/suppliers is a very unhealthy position for the NHS marketplace and PPIB data seemed to indicate that prices are already creeping upwards, as Figure 32 shows.

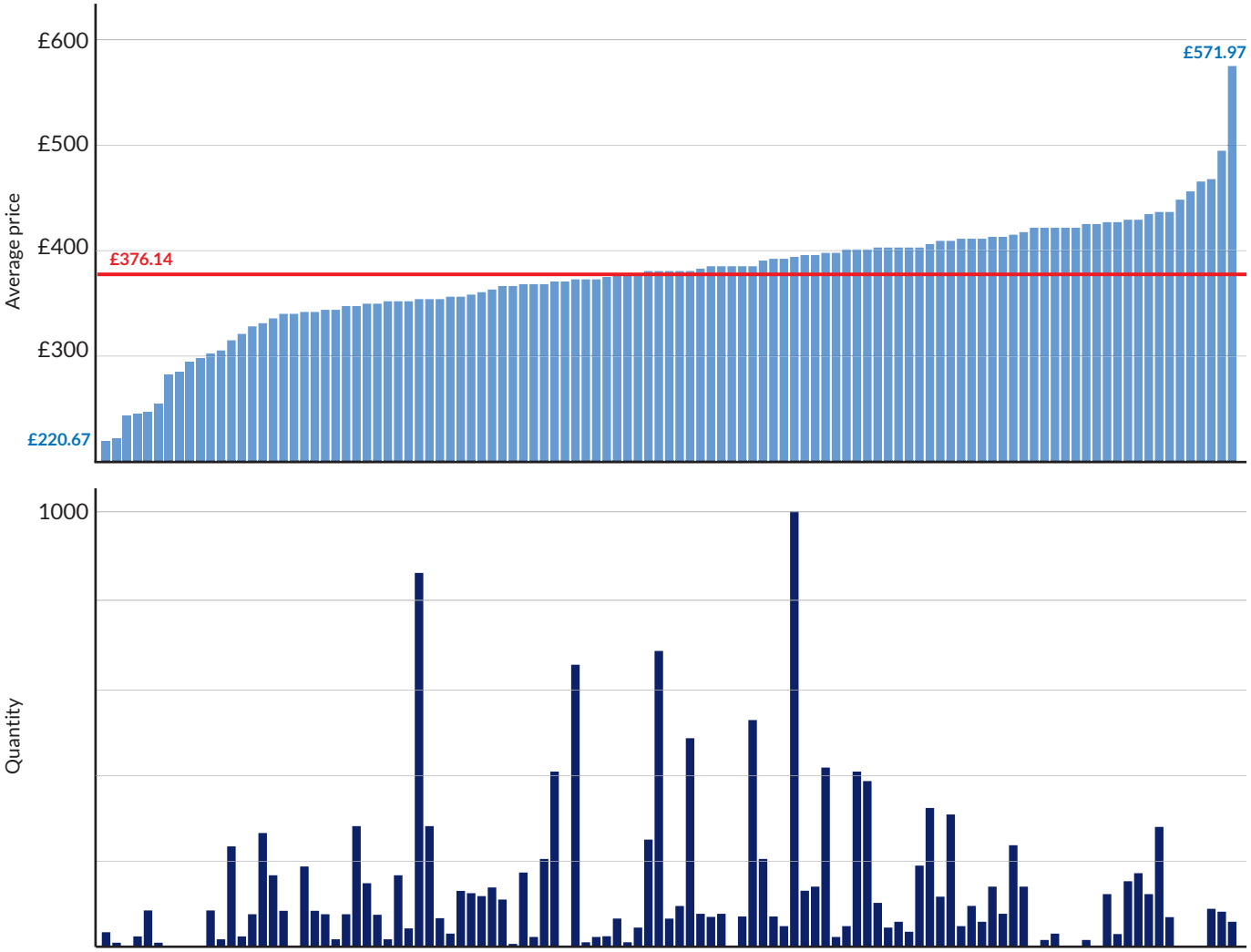
Figure 32: Average breast implant purchase price and volume, October 2017-April 2020



Source: PPIB

Further, there is considerable variation in implant prices paid by different NHS trusts with average prices ranging from £220 to £570, with no correlation to volumes purchased (Figure 33). This is something that has been seen in other GIRFT specialties.

Figure 33: Average breast implant purchase price and volume by trust (March 2017- March 2019)



Source: PPIB

Implant-based reconstruction may require other medical devices to support and cover the breast implant, especially when it is placed behind the breast skin. These are termed meshes and a large number of different providers produce them. We do not at present have procurement data around these, but as their usage increases, the clinical utility and costs of different models require urgent evaluation.

Future work to streamline procurement

Over the coming months, GIRFT will continue to work with trusts to better understand the variation in procurement costs in breast surgery and other specialties. The GIRFT programme recognises there are often sound clinical reasons behind the choice of device and treatment method and that patient quality outcomes, product evidence and product innovation are key considerations alongside supply chain efficiency and best value. As part of this review, GIRFT will provide the head of procurement at each trust with a curated Clinical Procurement Benchmarking and PPIB data-pack. GIRFT will ask procurement heads for validation and feedback before drawing any conclusions or making specific recommendations.

The Department of Health and Social Care is expecting the new procurement 'category towers'[96] to help trusts reduce the level of variation in procurement by flexing the buying power of the NHS. GIRFT will be working closely with trusts to help them adapt to this new procurement model.

Recommendation	Actions	Owners	Timescale
14. Enable improved procurement of devices and consumables through cost and pricing transparency, aggregation and consolidation, and by sharing best practice.	**a** Use sources of procurement data, such as Spend Comparison Service and relevant clinical data, to identify optimum value for money procurement choices, considering both outcomes and cost/price.	GIRFT	Within 24 months of publication of the GIRFT report
	b Identify opportunities for improved value for money, including the development of benchmarks and specifications. Locate sources of best practice and procurement excellence, identifying factors that lead to the most favourable procurement outcomes.	GIRFT	Within 24 months of publication of the GIRFT report
	c Use Category Towers to benchmark and evaluate products and seek to rationalise and aggregate demand with other trusts to secure lower prices and supply chain costs. At least 80% of NHS spend in breast surgery to be channelled through NHS Supply Chain, and market dominance issues addressed.	Trusts, commissioners, GIRFT	Within 24 months of publication of the GIRFT report

[96] *Category towers are part of the future operating model for NHS Procurement. There are 11 such towers. See www.nhsbsa.nhs.uk/sites/default/files/2017-06/FOM_general_guide_0.pdf for more information.*

Learning from litigation

As part of the wider quality improvement aims of the programme, GIRFT is reviewing litigation claims for different specialties. By identifying common themes in medical negligence claims, GIRFT can provide clinical teams with the opportunity to review, reflect and learn from litigation, adding to what can already be learnt from complaints, serious untoward incidents (SUIs)/ serious incidents (SIs)/ patient safety incidents (PSIs) and inquests. Such learning will ultimately improve patient care, reduce litigation and NHS costs.

During individual trust breast surgery visits, we found that the majority of clinical teams were unaware of breast surgery-related litigation and outcomes. As a result, these teams did not have the opportunity to learn or change practice in response to malpractice claims.

Data sources

Data about litigation is drawn from NHS Resolution records. NHS Resolution records claims related to breast surgery under the GMC registered specialty of the consultant surgeon: general surgery for breast surgeons or plastic surgery for plastic surgeons, with very small volumes under other specialties.

NHS Resolution provided data on the totality of claims in general surgery and plastic surgery between April 2012 and 2018. The breast specific claims were then independently identified and categorised into relevant themes, following defined criteria, by a senior breast surgery registrar and consultant breast surgeon.

Volumes of litigation and activity

Medical negligence claims described as 'breast surgery' are not limited to operations on the breast but also include claims arising from delay in diagnosis – usually of cancer.

Over a six-year period from 2012 to 2018, the number of claims identified as breast surgery-related was 1,178. However, 729 related to a single surgeon, Mr Ian Paterson, who has since been convicted of 17 counts of wounding with intent. For the purposes of our analysis, we have excluded these claims so we can focus on learning from the remainder.

This means that 449 claims are in scope. For context, data brought together as part of the GIRFT process shows that over the same six-year period over 600,000 operations on the breast were performed and over two million patients were seen for breast assessment/diagnosis.

Of the 449 breast claims, over half were filed under general surgery (54% (244)) and just under a third for plastic surgery (29% (128)). The remaining 77 were recorded as 'other' specialties. Clinical review of the claims indicates that the majority of these could be categorised under general surgery, meaning that overall, 71% of claims could be deemed to be related to general surgery. As plastic surgeons perform about 15.5% of breast operations and breast/general/other surgeons 84.5%, this suggests a disproportionate number of claims related to plastic surgery. However, through clinical review it was identified that many of the plastic surgery claims related to the use of PIP silicone implants.

Age and gender

The average claimant age was 46 years and the majority of claimants were female. 14 claimants (3.1%) were recorded as male.

Litigation costs

The annual costs of litigation related to breast surgery over the six-year span costs ranged from £5.57m to £9.59m, with a mean figure of £6.88m a year. This translates to a national average litigation cost of £89 for every breast surgery admission or procedure. Breast surgery admission/procedure costs range from around £270 to £14,000, with an average of around £2,600 (based on 17/18 ref costs, adjusted to 19/20 pay and prices).

Table 8: Volume and cost of breast surgery related litigation claims

Year	No. of Claims	% change in Claims No.	Total Cost (£m)	% change in Total Cost
2012/13	80		£ 6.62	
2013/14	78	-3%	£ 6.80	3%
2014/15	72	-8%	£ 5.98	-12%
2015/16	73	1%	£ 5.57	-7%
2016/17	74	1%	£ 6.71	21%
2017/18	72	-3%	£ 9.59	43%
Total	**449**		**£ 41.27**	

Source: NHS Resolution

In 2017/18, across the whole of the NHS, there were 10,673 new clinical negligence claims. The highest volume specialties were A&E/casualty (13%), orthopaedic surgery (12%), obstetrics (10%) and general surgery (9%).[97] Breast surgery accounted for less than 1% of all new claims.

Variation in costs between trusts

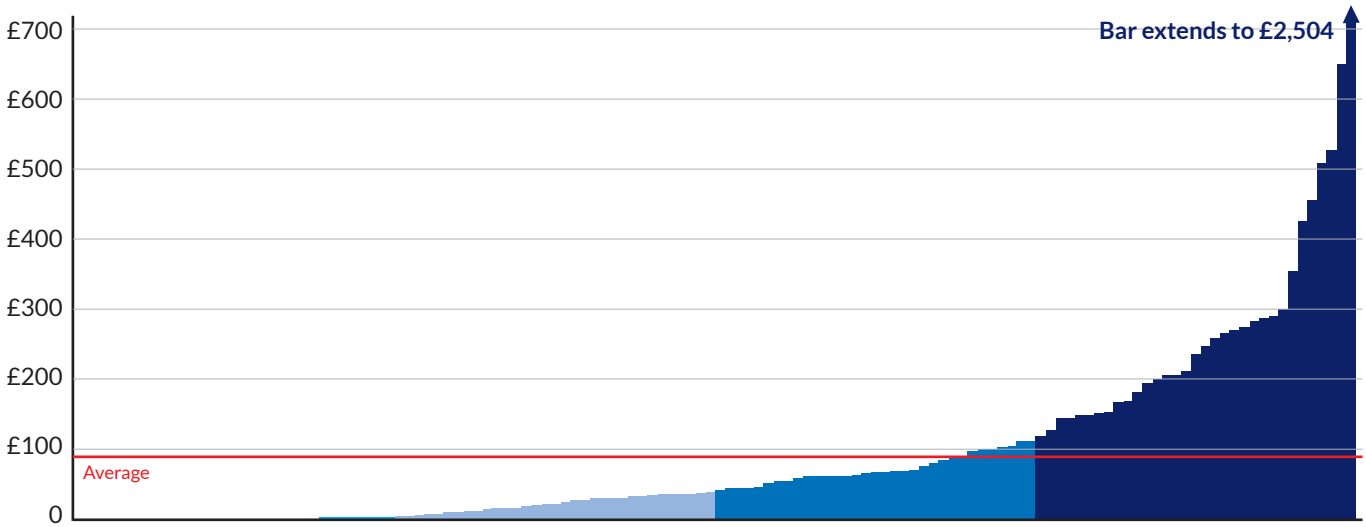
Between 2012 and 2018, volumes of litigation claims by provider ranged from none to 22 per year. Across the six-year period, eight trusts had no claims made against them whatsoever.

There was considerable provider variation in litigation costs ranging from £0 for those trusts with no breast surgery litigation to £2,504 per breast surgery admission. These average costs are dependent on the *value* of the litigation awarded, so are not necessarily related to *volumes* of litigation.

To provide trusts with their benchmark position, we have designed a litigation metric representing the average cost of litigation per activity for breast surgery. The average estimated litigation cost over five years (2013/14-2017/18) is the numerator and breast surgery activity the denominator. It must be noted that the denominator does not include any diagnostic and assessment activity undertaken by breast surgeons, even though litigation cases may relate to this aspect of breast surgery activity.

[97] *NHS Resolution (2018) Annual Report and Accounts 2017/18 https://resolution.nhs.uk/corporate-reports/*

Figure 34: Variation in estimated litigation costs for breast surgery per admission (including day cases) in England between trusts 2013-2018



Source: NHS Resolution

Analysis of litigation themes

For learning purposes, we categorised the claims under a broad set of themes. However, there is considerable overlap between themes and categorisation: for example, the majority of issues around breast implants related to unsatisfactory outcome of surgery (cosmesis).

In nearly 20 claims, there was insufficient case summary data to classify into a theme or category. One claim could involve several themes: this explains why there are numerically more themes than total claims and the sum of the percentage values is not 100.

The most frequently noted themes in litigation case summaries were:

Delay in diagnosis and treatment 33% (147 claims)

The majority of these claims were related to delays in breast cancer diagnosis, most commonly where a lump that was initially diagnosed as benign turned out to be cancer. About 18% were related to delays starting adjuvant therapy because of an operative complication or delay in identifying and treating a surgical site infection.

Unsatisfactory cosmetic outcomes 27% (121 claims)

60% of these noted dissatisfaction with cosmetic outcome of reconstruction (type of reconstruction was rarely recorded), breast reduction and augmentation.

Surgical decision making/ clinical judgement 22.5% (101 claims)

Two claims related to contralateral mastectomy undertaken at the time of index mastectomy for unilateral breast cancer surgery: both claimed that the cancer risk was overstated and the operation on the opposite breast unnecessary.

Post-operative complications 20% (88 claims)

42 claims related to surgical site infections (SSI), of which 19 required further surgery. A further 27 claims required further surgery not relating to infection, with 14 additional post-operative complications being managed without surgery. Venous thromboembolism (VTE) was not noted in any claims.

Claims related to breast implants 17.4% (78 claims)

90% of these claims involved implants used for reconstruction following cancer. Cosmetic dissatisfaction featured in the majority, either as the standalone reason or associated with infection or the type/size of implant used.

Failure to warn/ informed consent 12.7% (57 claims)

Failure to consent adequately for reconstruction accounted for over half of these.

How to improve patient outcomes and reduce litigation

It is likely that many claims in breast surgery are potentially avoidable through more individualised information and consent processes to facilitate high-quality shared decision-making: for example, providing written standardised, structured, procedure-specific information.

For the complex decisions around breast reconstruction, improved patient decision-making tools should be considered: effective communication has been highlighted by ABS and BAPRAS as the most important factor in achieving informed consent. This is particularly relevant for surgery that may alter the appearance of the breast or is aimed at refashioning a breast shape. Honesty and realism regarding likely cosmetic outcomes are crucial. Failure to meet cosmetic expectations can represent a failure of the consent process, with a mismatch between what the patient anticipates or hopes for and what the clinician knows is realistically deliverable. The Royal College of Surgeons has produced detailed guidance on consent,[98] as has the ABS.[99]

Incorrect or delays in cancer diagnosis can be minimised by breast multidisciplinary teams complying with national breast assessment guidelines and protocols, such as the Best Practice diagnostic guidelines for patients presenting with breast symptoms.[100]

Preventable post-operative complications and surgical site infections can be minimised by careful patient pre-assessment and optimisation, maintenance of strict theatre protocol, meticulous surgical technique and compliance with ABS Oncoplastic guidelines,[101] NICE's recently published guideline on Surgical site infections: prevention and treatment (NG125),[102] and the NICE public health guideline *Healthcare-associated infections: prevention and control (PH36).*[103]

Litigation claims related to Ian Paterson

Mr Ian Paterson was a surgeon who worked at the Heart of England NHS Foundation Trust (HEFT) and Spire Group of independent hospitals. In 2012, he was suspended by the GMC on suspicion of having conducted hundreds of unnecessary or inappropriate breast operations. A criminal investigation followed and in 2017, he was found guilty of 17 counts of wounding with intent, against nine women and one man. He was given a custodial sentence of 20 years.

NHS Resolution data reveals that 936 claims have been made against Mr Paterson, for incidents occurring between 1993 and 2011. To date, HEFT has paid litigation in excess of £22.64m; it has also contributed £3.6m to a global settlement fund of £37m for patients treated privately at Spire Hospitals.

The clinical themes from the Paterson cases have not been included in this report as considerable work has already been undertaken by the Royal Colleges, ABS and other professional bodies to establish what lessons can be learnt. In February 2020, the report of Independent Inquiry into the Issues raised by Paterson was published.[104] As well as including accounts from more than 80 patients, it made 15 recommendations to improve patient safety and quality of care both in the NHS and private sector.

Helping to prevent similar system failures

Even before Mr Paterson was suspended by the GMC in 2012, there had been a series of concerns raised about his professional conduct by patients, GPs and other breast surgeons. However, investigating authorities have suggested that it was hard to evidence that Mr Paterson's practice was unsafe, as data was not easily obtainable and there were no national comparators or standards.

We believe that the approach taken in our work to benchmark the totality of breast surgery activity, and the quality measures we have suggested, could provide the foundations for a more effective approach to monitoring outcomes at both a trust and individual surgeon level. These measures are robust and reliable as they are based on tested algorithms derived from contemporaneous HES data. We feel that this data could be used to assist with the identification of outlying practice, which will support some of the recommendations of the Paterson Inquiry.

[98] *www.rcseng.ac.uk/standards-and-research/gsp/domain-3/3-5-1-consent/*
[99] *https://associationofbreastsurgery.org.uk/media/64789/abs-summary-statement-consent-2018.pdf*
[100] *https://associationofbreastsurgery.org.uk/media/64328/cancer-diagnosis-v1.pdf*
[101] *https://associationofbreastsurgery.org.uk/media/65100/oncoplastic-reconstructive-surgery-v4.pdf*
[102] *See NICE (2019) NG125 Surgical site infections: prevention and treatment www.nice.org.uk/guidance/ng125*
[103] *See NICE (2011) PH36 Healthcare-associated infections: prevention and control www.nice.org.uk/guidance/ph36*
[104] *See www.patersoninquiry.org.uk/*

Recommendation	Actions	Owners	Timescale
15. Reduce litigation costs by application of the GIRFT programme's five-point plan.	**a** Clinicians and trust management to assess their benchmarked position compared to the national average when reviewing the estimated litigation cost per breast surgery admission. (Trusts will receive this information in the GIRFT 'Litigation data pack').	Trusts (clinicians and trust management)	For immediate action
	b Clinicians and trust management to discuss with the legal department or claims handler the claims submitted to NHS Resolution included in the data set to confirm correct coding to that department. Inform NHS Resolution of any claims which are not coded correctly to the appropriate specialty via *CNST.Helpline@resolution.nhs.uk*	Trusts (clinicians and trust management)	Upon completion of 15a
	c Once claims have been verified clinicians and trust management to further review claims in detail including expert witness statements, panel firm reports and counsel advice as well as medical records to determine where patient care or documentation could be improved. If the legal department or claims handler needs additional assistance with this, each trusts panel firm should be able to provide support	Trusts (clinicians and trust management)	Upon completion of 15b
	d Claims should be triangulated with learning themes from complaints, inquests, and serious untoward incidents (SUI)/ serious incidents (SI) / patient safety incidents (PSI) and where a claim has not already been reviewed as SUI/SI/PSI we would recommend that this is carried out to ensure no opportunity for learning is missed. The findings from this learning should be shared with all front-line clinical staff in a structured format at departmental/directorate meetings (including Multidisciplinary Team meetings, Morbidity and Mortality meetings where appropriate).		Upon completion of 15c
	e Where trusts are outside the top quartile of trusts for litigation costs per activity, GIRFT will be asking national clinical leads and regional hubs to follow up and support trusts in the steps taken to learn from claims. They will also be able to share with trusts examples of good practice where it would be of benefit.	GIRFT	Ongoing
16. Identify breast surgery clinical negligence claims at a national level to allow early detection of variation in breast surgery.	**a** NHS Resolution, supported by GIRFT, to categorise clinical negligence claims related to the specialty of breast surgery to enable these claims to be differentiated from general surgery and improve taxonomy of claims so that surgery of the breast can be easily identified when carried out by other specialties outside of breast surgery.	NHS Resolution, supported by GIRFT	For immediate action as part of the review of NHS Resolution's clinical coding of claims and core system review supported by GIRFT

The breast surgery workforce

Throughout this report, we have examined some of the challenges that breast surgery teams face in maintaining a high-quality, timely and responsive service to patients as demand evolves. These include ensuring rapid access to diagnosis and treatment – particularly for cancer – and providing greater choice to all patients, regardless of their geographical location, about treatment pathways.

For the specialty to respond effectively to these challenges, there must be the right mix of skills and capabilities within the breast surgery workforce. This reflects the ethos of the NHS Interim People Plan, which stated its intention to develop a workforce to deliver 21st century care.[105]

Clearly, doing this requires an understanding of what work is required, but also what resources the specialty already has. The work done as part of the GIRFT process is therefore invaluable, providing for the first time a full picture of the totality of breast surgery workload in every trust in England for both breast and plastic surgery.

From this, we would ideally be able to establish the numbers of breast and plastic surgeons required to meet current and future demand, and the skills and capacity we need for the future. However, at present, there is a lack of reliable information about the true size of the breast surgery workforce and, crucially, a lack of a lack of clarity or understanding about how much time a surgeon should devote to performing surgical procedures.

Breast surgery workforce data

The ABS, the specialist professional organisation for breast surgery, reports that its membership includes 520 consultant surgeons, 71 Staff Grade, Associate Specialist and Specialty (SAS) surgeons and 140 surgeons in training. About 20 ABS members are plastic surgeons. ABS consultant members are more likely to be those who devote all, or the majority, of their time to breast surgery; by contrast, SAS surgeons for whom breast surgery may only be part of their working week are less likely to be a member. We understand from ABS that it plans to carry out a more detailed workforce survey during 2020. We welcome this initiative, which can be considered in parallel with the BAPRAS workforce survey; it will be crucial for longer-term workforce planning and in particular identifying the WTE workforce required for specific service configurations, activity and case mix.

In the GIRFT questionnaire, we asked trusts about their breast surgeon workforce. We received responses from 125 trusts between July 2018 and August 2019. These suggest the current oncoplastic and reconstruction (excluding microvascular free flaps) workload is delivered by the equivalent of 453 WTE consultant breast surgeons and just under 170 SAS surgeons.

There is a wide variation between trusts in the number of WTE breast surgeons they report. The highest figure was 14; the lowest one and the average four breast surgeons per provider. About 60 providers have three surgeons or less and six have less than two. Some of the variation is accounted for by counting heads rather than WTE surgical time.

Plastic surgery workforce

BAPRAS is the main specialist association for plastic surgeons. In its 2018 edition of its longstanding and comprehensive workforce survey, covering the UK and Ireland, it found there were about 620 consultants, 270 specialty grade surgeons and 600 surgeons in training working in 70 plastic surgery units.

BAPRAS asks surgeons to indicate their subspecialist interests. Of the ten listed categories, breast surgery was the second most common, with 30% of plastic surgeons reporting it as a subspecialist interest.

However, this was a marked decline from the 2013 workforce survey, when 40% of plastic surgeons had said breast surgery was one of their subspecialist interests. This decline is mirrored by a 10% fall in microvascular reconstruction as a declared subspecialty interest over the same period.

From our perspective, this is significant because we have identified an existing inequity of access to free flap breast reconstruction. To increase access to free flap reconstruction as we have recommended, there will need to be an increase in the number of plastic surgeons with a subspecialist interest in oncoplastic breast surgery.

[105] *See www.longtermplan.nhs.uk/wp-content/uploads/2019/05/Interim-NHS-People-Plan_June2019.pdf*

Releasing breast surgeons to focus on surgery

Our data suggests that there are very different surgeon working patterns between providers, with variations between workload volumes and number of WTE surgeons. This results in surgeons at some trusts conducting far more operations than at others: one explanation may be case complexity.

However, overall the proportion of time that breast surgeons dedicate to operating is lower than we would have expected, and suggests surgeons are not consistently working at the top of their licence. This is an inefficient use of an expensively trained, uniquely skilled but scarce workforce.

A surgeon usually is employed to deliver ten four-hour sessions of service – so 40 hours in total – a week. This is termed whole time equivalent (WTE). In our questionnaire, we asked trusts how many of WTE sessions are dedicated to operating.

Only a handful of providers reported that their WTE breast surgeons had more than two operating sessions each week. Some WTE surgeons had only one operating session scheduled each week. We also heard on many visits that finding the time to meet the demand for free flap reconstruction within the cancer treatment targets was challenging for most plastic surgeons and plastic units, due to other competing priorities.

Limiting surgeons' access to operating time is worrying on many levels and affects patients, providers and surgeons: surgery is a skills-based specialty that requires constant practice and refinement to optimise outcomes.

Through deep dive discussions, it was apparent that instead of being deployed to operate, many surgeons are being used primarily in non-surgical activities. The greatest demand on their time is usually in outpatient clinics, supporting diagnostic and assessment clinics to meet the target times for cancer diagnosis. Our recommendations for evolving the process of managing new patient breast referrals should free up more surgical time for operating. However, it is also important for providers to facilitate more surgical time in other ways, by using the skills and qualifications of the wider team more effectively, which in turn can release surgeons from roles that do not specifically require a surgeon.

For example, there are several units where MDT members other than consultant surgeons play a key role in supporting outpatients. However, we also came across units where upskilling and merging of professional boundaries and skills for the benefit of patients is not well-established. This is not through a lack of will on the part of either the clinicians or the wider team – more that the processes have not been established and interested MDT staff have not been able to receive the training they need. This needs to change.

We believe that a greater part of the surgeon's workload should be surgery – and that providers need to find ways to make that possible by releasing surgical time and providing theatre time. We note the GIRFT report on vascular surgery recommended that every WTE vascular surgeon should conduct a minimum of three operating sessions a week.[106] Finally, we must also underline that the number of operating sessions a surgeon conducts is a measure of activity, rather than productivity or quality.

Pressures on the radiology workforce

There is a well-documented shortage of radiologists and radiographers in the UK, as set out in the Royal College of Radiologists' 2018 Workforce Census.[107]

Breast radiology is the second largest subspecialist interest in radiology, so the impact of staff shortages in radiology on the breast MDT cannot be overemphasised. A lack of radiology resource has a huge impact on the timely and high-quality assessment of the huge volumes of GP breast referrals. In turn, this affects the wider breast MDT's ability to deliver treatment within the cancer treatment targets.

Capturing multiple surgeon operating

There are a range of more complex or bilateral breast surgery procedures which frequently involve two consultants. This could be two breast surgeons, two plastic surgeons or one of each. Because most data entry systems allow only one consultant to be named as in charge of the case, it is often not possible to identify these dual consultant operations in HES.

Where trusts do not have a plastic surgery unit, they typically outsource the reconstruction to a plastic surgeon in a neighbouring trust. The reconstruction is then recorded in HES as a plastic operation and there is no record of the involvement of the breast surgeon who may have travelled form the referring trust for over an hour in some locations to conduct the mastectomy on 'their' patient (regarded and recommended as best practice).

[106] *https://gettingitrightfirsttime.co.uk/wp-content/uploads/2018/02/GIRFT_Vascular_Surgery_Report-March_2018.pdf*

[107] *See reports at www.rcr.ac.uk/press-and-policy/policy-priorities/workforce-and-staffing*

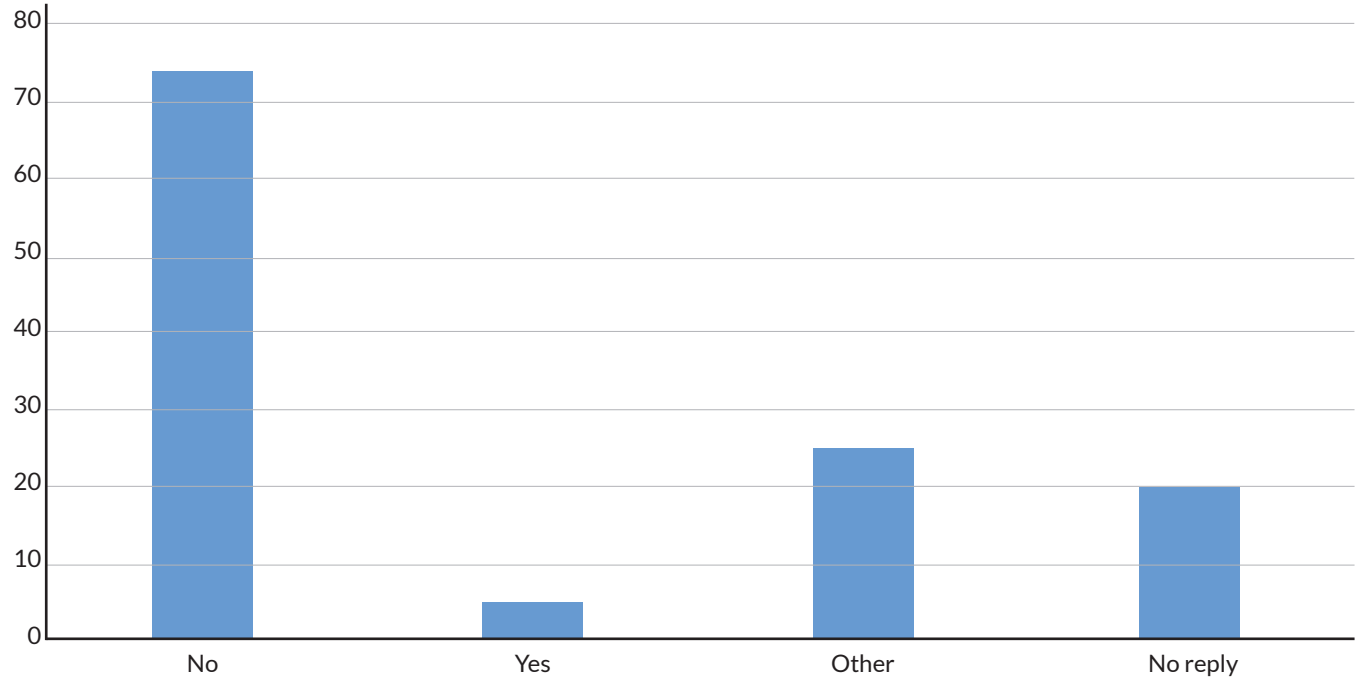
To enable more accurate workforce planning, improve productivity and better understand the complexity of modern surgical techniques, it is important that systems are developed that allow us to see when multiple consultants are involved in a single operation.

Examining the training of oncoplastic and breast reconstruction surgeons

Consultant oncoplastic breast surgeons train through one of two routes: either general surgery or plastic surgery. Under the current curricula, they double train: first acquiring essential general or plastic surgery skills and then, towards the end of this training, specialist oncoplastic breast surgery skills. However, some newly certified consultants may lack experience in some of the more complex or less common oncoplastic procedures, because the greater part of their training was focused on acquiring the general or plastic surgical skills.

Once qualified as an oncoplastic breast surgery consultant, surgeons from a general surgery background rarely use their general surgery skills and usually practice exclusively in oncoplastic breast surgery. This is illustrated by the fact that in over half of trusts, none of the consultants participate in the on-call rota for general surgery; in just over 20% of trusts, only one of the team does. By contrast, many trusts told us that plastic surgeons who offer breast surgery have to routinely utilise their other plastic surgery skills to support the on-call plastic surgery rota, which reduces their availability for breast reconstruction services.

Figure 35: Responses to GIRFT question 'do your consultant breast surgeons participate in the general surgery on-call rota?'



Source: GIRFT questionnaire

As we have already highlighted, a growing proportion of breast surgery involves in-depth oncology knowledge, to allow participation in multimodal treatment planning at MDT meetings, as well as plastic surgery skills. Oncoplastic breast surgery is becoming more specialised and the range of breast-specific techniques that surgeons need to learn is broadening. In particular, oncoplastic breast surgery trainees need to acquire skills in the full range of surgical options for breast-conserving and reconstructive surgery as well as operations used for aesthetic and cosmetic surgery. They therefore need to learn the skills of breast surgery and plastic surgery, and be part of regular oncology and oncoplastic MDT meetings, where both oncological and reconstructive strategy is discussed.

The expectation that surgeons can simply switch from general or plastic surgery to oncoplastic breast surgery within the last year or so of their training is unreasonable, both for surgeons and their patients. Further, it seems highly cost inefficient to spend time training individuals in skills that, when they become consultants, they will no longer routinely use.

There are different concerns around the training of plastic surgeons with an interest in breast surgery. While a small proportion of these will participate in diagnostics and oncology treatment, for the majority their training focuses on breast reconstruction techniques – particularly microvascular flap breast reconstruction surgery.

However, because at present there is not equitable and timely access to free flap surgery in all areas, some trainees are inevitably less exposed to training opportunities in this complex technique. The recent BAPRAS workforce survey suggests this is already translating into less specialism in breast surgery. Such training takes many years, so a reduction in specialist trainees today will have an impact on workforce availability and therefore service provision in the future, unless there are better training opportunities for microvascular surgeons. This is causing concern within ABS and BAPRAS, who have set up a working group working with GIRFT to address the issue.

In addition, breast and plastic surgeons' exposure to the full range of breast surgery operations used in aesthetic and cosmetic breast surgery is declining as the NHS no longer offers cosmetic surgery and increasingly no longer offers aesthetic surgery. Acquisition of these aesthetic and cosmetic skills is crucial to the delivery of a high-quality breast reconstruction service.

To address these growing skills issues, we believe that it would be beneficial to recognise breast surgery as a distinct specialty rather than remaining a sub-specialty of general surgery. A proposal to this effect is already with key stakeholders for consultation. In our view, the benefits of making breast surgery a separate specialty would include allowing specific breast surgery training from core years onwards, incorporating oncology knowledge and expertise, plus oncoplastic surgery skills. It would even open the possibility of teaching interventional radiology skills, which seems a likely direction of travel for the management of small cancers in the future.

Specialty-specific training would form the basis for a more focused and perhaps faster pathway to completion of oncoplastic training. This in turn should help address some of the inequities in access to surgery we have identified, with more surgeons equipped to conduct procedures using modern techniques.

Clearly, this is just one approach and we are aware that others are being considered by other stakeholders. It would take some time for such a change to be implemented so in the interim, we would welcome the introduction of a more flexible general surgery curriculum that better meets the needs of trainees who wish to specialise in breast surgery, and also better meets the needs of providers and patients.

Recommendation	Actions	Owners	Timescale
17. Align breast surgery workforce recommendations to the NHS People Plan	**a** Oncoplastic breast and plastic surgeons to practice at the top of their licence which includes: • all WTE oncoplastic breast surgeons to be allocated at least two, and ideally three operating sessions a week. • trusts to address over-reliance/utilisation of oncoplastic breast surgeons to support non-surgical activities.	Trusts	For completion within 24 months of publication of the GIRFT report
	b Ensure training for breast and plastic surgery trainees is fit for purpose.	HEE, the GMC and Royal Colleges	For completion within 24 months of publication of the GIRFT report
	c Address the shortage of trained microvascular plastic surgeons, so that free flap reconstructions are available more widely and equitably.	Specialty associations, working with HEE and the GMC	For completion within 24 months of publication of the GIRFT report
	d Specialty associations to work with the GMC to develop a road map for the creation of an oncoplastic breast surgery specialty.	Specialty associations to work with the GMC	For completion within 24 months of publication of the GIRFT report

Notional financial opportunities

This report sets out a series of ways to improve the delivery of NHS breast surgery services using the existing resources available to the specialty.

The most important improvements are to patient care and choice. The report recommends routes to improve equity of access to breast-conserving surgery and all reconstruction methods, as well as to surgery that is currently deemed to be of low clinical value. It also proposes making outpatient care more flexible, with patients in greater control.

There are also a range of ways identified that could provide a tangible financial benefit. Below, we calculate the notional financial opportunity from specific changes to practice as being between £15m and £26m a year. This opportunity is in addition to the potential cost savings in procurement.

These figures provide a financial value for a wide range of efficiency opportunities, which may not be cash-releasing.

The figures are based on a selection of metrics (shown in Table 9) and provide an indication of what may be possible. The metrics do not represent a comprehensive set of all opportunities discussed in the report. NB: The gross notional financial opportunities put an estimated value on the resource associated with variation based on all providers achieving at least the average or best quartile performance.

Table 9: Notional financial opportunities

Improvement	Lower estimate of the opportunity available			Higher estimate of the opportunity available		
	Benchmark	**Activity opportunity***	**Gross notional financial opportunity****	**Benchmark**	**Activity opportunity***	**Gross notional financial opportunity****
Reduce implant loss rate for reconstructions Opportunity = Reduction in procedures to remove and replace implant plus associated outpatient attendances. *Base data: April 14 - Mar 17.* *Cost estimated on 'typical' pathway for these patients: removal procedure; DC to insert expander; procedure to insert new implant for 50% of patients (some would have required this from initial surgery, without the loss); 5 outpatient attendances.*	*National average* 7.14% implant loss rate	54 loss and reconstruction pathways	£0.3m	*Best quartile* 4.32% implant loss rate	116 loss and reconstruction pathways	£0.6m
Increase day case rates - cancer excisions Opportunity = reduction in bed days. *Base data: April 15 - Mar 18.* *Cost estimated on saving of one day per spell moved from inpatient to day case, costed at national average excess bed day cost of breast surgery HRGs.*	*Best quartile* 80.5% day case rate	2975 bed days	£1.3m	*BADS target* 95% day case rate	6523 bed days	£2.9m

Table 9: Notional financial opportunities (continued)

Improvement	Lower estimate of the opportunity available			Higher estimate of the opportunity available		
	Benchmark	Activity opportunity*	Gross notional financial opportunity**	Benchmark	Activity opportunity*	Gross notional financial opportunity**
Increase day case rates - mastectomies with no immediate reconstruction Opportunity = reduction in bed days. *Base data: April 15 - Mar 18.* *Cost estimated on saving of one day per spell moved from inpatient to day case, costed at national average excess bed day cost of breast surgery HRGs.*	*Best quartile* 30.16% day case rate	1716 bed days	£0.8m	*BADS target* 75% day case rate	6442 bed days	£2.9m
Reduce length of stay for mastectomies with no immediate reconstruction Opportunity = reduction in bed days. *Base data: April 15 - Mar 18.* *Cost estimated on bed days associated with spells above median or upper quartile length of stay, costed at national average excess bed day cost of breast surgery HRGs.*	*Longer length of stay (upper quartile)* 2 day LoS	6482 bed days	£2.9m	*Median average / BADS* 1 day LoS	9736 bed days	£4.3m
Reduce length of stay for mastectomies with immediate implant reconstruction Opportunity = reduction in bed days. *Base data: April 15 - Mar 18.* *Cost estimated on bed days associated with spells above median or upper quartile length of stay, costed at national average excess bed day cost of breast surgery HRGs.*	*Longer length of stay (upper quartile)* 3 day LoS	1278 bed days	£0.6m	*Median average* 2 day LoS	2137 bed days	£0.9m

Table 9: Notional financial opportunities (continued)

Improvement	Lower estimate of the opportunity available			Higher estimate of the opportunity available		
	Benchmark	Activity opportunity*	Gross notional financial opportunity**	Benchmark	Activity opportunity*	Gross notional financial opportunity**
Reduce length of stay for mastectomies with free-flap reconstruction Opportunity = reduction in bed days. *Cost estimated on bed days associated with spells above median or upper quartile length of stay, costed at national average excess bed day cost of breast surgery HRGs.*	*Longer length of stay (upper quartile)* 7 day LoS	479 bed days	£0.2m	*Median average* 6 day LoS	798 bed days	£0.4m
Reduce outpatient follow-ups after cancer excisions Opportunity = reduction in outpatient follow up activity (in breast surgery, plastic surgery or general surgery) within 1 year of spell. *Cost estimated on national average outpatient follow-up for the above specialties.*	*National average* 4.1 attendances per procedure	13956 outpatient attendances	£1.8m	*Best quartile* 3.29 attendances per procedure	26263 outpatient attendances	£3.5m
Reduce outpatient follow-ups after non-cancer excisions Opportunity = reduction in outpatient follow up activity (in breast surgery, plastic surgery or general surgery) within 1 year of spell. *Cost estimated on national average outpatient follow-up for the above specialties*	*National average* 1.77 attendances per procedure	2358 outpatient attendances	£0.3m	*Best quartile* 1.44 attendances per procedure	4860 outpatient attendances	£0.6m
Reduce outpatient follow-ups after mastectomies with no reconstruction Opportunity = reduction in outpatient follow up activity (in breast surgery, plastic surgery or general surgery) within 1 year of spell. *Cost estimated on national average outpatient follow-up for the above specialties.*	*National average* 5.5 attendances per procedure	9460 outpatient attendances	£1.2m	*Best quartile* 4.39 attendances per procedure	16675 outpatient attendances	£2.2m

Table 9: Notional financial opportunities (continued)

Improvement	Lower estimate of the opportunity available			Higher estimate of the opportunity available		
	Benchmark	Activity opportunity*	Gross notional financial opportunity**	Benchmark	Activity opportunity*	Gross notional financial opportunity**
Reduce outpatient follow-ups after mastectomies with reconstruction Opportunity = reduction in outpatient follow up activity (in breast surgery, plastic surgery or general surgery) within 1 year of spell. *Cost estimated on national average outpatient follow-up for the above specialties.*	*National average* 9.93 attendances per procedure	5131 outpatient attendances	£0.7m	*Best quartile* 7.9 attendances per procedure	12408 outpatient attendances	£1.6m
Reduce volume of non-cancer excisions Opportunity = reduction in the percentage of excision activity that is non-cancer (achieved by reducing non-cancer excisions). *Base data: April 15 - Mar 18.* *Cost estimated on national average cost of excision activity for non-cancer patients (based on grouped HRGs and average day case costs)*	*Best quartile* 23.75% of excisions are non-cancer	3396 excisions	£5.6m	*Target rate* 20% of excisions are non-cancer	4653 excisions	£7.6m
Total			**£15.7m**			**£27.5m**

Note: unless otherwise stated, cost estimates are based on national average of 2017/18 reference costs, uplifted to 2019/20 pay and prices using tariff inflation. Opportunities are per annum.

In addition to the specific areas outlined in the table, the report has identified a total spend of £41.27m on litigation over a six-year period. In the coming years, we expect a decrease in litigation costs for breast surgery to occur as the volume of claims brought against the convicted surgeon Ian Paterson are predicted to fall now all his victims have been identified and had the opportunity to register a claim. In respect to the rest of the breast surgery claims, we expect the implementation of the GIRFT Programme's five-point plan to improve patient safety and reduce litigation costs for the specialty.

About the GIRFT programme

Getting It Right First Time (GIRFT) is a national programme designed to improve medical care within the NHS.

Funded by the Department of Health and Social Care and jointly overseen by the Royal National Orthopaedic Hospital NHS Trust and NHS England and NHS Improvement, it combines wide-ranging data analysis with the input and professional knowledge of senior clinicians to examine how things are currently being done and how they could be improved.

Working to the principle that a patient should expect to receive equally timely and effective investigations, treatment and outcomes wherever care is delivered, irrespective of who delivers that care, GIRFT aims to identify approaches from across the NHS that improve outcomes and patient experience, without the need for radical change or additional investment. While the gains for each patient or procedure may appear marginal, they can, when multiplied across an entire trust – and even more so across the NHS as a whole – deliver substantial cumulative benefits.

The programme was first conceived and developed by Professor Tim Briggs to review elective orthopaedic surgery to address a range of observed and undesirable variations in orthopaedics. In the 12 months after the pilot programme, it delivered an estimated £30m-£50m savings in orthopaedic care – predominantly through changes that reduced average length of stay and improved procurement.

The same model is now being applied in more than 40 different areas of clinical practice. It consists of four key strands:

1. a broad data gathering and analysis exercise, performed by health data analysts, which generates a detailed picture of current national practice, outcomes and other related factors;
2. a series of discussions between clinical specialists and individual hospital trusts, which are based on the data – providing an unprecedented opportunity to examine individual trust behaviour and performance in the relevant area of practice, in the context of the national picture. This then enables the trust to understand where it is performing well and what it could do better – drawing on the input of senior clinicians;
3. a national report, which draws on both the data analysis and the discussions with the hospital trusts to identify opportunities for NHS-wide improvement; and
4. an implementation phase where the GIRFT team supports providers to deliver the improvements recommended.

GIRFT and other improvement initiatives

GIRFT is part of an aligned set of workstreams within NHS England and NHS Improvement. It is the delivery vehicle for one of several recommendations made by Lord Carter in his February 2016 review of operational efficiency in acute trusts across England.

As well as support from the Department of Health and Social Care and NHS England and NHS Improvement, it has the backing of the Royal Colleges and professional associations.

GIRFT has a significant and growing presence on the Model Hospital portal, with its data-rich approach providing the evidence for hospitals to benchmark against expected standards of service and efficiency. The programme also works with a number of wider NHS programmes and initiatives which are seeking to improve standards while delivering savings and efficiencies, such as NHS RightCare, acute care collaborations (ACCs), and sustainability and transformation partnerships (STPs).

Implementation

GIRFT has developed an implementation programme designed to help trusts and their local partners to address the issues raised in trust data packs and the national specialty reports to improve quality. The GIRFT team provides support at a local level, advising on how to reflect the national recommendations into local practice and supporting efforts to deliver any trust specific recommendations emerging from the GIRFT visits.

GIRFT also helps to disseminate best practice across the country, matching up trusts who might benefit from collaborating in selected areas of clinical practice. Through all its efforts, local or national, the GIRFT programme strives to embody the 'shoulder to shoulder' ethos that has become GIRFT's hallmark, supporting clinicians nationwide to deliver continuous quality improvement for the benefit of their patients.

Glossary

Clinical terms

Aesthetic
In this report, aesthetic breast surgery refers to procedures designed to change the breast appearance because of a medical condition or indication. These include surgery to correct breast overgrowth in males and females resulting from congenital or medical conditions and surgery for congenital breast underdevelopment in females.

Autologous
An autologous breast reconstruction involves using the patient's own tissue, rather than an implant. Free flap reconstruction is an example of autologous reconstruction.

Bilateral
Bilateral refers to both breasts. Cancer can (rarely) be bilateral; patients can have a bilateral mastectomy and bilateral reconstruction.

Biopsy
A biopsy involves taking a small sample of tissue for further examination.

Breast-conserving surgery
Breast-conserving surgery is an umbrella term for surgery to remove breast cancer which does not involve removal of the breast (mastectomy).

Cosmetic
In this report, cosmetic breast surgery refers to procedures used to change the breast appearance for personal preference, rather than because of a medical condition or indication. Very little cosmetic breast surgery is provided on the NHS.

Excision
In this report, excision refers to the surgical removal of an area of tissue, either for diagnosis or for treatment. For cancer treatment this is known as WLE.

Free flap
In a free flap reconstruction, a transplanted flap of tissue from the patient's body is disconnected from its original blood supply and reconnected to different blood vessels closer to the breast. The most common approach is to use spare tissue on the abdomen (this is known as a DIEP flap).

Lipofilling
Lipofilling is the transfer of fat tissue from one part of a patient's body to the breast. It is typically used to address unevenness following breast surgery – whether that is in terms of symmetry with the other breast or apparent gaps in the operated breast following either breast conservation or reconstruction.

Mammoplasty
Sometimes spelled mammaplasty, this refers to any surgery to alter the shape or appearance of the breast. There are both reduction mammoplasties (breast reduction) and augmentation mammoplasties (breast enlargement).

Mastectomy
Surgical removal of the breast.

Mastitis
Infection of breast tissue. Most common among breastfeeding mothers.

Mastopexy
Surgery to lift the breast. It can be conducted as part of the same operation as a mammoplasty.

Microvascular anastomosis
In a free flap breast reconstruction, this refers to the surgical connection between the transferred veins or arteries and the existing tissue.

Oncoplastic
Broadly, the use of plastic surgery techniques to improve the aesthetic outcomes of breast cancer surgery. It is now standard practice; many breast surgery units are known as oncoplastic units.

PoLCV
Procedures of limited clinical value – an umbrella term used in commissioning referring to typically small volume procedures where clinical effectiveness has not been robustly proven.

Symptomatic
In this report, symptomatic referrals are those that come to breast surgery units from GPs, where the GP has identified any symptoms of potential breast cancer that require further investigation. The other type of referrals received by breast surgery units are from the NHS Breast Screening Programme and are known as 'screen-detected'.

Vacuum-assisted biopsy/excision (VAB/VAE)
The use of an image-guided vacuum device to make the procedure more precise and allow more tissue to be taken to further assess (biopsy) or remove the area (excision).

Organisations

ABS
The Association of Breast Surgery is a specialist organisation for healthcare professionals caring for any person with a breast problem. Members include surgeons but also nurses and other members of the breast care team.

BAAPS
British Association of Aesthetic Plastic Surgeons

BAPRAS
British Association of Plastic, Reconstructive and Aesthetic Surgeons

BCIR
The Breast and Cosmetic Implant Registry collects data about every implant inserted in England both in the NHS and in the private sector, for any reason. It was set up by NHS Digital and is on the Schedule of Approved Collections, which means that as part of the NHS Standard Contract trusts could potentially be penalised for not submitting data,

NABCOP
The National Audit of Breast Cancer in Older Patients (NABCOP) collates data about the care pathways and outcomes for older women (70+) with breast cancer compared to those in the 50-69 age group.

NCRAS
National Cancer Registration and Analysis Service.

NHSBSP
Under the NHS Breast Screening Programme (NHSBSP), all women in England between the ages of 50 and 71 are offered free screening for breast cancer, approximately every three years. The screening typically involves use of a mammogram to check for signs of breast cancer.

NMBRA
The National Mastectomy and Breast Reconstruction Audit (NMBRA) was an audit that, between 2008 and 2011, gathered data on reconstruction, based on trust returns and patient reported outcome measures (PROMs).

UKNFR
The UK National Flap Registry aims to collect information about all major free and pedicled flap operations carried out in the UK (including in private healthcare). Data entry is currently voluntary but BAPRAS and ABS encourage their members to register.

Appendix A: Pan-London suspected breast cancer referral form

This form is included as an example of the kind of approach to enhancing referral processes that could be used in different areas. It was approved for use during the COVID-19 pandemic only, pending further feedback and discussion from members of the RM Partners alliance and the NHS England London Clinical Advisory Group.

The version of the form provided dates from 1 April 2020. More recent versions may be available at: *www.healthylondon.org/resource/covid-19-cancer-referral-resources/*

DOB: NHS no:

PAN LONDON COVID-19 SUSPECTED BREAST CANCER/BREAST CLINIC REFERRAL FORM

REFERRAL DATE:

E-referral is the preferred booking method for suspected breast cancer/breast symptoms referrals. All referrals should be made within 24 hours.

Fax is no longer supported due to patient safety and confidentiality risks.

PATIENT DETAILS
SURNAME: **FIRST NAME:** **TITLE:**
GENDER: **DOB:** **AGE:** **NHS NO:**
ETHNICITY: **LANGUAGE:**
☐ **INTERPRETER REQUIRED** ☐ **TRANSPORT REQUIRED**
PATIENT ADDRESS: **POSTCODE:**
DAYTIME CONTACT☏:
HOME☏: **MOBILE☏:** **WORK☏:**
EMAIL:

CARER/KEY WORKER DETAILS
NAME: **CONTACT☏:** **RELATIONSHIP TO PATIENT:**

COGNITIVE, SENSORY OR MOBILITY IMPAIRMENT
☐ **COGNITIVE** ☐ **SENSORY** ☐ **MOBILITY** ☐ **DISABLED ACCESS REQUIRED**
PLEASE INCLUDE RELEVANT DETAILS:

SAFEGUARDING
☐ **SAFEGUARDING CONCERNS**
PLEASE INCLUDE RELEVANT DETAILS:

GP DETAILS
USUAL GP NAME:
PRACTICE NAME: **PRACTICE CODE:**
PRACTICE ADDRESS:
BYPASS☏:
MAIN☏: **FAX:** **EMAIL:**
REFERRING CLINICIAN:

DOB: NHS no:

COVID – 19 STATUS (please tick one of the boxes below before referring)

☐ **Not at risk** ☐ **At risk** ☐ **At very high risk**

Please indicate by ticking one box

☐ **SUSPECTED BREAST CANCER** will be assessed within 2 weeks

☐ **BREAST SYMPTOMS (CANCER NOT SUSPECTED)** will be assessed within 2 weeks

This form should NOT be used for patients who need to be referred because of a family history of breast cancer or for reconstructive surgery. Please refer by eRS or letter as per local guidelines.

SUSPECTED BREAST CANCER (NICE NG12 CRITERIA)
Please only use this section if you suspect breast cancer:

30 years and over

☐ unexplained/discrete breast lump

☐ unexplained lump in axilla

☐ Skin changes that suggest breast cancer
Tether / contour change/ peau d'orange

☐ **Unilateral** nipple symptoms
- ☐ Discharge: blood / watery
- ☐ inversion / retraction / ulceration
- ☐ other changes or concern

BREAST SYMPTOMS
Cancer NOT suspected:

☐ aged <30 years with a lump

☐ Persistent asymmetrical nodularity or thickening at review after menstruation

☐ Infection or inflammation that fails to respond to antibiotics

☐ Unilateral eczematous skin of areola or nipple:
Please do not refer until tried topical treatment such as 0.1% mometasone for 2 weeks

Please do not refer bilateral multiduct discharge.

☐ **Referral is due to CLINICAL CONCERNS that do not meet above criteria (the GP MUST give full clinical details in the 'additional clinical information' box at time of referral)**

Recommendations for management of BREAST PAIN:

Breast pain alone is not a sign of breast cancer and should be managed with the following advice:

1) Provide patient with information sheet: https://breastcancernow.org/information-support/have-i-got-breast-cancer/benign-breast-conditions/breast-pain

2) If required, analgesia (e.g. 4-6 weeks NSAID [oral /topical]) or paracetamol

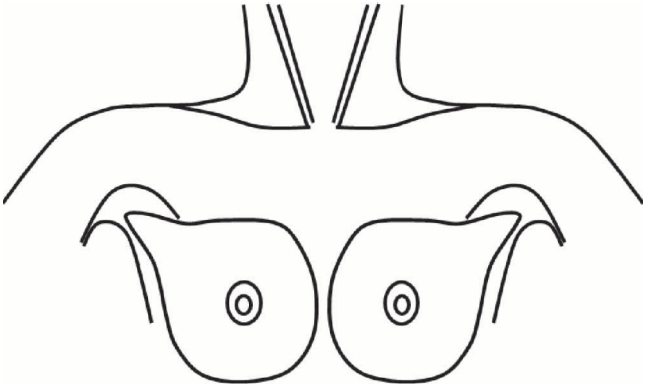
Recommendations for investigations and management of GYNAECOMASTIA see ABS guidelines:

https://associationofbreastsurgery.org.uk/media/65097/abs-summary-statement-gynaecomastia-2019.pdf

DOB: NHS no:

EXAMINATION FINDINGS

Please mark the breast diagram below and/or provide a clinical description below it.



HOW TO MARK THE DIAGRAM

Place the mouse cursor over the diagram at the position of the lesion. Click the left mouse button. Use the keyboard to mark the diagram (X marks the lesion). Use the mouse or arrow keys to move left or right or to adjacent lines. Please do not press the <ENTER> key as it may cause alignment problems with your markers.

CLINICAL DESCRIPTION (including site, size, consistency and axillary involvement):

Additional clinical information:

Personal/relevant patient information:

Past history of cancer:

History of breast cancer:

Relevant family history of cancer:

- ☐ **I have discussed the possible diagnosis of cancer with the patient**
- ☐ **The patient has been advised that they will be contacted by secondary care by telephone**
- ☐ **I have counselled the patient regarding that they should prioritise this appointment but expect changes to routine investigations and management. I have offered the pan London COVID -19 patient information leaflet. Offering written patient information increases patient experience and reduces non-attendance.**
  Press the <Ctrl> key while you click here to view the leaflet
- ☐ **This patient has been added to the practice suspected cancer safety-netting system**
  Press the <Ctrl> key while you click here to view Pan London Practice-based Suspected Cancer Safety Netting System

INVESTIGATIONS

Please ensure this referral includes ALL the relevant investigations including blood tests and imaging. If there are any pending test results that you have organised at the time of this referral please provide information including TYPE OF INVESTIGATION requested (bloods, imaging) and TRUST performing the tests in the box below.

BREAST IMAGING STUDIES (in past 3 months) Please include date: and location:

DOB: NHS no:

RENAL FUNCTION (most recent recorded in past 3 months)

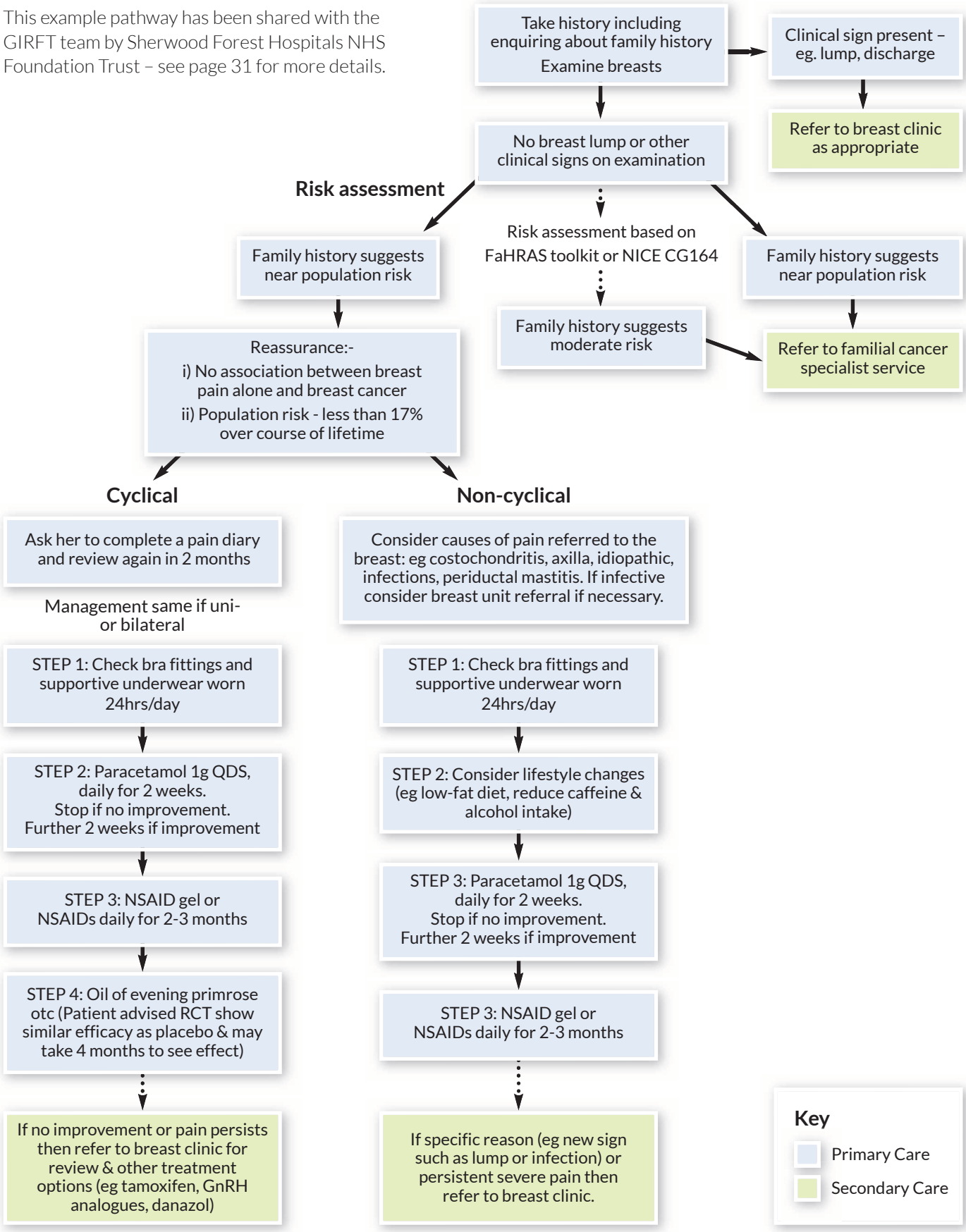
MEDICAL HISTORY

ALLERGIES

MEDICATION

Appendix B: Example mastalgia pathway

This example pathway has been shared with the GIRFT team by Sherwood Forest Hospitals NHS Foundation Trust – see page 31 for more details.



Information:
http://www.patient.co.uk/health/breast-pain-leaflet
Breast Pain by BCC
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3275318/

Appendix C: Proposed metrics for breast surgery

Drawing on our HES data analysis for 2014-17 and 2015-18, we benchmarked key aspects of breast surgery practice and identified a series of key metrics. The 2014-17 data has been presented at each trust with the England comparator and some of it is available in the data packs. It has been extracted and summarised below. These metrics consist of:

- service indicators that may help to explain variation (demographics, surgery complexity, cancer stage, etc), plus
- breast surgery quality indicators that can be reliably extracted from HES (e.g. unplanned return to theatre and unplanned removal of implant). These can be measured at individual trust level and compared within an ICS and/or England.

The quality of trust data capture (PAS and clinical coding) will be reflected in the metrics. Clinical involvement with data capture, especially regarding clinical coding, is essential to enable accuracy and reflect complexity, otherwise comparisons will have limited value.

In line with the approach taken throughout our work, these metrics are based on data covering all admissions for surgery on the breast, regardless of the specialty of the operator.

Admissions for index procedures reliably captured on HES are:

- Breast excision (for cancer and non-cancer reasons)
- Mastectomy (for cancer or risk reduction)
- Breast reconstruction (immediate and delayed)
  - Implant-based
  - Autologous

Key service metrics 2015-18 GIRFT HES data unless otherwise stated

Table 1: Patient demographics for key index procedures

Metric	Excision (ALL) (2014-17)	Mastectomy (ALL)	Mastectomy+ Implant (cancer)	Mastectomy+ Flap (cancer)
Mean Age	57yrs	65yrs	51yrs	50yrs
<50yrs	32%	19%	47%	41%
50-69yrs	49%	42%	48%	56%
>70yrs	19%	38%	5%	2%
% most deprived quintile Carstairs Deprivation Index	16%	15%	13%	16%
% Charlson co-morbidity	20.5%	30%	14%	13%
% BAME	9%	7.5%	8%	11%

Table 2: Case mix/complexity for key index procedure

	England average
Volume (%) of image guided excision surgery	40%
Volume (%) admissions for bilateral surgery (cancer diagnosis unilateral or bilateral)	
excisions (ALL)	2.5%
mastectomy for cancer	8%
mastectomy/ immediate reconstruction for cancer	
Implant reconstruction	15%
Autologous reconstruction	11%
Delayed breast reconstruction	10%
% cancer excisions recorded as mammoplasty OPCS codes	2017/18: 9.5%

Table 3: Cancer referral and treatment patterns (surrogate for cancer stage in lieu of NCRAS data)

		England average
Ratio of number of NHSBSP (PHE) referrals to number of cancer patients undergoing surgery		2013-16: 42%
Volume (%) of breast excisions for cancer		68%
by age group	<30yrs	4%
	30-49	47%
	50-69	82%
	>70yrs	87%
For DCIS, the volume of		
cancer excisions		8.3%
mastectomy		6%
mastectomy/ immediate breast reconstruction		14%
Volume (%) cancer surgery performed as breast conservation		68.5%
by age group	<50yrs	60%
	50-69yrs	74%
	>71yrs	62%
Axillary clearance rates (volume %) by key breast procedure		
Excision for cancer		9%
Mastectomy		33%
Mastectomy/immediate breast reconstruction		21%
Volume (%) Immediate reconstruction		27%
by age group	<50yrs	48%
	50-69yrs	30%
	>71yrs	5%

Potential key breast surgery quality indicators (2014-17 GIRFT HES benchmark data unless otherwise stated)

Table 1: Cancer wait times

Metric	Existing operational standard
2 week wait: urgent cancer/symptomatic referrals	93%
31 day wait: diagnosis to first treatment*	96%
62 day wait: first treatment from urgent GP referral	85%

*To be replaced by 28FDS in 2020/21

Table 2: Participation in breast reconstruction data registries

Metric	Benchmark	GIRFT Target
% of all implant insertion/removal/replacement HES admissions recorded in BCIR	Not available	95%
% of all flap-related HES admissions recorded in UKNFR	Not available	95%

Table 3: Use of appropriate breast speciality TFC codes

Metric	GIRFT Benchmark	GIRFT Target
Breast surgery admissions captured under TFC 100 (general surgery)	20%	<5%
Breast surgery OPD attend captured under TFC 100 (general surgery)	Not available	<5%

The GIRFT target is set **as equal or less than** the GIRFT HES derived benchmark unless other published targets stated.

Table 4: Breast excision surgery (ALL diagnoses)

Metric	GIRFT Benchmark	GIRFT Target
% bilateral	2.5%	N/A
Benign to malignant ratio	68%	N/A
Excisions for benign/normal conditions	25%	<25% of ALL excisions
Excisions for CANCER (WLE) - Day case rate - Re-excision rate	68% 71% 19%	N/A BADS 90% AsBrS 10%
Emergency readmission rate (ALL) - 30 days - 90 days	 2.4% 4.1%	 <2.4% <4.1%
Haematoma rate	1.6%	<1.6%
Excision for cancer OPD attends 1yrs	3.3	<3.3
Excision for cancer OPD attends 5yrs	7	<7

Table 5: Mastectomy +/- reconstruction outcomes (for cancer)

	Mastectomy	Mastectomy + implant		Mastectomy + autologous (free) flap	
Metric	**Unilateral**	**Unilateral**	**Bilateral**	**Unilateral**	**Bilateral**
Day case	19%*	2-3%		NA	
Length of stay (lower quartile)	1 night	1night		5 nights	
Return to theatre same admission	NA	NA		6.2%	
Emergency readmission rate					
- 30 days	5.6%	7%	10%	10%	12.5%
- 90 days	9%	11%	14%	12%	15%
Haematoma rate <=30days	5%	4.5%	6%	9%	8.5%
Wound complications up to 6mths	10%	16%	21%	24%	30%
Unplanned implant removal (2016/17)		7%**			
Average number post reconstruction procedures > 90 days - 5 years		1.6	1.8	1.3	1.6
Post-op OPD attends 1yrs	5.5	10	12	10	11
Post-op OPD attends 5yrs	11	22	22	20	21

Other national targets

*BADS day case for mastectomy is recommended as 75%
**ABS and BAPRAS Oncoplastic guideline unplanned implant removal recommended target at 3 months 5%

Definitions

Day case - where LoS =0. Rate is % of all relevant procedures.

Long LoS - (>= national upper quartile)

Re-excision - 2nd breast excision (re-excision or mastectomy) on same breast < 1 yr post-procedure

Emergency readmission - any cause <= 30 and 90 days post-procedure

Haematoma - during operation admission/readmission <=30 days post-procedure

Return to theatre is for autologous (mainly free flap)reconstruction and is based on the following OPCS codes being picked up within the same admission as the index procedure:

- L985: Revision of microvascular vessel anastomosis code
- Y242: Attention to microvascular repair of organ NOC
- B295: Revision of reconstruction of breast

Unplanned implant removal - Implant removal on same breast < 1 year post-procedure (applicable for implant reconstructions only)

Post-op OPD attends - Average (mean) number of outpatient department attendances per patient at 1 year and up to 5 years post-procedure

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- the NHS Breast Screening Programme (NHSBSP);
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- the UK National Flap Registry (UKNFR) and The Breast and Cosmetic Implant Registry (BCIR);
- the National Cancer Registration and Analysis Service (NCRAS); and
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