RCS
ADVANCING SURGICAL STANDARDS

From innovation to adoption

Successfully spreading surgical innovation

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From innovation to adoption

Successfully spreading surgical innovation

Foreword

Surgeons have a rich tradition of innovation, pioneering new techniques and developing technology that improves and extends lives. In our first report on innovation, *From Theory to Theatre*,[1] we explored the barriers to surgical research and called for increased investment and support to safeguard the future of surgical innovation. Since then, we have worked with our partners, the National Institute of Health Research (NIHR), the Rosetrees Trust and Cancer Research UK (CRUK), to establish a national network of surgical trial centres to develop and expand clinical trials in surgery, raise surgical standards and transform the quality of patient care across a number of conditions.

Support for surgical research remains vital, but it is one side of the coin. Successful innovation requires both the discovery and the implementation of a new technique. Like research, diffusion of surgical innovation in England has been patchy and there is much more to do to ensure the value of innovation is realised for every patient.

In this report we present a detailed analysis of five surgical case studies and explore the barriers and the drivers that helped to shape patterns of adoption in the NHS. By studying these experiences we have identified, for the first time, the critical factors that underpin surgical adoption. These factors occur along a pathway of surgical innovation. By mapping out this pathway, we hope to stimulate a more systematic approach to the uptake of surgical innovation, providing greater certainty and improved benefits for commissioners, clinicians and patients.

I would like to thank the contributors to this report for sharing their knowledge and experience and providing insights that will help us innovate in the future. I hope that stakeholders from the government, the NHS, healthcare professions, charities, research funders, researchers and industry will reflect on the findings and recommendations in the report and establish a new consensus to underpin surgical adoption in England.

Professor Norman Williams
President, The Royal College of Surgeons of England

Executive summary

From the first antiseptic operation, through to organ transplantation, keyhole techniques and robotic technology, surgery has revolutionised NHS care and challenged our expectations about the outcomes of healthcare.

'Innovation' can seem an abstract concept but by challenging the status quo, testing new principles and discovering superior techniques, the process can drive improvement in surgery, bringing new benefits to patients. Furthermore, the government has made clear in *Innovation, Health and Wealth*[2] that it wishes to establish the NHS as a world leader in innovation, delivering economic benefits to the UK economy, efficiency benefits to the health service and health benefits to the population. Driving innovation in surgery is fundamental to achieving this vision.

This is the second report in a series. Our first report, *From Theory to Theatre*,[1] explored the barriers to translational research that threaten to stifle surgical innovation and identified a series of actions to deliver high quality surgical research. But the challenges do not stop there. The fruits of research are of little value if they are poorly implemented. Discovery only matters if it reaches and benefits patients.

Spreading innovation in surgery is an attractive principle, but it can be difficult to achieve in practice. The diffusion of surgical innovation has posed particular challenges, from evidence, to training, to capacity. For example, the absence of appropriate evidence underpinning new techniques can inhibit investment in skills or infrastructure, and limit clinical and patient demand for the innovation. The result has been that many innovations that have been developed in England have failed to spread to the same extent as in other countries.

If we are to address the slow diffusion of innovation we must learn from experience. This report sets out what makes adoption of surgical innovation different and why we need a new approach. It is based on a review of five mainstream surgical procedures across a number of specialties, in which we analyse patterns of uptake and explore the factors that helped and hindered surgical adoption in England, based on the insights of clinical experts.

As a result, we have developed a pathway of surgical innovation, made up of six critical factors that underpin surgical adoption.

1 Early identification of the promise of an innovation

Clinicians
Commissioners
Providers

Promising new techniques arising from research should be identified without delay. Early recognition helps to catalyse the overall process of adoption by ensuring that the NHS focuses its attention on changes that bring the greatest benefits to patients.

2 Leadership to champion and advocate its adoption

Clinicians
Providers

Leaders articulate the benefits of the innovation and act as proponents of change. Leadership at a clinical, managerial and policy level helps set out a clear vision and a goal, which can be used to engage others and win support to deliver change.

3 Establishing the infrastructure to enable its use

Commissioners
Providers
Surgical profession
MDTs

Surgical innovation relies on the development of new knowledge and skills, the use of new equipment and technology and the reconfiguration of services. Teams will need to work together differently and engage others in new ways. Local and national action is therefore critical to establish the right surgical capacity and organisational structure to deliver change.

The pathway of surgical innovation

4 Defining what should be implemented and how its impact will be measured

NICE
Specialty associations
Strategic clinical networks

5 Developing levers and incentives to encourage appropriate adoption

DH
NHS England
NICE

6 Providing information to support clinical adoption and patient choice

Specialty associations
NICE
Patient charities

The development of clinical guidance by the National Institute for Health and Care Exellence (NICE) and surgical specialty associations establishes a common set of principles and practices that underpin an innovation. By codifying the core components of care, guidance becomes a reference point for commissioners, providers and healthcare professionals, enabling them to adopt innovation safely and consistently. The use of new procedures should be recorded by providers to support monitoring of both implementation and impact.

Providers and commissioners face a host of competing healthcare priorities amid unprecedented budgetary pressures. The adoption of innovation must be aligned to the quality and efficiency imperatives that underpin NHS decision-making. Payment schemes such as the Commissioning for Quality and Innovation (CQUINs) framework and best practice tariffs can be used to reward providers for delivering quality goals, helping to win buy-in for change within the NHS, and to ensure that adoption of new procedures becomes a local priority.

Patients rely on clear and accurate information to participate in decisions about their care in partnership with clinicians, and to make an informed choice about new surgical procedures that may benefit them.

These factors occur in the pathway as part of a wider innovation ecosystem, and although the relative importance of each factor will vary according to the innovation in question, it is important that each is addressed if rapid and consistent diffusion is to occur.

As leaders of the profession, we look forward to working with the NHS to deliver marked improvements in patient access to new, life-changing procedures as soon as possible. We hope that this report – and the pathway it identifies – will make a contribution.

Recommendations

We have identified 15 recommendations for short and medium term actions that will enable the surgical profession, working with key partners in the NHS and government, to address the six critical factors along the pathway of surgical innovation.

1 Early identification of the promise of an innovation

Recommendation 1: NHS England should work in partnership with NICE and The Royal College of Surgeons of England (RCS) to develop a horizon-scanning process to identify and review promising new surgical procedures.

2 Leadership to champion and advocate its adoption

Recommendation 2: Strategic clinical networks should be required to review and advise on the roll-out of innovative surgical procedures at a regional level.

Recommendation 3: Surgical specialty associations should develop good practice guidance to support clinical teams to work effectively together at a local level to deliver an effective business case and drive organisational change.

3 Establishing the infrastructure to enable its use

Recommendation 4: NHS England should work in partnership with NICE and the RCS to agree the preferred model of service delivery (including how best to achieve economies and qualities of scale). The RCS should provide advice on training requirements, including the number of centres, to safely introduce the new technique.

Recommendation 5: NICE technology appraisal guidance that addresses surgical procedures should have a mandatory training direction attached to it and local compliance with training arrangements should be evaluated as part of clinical audit.

Recommendation 6: Tariffs for new procedures should be established within three months to ensure providers can be reimbursed for the procedure as soon as possible. These tariffs should be refined each year as part of the reference costs return by providers.

Recommendation 7: The NHS tariff should be adjusted for new surgical procedures, to include reimbursement in the first year to cover the training needs of providers that undertake that procedure. Provision of this training should be a contractual requirement for providers, and providers should demonstrate compliance with training programmes in order to be reimbursed through the tariffs for those procedures.

4 Defining what should be implemented and how its impact will be measured

Recommendation 8: Relevant specialties should develop clinical guidance on new surgical techniques as early as possible building on the work of NICE.

Recommendation 9: NHS England should work in partnership with NICE and the RCS to agree the point at which the procedure should be reviewed as part of NICE's technology appraisal programme (where this is appropriate).

Recommendation 10: Data collection for all new procedures should begin as soon as practically possible in the development cycle and be carried out to the standards required by the NICE interventional procedure guidance. This should be led by the relevant specialty association and appropriate guidance should be issued by the Association of British Healthcare Industries (ABHI).

Recommendation 11: Promising new procedures should be supported with dedicated terminology within the Systematized Nomenclature of Medicine Clinical Terms (SNOMED) to ensure accurate coding of the procedure. NHS England should assess the roll-out of SNOMED clinical terminology and take the requisite steps to ensure that it is used consistently in all parts of the NHS.

5 Developing levers and incentives to encourage appropriate adoption

Recommendation 12: Best practice tariffs and CQUINs should be developed for use by commissioners to reward providers for the adoption of promising new surgical procedures.

Recommendation 13: Providers of NHS care should be required to report on how they are supporting surgical research and the adoption of new techniques and technologies, as part of their annual quality account.

6 Providing information to support clinical adoption and patient choice

Recommendation 14: Patient groups should work with surgical specialty associations to develop appropriate information for patients on new surgical procedures.

Recommendation 15: Patients should be offered a choice of different surgical interventions that are appropriate for them, including new practices and techniques.

Background

Developing and implementing a formula for successful innovation has proved difficult. Over time a series of government reviews led by Sir David Cooksey – the Life Sciences Review and the current strategy, *Innovation, Health and Wealth*[2] – have recognised the broad benefits of health innovation for patients, the NHS and our wider economy. They have sparked numerous initiatives to support research and discovery, and make sure new technologies, ideas and practices become 'business as usual' for the NHS.

Nevertheless, identifying and supporting clinical talent, investing time and resource into ideas to test their worth, and managing change across an organisation as large and fragmented as the NHS still feels like a formidable challenge. Just getting to the stage at which evidence on the effectiveness of an innovation can be collected is a lengthy process; problems remain in securing funding to undertake the research and gaining ethical approval for the trial. For example, clinical ethics committees (which differ from research ethics committees) in trusts play an important role in getting research started but they are still not present in every trust.

For the purposes of this report, we understand innovation to be "an idea, service or product, new to the NHS or applied in a way that is new to the NHS, which significantly improves the quality of health and care, wherever it is applied".[1]

The recent review of innovation, *Innovation, Health and Wealth: Accelerating adoption and diffusion in the NHS*,[2] identifies eight key themes to promote greater uptake and diffusion, which underpin the current NHS agenda. These are:

- Reducing variation in the NHS, and driving greater compliance with NICE guidance.
- Working with industry to develop and publish better innovation uptake measures and more accessible evidence and information about new ideas.
- Establishing a more systematic delivery mechanism for diffusion and collaboration within the NHS by building strong cross-boundary networks.
- Aligning organisational, financial and personal incentives and investment to reward and encourage innovation.
- Improving arrangements for procurement in the NHS to drive up quality and value, to make the NHS a better place to do business.
- Instigating a major shift in culture within the NHS, developing people by 'hard-

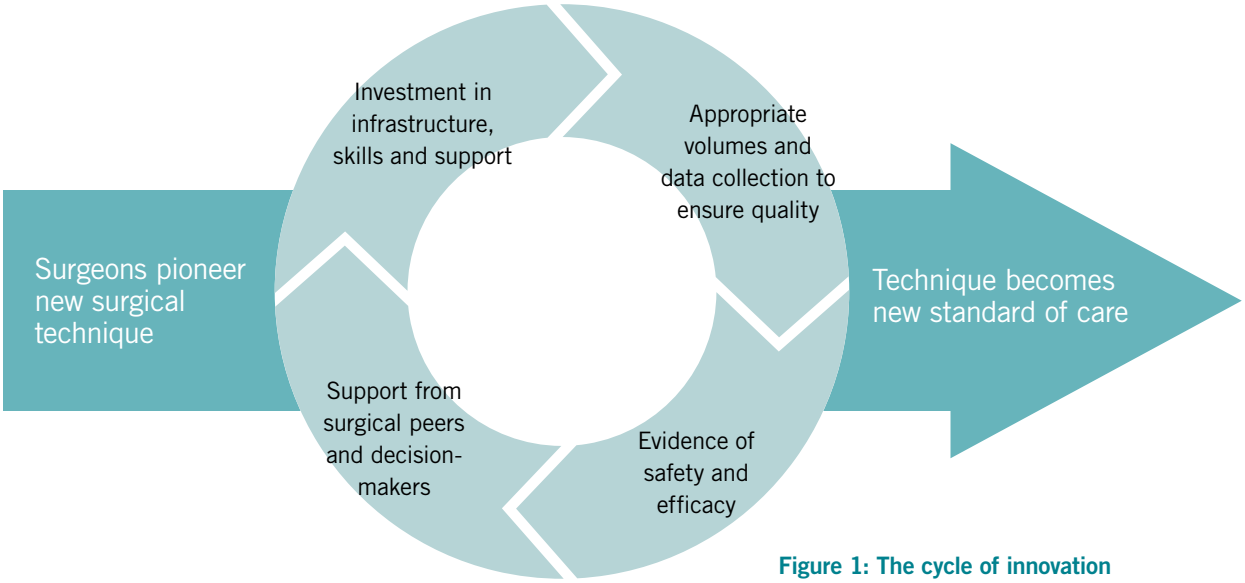


Figure 1: The cycle of innovation

wiring' innovation into training and education for managers and clinicians.
- Strengthening leadership in innovation at all levels of the NHS, setting clearer priorities for innovation, and sharpening local accountability.
- Identifying and mandating the adoption of high-impact innovations in the NHS.

By getting these enablers right we can start to create a virtuous circle, with the availability of evidence supporting the case for investment in skills and infrastructure, which in turn leads to greater uptake and the development of stronger evidence, as set out in **Figure 1**.

The critical question is: how do these themes apply to surgical practice? There is a clear role for the NHS, the government and the surgical profession to understand how the adoption and diffusion of new, innovative surgical practices can be accelerated.

Our first report in this series, *From Theory to Theatre*,[1] made a strong case for embedding a culture of surgical research within the NHS to ensure the continued development of new and innovative surgical techniques and practices. We are delighted that the government has since accepted the report's major recommendations towards 'hard-wiring' research into fabric of the NHS and supporting this through the NIHR's ongoing commitment to investment in high quality surgical research. Meanwhile, the RCS has established a new network of surgical research centres to deliver the infrastructure, skills and investment for success.

The next challenge, which this report seeks to address, is how to shape the mechanisms for uptake of surgical innovations in a practical way, and ensure their benefits are realised for patients as quickly as possible. The case studies in this report demonstrate how long it can take to get from innovation to adoption in surgical research. The solutions to this lie in infrastructure, training and leadership.

Methodology

The report examines five different surgical procedures:

1. Sentinel lymph node biopsy – a low-impact diagnostic procedure on the underarm region for determining the stage of breast cancer.
2. Enhanced recovery – a multi-stage pre-, peri- and postoperative clinical pathway for ensuring patients recover as quickly and fully as possible.
3. Laparoscopic colorectal surgery for cancer – a minimally invasive procedure for removing cancerous tissue from the bowel and/or rectum of a patient.
4. Robotically assisted radical prostatectomy – a minimally invasive procedure for precisely removing a cancerous prostate gland and surrounding tissue with the assistance of a complex, high-cost surgical robot.
5. Total mesorectal excision – a highly technical procedure for meticulously removing a defined section of the bowel to remove cancerous cells and prevent recurrence.

These procedures were chosen because:

- each is deemed 'innovative' – they involve principles or practices that are, or were, new to the NHS with the potential to improve the outcomes and experiences of patients; and
- the combination of procedures allows a range of surgical specialties to be considered.

Data on treatment numbers were elicited through parliamentary questions, which provided Hospital Episode Statistics (HES) data for each procedure that took place in the NHS in England.[3–6] These data were analysed in detail to identify patterns of uptake over time and to identify the impact of any national initiatives intended to improve adoption, such as national training programmes and the use of financial incentives. Data from relevant clinical audits were also analysed.

We conducted a series of detailed interviews with leading surgeons who were involved in the discovery and/or adoption of the procedures covered within this report, as well as with senior NHS stakeholders who have an overarching view of the process by which surgical innovations are integrated into NHS practice. This informed our understanding of the following factors:

- the patterns and the extent of uptake of each surgical procedure or technique;
- whether the speed and breadth of uptake is deemed to be appropriate; and
- the key barriers and enablers to successful implementation.

Where appropriate we shared the data with the clinical experts to gain a surgical opinion on the treatment rates. Our findings from the data

and the key themes to emerge from the clinical commentary were used to identify the six factors that underpin surgical adoption. From this we developed a pathway of surgical innovation to underpin the rapid and consistent roll-out of new surgical procedures in the NHS.

Our review culminated in the formulation of 15 recommendations to enable the surgical profession, working with key partners in the NHS and government, to realise the success factors for surgical innovation across the pathway.

It should be noted that the contributions of the clinical experts are based on their own practice and individual views and are not representative of the practice or views of the surgical profession as a whole, nor of the organisations for which they work.

Surgical innovation in practice

Sentinel lymph node biopsy

Key findings

- The perceived lack of robust evidence was an initial barrier to the timely adoption of sentinel lymph node biopsy (SLNB) in the UK.
- Clinicians who advocated change were often met with resistance from surgical colleagues and managers who were reluctant to support a new technique that was being practised on a relatively small scale.
- Clinical champions played a key role in convincing the Department of Health (DH) to implement a national training programme, and in driving participation in training across England.
- Support from the DH provided essential start-up funding, created the infrastructure to deliver training on the scale required, and established a national mandate for change.
- The national training programme enabled swift and safe roll-out of the technique. Financial and logistical challenges existed in some trusts, but in most cases these were overcome through local support and problem solving.
- Participation in the *NEW START* national training programme and the wider adoption of SLNB were deliberately aligned to key NHS imperatives to help convince trusts of their utility.
- The use of payment mechanisms such as best practice tariffs and CQUINs has played a role in rewarding the use of SLNB in more recent years.
- The inclusion of SLNB within NICE and professional guidance helped to cement its position today as the standard of care.

About the procedure

The sentinel lymph node is defined as the first node or group of nodes to which cancer cells are most likely to spread from the primary tumour. Sentinel lymph node biopsy is a procedure in which the sentinel lymph node is identified, removed and examined to determine whether cancer cells are present. A positive SLNB result indicates that cancer is present in the sentinel lymph node and may be present in other nearby lymph nodes and, possibly, other organs. This information can help a doctor determine the stage of the cancer and develop an appropriate treatment plan.[7]

If the sentinel node or nodes are found to be negative, there may be no need for further clearance to look for involved lymph nodes. For some breast cancer patients, SLNB avoids the need for more extensive surgery and is associated with a low false negative rate. Side effects including lymphedema, seroma, numbness, pain and

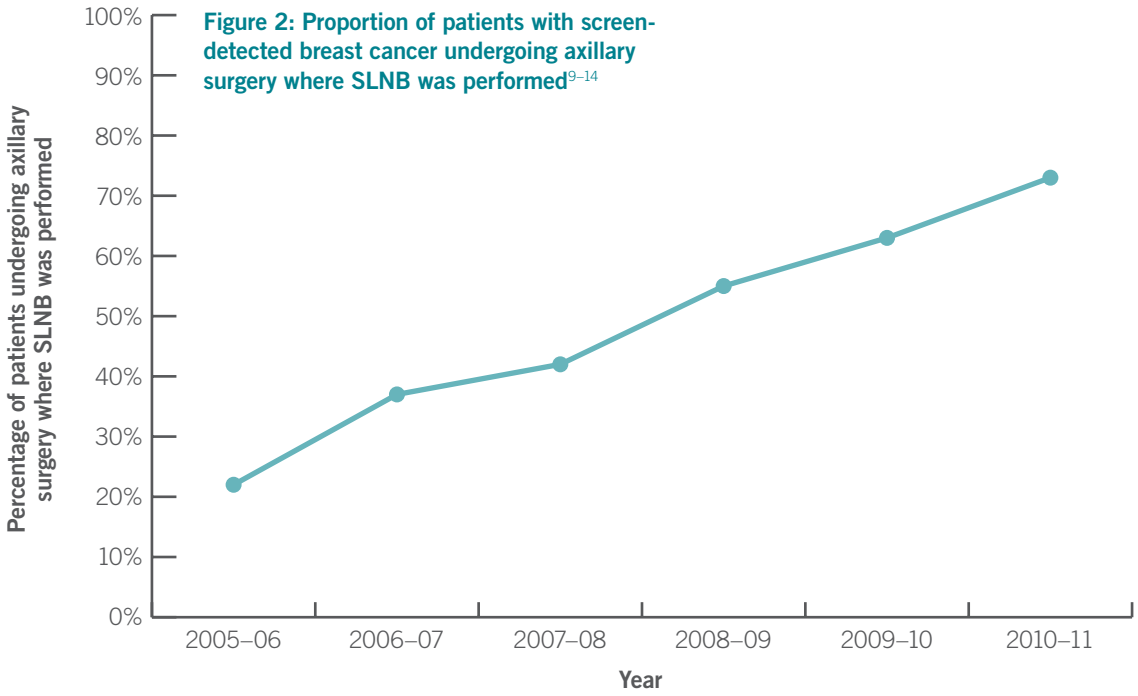
difficulties with movement of the arm are likely to be reduced or avoided through the use of SLNB.[8]

Patterns of uptake

A new treatment code for SLNB was introduced to the Office of Population Censuses and Surveys (OPCS) classification for 2006/2007 (which is used to classify the activity of hopsitals and remunerate them accordingly). However, an analysis of the HES data shows a marked decline in SNLB procedures recorded between 2007/2008 and 2010/2011. This is due to substantial errors in clinical coding, which render the data inaccurate. A more accurate analysis is considered to be the data from the NHS Breast Screening Programme, which covers around 30% of breast cancer cases in the UK. **Figure 2** shows the proportion of patients with screen-detected breast cancer undergoing axillary surgery where SLNB was performed.

Data from the NHS Breast Cancer Screening Programme show that in 2010/2011 there were at least 10,535 procedures performed for cancers detected through the NHS Breast Cancer Screening

Figure 2: Proportion of patients with screen-detected breast cancer undergoing axillary surgery where SLNB was performed[9–14]



Programme.[14] The data also demonstrate a significant year-on-year increase in the number of patients receiving the procedure since the introduction of the *NEW START* national training programme in 2006 (see **Box 1**). The limitation of the breast screening programme data is that it only covers screen-detected cancers, which account for about a third of all UK breast cancers.[15] Breast units will perform the procedure on both screen-detected cancers as well as patients with symptomatic breast cancer not identified through screening, the latter of which is the larger group. The data is therefore considered to be indicative of wider trends.

More accurate coding would provide a full picture of all SLNB procedures undertaken in the NHS. Accurate, timely intelligence of this sort is important in supporting appropriate uptake of new procedures, by highlighting differences in practice around the country.

Spreading SLNB

SLNB was first developed in the USA in the mid 1990s. By the end of the decade the practice had spread to Europe and was beginning to be recognised as the standard of care. At this time the UK trailed behind other world-leading cancer centres. SLNB was not part of clinical practice, which was uncharacteristic given the UK's strong heritage in breast cancer treatment and care.

By 2006 less than 10% of surgeons were using SLNB, and most of these surgeons were located in a small number of specialist services.

The introduction of the NHS Breast Cancer Screening Programme led to a dramatic increase in early detection of breast cancer, before tumours had spread to nearby lymph glands. This meant that many thousands of women would undergo invasive lymph node clearance, putting them at greater risk of complications that could have been avoided through the use of SLNB.

A number of surgeons began to call for the adoption of SLNB, but the procedure did not have a clear UK champion. Those who advocated change were often met with resistance from surgical colleagues and managers who were reluctant to support a new technique that was being practised on a relatively small scale. The depth of evidence supporting the procedure was also questioned by some. Momentum for change developed slowly, as clinical backing became more widespread and increasing numbers of surgeons were involved in clinical trials and gained experience of the procedure. These factors created the ethical imperative and critical mass of support to modernise clinical practice in the UK.

Professor Robert Mansel in Cardiff become the lead proponent of SLNB and proposed

1 The *NEW START* training programme

In 2006, the Department of Health launched the *NEW START* national training programme for sentinel lymph node biopsy. *NEW START* was the world's largest structured and validated surgical training programme to ensure safe and effective use of the procedure in the UK. The first principle of the programme was to safeguard patient safety. Training was multi-professional, building the skills and knowledge of the whole surgical team across different specialties. It was conducted on a standardised regional basis which then spread to localised training initiatives.

The DH provided £150,000 to 'pump prime' the programme, which was administered through the RCS. The RCS established a steering committee to produce guidelines and materials and to drive the implementation of the standardised training model. This helped to secure further buy-in from clinicians to take part in the programme and deliver the necessary changes in surgical practice. Fiona MacNeill and Mo Kesh Ghar worked with Professor Mansel to champion the programme and secure participation across England.

a detailed training model to the National Cancer Action Team, discussed in **Box 1**.

Evidence through randomised control trial was not available before 2011 when the NSABP-32 trial[16] was published. Nonetheless, indirect and circumstantial evidence was deemed sufficient to support the introduction of the training programme. Some sceptics within the profession remained, and the absence of evidence was used to support their decision to not to adopt SLNB. SLNB represented an extension of principles used in axillary node sampling, which had been gaining traction and for which there was some limited evidence. Surgeons who were already convinced of the merits of this procedure were more ready to accept the benefits of SLNB.

Since SLNB can be performed as day case, which reduces length of stay and frees up surgical capacity, the main financial barrier to uptake was the cost of training. Individual trusts provided financial support for their surgical teams to be trained, which allowed the programme to become self-financing. A discounted price was offered for ten or more team members to encourage full team participation (as low as £1,000 per team). Some trusts were quick to train their surgical teams; others were reluctant to invest initially, largely owing to the issue of 'siloed' budgeting. There were instances where surgical teams used reserve charitable money, or personally financed the training. This prompted the DH to write to all trusts to stress the importance of the initiative.

Infrastructure issues were a limiting factor within some of the smaller trusts. Trusts operating without a local nuclear medicines unit and pathology teams were unable to offer the procedure to all patients, because of the need for rapid access to isotopes. Infrastructure issues were deliberately discussed with individual trusts through the training programme to help providers develop local solutions.

SLNB today

Since the *NEW START* programme officially ended in December 2009, training has continued locally through an apprenticeship model, resulting in comprehensive coverage. *NEW START* is widely regarded as an exemplary surgical training programme that was instrumental to the spread of SLNB. With only a small initial investment and a well applied training model, the roll-

out achieved coverage of 85–95% of breast surgeons and has saved 25,000 women each year an unnecessary axillary clearance.[17]

> *"*NEW START *is a unique training programme that establishes a benchmark for future surgical training. It demonstrates that carefully planned multi-professional training can translate specialist performance standards across a national service and abolish learning curves so ensuring patient safety during training".*[18]

SLNB is now reflected within clinical guidance, including the NICE clinical guideline, *Early and locally advanced breast cancer*,[19] the NICE breast cancer quality standard[20] and the Association of Breast Surgery *Surgical guidelines for the management of breast cancer*.[21] The guidance consolidates the new standard of care, helping to embed the practice and ensure take-up within outlying breast cancer units.

Payment mechanisms have also supported the wider use of SLNB. For example, best practice tariffs for day case surgery were extended to breast surgery in both 2011/2012 and 2012/2013. These incentivise day cases in sentinel node mapping and resection and simple mastectomy.[22] In 2011/12 this increased the tariff payment for both procedures by £300 each over the standard elective rate (a 28% increase for SLNB).[23] Meanwhile, a number of local CQUIN schemes have been put in place that aim to increase the number of day case procedures for breast surgery, and reduce overall length of stay.[24]

It has been argued that a national training programme should have been introduced more quickly given the demonstrable improvement that SNLB has made to patient care, clinical outcomes and hospital efficiency. It is unlikely, however, that widespread participation of surgeons in the training programme would have been possible without some appetite for change on which to build.

Surgical innovation in practice

Enhanced recovery

Key findings

- Early use of enhanced recovery practice in the UK varied significantly between NHS trusts with some trusts using few, if any, elements of the pathway.
- A number of strong clinical champions emerged and pioneered the pathway, compelling the DH to support national roll-out to ensure every patient could benefit.
- The involvement of the DH helped to codify the principles and practices of enhanced recovery, and established the infrastructure and national-level endorsement and guidance required to implement the model.
- At a local level, strong multidisciplinary team working and an organisational culture helped to drive the required changes to practices and systems, although a failure to collect enhanced recovery data in a systematic and timely way has stymied progress.
- The use of payment schemes such as CQUINs has helped to overcome the reluctance of some trusts to accept the financial and patient benefits because of concerns about costs and unplanned implementation.
- Further action is required both nationally and locally to help cement enhanced recovery as the standard of care within modern clinical practice. A lack of evidence to underpin the whole pathway continues to validate a partial approach to implementation within some trusts.

About the procedure

Enhanced recovery is a model of care that is delivered across the entire surgical pathway to improve patient fitness and reduce complications before, during and after surgery. The approach optimises individual recovery, allowing patients to resume normal life more quickly after surgery, and secures efficiencies for NHS trusts through reduced length of stay and lower rates of morbidity.[25]

A standardised pathway is underpinned by clinical protocols that set out optimal practices and procedures at each stage. For example:

- On admission: pre-operative carbohydrate loading and fluid hydration is encouraged.
- During surgery: new minimally invasive techniques and fluid management technologies are deployed wherever possible and epidural anaesthesia is used wherever possible.
- After surgery: planned mobilisation, avoidance of opiate-based analgesia and high quality post-discharge care.

2 The Enhanced Recovery Programme Partnership

The ERP was launched in April 2009 by the Department of Health, NHS Improvement and the National Cancer Action Team, representing the only implementation programme of its kind in the world. The purpose of the programme was to help codify the principles and practices of enhanced recovery within a standardised pathway, and to develop guidance and tools to help embed the model within the NHS.

In the first year of the programme, the DH convened expert workshops in early implementer sites to define the components of the pathway, run educational meetings and develop guidance that would underpin enhanced recovery roll-out and secure wide clinical buy-in. In the second year, innovation sites in each Strategic Health Authority were established in order to drive adoption within each region through workshops and sharing good practice, tailored to address local needs and circumstances. Surgical training needs (for example to deliver the best intra-operative care) were addressed by other national programmes, such as the National Training Programme in Laparoscopic Colorectal Surgery (LAPCO).

In April 2012, the ERP published *Fulfilling the potential: a better journey for patients and a better deal for the NHS*,[25] which set out a series of best practice examples from across the pathway, and put forward the value proposition for emerging NHS commissioners, with the aim of making enhanced recovery part of routine NHS practice.

The pathway also supports patients to be involved in their care and take active steps to achieve enhanced recovery – for example, to improve their fitness pre-surgery and take on greater responsibility for their own rehabilitation.[26]

Enhanced recovery is also grounded in principles of shared decision-making in which patients are partners in their care, taking active steps to improve their fitness before surgery, and aiding their own recovery.

Enhanced recovery pathways are most established within colorectal, orthopaedic, gynaecological and urological surgery, although the principles are now being used in other specialties, and have wider application for hospital medicine, particularly acute care. Unlike the other procedures examined within this report, enhanced recovery requires changes to both clinical systems and interventions. This has presented unique challenges and opportunities for its adoption and spread within the NHS.

Patterns of uptake

The transition to enhanced recovery involves multiple changes along the pathway, which poses practical challenges for data collection. National-level measurement of enhanced recovery programmes (ERPs) has focused on outcomes rather than activity, hence it is difficult to provide a clear picture of the spread of enhanced recovery across England. However, a recent report published by the DH highlighted the good progress that had been made in the adoption of enhanced recovery practice, with NHS trusts known to be implementing enhanced recovery demonstrating high levels of compliance with most elements of the pathway (13 of the 19 elements), as well as achieving:[25]

- higher than average scores in the national inpatient survey;

Enhanced recovery pathways lead to better outcomes and improves the patient experience.

John McGrath, National Clinical Lead

- reductions in lengths of stay since the 2008–2009 baseline;
- comparable rates of readmission; and
- reductions in bed days despite rises in activity for almost all the procedures.

However, variation in practice still exists across the country in each of the four specialties and further action is required to drive adoption beyond key centres.

Spreading enhanced recovery

Enhanced recovery was pioneered by gastrointestinal surgeon Henrik Kehlet in Denmark in 2000. In the UK, pockets of interest began to develop soon after, primarily among colorectal surgeons, although practices were initially sporadic, geographically dispersed and non-aligned. A number of clinical advocates worked to champion enhanced recovery among national decision makers, until the decision was taken to establish the Enhanced Recovery Partnership Programme (ERP) in 2009 (see **Box 2**).

Before the ERP was introduced, the use of enhanced recovery practice varied significantly between NHS trusts, with some trusts using few, if any, elements of the pathway. The ERP standardised enhanced recovery practice, creating an imperative for action and the guidance needed to increase adoption.

Despite this, implementation was not universal, and work is ongoing to embed enhanced recovery as the standard of care. This is in part due to the lack of evidence to underpin the whole pathway (despite the fact that there is good evidence for some individual elements). This continues to validate a partial approach to implementation in some trusts.

While clinical leadership was pivotal in the early years of the programme, once the pathway was standardised and had won greater acceptance, the ethos that characterised individual teams – in particular good multidisciplinary relationships, trust and a commitment to drive change – became a more important condition of adoption.

However, not all parts of the pathway could be delivered through clinical will and changes in surgical practice alone. Interventions such as comprehensive preoperative services, postoperative rehabilitation and investment in new technology such as oesophageal Doppler monitoring rely on support from hospital managers and a commitment to invest. Although benefits are soon realised through a reduction in length of stay and readmission rates, managers were initially slow to accept the financial and patient benefits owing to concerns about costs and unplanned implementation.[27]

3 The London enhanced recovery CQUIN scheme

The CQUIN covered four specialties/procedures: urology, gastrointestinal surgery, abdominal and vaginal hysterectomy and orthopaedics.

Each component was worth 25% of the CQUIN value:

1. Recording comprehensive information about enhanced recovery patients on the national database.
2. Ensuring that the majority of patients admitted for colorectal surgery receive goal directed fluid therapy.
3. Targeted day of surgery admission.
4. Targeted length of stay for patients undergoing the eight specified operations.

Research has shown that in 2010/2011, 12 of the 20 providers (60%) who supplied data on their CQUIN schemes achieved the full payment for the CQUIN, effectively driving the use of enhanced recovery in those trusts.[28]

As in the United States in the early 2000s, the recent use of financial incentives to reward enhanced recovery practices has helped to accelerate adoption. In 2011, an enhanced recovery CQUIN scheme was introduced in London (see **Box 3**) and further schemes have been established in the North East, South East and South West. Research has shown that 12 of the 20 providers (60%) who supplied data on their CQUIN schemes achieved the full payment for the CQUIN.[28] Similarly, the use of a best practice tariff (BPT) for fractured neck of femur and primary total hip and knee replacement have aided the transition to enhanced recovery owing to the reduced length of stay required by the BPT.

In the short term CQUINs brought immediate cost benefit for providers, allowing the clinicians to embed enhanced recovery practices and generate the efficiencies that would justify support from trusts in the long term.

The monitoring of performance in line with incentive schemes has helped to track the spread of enhanced recovery practices, although overall data collection has been relatively weak. This has also affected the extent to which enhanced recovery has gained traction in different parts of the NHS. Robust, timely data collection has led to accelerated processes of change and adoption on a number of levels:

- Team level data supports changes in practice, allowing teams to "test, evaluate and embed changes based on evidence of their own practice".[29]
- Local level collection forms an important part of the business case for providers and commissioners.
- National data collection helps pinpoint where further action or support is need to drive adoption.

Professional bodies will play a crucial role in ensuring that models of care are sustainable beyond the lifespan of the national programme and regional payment schemes. This will involve embedding practice within clinical training and demonstrating national leadership to cement enhanced recovery within modern surgical practice.

Surgical innovation in practice

Laparoscopic colorectal surgery

Key findings

- The quality of the evidence for laparoscopic colorectal surgery meant that the technique received a positive recommendation through NICE's technology appraisal process, which carries with it a legal requirement for NHS providers to make the treatment available within three months.
- However, this requirement was waived for four years owing to a lack of appropriately trained surgeons in the NHS to deliver the desired workload, meaning the availability of the treatment on the NHS was not mandated.
- Strong clinical leadership, and advocacy from the then National Clinical Director for Cancer, was instrumental in securing action and adequate funding from the DH to ensure that this legal duty could be fulfilled by training surgical teams in the NHS through a national training programme (NTP).
- The novel approaches of the NTP further fuelled the speed of the programme and ensured adequate data were collected to continually demonstrate the benefits of the programme and maintain funding and momentum in the surgical community.

About laparoscopic colorectal surgery

Colorectal surgery encompasses a broad range of surgical techniques that are used to treat a wide number of conditions, including cancer, Crohn's disease and diverticulitis. LAPCO focuses on resection operations, which aim to remove cancerous tissue from the bowel or rectum of a patient.

Laparoscopic surgery, otherwise known as keyhole or minimally invasive surgery, is performed by making a small number of short incisions in the abdomen of a patient. The patient's abdominal cavity is then partially inflated using carbon dioxide to allow surgeons to operate on internal tissue and organs using special miniature surgical tools and a small flexible camera (laparoscope), which are inserted through the incisions. The technique is considered more complex to perform than conventional open surgery. However, owing to the minimally invasive nature of the technique, blood loss, pain, risk of infection and other surgical complications are reduced, meaning postoperative healing times and recovery of bowel function are significantly improved for patients who have undergone a laparoscopic rather than open operation.[30–37]

Spreading laparoscopic colorectal surgery

Laparoscopic colorectal surgery began to be performed in complex cases in the early 1990s. There were initial concerns over patient safety owing to the complexity of the technique, and surgical associations therefore advised caution, though subsequent studies demonstrated the safety of the technique once an appropriate level of proficiency was achieved by a surgical team.

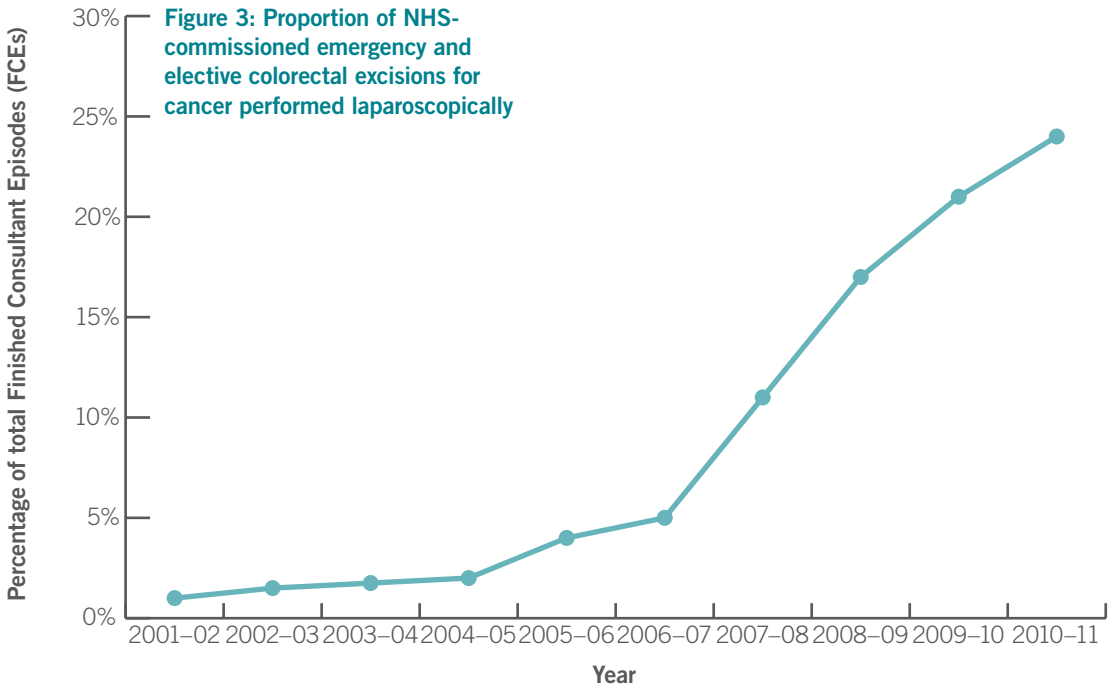
The emergence of encouraging data from multi-centre randomised trials including the Medical research Council CLASICC trial, the USA COST trial, and the European COLOR trial showed that laparoscopic surgery reduced postoperative pain, reduced hospital stay and reduced complications, prompting increased uptake of laparoscopic practice among the surgical community in England and beyond.[38–40] The scale and quality of this evidence led to the referral of the technique to NICE to undergo a full technology appraisal.

In 2006, NICE issued technology appraisal guidance stating that laparoscopic colorectal surgery should be offered to patients as an alternative to open surgery when deemed clinically appropriate, by a trained surgeon.[41] However, the National Cancer Action Team (NCAT) identified that there was insufficient capacity in the NHS' surgical workforce to fulfil the legal requirement for providers to make the treatment available within three months. This was due to the lack of surgeons trained in laparoscopic technique – at the time less than 10% of surgeons had the appropriate level of competency to perform the procedure.

At this point a small number of surgeons, including Robin Kennedy, consultant colorectal surgeon at St Mark's Hospital in London, put pressure on the Department of Health and NCAT to fund a national training programme (NTP). Once agreement had been reached, a three year waiver for the NICE guidance was issued by the DH to allow time to undertake the training programme and address the deficit in laparoscopic skills among the surgical workforce in England.

The national LAPCO training programme was initiated in 2007. In January 2008, ten groups were allocated training centre status across the country, and in September 2008 three national leads were appointed, including Mark Coleman as the National Clinical Lead. Professor George Hanna at Imperial College undertook research alongside the NTP, collecting data and analysing aspects of the training such as the best method of gaining competence in the procedure, optimal techniques in laparoscopic colorectal training and what constitutes surgical competence.

Figure 3: Proportion of NHS-commissioned emergency and elective colorectal excisions for cancer performed laparoscopically



The LAPCO programme was designed in such a way as to reduce the learning curve of surgeons being trained in laparoscopic colorectal surgery, and thereby accelerate the spread of the technique in the NHS. Where the traditional surgical training model of 'see one, do one, teach one' requires in the region of 80 to 150 procedures to be undertaken to achieve a professional level of competency, the LAPCO programme concentrates learning over a short period of time and provides more hands-on exposure to the technique, thus shortening the learning curve to around 20–25 procedures.

The use of online Global Assessment Score (GAS) forms to capture local training activity and outcomes have also proven to be a simple and highly effective way of capturing data concerning both training compliance and outcomes, which has contributed to the evidence base, in particular demonstrating the learning curve for the procedure associated with the programme. Furthermore, the 'train the trainer' element of the programme ensured that the number of qualified trainers has increased in line with the number of trainees.

By 2008, in the region of 37% of surgical sites across England had signed up to the LAPCO programme, though there was a dearth of training centres in the North West and the West Midlands.

As training capacity gradually expanded this need was met, and in October 2010 the waiver of the NICE technology appraisal was lifted.

NHS data show that the proportion of NHS-commissioned colorectal excisions for cancer undertaken laparoscopically has increased year on year since the introduction of the LAPCO programme in 2007, from 5% in 2006/2007 to 25% in 2010/11. This is demonstrated in **Figure 3** above, which covers both emergency and elective procedures. Additional analysis of elective-only HES data by the LAPCO programme show that coverage reached 40% during April 2012.[42]

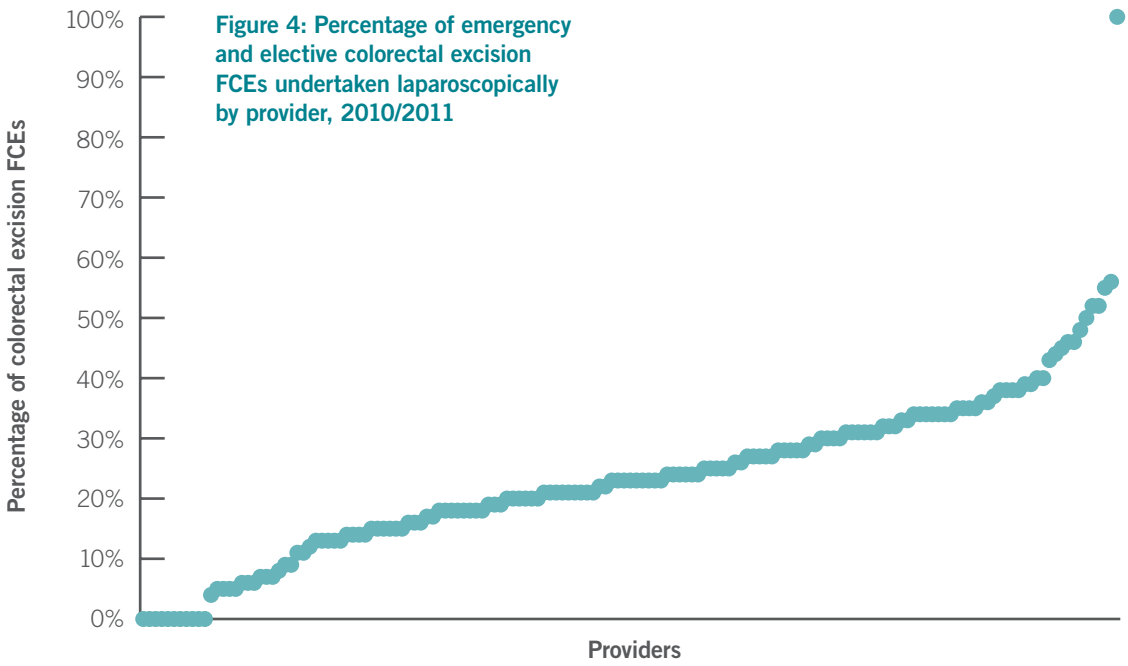


Figure 4: Percentage of emergency and elective colorectal excision FCEs undertaken laparoscopically by provider, 2010/2011

However, there is considerable variation amongst NHS providers in the proportion of procedures being undertaken, as set out in **Figure 4**. This demonstrates the potential of the programme to yet increase the proportion of appropriate procedures undertaken nationally. The second and third quartiles of providers each undertake between 23% and 31% of their procedures laparoscopically, and only one provider performed more than 56% in this manner.

Laparoscopic colorectal surgery today

The LAPCO training programme is widely considered a success, having addressed the shortage of laparoscopic expertise in the NHS, and achieving the desired rate of 25% of procedures being performed in this manner.[43] Models also show that the NTP has more than paid for itself with savings delivered in the region of £11 million (based on the modelled cost of rolling out the procedure without the mentorship-based programme).

All major current guidance – the NICE technology appraisal and subsequent clinical guidelines from NICE and the Association of Coloproctology of Great Britain and Ireland (ACPGBI) – recommends laparoscopic colorectal surgery as an alternative to open surgery to treat colorectal cancers, though all of the guidance notes the need for surgeons undertaking the technique to have undergone appropriate training.[41,44,45]

The LAPCO training programme continues, although Department of Health funding for the programme ended in April 2013, and training is now arranged and funded between the trainee's and trainer's trusts. More than 136 consultant surgeons had been trained through the LAPCO programme by the end of March 2013, with trainers in 61% of all colorectal MDTs in England;[46] full coverage is yet to be achieved. Charities such as Beating Bowel Cancer have also backed the need to promote informed choice among patients of whether to undergo a laparoscopic procedure.[47]

Surgical innovation in practice

Robotically assisted radical prostatectomy

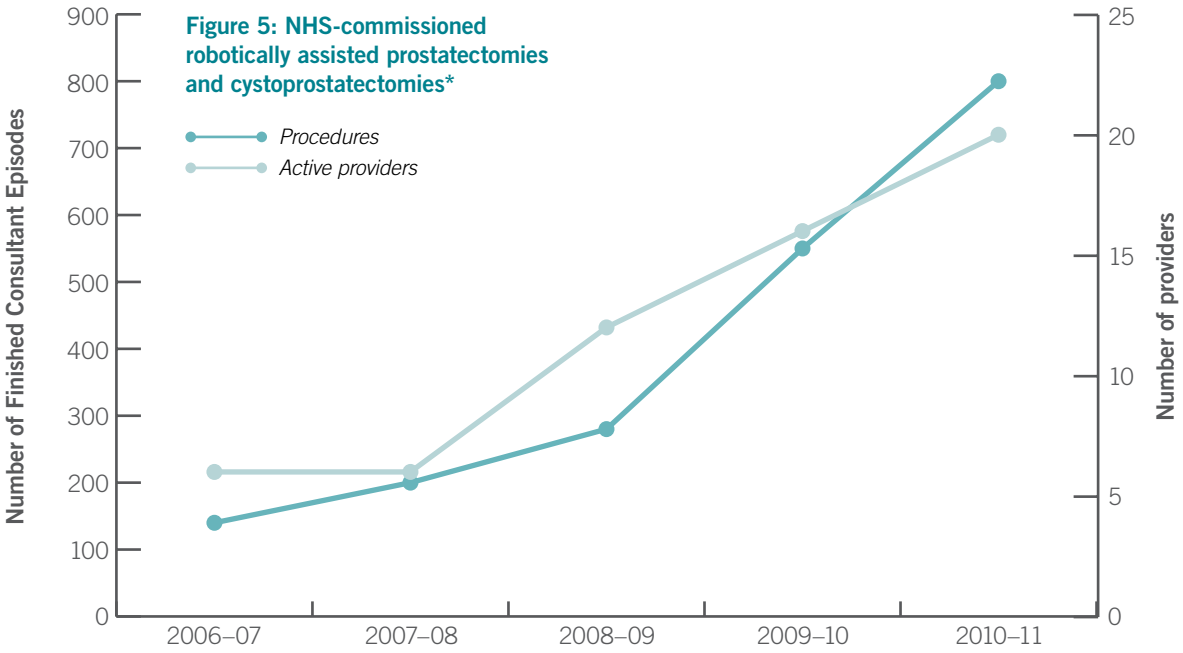
Key findings

- The first robotic surgery was offered to NHS patients in 2004. However, to date, funding for the procurement of surgical robots has mainly come from charitable donations and endowments. The lack of a substantial evidence base has meant that, until early 2014, a strong signal from national guidance was not given, which has fuelled NHS trusts' reluctance to invest in surgical robots.
- This is perpetuated by wider problems in undertaking surgical research, including clinical equipoise, and the necessity for individual surgeons to gain the same level of proficiency in different procedures. The relatively small number of robots in the UK, and the costs associated with data collection, have further slowed the production of evidence for the procedure.
- This has meant that the geographic spread of the technology has been varied and limited to trusts with such resources available.
- In 2010/2011, 20 providers performed robotically assisted procedures on the NHS, accounting for 13% of all prostatectomy and cystoprostatectomy procedures. Proponents of the technique advocate for a doubling in the number of robots in use in the NHS.

About robotically assisted radical prostatectomy

Robotically assisted radical prostatectomy (RARP) involves the complete removal of the prostate and seminal vesicles using a complex robotic device to aid the surgeon in performing the operation laparoscopically. A commonly used device is the da Vinci Surgical System®, produced by Intuitive Surgical, which translates the movements of a surgeon's hands to highly accurate, small movements of robotic pincers which operate on internal tissue and organs through small incisions made in the patient's skin.

It is used as an alternative to open and standard laparoscopic prostatectomies to treat in situ or localised prostate cancer. The technique is also used to perform cystoprostatectomies, which involves the removal of all cancer-bearing tissues in the pelvis including the prostate, urinary bladder and regional lymph nodes. The procedure is primarily indicated for patients with localised bladder cancer.



**Data were provided for both prostatectomy and cystoprostatectomy procedures (which also includes the surgical removal of the urinary bladder), where the procedure was the main or secondary procedure listed for that finished consultant episode (FCE).*

Spreading RARP

Surgery for the treatment of prostate cancer was pioneered in the USA in the early 1980s, though the use of robots in these procedures began a decade later by surgeons in Frankfurt, Germany. This use of robots to assist with the procedure was refined by surgical teams in Detroit, USA by 2001, after which use of the procedure grew rapidly in the USA.

During the 1990s pockets of interest in RARP were developing in the UK. Despite this, surgical advancement was focused on refinements to the open prostatectomy technique, meaning the latter was the predominant technique for performing prostatectomies in the UK around the year 2000.

However, following the publication of *The NHS Cancer Plan: a plan for investment, a plan for reform*[48] by the Department of Health in 2000 and the accompanying guidance on *Improving Outcomes in Urological Cancers*[49] in 2002, specialist cancer centres began to be established in each cancer network in England. This had the effect of increasing surgical volumes in those specialist centres which paved the way for some trusts to make the significant financial investment in the robot technology.

The first robotically assisted prostatectomy in the NHS was undertaken in 2004 at St Mary's Hospital in London by a team led by Chris Ogden. From 2006/2007 onwards a series of codes were introduced to the NHS that allowed the the procedures to be routinely recorded and classified by the means of excision (open, laparoscopic, robotically assisted). **Figure 5** shows how the number of providers undertaking robotically assisted

procedures has increased since 2006/2007, alongside a marked increase in the number of procedures being undertaken nationally.

However, as demonstrated by **Figure 6**, the proportion of all prostate procedures that were performed using this method, though increasing, remains relatively small, growing from 3% in 2006/2007 to 13% in 2010/2011.

Although the number of robots used to perform NHS operations over the last five years has increased, it is important to note that none of them has been funded directly by the NHS. The national tariff does not include an additional payment reflecting the costs of the technology, though in some areas of the country local top-ups to the tariff have been negotiated to offset maintenance costs. Rather, funding from charitable donations and endowments has been used by the different centres to meet the significant costs of procuring and maintaining the technology (around £1.5 million, plus annual maintenance costs).[50] This has meant that the geographic spread of the technology has been varied and limited to trusts with such resources available, as demonstrated by **Figure 7**.

This geographical variation is largely due to a lack of clinical guidance that assesses the cost-effectiveness of the procedure. RARP has not undergone a technology appraisal and therefore it is not mandatory to provide the procedure on the NHS. Furthermore, the existing NICE guidance does not differentiate between the benefits of the robotically assisted and the laparoscopic technique:

> *"Robotically assisted laparoscopic prostatectomy is a development of this procedure but it is not yet clear whether there is any advantage over conventional laparoscopy."*[51]

This lack of distinction is also reflected in guidance from the British Association of Urological Surgeons.[52]

However, recent NICE clinical guidelines for the diagnosis and treatment of prostate cancer support the uptake of RARP and recommend that commissioners should consider providing robotic surgery to treat localised prostate cancer. NICE recommends that robotic systems should be based in centres that are expected to perform at least 150 robot-assisted laparoscopic radical prostatectomies per year, in order to ensure they are cost effective.[53]

Despite there being a consensus in the urological surgical profession in the UK that RARP delivers improved outcomes for patients, including better cancer control, better maintenance of sexual function and continence and faster recovery, the current guidance is ultimately underpinned by the lack of a

substantive evidence base documenting the relative advantages of the procedure. This is fuelled by wider problems in undertaking surgical research, including clinical equipoise, and the necessity for individual surgeons to gain the same level of proficiency in different procedures, for example robotically assisted and laparoscopic prostatectomies. The relatively small number of robots in the UK, and the costs associated with data collection, have further slowed the production of evidence for the procedure.

RARP today

In 2010/2011, 20 providers performed robotically assisted procedures on the NHS, accounting for 13% of all prostatectomy and cystoprostatectomy procedures. Proponents of the technique believe at least 80% of prostatectomies in the UK should be robotically assisted, requiring a doubling of the number of robots in use in the NHS, and adjustments to their operation to ensure patient throughput five days a week, in line with the US model. This would be more efficient than the current UK practice and ensure high volume centres are sustained with consequential financial and clinical benefits in terms of surgical experience levels.

A 2012 review comparing RARP with other techniques in terms of perioperative complications found that blood loss and transfusion rates were significantly lower with RARP than other techniques, although all other features were similar regardless of the surgical approach. The data showed lower overall complication rates for RARP and low prevalence of specific surgical complications such as lymphocele/lymphorrea, urine leak and reoperation.[54]

Further outcomes data for RARP (reportation rates and patient-reported outcomes) will be captured as part of the National Prostate Cancer Audit (NPCA), which started on 1st April 2013 and is managed as a partnership between a team of clinical, cancer information and audit experts from the Royal College of Surgeons' Clinical Effectiveness Unit, the British Association of Urological Surgeons, the British Uro-oncology Group, and the National Cancer Registration Service. The first annual report from the NPCA will be published in October 2014 and will present an analysis of the organisational audit and existing datasets.

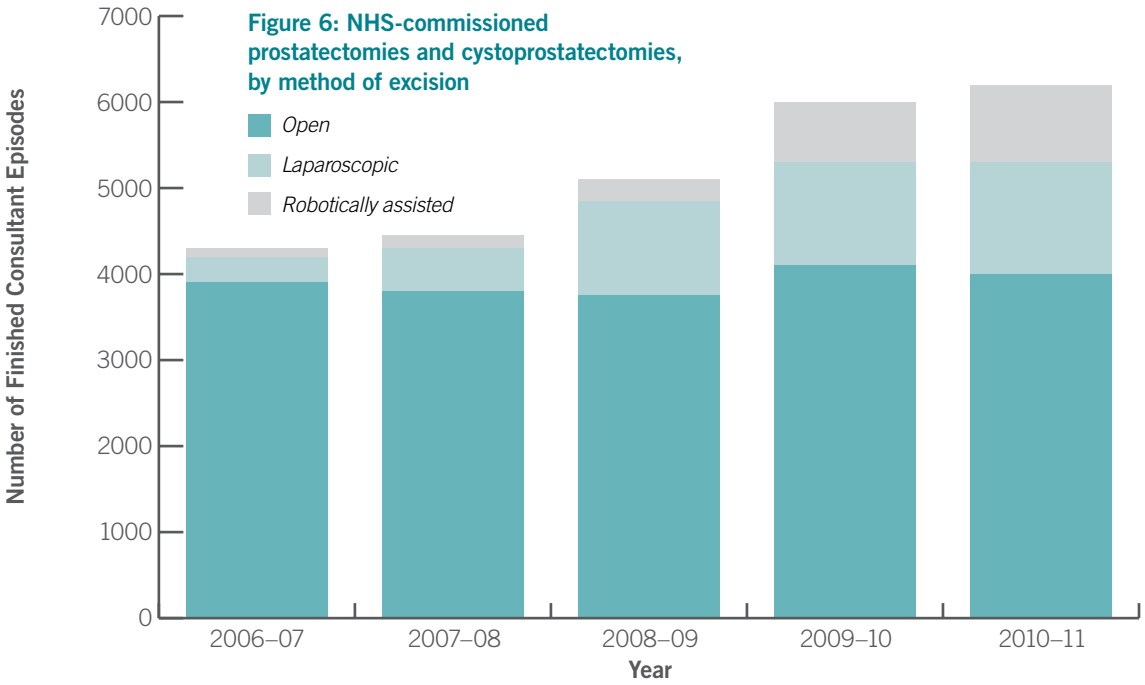


Figure 6: NHS-commissioned prostatectomies and cystoprostatectomies, by method of excision
Open
Laparoscopic
Robotically assisted
Number of Finished Consultant Episodes
7000
6000
5000
4000
3000
2000
1000
0
2006–07
2007–08
2008–09
2009–10
2010–11
Year

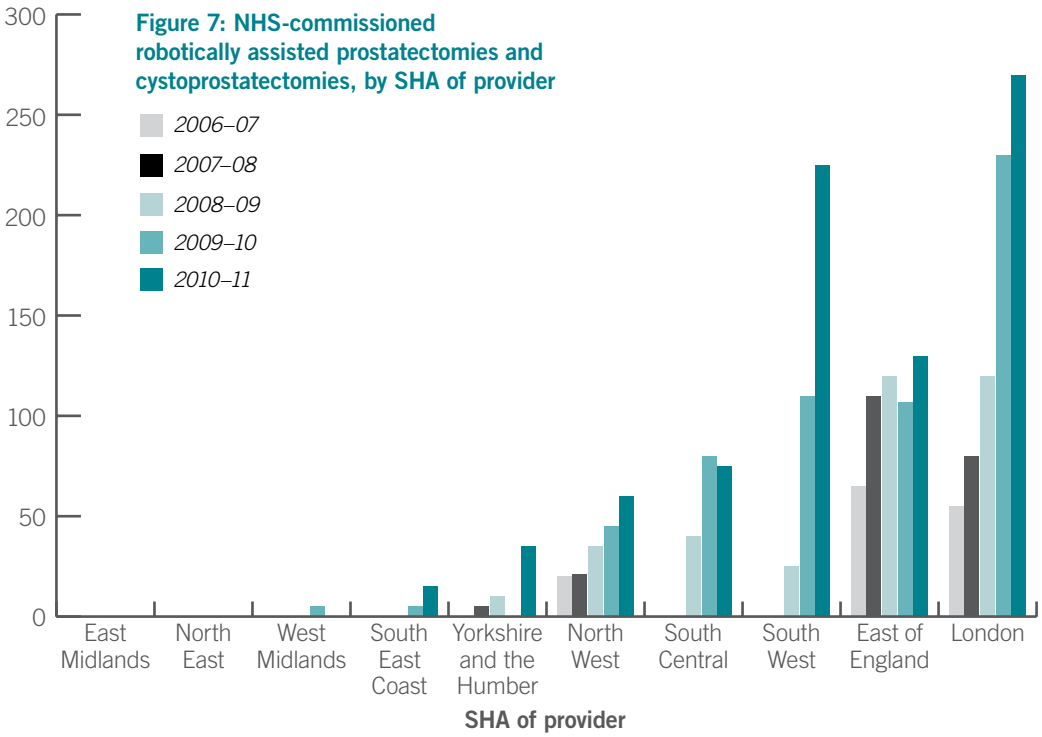


Figure 7: NHS-commissioned robotically assisted prostatectomies and cystoprostatectomies, by SHA of provider
2006–07
2007–08
2008–09
2009–10
2010–11
300
250
200
150
100
50
0
East Midlands
North East
West Midlands
South East Coast
Yorkshire and the Humber
North West
South Central
South West
East of England
London
SHA of provider

Surgical innovation in practice

Total mesorectal excision

Key findings

- Total mesorectal excision (TME) was pioneered in the UK in the early 1980s but national involvement in spreading the procedure in England only came over 20 years later, despite other regions implementing national programmes in the 1990s.
- A lack of systematic data collection in the NHS, combined with the ongoing challenges in undertaking prospective randomised control trials in surgery, meant that a sufficiently compelling evidence base for the procedure was not developed until some 20 years after it was first performed.
- The complexity of the practice meant training could only be delivered by experts in the procedure which were relatively few in number in the first 20 years of the procedure's life.
- Strong clinical leadership from Professor Heald and his surgical colleagues was instrumental in generating the initial pull factor for implementing TME within the NHS, and delivering the training programme itself.
- Involvement of the then National Clinical Director for Cancer secured backing from the Department of Health to spread the procedure. Combined with new cohort evidence, this resulted in the NHS commissioning the Multidisciplinary Team-TME Development Programme in 2003, which funded the Pelican Foundation to deliver a national training programme.
- Funding for the national training programme was necessary for nationally resourcing and regulating an intensive training requirement for the procedure and the associated safety considerations.

About the procedure

Total mesorectal excision (TME) is a surgical technique used to treat bowel cancer, which involves the precise removal of the entire lining of the lower bowel. Key to the procedure is the surgeon's ability to remove this section of the bowel along a natural tissue boundary that results from the different embryological origins of the components of the bowel and surrounding tissue. Cleanly cutting away the bowel section along this so-called 'holy plane' greatly reduces the chance of the cancer recurring as the plane is preserved and cancerous cells are contained to the section of the bowel that is removed.

Owing to its precise nature, the procedure requires a high level of technical skill on the part of the surgeon. The procedure is particularly

challenging to be performed laparoscopically compared to some other colorectal operations.

Spreading TME

The concept of TME was first introduced by Professor Bill Heald in Basingstoke Hospital in the late 1970s. At that point colorectal surgery for cancer involved a clinical balance as to how much tissue to remove around the tumour – the removal of a greater amount of tissue reduces the risk of the cancer returning (recurrence) but often has a negative impact on other outcomes such as bowel function or the need for a colostomy. Owing to the desire to preserve the bowel function of patients as much as possible, mortality rates due to recurrence in patients who had undergone colorectal surgery for cancer were around 50%. TME avoided this by meticulously removing the entire tissue enveloping the lower bowel based on a distinction of tissue of different embryological origins.

In 1979 the Wessex Cancer Trust funded a staff member to collect data around the technique that was being performed by Professor Heald and colleagues at Basingstoke. Charitable donations then saw the Basingstoke Bowel Cancer Research Programme established, which ensured data collection continued in the following decade.

In the early 1980s Professor Heald published his first cohort study of approximately 135 TME surgical cases which demonstrated recurrence rates of only 3.7% – outcomes markedly better than those generally observed at the time. Despite this, further evidence was not produced following this study. The lack of further data and the absence of compulsory consecutive surgical data collection in the NHS further stymied the development of an evidence base in the UK for the next 20 years. As a result of this, TME practice in the UK was limited to a very small number of interested specialists for most of the 1980s and 1990s.

Scandinavia became the first region to formally adopt TME in the early 1990s, following initial interest in Professor Heald's work from three surgeons in Sweden. Throughout the 1990s Professor Heald was regularly invited to provide training workshops to interested surgeons and their teams in Scandinavia and beyond, facilitated by camera equipment donated by Sony that allowed him to broadcast his operations and teach the complex technique to large groups of surgeons.

In the UK, in collaboration with Sir Peter Michael, Professor Heald formed the Pelican Cancer Foundation in 2000 to work to disseminate TME

in the UK to the increasing number of interested surgical teams. The foundation gradually developed from the small Basingstoke Bowel Cancer Research Programme into a professional teaching academy, receiving around £5 million in local donations to develop the Ark training facility, on land donated to the purpose by the local NHS.

However, national involvement in spreading the procedure in the UK only began following a visit by Professor Mike Richards, National Clinical Director for Cancer, to Stockholm in 2000 to observe the country's national approach to the adoption of TME, and to verify the outcomes associated with the procedure. Convinced of the benefits of the procedure following his visit, Professor Richards made the case for TME at the Department of Health. His efforts coincided to a degree with the first widely-accepted evidence for the benefits of the procedure, stemming from Anna Martling at the Swedish Karolinska Institutet, and further validation work from John MacFarlane from the University of British Columbia, who had taken a sabbatical at Basingstoke.

The result was that the NHS commissioned a National MDT-TME Development Programme in March 2003, which provided the Pelican Foundation with a significant grant in order to roll-out training for TME more widely within the NHS. This provided not only the resource to expand the programme but also structure and credibility to the programme which allowed the spread of the training to be more rapid and more regulated, addressing the safety issues associated with teaching a complex new surgical technique.

TME today

The major role of TME in colorectal surgery is now recognised in all major clinical guidance in the UK. The recent clinical guideline for colorectal cancer published by NICE states that "TME is the accepted standard resection for most rectal cancers".[44] NICE Improving Outcomes guidance gives a strong direction to the national training programme, stating "Every MDT which treats patients with rectal cancer should undergo training in total mesorectal excision".[55] The current clinical guidelines from the specialty association, the Association of Coloproctology of Great Britain and Ireland (ACPGBI), recognises "... the practice of total mesorectal excision (TME) surgery has become the standard of care in the UK. As a result, local recurrence following surgery has fallen significantly."[45]

TME training in the NHS also continues, including through the national LAPCO programme and Low Rectal Cancer National Development Programme (LOREC).

Despite this clear direction, routine data collection regarding TME in the NHS remains very poor. No dedicated OPCS-4 codes exist for the procedure.[56] As such, it is not possible to accurately gauge the impact of the training programme and measure how far TME has spread within the NHS in England. Anecdotal evidence from some surgeons suggests that fewer than half of all rectal cancer cases are treated with TME, despite the fact that all but the very earliest colon cancers are best treated with the procedure. Advocates of the procedure with experience of its spread suggest that the NHS should mandate consecutive surgical data collection to gauge a more accurate picture of practice and outcomes regarding new techniques and technologies, which would inform an evidence base for these innovations.

Conclusions

Overcoming the barriers to innovation

Through the examination of these different types of surgical innovation, we have been able to identify critical blocks to their spread, as well as the moments or interventions which ultimately led to their widespread adoption.

Although the circumstances of a particular innovation will inevitably differ, there are common issues that need to be addressed for any innovation to spread.

- **Establishing evidence:** establishing sufficient evidence to satisfy commissioners, providers, clinicians and patients of the safety and efficacy of a new procedure can be challenging. This is due to a number of factors including the level of skill required to undertake often complex new techniques, a lack of investment in surgical research, and the challenges of clinical equipoise in developing gold standard evidence. NICE interventional procedure guidance is a useful starting point because it evaluates safety and efficacy, but it does not include an evaluation of comparative clinical effectiveness or cost effectiveness, nor does it send a clear implementation signal to the NHS owing to a lack of appropriate evidence.
- **Building new skills:** new techniques will often require new skills. Training must be delivered on the right scale and at the right pace to assure the quality, safety and efficiency of a new technique. The quality of delivery and the safety of many techniques requires the surgeon to undertake appropriate volumes of procedures.
- **Establishing the correct infrastructure:** surgical innovation may require new equipment, working arrangements or the configuration of services, requiring capital investment as well as service redesign. This is in contrast to the introduction of many pharmacological innovations which may require additional investment, but are associated with relatively modest (if any) changes in clinical practice.
- **Clinical and patient demand:** ultimately clinicians must want to use an innovation and patients must want to receive it if it is to disseminate into widespread use. This will require the provision of appropriate information on its benefits and risks.

The absence of evidence can make it harder to secure the investment needed to develop surgical

skills and establish the correct infrastructure to support the innovation's wider use. Breaking this cycle is critical to establishing an environment in which new practices and procedures can begin to be cultivated in the NHS. By getting these enablers right we can start to create a virtuous circle, with the availability of evidence supporting the case for investment in skills and infrastructure, which in turn leads to greater uptake and the development of stronger evidence.

Through the case studies in this report, we have identified six common factors that help to overcome these issues and encourage the spread of innovation:

1. Early identification of the promise (ie the potential benefits) of an innovation.
2. Leadership to champion and advocate its adoption.
3. Establishing the infrastructure to enable its use.
4. Defining what should be implemented and how its impact will be measured.
5. Developing levers and incentives to encourage appropriate adoption.
6. Providing information to support clinical adoption and patient choice.

These factors occur along a pathway of surgical innovation. Although the relative importance of each factor will vary according to the innovation in question, it is important that each is addressed to underpin rapid and consistent diffusion. The pathway works first at a local and then a national level. It underpins local discovery and piloting by surgeons and their teams, followed by national level action by different parts of the NHS.

We hope that the pathway of surgical innovation will become an immediate reference point for anyone with an interest in realising the benefit of health innovation. Our recommendations set out a series of short and medium term actions to underpin the delivery of the pathway for every new surgical innovation. It should be noted that not every success factor can be effectively written into policy or guidance. Innovation will always depend in part on the qualities of the individuals involved – the strength of leadership, team working and tenacity – but by establishing the right framework to support adoption, these attributes can be most effectively nurtured and deployed.

References

1. The Royal College of Surgeons of England. *From Theory to Theatre: Overcoming barriers to innovation in surgery.* London: RCS; 2011.
2. Department of Health. *Innovation, Health and Wealth: Accelerating adoption and diffusion in the NHS.* London: DH; 2011.
3. HC Deb 24 Apr 2012, c860W
4. HC Deb 24 Apr 2012, c871W–872W
5. HC Deb 24 Apr 2012, c852W
6. HC Deb 23 Apr 2012, c712W–713W
7. Checking the lymph nodes for breast cancer in women. MacMillan. http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Breast/Treatingbreastcancer/Surgery/Checkingthelymphnodes.aspx#DynamicJumpMenuManager_4_Anchor_1 (cited February 2014).
8. Types of breast cancer surgery: Sentinel Lymph Node Biopsy. *Cancer Research UK*. http://www.cancerresearchuk.org/cancer-help/type/breast-cancer/treatment/surgery/types-of-breast-cancer-surgery#sentinel (cited February 2014).
9. NHS Breast Screening Programme and Association of Breast Surgery. *An audit of screen detected breast cancers for the year of screening April 2005 to March 2006.* London; NHS: 2007.
10. NHS Breast Screening Programme and Association of Breast Surgery. *An audit of screen detected breast cancers for the year of screening April 2006 to March 2007.* London; NHS: 2008.
11. NHS Breast Screening Programme and Association of Breast Surgery. *An audit of screen detected breast cancers for the year of screening April 2007 to March 2008.* London; NHS: 2009.
12. NHS Breast Screening Programme and Association of Breast Surgery. *An audit of screen detected breast cancers for the year of screening April 2008 to March 2009.* London; NHS: 2010.
13. NHS Breast Screening Programme and Association of Breast Surgery. *An audit of screen detected breast cancers for the year of screening April 2009 to March 2010.* London; NHS: 2011.
14. NHS Breast Screening Programme and Association of Breast Surgery. *An audit of screen detected breast cancers for the year of screening April 2010 to March 2011.* London; NHS: 2012.
15. NHS Cancer Screening Programmes. *NHS Breast Screening Programme: Annual Review 2011.* London; NHS: 2011.
16. Krag DN, Julian TB, Harlow SP et al. NSABP-32: Phase III, Randomized Trial Comparing Axillary Resection with Sentinal Lymph Node Dissection: A Description of the Trial. *Ann Surg Oncol* 2004; 11(3 Suppl): 208S–210S.
17. NEW START data (on file).
18. Goyal A, MacNeill F, Newcombe RG, et al. *Results of the UK NEW START sentinel node biopsy training program: A model for future surgical training.* Poster Discussion at the 2009 Breast Cancer Symposium.
19. NICE. *Early and locally advanced breast cancer: diagnosis and treatment.* Cardiff: National Collaborating Centre for Cancer; 2009.
20. NICE quality standard: breast cancer (QS12). Issued September 2011. http://guidance.nice.org.uk/QS12 (cited February 2014).
21. Association of Breast Surgery at Baso 2009. Surgical guidelines for the management of breast cancer. *Eur J Surg Oncol* 2009; 35(Suppl 1): 1–22.
22. NHS Care Records Service, Best practice tariff: day case 2011-12, accessed 14 September 2012 via http://www.ic.nhs.uk/SUS_eLearning/SUS_R9_data_access_service/modules/su12_pbr/t6/su12t6p5_1.htm [no longer available]
23. Department of Health. *Payment by Results: Guidance for 2011–12.* Leeds: DH; 2011.

24. Commissioning for Quality and Innovation (CQUIN) payment scheme. NHS Institute for Innovation and Improvement. http://www.institute.nhs.uk/commissioning/pct_portal/cquin.html (cited February 2014).
25. NHS Improvement Enhanced Recovery Partnership. *Fulfilling the potential: a better journey for patients, a better journey for the NHS.* Leicester: NHS; 2012.
26. NHS Improvement. *My role and my responsibilities in helping to improve my recovery.* NHS Public information leaflet, 2013.
27. Kuper M, Gold SJ, Callow C et al. Intraoperative fluid management guided by oesophageal Doppler monitoring. *BMJ* 2011; 342: d3016.
28. MHP Health Mandate. *Paying for quality – An analysis of the impact of the 2010/11 Commissioning for Quality and Innovation scheme in London.* London: MHP Health Mandate; 2012.
29. Department of Health. *Enhanced Recovery Partnership Programme Report.* Leeds: DH; 2011.
30. Lacy AM, Garcia-Valdecasas JC, Delgado S et al. Laparoscopy-assisted colectomy versus open colectomy for treatment of non-metastatic colon cancer: a randomised trial. *Lancet* 2002; 359: 2,224–29.
31. Leung KL, Kwok SPY, Lam SCW et al. Laparoscopic resection of rectosigmoid carcinoma: prospective randomised trial. *Lancet* 2004; 363: 1187–92.
32. Stage JG, Schulze S, Møller P et al. Prospective randomized study of laparoscopic versus open colonic resection for adenocarcinoma. *Br J Surg* 1997; 84: 391–96.
33. Delaney CP, Kiran RP, Senagore AJ et al. Case-matched comparison of clinical and financial outcome after laparoscopic or open colorectal surgery. *Ann Surg* 2003; 238: 67–72.
34. Kiran RP, Delaney CP, Senagore AJ et al. Operative blood loss and use of blood products after laparoscopic and conventional open colorectal operations. *Arch Surg* 2004; 139: 39–42.
35. Milsom JW, Bohm B, Hammerhofer KA et al. A prospective randomized trial comparing laparoscopic versus conventional techniques in colorectal cancer surgery: a preliminary report. *J Am Coll Surg* 1998; 187: 46–54.
36. Braga M, Vignali A, Gianotti L et al. Laparoscopic versus open colorectal surgery: a randomised trial on short-term outcome. *Ann Surg* 2002; 236: 759–66.
37. Duepree HJ, Senagore AJ, Delaney CP, Fazio VW. Does means of access affect the incidence of small bowel obstruction and ventral hernia after bowel resection? *Laparoscopy versus laparotomy. J Am Coll Surg* 2003; 197: 177–81.
38. Guillou PJ, Quirke P, Thorpe H et al. Short-term endpoints of conventional versus laparoscopic-assisted surgery in patients with colorectal cancer (MRC CLASICC trial): multicentre, randomised controlled trial. *Lancet* 2005; 365: 1718–26.
39. Clinical Outcomes of Surgical Therapy Study Group. A comparison of laparoscopically assisted and open colectomy for cancer. *N Engl J Med* 2004; 305: 2050–59.
40. Hazebroek EJ; Color Study Group. COLOR: a randomized clinical trial comparing laparoscopic and open resection for colon cancer. *Surg Endosc* 2002; 16: 949–53.
41. NICE guidance. Laparoscopic surgery for colorectal cancer (TA 105). Issued August 2006. http://publications.nice.org.uk/laparoscopic-surgery-for-colorectal-cancer-ta105 (cited February 2014).
42. Proportion of Colorectal Resections Undertaken Laparoscopically in England. LAPCO. http://www.lapco.nhs.uk/activity-latest-HES-data.php (cited February 2014).
43. Implementation of NICE's Laparoscopic Colorectal Surgery Appraisal NHS Management Note.

LAPCO. http://www.lapco.nhs.uk/about-the-programme.php#Notes (cited February 2014).
44. NICE guidance. Colorectal cancer: the diagnosis and management of colorectal cancer (CG131). Issued November 2011. http://publications.nice.org.uk/colorectal-cancer-cg131 (cited February 2014).
45. The Association of Coloproctology of Great Britain & Ireland. *Guidelines for the Management of Colorectal Cancer, 3rd edition.* London: ASCBGI; 2007.
46. National Training Programme – Updates. LAPCO. http://www.lapco.nhs.uk/ (cited February 0214).
47. Beating Bowel Cancer. *Equity and Excellence for Bowel Cancer.* London: Beating Bowel Cancer; 2012.
48. NHS. *The NHS Cancer plan: a plan for investment, a plan for reform.* London: NHS; 2000.
49. National Institute for Clinical Excellence. *Improving Outcomes in Urological Cancers: The Manual.* London: NICE; 2002.
50. Oxford Radcliffe Hospitals' Board meeting minutes, 29 January 2009. http://www.oxfordradcliffe.nhs.uk/aboutus/trustboard/tbdocs09/jan/090129roboticsurgery.pdf (cited17 September 2012). [no longer available]
51. NICE guidance. Laparoscopic radical prostatectomy (IPG193). Issued November 2006. http://guidance.nice.org.uk/IPG193 (cited February 2014).
52. BUG, BAUS and BPG. *MDT (Multi-disciplinary Team) Guidance for Managing Prostate Cancer.* London: BAUS; 2009.
53. NICE clinical guidelines. Prostate cancer: diagnosis and treatment (CG157). Issued January 2014. http://publications.nice.org.uk/prostate-cancer-diagnosis-and-treatment-cg175 (cited April 2014).
54. Novara G, Ficarra V, Rosen R et al. Systematic Review and Meta-analysis of Perioperative Outcomes and Complications after Robotically-assisted Radical Prostatectomy. *Eur Urol* 2012; 62: 431–52.
55. NICE. *Improving Outcomes in Colorectal Cancers (Manual Update).* London: NICE; 2004.
56. The NHS Information Centre's Cancer Data Manual (http://www.ic.nhs.uk/webfiles/Services/Datasets/cANCER/appendixforcolorectalcancer.pdf) [no longer available] stipulates that code H33.8, 'Other specified excision of rectum', should be used to record TME procedures, though over the last ten years this code has constituted less than 4% of recorded colorectal surgery procedures for colorectal cancers and therefore is clearly not being used comprehensively.

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