MHP Health Mandate

RCS ADVANCING SURGICAL STANDARDS

From Theory to Theatre

Overcoming barriers to innovation in surgery

4.5 million

the number of NHS hospital admissions which resulted in surgical care in 2009/10, on average one every seven seconds[1]

the average number of surgical episodes experienced by a person in their lifetime

5

11.2 million

the number of hospital-bed days relating to surgery in the NHS in 2009/10[1]

19,500

the number of surgeons and surgical trainees in the NHS[2]

£1.55 billion

the estimated amount spent on surgery by the NHS in 2010[3]


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Foreword

"The College is committed to advancing and encouraging all aspects of surgical research

Over the past decade we have seen a significant increase in the amount of money invested by government in medical research, reaching over £1.5 billion in 2008/9. Of this significant sum, only a tiny fraction is invested in surgical research, even though more than one in four care episodes within the NHS are surgical. High quality research in surgery is essential for improving patient care and outcomes. Without the investment that enabled their development, the advances in surgery that benefit patients today would not have been possible. We cannot afford to discourage surgical innovation.

This report demonstrates the importance of translating new techniques and technologies into surgical practice and also highlights our concern that this process has been slow and not sustained. The issues raised here need immediate action: it is essential we start to implement solutions now.

I hope that the recommendations presented in this report will rally all stakeholders, research funders, politicians and surgeons themselves. The College is committed to advancing and encouraging all aspects of surgical research. I would like to extend my thanks to the expert group for giving us the benefit of their experience and knowledge. Let us start bringing down the barriers to surgical innovation in the UK.

John Black
President
The Royal College of Surgeons

Chapter one
Introduction

Surgery forms the backbone of the treatment and management of many common medical conditions yet often has a lower public profile than other forms of treatment. The vast majority of people will benefit from surgery at some point in their lifetime and, on average, nine hospital admissions which result in surgical care are made every minute in England.[1]

Surgical interventions are either specific procedures involving the surgical team or part of a multi-disciplinary approach that involves other clinicians and forms of treatment, such as drugs or physiotherapy, in helping to manage the patient's health issues. Surgery is an important intervention – surgery cures more cancers than any other form of intervention, including radiotherapy and chemotherapy.[4]

The recently published NHS Outcomes Framework[5] outlines fives domains covering the delivery of healthcare in the NHS, under which key indicators are measured. High quality surgery contributes to improvements in a range of outcomes and will be expected to contribute to delivering progress on every domain of the NHS Outcomes Framework.

High quality surgery is based on research by surgeons and other healthcare professionals that proves an intervention is safe and effective. Research can take many forms including fundamental investigations of the underlying biology of a disease; the development and evaluation of new technologies such as implants and devices, and of new techniques in surgery; wider work into the way in which research is undertaken; and large scale evaluations of surgical practice and delivery. In short, the scope of surgical research ranges from laboratory work to large scale trials involving many patients in the United Kingdom and worldwide. This report focuses on the translational aspects of this research – how new techniques and technologies are developed, evaluated and implemented in clinical practice.

Despite its importance, there are a range of challenges for translational surgical research. Most surgeons in clinical practice are under pressure to treat as many patients as efficiently and effectively as possible. There

are challenges in designing appropriate trials and recruiting patients to them. Research is expensive and surgery must compete with other disciplines to secure limited funding. Finally, understanding and undertaking high quality research is often only a small element of a surgeon's training, potentially leading to it being undervalued by the profession.

Addressing the challenges

In order to help address these challenges, and to ensure that surgery remains at the forefront of medical progress, the Royal College of Surgeons convened a group of leading experts to assess the key challenges and barriers to high quality translational research in surgery and develop recommendations as to how these barriers could be overcome, taking into account the current reform agenda within the NHS and medical science research. This report summarises the findings and recommendations of the expert group and sets out a range of actions for different stakeholders, including the Royal College of Surgeons, to consider.

The expert group included individuals directly involved in surgical research, leaders of large, research-intensive organisations and senior managers and clinicians responsible for the wider delivery of NHS healthcare programmes. The Royal College of Surgeons is grateful for their insights and contributions. The findings and recommendations – and any errors – are the responsibility of the College alone.

Delivering high quality research is the responsibility of anyone involved in any aspect of surgery. This report is intended to stimulate debate and fresh thinking, both within and outside the surgical community, on how the quality, quantity and translation of surgical research into patient care could be improved. The Royal College of Surgeons believes that the recommendations represent a balanced, achievable and affordable programme which, if implemented, could benefit a wide range of patients in the years to come.

1 SURGERY AND THE NHS OUTCOMES FRAMEWORK[7]

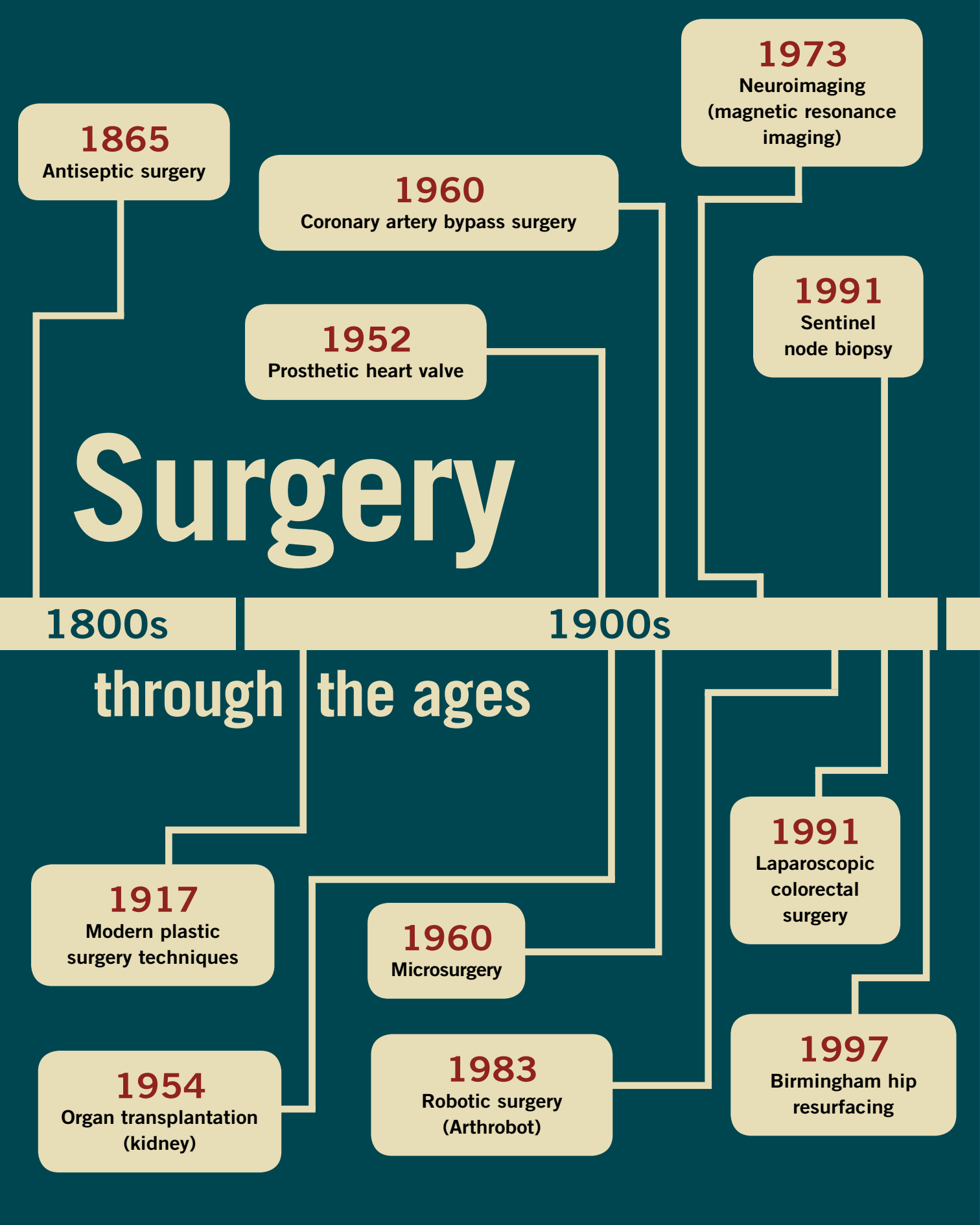
Domain 1: Preventing people from dying prematurely – recording the mortality rates following a surgical intervention is one way in which the framework will help identify best practice in treating patients with life-threatening conditions.

Domain 2: Enhancing quality of life for people with long-term conditions – surgery has a role to play in helping some patients manage their long-term conditions, where treatments such as drug therapy are not sufficiently effective. For example, rheumatoid arthritis patients may undergo surgery to radically treat the symptoms of their disease.

Domain 3: Helping people to recover from episodes of ill health or following injury – surgical intervention is the primary treatment for many patients. Surgical teams have a role in achieving high quality outcomes as well as reducing readmissions.

Domain 4: Ensuring people have a positive experience of care – the role of a surgical team extends beyond the operating theatre. This includes a high standard of pre- and post-operative care and making sure that patients receive the right care at the right time.

Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm – surgical teams have a duty to ensure the treatment they provide to patients does not do avoidable harm. This includes both serious adverse events, and surgery-specific 'never events' such as 'wrong –site' surgery and 'retained instrument' post-operation.


1973
Neuroimaging (magnetic resonance imaging)
1865
Antiseptic surgery
1960
Coronary artery bypass surgery
1991
Sentinel node biopsy
1952
Prosthetic heart valve
Surgery
1800s
1900s
through the ages
1991
Laparoscopic colorectal surgery
1917
Modern plastic surgery techniques
1960
Microsurgery
1997
Birmingham hip resurfacing
1983
Robotic surgery (Arthrobot)
1954
Organ transplantation (kidney)

Chapter two

Surgical research matters

"Operations are now safer, less invasive and more effective

The story of surgery is one of progress. Operations are now safer, less invasive and more effective, with better outcomes, shorter recovery times and fewer adverse events such as infection. The range of procedures that can be performed safely and routinely has expanded dramatically. This would not have been possible without high quality research.

Most research involves multidisciplinary input, with surgeons working alongside other healthcare professionals, epidemiologists, statisticians, health economists and patients in designing and implementing research protocols.

There are many inspiring examples of how surgical research has either saved or dramatically improved patients' lives. The nature of surgical research and its objectives has varied over time. However, the examples included in this chapter have the unifying characteristic of having changed clinical practice.

Improved surgery is based on developments in our knowledge and understanding of the basic science that underpins disease. Although this report does not focus on improving basic science research, there are many examples of how this has led to surgical benefits.

2 VIABILITY OF DONOR KIDNEYS

A recent study of donor kidney viability analysed the outcomes of patients who received donor kidneys taken from patients who had experienced a controlled cardiac death, ie died from major heart failure after being withdrawn from life-support following a brain trauma. Traditionally, kidneys taken from these donors were thought to be inferior to those taken from patients who experienced a brain-stem death, due to the damage caused to the kidney from lack of blood supply in the period between cessation of the heart and the artificial preservation of the organ with cold fluid, the period of so-called 'warm ischemia'. The study showed that kidneys from controlled-cardiac-death donors are equivalent to kidneys from brain-stem-death donors. This discovery has the potential to effectively double the rate of viable kidney donations and prevent some of the 700 deaths per year in patients awaiting a donor kidney in the UK.[6]

"Laparoscopic colorectal surgery is more tolerable and less painful for patients, and offers faster recovery times than traditional open bowel surgery

3 NEW TECHNIQUES AND TECHNOLOGIES

Sentinel lymph node biopsy

If left untreated, cancerous tumours can spread (metastasise) throughout a patient's body. Metastatic cancer usually spreads first from the primary tumour site into the part of the immune system that drains waste fluid and cells from tissue (the lymphatic system). Assessing whether a cancer has spread from its primary site, and the extent to which this may have occurred, is important for a clinician in planning an appropriate course of treatment for an individual with cancer. Pioneered in breast cancer, sentinel lymph node biopsy is a technique to identify for biopsy the sentinel lymph nodes nearest a tumour – the lymph nodes to which a cancer normally spreads first. The sentinel lymph node is identified by injecting blue dye or a radioactive substance into the body near the tumour. This technique can avoid the need for a larger-scale removal of the lymph nodes around a cancerous tumour as a biopsy measure, which can cause additional pain and, in some cases, chronic swelling.

Laparoscopic bowel surgery

Diseased sections of the large bowel often need to be removed from patients who have a variety of conditions such as cancer or inflammatory bowel disease. Laparoscopic colorectal surgery involves the use of 'keyhole' methods, using small cameras and compact surgical equipment to precisely remove part or all of the bowel and sew or staple the ends of the remaining bowel together (resection). This technique is more tolerable and less painful for patients, and offers faster recovery times than traditional open bowel surgery, leading to shorter stays in hospital and an improved patient experience.

Research into new technologies or techniques is just as important. It can change the way in which surgery is undertaken, widen the pool of patients that could benefit from surgery, improve success rates and shorten recovery times.

Research can also lead to improvements in process and the way in which healthcare teams work, improving safety, enhancing patients' recoveries and maximising the efficiency of healthcare delivery.

4 NEW PROCESSES

Enhanced Recovery Programme

The Enhanced Recovery Programme, originally developed by the NHS Institute for Innovation and Improvement, combines the organisation of care and clinical management to achieve improvements in patient outcomes, reduced length of stay in hospital, efficient use of resources and a better environment for staff. Clinical factors include pre-operative planning; a focus on less-invasive surgical techniques; adequate pain management and prevention of nausea and vomiting; and significant attention to nutrition and hydration, which has been shown to aid recovery. Regarding practical management, the programme focuses on improved processes and room layout, procedure-specific care plans and training for staff in ordering tasks around a procedure. Length of stay data and readmissions rates are then monitored by the hospital to demonstrate the effectiveness of implementing the programme.[7]

5 NATIONAL AUDIT PROGRAMMES

Fractured neck of femur audit

Fractured neck of femur is the most serious consequence of falls among older people, with 30% of patients dying within a year.[8] Timely, high quality surgery has been shown to save lives, improve patient outcomes and reduce the length of stay of those patients in hospital.[8] Led by the College of Emergency Medicine, the national audit of fractured neck of femur patients collected data between 2004–2009 on the management of pain in patients with this condition, as well as times to x-ray, admission and operation. The audit tracked a 10% increase in the proportion of patients receiving an x-ray within one hour, an increase from 72% to 90% of patients being admitted within four hours, and a steady improvement in the proportion of patients undergoing surgery within 1–2 days of admission.[9]

National lung cancer audit

Lung cancer remains the biggest cancer killer in the UK and, despite marked improvements in outcomes in the last thirty years, survival rates remain much lower than for other forms of cancer, and lower than in other comparable countries.[10]

Run jointly by the NHS Information Centre and Royal College of Physicians, this UK audit has been collating data online since 2005 on the treatment of lung cancer and outcomes achieved. By case-mixing the data, an attempt can be made to explain variations in treatment and outcomes, allowing for improvements to be made in these areas. A number of recommendations for providers to review their lung cancer services have already been produced following the audit, including those providers whose provision of surgery (tumour resection), chemotherapy or CT (computed tomography) scanning is much lower than the national average.[11]

Evaluating variations in the delivery and quality of clinical care can lead to improvements in healthcare delivery, enabling different teams to learn from each other and encouraging improvements in care. The national clinical audit programme has, through the routine collection of data, enabled important improvements in outcomes. Clinical audit can also play an important role in research by:

- evaluating the efficacy of different techniques
- analysing variations in care
- facilitating further research into patterns of care
- identifying patients who may be suitable for participation in clinical trials or centres that could participate in research studies.

The examples provided demonstrate how research has changed clinical practice, leading to improvements in outcomes for patients. Looking forward, there is a range of ongoing research that promises to change clinical practice for future generations.

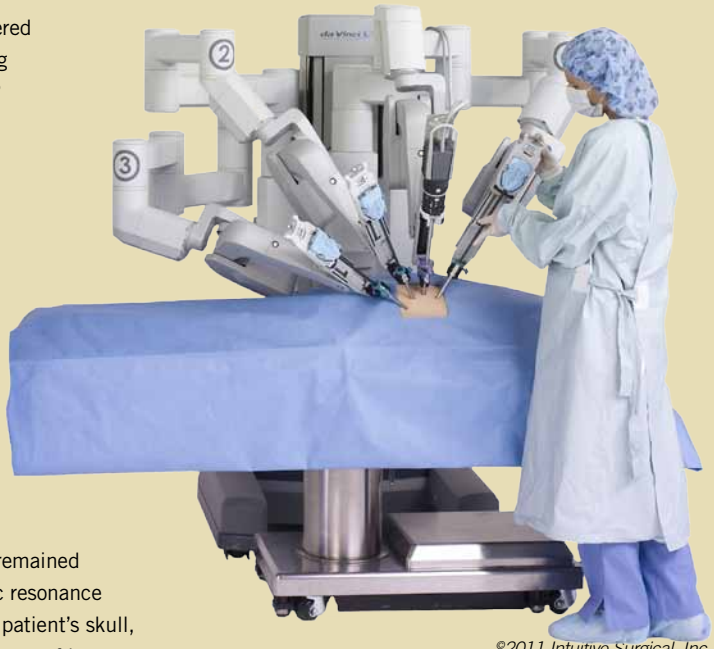
6 EARLIER-STAGE SURGICAL RESEARCH

Stem-cell tracheal transplant

A new approach to organ replacement has been pioneered by British and Italian surgeons who have replaced damaged tracheas (windpipes) using scaffolds re-populated with the patient's own stem cells. The use of stem cells can greatly reduce the risk of organ rejection as the body's immune response does not occur. This form of regenerative medicine may present a viable alternative to some conventional transplantation using donor organs in within two decades.[12]

Robotic prostatectomies

Developments in robotic surgical instruments have offered great improvements in the outcomes achieved following organ removal procedures. An example is the da Vinci® robot, developed in the USA, which allows for the precise and minimally invasive removal of the prostate (prostatectomy) through a number of keyhole incisions made by cauterising, camera-guided robotic arms. Benefits include significantly less pain for the patient, a faster recovery time and a decreased risk of damaging the nerves that control urination and erectile function which run across the prostate. Despite the benefits in outcomes offered by the technology, in 2008 only six machines were operating on the NHS.[13]



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Laser excision of brain tumours

Surgeons in France have undertaken the world's first laser excision of a brain tumour while the patient remained conscious. Using local anaesthetic, and MRI (magnetic resonance imaging) to guide the laser through a 3mm hole in the patient's skull, surgeons were able to destroy the tumour with two minutes of laser treatment. The laser casing itself was cooled to prevent potential clotting of blood in the brain or epileptic fits resulting from the heat. The patient was able to return home the same day. Small scale trials of this technique involving patients with brain tumours who have not responded to other forms of treatment have shown promising outcomes, with the majority of patients going into remission.[14]

> *"The combined spend of the Medical Research Council and the National Institute of Health Research on surgical research in 2008/9 was £25.5 million, out of a total research budget of £1.53 billion*

there are challenges in undertaking surgical research, particularly in the area of new surgical techniques and technologies where – despite the examples described above – it remains somewhat limited in extent, scope and ambition when compared to other forms of research. For example:

- The combined spend of the Medical Research Council (MRC) and the National Institute of Health Research (NIHR) on surgical research in 2008/9 was £25.5 million,[15] out of a total research budget of £1.53 billion.[16,17] The MRC currently funds four surgical trials in the UK and the NIHR funded seven new trials in 2009.[15]
- In 2009, the pharmaceutical sector spent £4.4 billion on research and development in the UK.[18] The Medicines and Healthcare Regulatory Authority (MHRA) received 252 applications for phase 1 trials for medicines in 2009/10, and approved 842 post-phase 1 trials.[19]

It has long been recognised that the UK is a favourable environment for undertaking pharmaceutical research, due to an appropriate infrastructure, high calibre academic centres and access to the NHS for clinical trials, in spite of perceived regulatory burdens. However, medical research in other areas, including surgery, does not enjoy the same profile or level of investment, despite the competitive advantages the UK can offer over other global locations.

In particular, support for academic departments of surgery is declining as public and university funding is increasingly focused on other areas of biological science. The role of these departments is central to driving surgical research and a degree of leadership from government and the academic sector will be required to ensure their role in research flourishes.

Recommendation 1: As part of implementing its Plan for Growth, the government should undertake a review of public funding of translational research in surgery and academic departments of surgery in delivering this research.

Chapter three

Improving surgical research for the benefit of patient care

The quality and quantity of surgical research, particularly when being translated into surgical practice, must be increased to address the disparity between surgery and other treatments. Otherwise there is a danger that opportunities to improve the quality of patient care and the outcomes delivered will be lost.

The experts who contributed to this report identified a range of challenges that need to be overcome. These can be classified broadly into three themes:

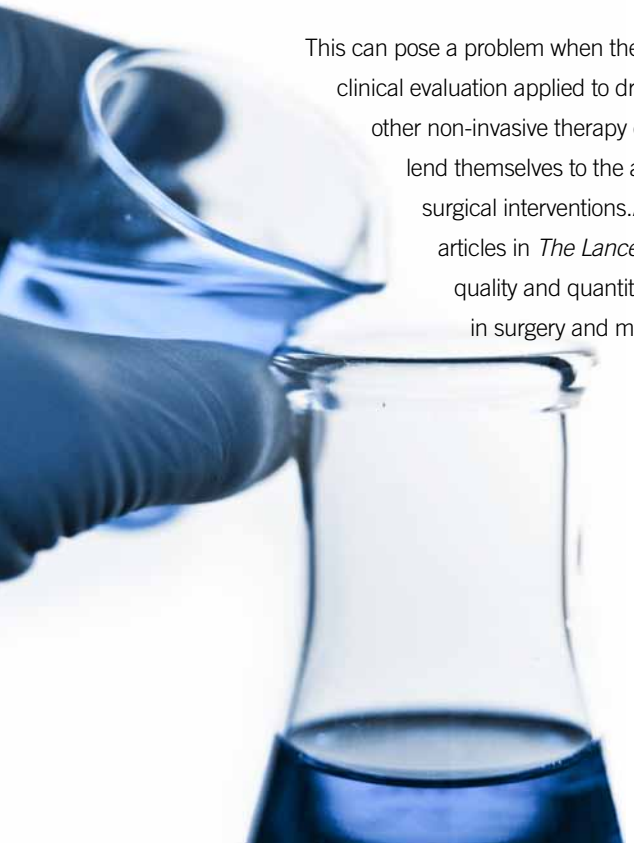
- The importance of a strong research base to underpin developments and advances in surgery has not been recognised, making it difficult for surgery to compete for funding with other types of research such as randomised clinical trials for drugs.
- The outputs of research – such as better techniques, technologies and processes – are not always widely and rapidly adopted because of the difficulties in getting funding to produce the evidence. There are also differences in how national guidance is implemented locally and the level of monitoring. Together, these further reduce the motivation to undertake further research.
- The culture within the surgical profession is not always conducive to supporting research, with surgeons themselves not always effective advocates for, or champions of, surgical research and evidence-based surgery.

These challenges are both caused by, and contribute to, an underpinning theme: the research infrastructure,

including funding, is less well developed for surgery than it is for other interventions. However, experts believe that these challenges can be addressed. This chapter explores the reasons why these challenges exist and how they could be overcome effectively.

Improving the quality of research

Research is usually funded on the strength of the proposal and its subsequent peer review. While this is entirely rational given that demand for research funding outstrips supply, it can reinforce existing patterns of research funding. Areas that are already perceived to be strong are likely to develop stronger proposals which therefore attract greater funding, further strengthening their quality and reach. In contrast, areas perceived to be weaker are unable to secure the necessary resources to improve. In this sense, it is vitally important that the quality of surgical research is high and seen to be so.



This can pose a problem when the gold standards for clinical evaluation applied to drug evaluation and other non-invasive therapy do not necessarily lend themselves to the assessment of surgical interventions.A recent series of articles in *The Lancet* discussed the quality and quantity of clinical research in surgery and made recommendations for ways to develop the assessment of innovation.[20–22] It was suggested that there needs to be increased understanding about the selection of the most appropriate form of evaluation from new and existing options.

The process of designing, delivering and evaluating a research project is complex. There are several critical stages, including:

- developing the right research question
- identifying and collaborating with the best team to conduct the research
- testing the feasibility of the proposed intervention
- ensuring the quality of the intervention in the trial is controlled
- designing high quality trials to establish the efficacy or effectiveness of the novel surgical interventions
- recruiting sufficient surgeons and patients to power the research
- gaining informed consent from trial participants and randomising them accordingly.

Getting each of these stages right requires particular skills and experience. It should be noted that the attributes required to do this may be different from those required to be a surgeon in clinical practice. For example, surgeons have to be leaders of their teams in an operating theatre, often making rapid decisions that will have a significant impact on their patient's outcomes.

In a research environment surgeons need to be collaborators, often developing considered opinions through dialogue with a large and diverse team. They may not lead this team and instead need to be an active member who contributes to a successful multi-disciplinary effort.

Surgical training is currently focused on preparing surgeons for their clinical roles within the NHS, ensuring they have the appropriate skills to progress in their chosen specialty. There may be scope for increasing the emphasis on understanding and conducting research within this training.

Recommendation 2: Research modules should be incorporated into surgical training. For example, these could include study design, randomisation or good clinical practice (GCP) training for research.

Many surgeons will have little exposure to, or experience of, research, instead choosing to focus on developing the skills which will be vital to their surgical practice in delivering care in their chosen specialty.

Recommendation 3: Surgical trainees should be encouraged to participate in ongoing research. For example, trainees could be encouraged to work with multi-disciplinary research teams to design studies and contribute to research portfolios.

It should be recognised that there are technical and practical difficulties in conducting surgical trials which are greater than those experienced in other forms of clinical research. For example, securing consent from patients to be randomised to different trial arms can be challenging, particularly when the forms of intervention are very different, often with different side effects. There are, however, a number of examples of good practice that could be shared and applied across studies. For example, the ProtecT trial for early-stage prostate cancer interventions has successfully developed tools to support patients in consenting to randomisation, resulting in high levels of recruitment. These tools have required significant investment but could be adapted for other trials.

7 ProtecT TRIAL

This randomised controlled trial (RCT) was run at nine sites across the UK, comparing the effectiveness of three interventions in over 1,500 men with localised prostate cancer between 2001–2008.[23] The three interventions were:

- surgical prostatectomy
- conformal (highly accurate) radiotherapy
- regular monitoring of prostate-specific antigen (PSA) levels to inform any future intervention.

Importantly, a pilot study was conducted before the beginning of the trial to compare the effectiveness of different recruitment strategies for randomised trials.

Patients had a detailed verbal consutlation with a nurse or consultant urological surgeon where the relative benefits of the different interventions were discussed. Patients were then asked if they would be willing to be randomly assigned to one of these interventions (as opposed to selecting one of the interventions themselves). Results showed that around 70% of patients agreed to randomisation.[24]

Based on the results of this pilot study, tools have been developed to aid the healthcare professional in undertaking this discussion with a patient.

If implemented, these recommendations would have the effect of increasing the exposure of surgeons to the culture and methodology of research, so providing greater opportunities for them to develop the skills that are required to design and participate in their own high quality research.

Ensuring there is a supportive culture for research within the profession

For high quality research proposals to be developed, it is important that ambitious and talented surgeons are encouraged to think about research and participate in it. Therefore, the culture of the whole surgical profession needs to be supportive of research, with research being seen as a prestigious, valuable and rewarding endeavour. There are, however, a range of cultural issues which can hamper this:

- The gradual decline over the past twenty years of support for surgical research has led to a lack of mentors and role models for aspiring surgeons.
- Surgeons feel a very personal responsibility for the outcomes of their patients. This can run counter to the concept of entering patients into a trial where – by definition – it is not known which intervention will be offered and therefore the clinician has to abdicate an element of control.
- Surgeons tend to focus on authoring and publishing their own papers based on their own smaller studies. This inhibits the recruitment of patients to large scale trials, compromising the overall power of surgical research.
- Undertaking high quality research is a multidisciplinary effort. Surgeons are typically effective leaders of teams in a surgical environment but this form of leadership may not always translate to a research environment where a more collaborative approach is required.
- The links between the surgical profession and commercial developers of healthcare technology are less well established than in other areas of medical research, such as pharmaceuticals. This can hinder the translation of research and limit access to funding and expertise in developing and conducting trials.

“It is recommended that a 50:50 clinical academic split is available for surgeon clinician–scientists to ensure that the individual maintains specialist surgical skills and also develops a research portfolio

It should also be noted that surgical research can often involve developing capability in new techniques or procedures, which may or may not prove to be effective. As a craft specialty, surgeons learn new techniques or procedures through practical experience in order for them to be able to perform the new technique or procedure safely and effectively. The significant investment of time, effort and resources for an uncertain return and can act as a disincentive to participate in research.

Central to addressing these issues is creating a supportive culture for research whereby endeavours by surgeons in this area are recognised and rewarded. A range of practical steps should be taken to achieve this.

Recommendation 4: Personal incentive schemes for clinicians, such as clinical excellence awards, should be used to reward both surgeons who undertake high quality surgical research and those surgeons who successfully participate in large trials, for example by recruiting significant numbers of patients.

Recommendation 5: Consultant appointment panels should place a greater emphasis on participation in clinical research, rather than simply the publication of papers, in their selection criteria.

Recommendation 6: Providers of NHS services should be motivated to support surgical trials through the use of incentives such as the Commissioning for Quality and Innovation (CQUIN) framework.

Recommendation 7: A network should be established to enable aspiring researchers to make contact with, and seek guidance from, more experienced surgeons and other clinicians in their field who may be able to act as research mentors.

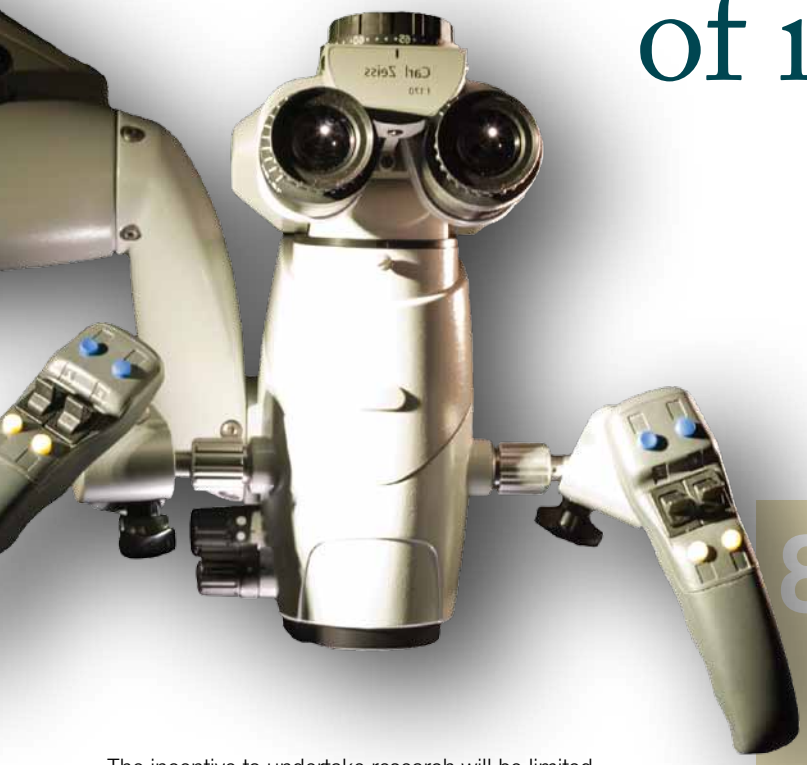
Recommendation 8: A mechanism should be designed to help surgeons identify opportunities to learn and collaborate with experienced academic surgeons. This would enable training in grant writing and mentoring and increase awareness of potential sources of commercial funding.

The culture and priorities of some research funders is also not well suited to supporting surgical research. This can be because the criteria for allocating funds does not fit well with surgical practice. For example, some major research funders stipulate that recipients must spend at least 60–80% of their time on research, rather than standard clinical practice. Although this may work well for physicians, surgery as a craft specialty requires surgeons to maintain a certain volume of practice to develop and maintain appropriate levels of expertise. For example, and for very good reasons, the improving outcomes guidance on a range of different cancers stipulates that surgical teams must perform a relatively high volume of procedures such as radical prostatectomies to be deemed to be safe and effective teams.[25] It is recommended that a 50:50 clinical–academic split is available for surgeon clinician–scientists to ensure that the individual maintains specialist surgical skills and also develops a research portfolio.

Recommendation 9: Funders should give explicit consideration to supporting research on surgical innovation and the basic science and engineering that support it. Funders should also consider relaxing the stipulation that clinician–scientist awardees should spend the majority of their time on research, for example a 50:50 split is recommended for surgical academics.

Chapter four

Improving the uptake of innovations in surgery



The incentive to undertake research will be limited if the results of that research do not inform the development of clinical practice. For example, it can be both frustrating and wasteful to prove the effectiveness of an intervention only to find that it does not disseminate into wider practice. Conversely, demonstrating that high quality research does lead to a more rapid spread will help to incentivise both the funding and practice of research.

In the past some surgical innovations have been discovered and developed in the UK but adopted elsewhere more rapidly, resulting in UK patients being among the last to benefit.

8

TOTAL MESORECTAL EXCISION (TME)

This procedure involves the precise and complete removal of a part of the lower sections of the bowel and associated lymphatic tissue as a treatment for rectal cancer. This total excision reduces recurrence rates of the cancer, which it is often not possible to re-operate on. As such, the technique improves the survival of patients by up to five years versus the standard procedure.[26]

The technique was first developed at the Pelican Bowel Cancer Research Unit in Basingstoke by Heald and Ryall in the early 1980s. Concern around bowel cancer survival rates saw national training programmes introduced in the Netherlands, Norway and Sweden in the early 1990s with the procedure becoming part of routine clinical practice in those countries, resulting in positive effects on the outcomes of rectal cancer patients.[27–29] However, the establishing of TME as routine clinical practice in the UK came a decade later, despite the procedure being pioneered in England.[30]

The group of experts identified three key factors in influencing whether an innovation spreads:

- The availability of national guidance setting out when use is appropriate. This helps providers and commissioners to know when and how a new technology should be adopted. For example, the National Institute for Health and Clinical Excellence (NICE) has issued technology appraisal guidance on the use of laparoscopic colorectal surgery, signalling to commissioners and providers that it is a clinically sound and cost-effective technology.
- The establishment of training programmes to ensure that qualified surgeons are able to undertake new techniques to a high standard of quality and safety, thereby enabling more patients to benefit. For example, the UK NEW START training programme in sentinel node biopsy has seen the rapid and safe uptake of the technique among surgeons who had not before performed the procedure, with consequential benefits for patients.[31]
- The availability of readily accessible information on trials and studies in progress, enabling clinicians to participate in research or to refer patients to trials, monitor what techniques they may wish to adopt in the near future and gain familiarity with new techniques. For example, Cancer Research UK publishes information on cancer trials which are currently recruiting in the UK.[32]

Unfortunately, many surgical interventions are not subject to technology appraisal guidance issued by NICE. This is in large part because the evidence available to support the development of guidance is often sparse. The role of the NICE in informing clinical practice and opinion is well established. NICE issues a range of different forms of guidance, some of which (eg technology appraisals) are accompanied by strong implementation signals while others (eg interventional guidance) are more advisory in nature. Guidance on surgical interventions usually falls into the latter category, offering advice on safety and efficacy rather than cost effectiveness.

There are, however, a number of levers which could be utilised to encourage appropriate uptake of surgical innovations. These include:

- Creating 'choice guarantees' where more than one treatment option exists (for example, laparoscopic and open bowel surgery). This is particularly important for ensuring that patients are not disadvantaged by situations such as one surgeon choosing not to adopt a new technique despite evidence of the benefit to the patient.
- Publishing information on the uptake of new techniques in provider quality accounts, ensuring that it is seen by patients, commissioners and staff as a point of differentiation. For example, patients may wish to choose to be treated at a hospital which offers minimally invasive treatment options.
- Providing information to patients (either directly or through materials developed by charities), to help them to make an informed decision about the most appropriate treatment option, including newer technologies.
- Disseminating information on new techniques to clinicians, ensuring they are aware of changes in practice through mechanisms such as the national electronic library for health or NHS Evidence
- Incentivising the uptake of new technologies through schemes such as Commissioning for Quality and Innovation (CQUINs), whereby commissioners and providers identify priorities for improvement that are linked to payment. For example, commissioners could opt to reward providers for implementing a new technique with a reduced morbidity profile or improved outcomes.
- Creating best practice tariffs where a clinically superior intervention is available that may not otherwise be used. For example, a technology that requires greater upfront investment but offers superior long-term benefits may not be economic on existing tariffs, which are often based on the average costs of current practice.
- Ensuring that appropriate use of interventions is considered as part of the revalidation process for surgeons. For example, a surgeon should be required to demonstrate that he or she is keeping up to date with the latest clinical practice or is taking steps to ensure that patients are not disadvantaged by a failure to do so.

Recommendation 10: The NHS Commissioning Board should make full use of the range of options available to encourage the spread of surgical innovation. As part of its duty to promote innovation, as set out in the NHS Constitution, the Board should publish annual updates on the extent to which new, proven technologies have been adopted in routine NHS practice and set out what steps will be taken to address any barriers.

Recommendation 11: The Department of Health and the surgical profession should explore how the best information on new technologies (with appropriate evaluation) can be disseminated to all relevant surgeons.

When a new surgical technology is implemented in the NHS, it will be important to evaluate what impact it has on routine practice, including on patient outcomes, service productivity and costs. Clinical audits can play a significant role in assessing variations in clinical practice, processes and the outcomes achieved. Participation in such audits should be mandated and the development of new surgical audits should be encouraged.

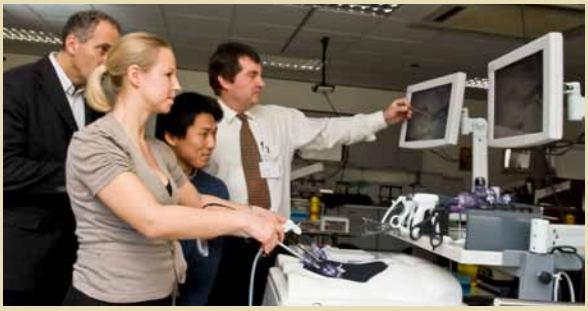
Recommendation 12: Participation in established clinical audits should be mandated through commissioning contracts, ensuring that providers only receive full payment for an activity when data are submitted. Audit participation can also be strengthened through revalidation. Where clinical audits exist they should be fully exploited for research purposes.

Recommendation 13: New clinical audits should be developed for areas of practice where audits do not exist. New and existing audits should include the facility to capture data on the use of new techniques. Information about research projects and new techniques should be available through the audit to surgeons who contribute data to allow them to keep up to date with developments in practice.

Training has played a critical role in ensuring the roll-out of techniques such as laparoscopic bowel surgery and sentinel node biopsy. In the case of laparoscopic bowel surgery, a national training programme (LAPCO) was established to ensure that colorectal surgeons had the appropriate levels of competency. For sentinel node biopsy, regional training roadshows were established. Both these examples contrast with total mesorectal excision, where the absence of a training programme for UK clinicians hindered uptake for 20 years, despite that fact that the technique is highly cost effective. It should be noted that total mesorectal excision did not benefit from the same level of evidence from randomised control trials as the other two techniques.

9 LAPCO TRAINING PROGRAMME

Funded by the National Cancer Action Team and the Department of Health, the LAPCO national training programme for laparoscopic colorectal surgery (LCS) was devised in 2007 to address the shortage of trained surgeons which hindered the implementation of the new NICE guidelines on laparoscopic bowel resection.



The programme itself consists of training for theatre teams, tailored to their level of experience, including theory training, wet lab simulations, clinical immersion days (back-to-back procedures) and live observation of procedures by a trainer outside of the training site. It is estimated that 460 surgeons trained in LCS will be required to deal with the NHS caseload; currently 200 surgeons are undertaking or completing LAPCO training, building on the 45 trained surgeons who performed LCS in 2006.[33]

"providers should be incentivised to release surgeons to participate in appropriate continuing professional development programmes

The proposed changes to training budgets heralded by the NHS White Paper, which will see responsibility for the funding of training devolved to individual providers, pose a challenge to ensuring that practising surgeons are trained in new techniques.

Although the principle of using training as a mechanism through which different providers can compete for staff and patients (as they do in other sectors of the economy) is sound, there are practical difficulties in applying this approach to the training of existing surgeons in new techniques. Training itself is not a prohibitively expensive activity to undertake at a trust level. However, there are significant economies of scale to be realised from developing new training programmes on a regional or national basis, as well as quality benefits.

It should, however, be recognised that there has been no consistent and rational basis for ensuring that new national training programmes have been developed and funded, resulting in either delays in the roll out of new technologies or some surgeons using new techniques without sufficient training or experience.

There are a range of practical solutions which could be implemented, including:

- Treating national training programmes in new techniques for established clinicians as part of the research implementation process, funding them through central research and development budgets.
- Enabling NICE to create a mandate in guidance that training should take place if the evidence for the intervention is strong, ensuring that commissioners only procure the intervention from appropriately trained surgeons.
- Allocating a dedicated training uplift to the tariff for new techniques for an interim period, with providers being required to demonstrate that surgeons have taken part in an accredited training programme.

Recommendation 14: The Department of Health should consider how the efficiency and quality benefits of nationally commissioned training programmes can be retained as part of the reforms to the funding of training in the NHS. A clear and consistent mechanism for funding high quality training on new surgical techniques and interventions should be identified, thereby enabling surgeons to make use of new techniques as and when they are proven to be effective.

Recommendation 15: As part of the payment system for surgical activity, providers should be incentivised to release surgeons to participate in appropriate continuing professional development programmes.

Making surgeons better advocates for surgical research

The challenges outlined in this report have all contributed to a culture whereby surgeons have not been the most effective advocates for and of surgical research. The measures outlined above would – if implemented – help to address this by demonstrating to surgeons the importance of research, ensuring that it is recognised as an important and prestigious endeavour which is performed to high standards, and facilitating the rapid dissemination of research findings. Furthermore, a focus on translation (developing and then implementing new techniques and technologies into surgical practice) will also help to change the culture both within surgery and also with wider stakeholders. Surgeons can champion surgical research by:

- Working with provider organisations to ensure that surgical research receives due prominence in organisational research strategies.
- Collaborating with colleagues to ensure that, where appropriate, surgery is reflected in multi-disciplinary research projects.
- Engaging with commissioners to ensure that there is appropriate surgical input to the development of commissioning policies and that these reflect the importance of 'research-active' surgery environments.
- Contributing to the development of national policy to ensure that appropriate national disease strategies address any shortfalls in surgical research.

- Contributing to efforts to streamline research bureaucracy, for example through initiatives such as the recently published Academy of Medical Sciences' review of the regulation and governance of medical research.[34]
- Engaging with patients and charities to ensure that they are aware of, and demand access to, the latest techniques.

In addition to this, there is a role for the Royal College of Surgeons in advocating the importance of research in surgery to ensure that it receives equal status and prioritisation as research into other forms of treatment, such as pharmacotherapy.

Chapter five

Summary of recommendations

Recommendation 1: As part of implementing its Plan for Growth, the government should undertake a review of public funding of translational research in surgery and academic departments of surgery in delivering this research.

Recommendation 2: Research modules should be incorporated into surgical training. For example, these could include study design, randomisation or good clinical practice (GCP) training for research.

Recommendation 3: Surgical trainees should be encouraged to participate in ongoing research. For example, trainees could be encouraged to work with multi-disciplinary research teams to design studies and contribute to research portfolios.

Recommendation 4: Personal incentive schemes for clinicians, such as clinical excellence awards, should be used to reward both surgeons who undertake high quality surgical research and those surgeons who successfully participate in large trials, for example by recruiting significant numbers of patients.

Recommendation 5: Consultant appointment panels should place a greater emphasis on participation in clinical research, rather than simply the publication of papers, in their selection criteria.

Recommendation 6: Providers of NHS services should be motivated to support surgical trials through the use of incentives such as the Commissioning for Quality and Innovation (CQUIN) framework.

Recommendation 7: A network should be established to enable aspiring researchers to make contact with, and seek guidance from, more experienced surgeons and other clinicians in their field who may be able to act as research mentors.

Recommendation 8: A mechanism should be designed to help surgeons identify opportunities to learn and collaborate with experienced academic surgeons. This would enable training in grant writing and mentoring and increase awareness of potential sources of commercial funding.

Recommendation 9: Funders should give explicit consideration to supporting research on surgical innovation and the basic science and engineering that support it. Funders should also consider relaxing the stipulation that clinician–scientist awardees should spend the majority of their time on research, for example a 50:50 split is recommended for surgical academics.

Recommendation 10: The NHS Commissioning Board should make full use of the range of options available to encourage the spread of surgical innovation. As part of its duty to promote innovation, as set out in the NHS Constitution, the Board should publish annual updates on the extent to which new, proven technologies have been adopted in routine NHS practice and set out what steps will be taken to address any barriers.

Recommendation 11: The Department of Health and the surgical profession should explore how the best information on new technologies (with appropriate evaluation) can be disseminated to all relevant surgeons.

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