BRITISH JOURNAL OF HOSPITAL MEDICINE

EDITORIAL

Safety and transparency in surgical innovation

Advances in healthcare require safe and transparent innovation. Currently in surgery it can be difficult to identify when innovation is occurring because of inconsistent oversight and reporting. New ways of identifying, monitoring and reporting surgical innovation are called for in order to optimise the process.

Jane M Blazeby[1]

Sian Cousins[1]

Anne Pullyblank[2,3]

Author details can be found at the end of this article

Correspondence to:
Jane M Blazeby;
j.m.blazeby@bristol.ac.uk

How to cite this article:
Blazeby JM, Cousins S, Pullyblank A. Safety and transparency in surgical innovation. Br J Hosp Med. 2022. https://doi.org/10.12968/hmed.2022.0073

Introduction

Innovation in surgery is exciting and often generates attention. Led by innovators and early adopters, it is undertaken for a variety of reasons, but a central focus is ultimately to improve the clinical and cost effectiveness of existing treatments. While many innovations do lead to substantial patient benefit, sometimes unexpected issues and side effects occur. Sadly, a number of well-known promising surgical innovations were eventually found to be harmful and withdrawn from use, one example being transvaginal mesh (Heneghan et al, 2017).

When this happens, public enquiries have been initiated and, on some occasions, legal proceedings have ensued. Patients have suffered, with many requiring revision surgery. This is why it is important to consider how surgical innovation occurs. An independent inquiry in 2020, led by Baroness Cumberlege, investigated the introduction of new medical devices, concluding that improvements must be made to introduce robust and efficient evaluation, patient-centred data capture and more transparent communication (Cumberlege, 2020).

In the National Institute for Health Research Bristol Biomedical Research Centre, several studies have investigated innovation in surgery. The INTRODUCE study (Cousins et al, 2019) retrieved NHS hospital policies from England and Wales and used thematic analysis to examine when hospitals determine local governance to be sufficient for the delivery of innovative surgery and invasive procedures. Findings were in keeping with the Cumberlege report. Surgical innovation is very different to innovation that occurs with new medicines, which has a much clearer process overseen by the appropriate national bodies. Work is now underway to improve how innovation in surgery occurs, engage the sector and better understand the challenges. This has included an initial series of engagement events in partnership with the AHSN Network (the collective name of the 15 Academic Health Sciences Networks in England).

Pharmaceutical innovation

Regulation of pharmaceuticals is rigorous. Innovative products undergo pre-clinical then early phase clinical testing. National oversight is provided by research ethics committees, for example the Health Research Authority or institutional review boards. Following later phase studies, multicentre randomised controlled trials often take place that compare the product with standard care or a placebo. The results are independently scrutinised by licensing authorities, for example the Medicines and Healthcare products Regulatory Agency or the Food and Drug Administration. Once the product is formally approved, it is made available for widespread use. Some regulatory agencies then provide systems for voluntary reporting of suspected side effects, which is particularly valuable for longer-term follow up, for example the Medicines and Healthcare products Regulatory Agency yellow card scheme.

Surgical innovation

Currently, new surgical and invasive procedures may be undertaken with very little formal oversight, ie a surgeon can change part of an operation or conduct a novel operation on a patient in a hospital without gaining approval from a research ethics committee or any formal body. Some hospitals require that surgeons apply for permission from clinical

effectiveness committees (also referred to as new procedures committees). Such committees are in place in the UK, the USA and other countries, although little is known about their conduct. This was the subject of the Bristol Biomedical Research Centre INTRODUCE study (Cousins et al, 2019). Systematic reviews summarising reporting of the introduction of new procedures and devices show how few formally gain research ethics or local hospital committee oversight, as shown by the study by Pathak et al (2021) that looked at published reports of minimally invasive transthoracic liver resection. The Bristol Biomedical Research Centre research also found that new procedures and devices were introduced by surgeon innovators without sequential creation of evidence. There is a lack of incremental evaluation, and robust comparison with existing procedures is uncommon. Selection of the desired outcomes, measurement and reporting is inconsistent, which hinders data synthesis and evidence generation. In addition, few studies examine the costs of innovation.

Information that patients receive before innovative surgery was also examined. Interviews with surgeons showed that they believed patients held the view that 'new' was best. However, surgeons reported that managing these expectations could be difficult, particularly if patient views aligned with their own (Zahra et al, 2020). Providing the most relevant information and ensuring that it is balanced is challenging. The study concluded that:

> **'Participants stated that if a procedure was innovative, patients should be provided with additional information extending beyond that given during routine surgical consultations. However, difficulty defining innovation had implications for whether patients were informed about novel components of surgery and how the procedure was introduced (ie as part of a research study, trust approval or in routine clinical practice). Furthermore, data suggest surgeons found it difficult to establish what information is essential and how much detail is sufficient, and governance surrounding written and verbal information provision differed between NHS Trusts' (Zahra et al, 2020).**

There is clearly room for improvement in terms of following best practice guidance on transparency, so that patients are given a full picture of what is proposed and can make a well-informed judgement on that basis. Transparency is important for staff who can then make autonomous decisions about their involvement. These studies have demonstrated that there is a need to improve the collection of outcome data of surgical innovation and to monitor it in the short and long term. This will help to establish whether a new procedure works and how it compares with standard care. A core set of outcomes has been developed to be measured and reported when surgical innovation is occurring (Avery et al, 2019).

National guidance for surgical innovation is available from professional bodies. In the UK, the National Institute for Health and Care Excellence Interventional Procedures Advisory Committee provides recommendations for procedures not yet established in clinical practice, and established procedures where new evidence has called into question effectiveness or safety. This process may recommend that procedures are undertaken with research oversight, with special arrangements, or with standard arrangements alone. Changes in the regulation of devices are occurring, but widespread use of innovative devices once CE marked is still currently permitted.

Innovation oversight: what is needed?

For innovation to occur transparently and safely it requires oversight. Registration with an appropriate organisation and monitoring are needed. Two key issues to address as a priority are:

1. Which innovations in surgery and invasive procedures can be performed with clinical effectiveness committee oversight?
2. Which innovations require application to a research ethics committee?

If local hospitals do provide the oversight, further challenges that need addressing will typically include how to optimise patient information provision and informed consent; how are adverse effects collated, shared and reported; and which outcomes should be measured to maximise learning and decision making (ie whether to abandon, pause, modify or further evaluate the procedure). Work is needed to improve the culture within surgery (and other

Key points

- Surgical innovation has potential patient benefits and, when successful, can revolutionise care.
- Surgical innovation has some known risks and unknown consequences.
- Oversight is needed in order to optimise informed consent, surgical preparations, and reporting of risks and benefits.
- Oversight of innovation in the surgical sector is minimal compared to innovation in the pharmaceutical sector. In some cases, local hospitals will approve new and modified procedures, and this can occur without registration. Hospitals have differing views on what constitutes innovation, and it is currently unclear when research ethics approval is required.
- Clarity about appropriate oversight for safe and transparent innovation in surgery is needed.

specialities that involve invasive procedures) to encourage more registration of procedures and sharing of results, even when problems occur.

Changing the system for oversight of surgical innovation will require thought, investment and leadership. There will be many benefits. It will make innovation transparent. Shared data will speed up evaluation and ultimately the implementation of effective treatments in practice. Patient harm will be minimised by prompt identification of adverse events. It is hoped that the proposed changes will create an environment where innovation is nurtured, encouraged and streamlined, and that this will inform world-leading advances that are of benefit to patients.

Author details

[1]Bristol Biomedical Research Centre and Bristol Centre for Surgical Research, Bristol Medical School, University of Bristol, Bristol, UK

[2]West of England Academic Health Science Network, part of the AHSN Network, Bristol, UK

[3]Department of Surgery, North Bristol NHS Trust, Bristol, UK

References

Avery K, Blazeby J, Wilson N et al. Development of reporting guidance and core outcome sets for seamless, standardised evaluation of innovative surgical procedures and devices: a study protocol for content generation and a Delphi consensus process (COHESIVE study). BMJ Open. 2019;9(9):e029574. https://doi.org/10.1136/bmjopen-2019-029574

Cousins S, Richards H, Zahra J et al. Introduction and adoption of innovative invasive procedures and devices in the NHS: an in-depth analysis of written policies and qualitative interviews (the INTRODUCE study protocol). BMJ Open. 2019;9(8):e029963. https://doi.org/10.1136/bmjopen-2019-029963

Cumberlege J. First do no harm: the report of the independent medicines and medical devices safety review. 2020. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf (accessed 3 March 2022)

Heneghan C, Aronson JK, Goldacre B et al. Transvaginal mesh failure: lessons for regulation of implantable devices. BMJ. 2017;359:j5515. https://doi.org/10.1136/bmj.j5515

Pathak S, Main BG, Blencowe NS et al. A systematic review of minimally invasive trans-thoracic liver resection to examine intervention description, governance, and outcome reporting of an innovative technique. Ann Surg. 2021;273(5):882–889. https://doi.org/10.1097/SLA.0000000000003748

Zahra J, Paramasivan S, Blencowe NS et al. Discussing surgical innovation with patients: a qualitative study of surgeons' and governance representatives' views. BMJ Open. 2020;10(11):e035251. https://doi.org/10.1136/bmjopen-2019-035251