RCS Future of Surgery Commission

NIHR Bristol BRC Surgical Innovation Theme

Background

The development and introduction of drugs in to clinical practice follows a well-regulated evaluation pathway. After licencing, there is additional monitoring with long term surveillance. The lack of rigorous assessments of new surgical devices have resulted in high profile medical devices that have been adopted widely only later to have been shown to be fundamentally flawed (e.g. metal on metal hips). These cases have caused considerable patient harm and cost and have been a barrier to effective surgical innovation.

Innovative surgical devices receive regulatory approval based on in vitro, animal studies and small case series (CE marking). Benchtop / animal models have limited applicability and case studies are of low methodological quality. These studies are often led or funded by medical device companies and reported by surgical innovators enthusiastic for the technology. There is a lack of transparency in how outcomes reported from the early studies are selected and defined limiting data synthesis and early identification of problems. Patients, the public and wider surgical community are rarely involved in innovation study design. Once released it is uncommon for well-designed and conducted early / later phase studies to take place. The IDEAL Collaboration (Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the Quality of Research in Surgery) has set out guiding principles (stages) for surgical device innovation. However, IDEAL has not been adopted and the optimal pathway and evaluation of early phase surgical procedures and devices remains unclear.

In 2017 the University of Bristol were awarded a NIHR Biomedical Research Centre. The Bristol Centre for Surgical Research as part of the Bristol NIHR BRC were invited to lead a theme on surgical innovation. Importantly this is the one of only three surgical themes in England supported by a NIHR BRC.

The successful award of the BRC was predicated on the work done in Bristol by the Medical Research Council (MRC) ConDuCT-II Hub and the Royal College of Surgeons (RCS) Trial Centre. The ConDuCT-II Hub developed high-quality, cutting-edge methodological research of relevance to pragmatic randomised controlled trials (RCTs) in surgery. It established valuable methods to ensure optimal recruitment into surgical trials, identified amongst others issues important trial reporting flaws related to outcome selection and measurement. It is working in collaboration with the COMET initiative to address this. The RCS Surgical Trial Centre underpinned clinical trial activity and put Bristol firmly in the vanguard of surgical trials.

Surgical Innovation Theme Overview

The overall aim of the surgical innovation theme is to transform early phase study design. We intend to do this broadly through two approaches. Firstly, to develop methods for safe, efficient

and transparent translation of innovation. Secondly, to expedite the rejection of ineffective techniques and to lead to randomised clinical trials to establish the evidence.

We have developed work streams led by surgical clinical academics and non-clinical academics from a variety of backgrounds to achieve our aims. The **evaluation of surgical innovation** will be achieved in three work streams to improve

1. **Early phase design & intervention definition**
2. **Information provision & informed consent**
3. **Selection, measurement & reporting outcomes**

We are currently critically analysing the pathways of surgical innovation including the ethical and regulatory barriers to rapid, effective and safe adoption of new technology in to everyday clinical practice.

As an example, one significant challenge in the evaluation of surgical device development is outcome reporting. Numerous outcomes are selected and reported, making data synthesis difficult and risking outcome reporting bias. RCTs have improved methodologically due to the development of core outcome sets (COS). COS have generally focused on specific conditions and/or surgical procedures. A COS is an agreed set of outcomes that should be reported in all studies of a condition/procedure. COS for early phase studies may have different domains to those needed for RCTs. The development of an agreed standard "core" set of outcomes to be measured in all trials to facilitate cross-study comparisons, meta-analysis, and minimize outcome reporting is needed. There are no COSs to aid earlier and later phase studies with innovative surgical technologies and devices. Consequently, it is difficult to judge whether to proceed to full evaluation or abandon new technologies. A generic COS for studies reporting surgical device innovation would be invaluable to a wide variety of stakeholders. The MRC through their Hubs for Trials Methodology Research (HTMR) have funded a workshop with a wide range of stakeholders (surgeons, industry, academics, patients, health technology regulators, journal editors) to explore the feasibility of developing a generic COS for surgical innovation

It is our intention at the end of 5 years of NIHR funded research to be in a position to have analysed the barriers to safe and effective surgical innovation and to explore interventions to meet the current challenges. We are hosting the annual IDEAL conference in Bristol in September 2018 to build inter-disciplinary links and focus the need for change in the evaluation and adoption (or rejection) of surgical innovation.

Work streams 4-6 will focus on the **design of interventions and co-interventions.** We intend to

4. **Identify active (clusters) of interventions/co-interventions using network meta-analyses**
5. **Utilise surgical registries to identify outliers, innovators and successful interventions**
6. **Develop novel co-interventions using mixed methods**

Academics in Bristol (including Professor Nicky Welton) have pioneered statistical techniques such as network meta-analysis to be able to improve the comparison of novel techniques that have not necessarily been compared in head to head RCTs. Professor Welton will lead on new methods to assess and compare. rapidly evolving surgical technologies. We will work with the National Joint Registry (led by Professor Ashley Blom) to aid the understanding of the behaviours and outcomes of surgical innovators and surgical innovation in everyday clinical practice. And Professor Gooberman-Hill is developing co-inventions to optimise outcomes of orthopaedic procedures (e.g. pre and post-operative methods to optimise sleep which is linked to pain control and function).

Training and capacity building

The evaluation of new surgical devices and procedures requires both early phase and later phase studies (e.g. randomised clinical trials and registries). It is also important for the future or surgery that we educate surgeons and surgical trainees in methods to evaluate surgery. The new consultants can then lead future trials and be involved in them this establishing a generation of surgeons who understand and implement evidence-based practice. Bristol has a track record in training surgeons of the future in these areas. We run the annual Bristol and Oxford Surgical Trials intervention Course (BOSTiC) to educate surgical trainees and those interested in trials evaluating surgery. Over the past six years more than 200 surgical trainees have attended the course.

The Bristol STC has led the development of major RCTs in surgery and supported trainee research collaboratives to perform large scale audits and clinical research. It supports news chief investigators and principal investigators to do this.

Conclusions

Safe and efficient surgical innovation requires a well structured and clear evaluation pathway. Recent scandals in surgical innovation have highlighted the current scheme is not fit for purpose. Surgeons and academics at the NIHR Bristol BRC are researching methods to inform the future development of improved surgical innovation pathways, improved evaluation of innovation and more rapid adoption (and discarding) of surgical techniques and technology in everyday clinical practice.

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