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Surgical research in the UK is thriving. National Institute Health Research (NIHR) funding for randomised controlled trials (RCTs) in surgery has more than doubled in the last decade. The Royal College of Surgeons of England has created seven surgical trials centres and 15 posts for surgical subspecialty champions to promote research and evidence-based practice (Royal College of Surgeons, 2017). Surgeons are collaborating, and trainee research collaboratives actively design and conduct large scale audits and recruit patients into successful RCTs (Nepogodiev D, 2017). New courses designed to meet the increasing demand and rigours of evidence-based surgery have been developed, they are well attended and very popular (BOSTiC, 2018). Underpinning the change in surgical culture has been the development and application of novel methods to optimise surgical trial design and conduct. This is overcoming hitherto often quoted barriers to trial participation in surgery including recruitment issues, intervention standardisation and outcome selection, measurement and reporting (Blencowe N, 2017). All these activities and initiatives may lead to improvements in patient health and surgery although specific evidence to support this is yet to materialise. There is, however, growing evidence to suggest that participation in research in general improves outcome (Ozdemir 2015, Jonker 2018, Downing 2017).

In an analysis of risk-adjusted mortality for acute hospital admissions it was found that mortality was lower (even after adjusting for staffing and other structural factors) in Trusts that were research active compared to non-research active organisations (Ozdemir, 2015). Three indicators were used to define research activity, i) NIHR Comprehensive Clinical Research Network (CCRN) funding, ii) numbers of patients recruited into NIHR CRN portfolio studies, and, iii) Trust teaching status (classified by the Medical School Council in England). The observed association was strongest in Trusts in the top tertile of CCRN funding and patient recruitment. In a retrospective study of 129 hospital Trusts in England NIHR study activity data, summary hospital-level mortality indicator scores and Care Quality Commission (CQC) ratings were analysed adjusting for clinical staffing levels in each Trust. A significant association between the number of studies and participants with summary hospital-level mortality and CQC ratings was observed with correlations between the number of participants recruited into interventional studies especially strong (Jonker, 2018). Although this emerging evidence is not specific to surgery there has been one study which examined outcomes following colorectal cancer surgery and Trust research activity which shows similar findings (Downing 2017). Data were linked between patients diagnosed with colorectal cancer, annual accrual into NIHR Cancer Research Network research interventional studies and 30-day post-operative mortality and 5-year survival rates. The observed effects of benefit for research participation were not limited to cancer 'centres of excellence'. Patients treated in trusts with high research participation had lower postoperative mortality ($p < 0.001$) and improved survival ($p < 0.001$) after adjustment for case mix and hospital-level variables than patients treated in low research active trusts. The improvements were increased with the level and years of sustained research activity. It is possible therefore that research activity (at least involvement in NIHR portfolio studies and especially interventional studies) does improve patient outcome although further research is needed to confirm these findings especially in other types of surgery. There is also a need to explore what factors lead to improved outcome. It is unclear whether its associated with organisational performance and culture, multi-disciplinary teams and/or individual clinician expertise and behaviour or whether benefits are related to interconnected activities within hospital Trusts.

Whilst the increased research activity in surgery is exciting and the early data show that research active trusts have better patient outcomes, the research being undertaken and used as a benchmark is mostly later phase studies (RCTs/cohort/audits). There is much less research undertaken in surgery around novel and developing procedures. Surgical innovations and modifications tend to be undertaken as part of usual practice or with minimal regulation. Individual clinicians introduce, adopt and iteratively modify devices and procedures without gaining research approvals or consistently reporting outcomes. It is highly unusual for innovations to be systematically evaluated

from 'first in human', early phase to later phase studies within the research context. Because surgical innovation is not strictly governed it results in widespread variation in practice. Some surgeons use newer techniques and devices, others continue to practice standard procedures. There is therefore an opportunity to further improve patient health by improving the introduction of new surgical techniques and devices. The development and implementation of methods that are transparent and acceptable to ensure the safe translation and evaluation of new techniques will achieve this and make the process efficient.

The Bristol NIHR Biomedical Research Centre (BRC) includes a theme on 'Surgical innovation' (Bristol BRC, 2018). Its focus is to create and implement mechanisms for safe and transparent introduction and evaluation of innovative and evolving surgical procedures. The aim is to inform which promising interventions should undergo full trial evaluation and which should be abandoned. It will also develop interventions to optimise information provision for patients being offered new and evolving surgeries. This means patients will receive consistent and understandable information about new procedures. Similarly work to establish standard outcome reporting of new interventions will be undertaken so that that data can be combined in evidence syntheses. This will allow early identification of problems associated with new interventions and therefore limit patient harm. Ultimately working with key stakeholders it is hoped that the next decade will establish and implement methods to improve the evaluation of surgical innovation. It is also hoped that regulation could be modified or improved to reflect the unique demands of surgical innovation and that this will dovetail with the success of RCTs in surgery and ultimately improve patient care.

Jane M Blazeby

Robert Hinchliffe

Key points

There has been a change in the culture and practice of surgical research in the UK over the past decade.

There is support from the Royal College of Surgeons of England and successful surgical RCTs funded by the NIHR.

Methods to improve the design and conduct of surgical RCTs have been developed and implemented with NIHR and MRC funding.

Evidence is accumulating to show that participating in research improves outcomes *per se*.

There, however, remains a need for better methods and regulation of the early evaluation of surgical innovations and better methods for the evaluation of standard procedures that are undergoing incremental modifications.

The Bristol NIHR Biomedical Research Centre Surgical Innovation theme is tackling three of the key issues to the early evaluation of surgery to, i) establish when a surgical intervention is sufficiently stable to evaluate it within an RCT, ii) optimise information provision and informed consent for patients undergoing innovative and evolving procedures and devices, and, iii) set standards for outcome selection, measurement and reporting of early phase studies.

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