Should surgical training include involvement in a clinical trial?

The next generation of surgical consultants will need research experience to advance the specialty, writes **Morton Dion**, but **Colin Bicknell** worries about increasing the time trainees spend away from the operating theatre, where they learn their craft

Morton Dion professor of surgery, Academic Department of Surgery, University Hospitals Birmingham NHS Foundation Trust, Birmingham, B15 2TH, UK **dion.morton@uhb.nhs.uk**

YES

Clinical trials in surgery are sometimes perceived as a luxury—difficult to perform, rarely informative, and certainly activities that should be restricted to academia. Despite challenges, the benefits that surgical trials bring can be substantial, enabling safe and controlled evaluation and dissemination of new techniques and technologies.

The rapid proliferation of new technologies is increasing the demand for research, and many clinicians will be needed to run these clinical trials, way more than the number in academic units. Surgical trainees, the next generation of consultants, will have been failed by their trainers if they are not competent and confident clinical researchers. Without specific training, there is little chance that they will be capable or willing to undertake challenging clinical trials as consultants.

Building a surgical evidence base

Without a sound evidence base, surgical practice will evolve in a sporadic and haphazard fashion. Clinical trials seek to consider important patient centred questions. Surgical studies have the additional benefit, beyond that of drug trials, of disseminating best technical practice. For example, in the development of laparoscopic surgery for colorectal cancer, three international trials on two continents[1-3] showed safety and efficacy, disseminated the technique, and led directly to the funding and development of national training schemes.[4] A similar process is now under way in robotic surgery.[5] This is what patients expect and what we must therefore deliver by equipping new surgeons with the skills they need.

Surgical care extends well beyond the operating theatre. Surgeons have a key role in selecting patients and care after operations. Advances in perioperative care developed in the past decade, including optimisation before operations and better recovery,[6 7] have been translated into routine clinical practice. Multinational studies showed the value of these developments and encouraged clinicians and funders to develop their own local care pathways.

Complex trials in surgical care need the involvement of multidisciplinary teams of surgeons, anaesthetists, pain specialists, and intensivists as well as nurse specialists and primary care physicians. In future, many thousands of patients will need to be entered into carefully monitored studies, requiring close collaboration between different specialties and engagement of trial methodologists to en-

TINO SORIANO/NATIONAL GEOGRAPHIC/ALAMY

Colin D Bicknell clinical senior lecturer and honorary consultant vascular surgeon, Imperial College London, London, UK **colin.bicknell@imperial.ac.uk**

NO

The premise of this question is that all surgical trainees might benefit from taking part in a clinical trial. Although at first glance this would seem to be a laudable training goal, there are several considerations.

First and foremost is that of balancing the needs of the trainee. Surgery is a craft specialty, and training in the technical and team skills needed to provide the best quality surgical outcomes and lead a theatre team must be the primary aim of training.

We risk a landslide

With the European Working Time Directive, the new contract in the United Kingdom, and rising public expectations, the time available to surgical trainees to learn their craft in theatre is being eroded, and we risk a landslide.[15] The numbers of litigation cases, suspensions, and complaints are rising, especially for surgeons who have just started independent practice. Trainees are kept awake at night worrying about getting the top clamp on a ruptured aneurysm or whether they will miss the first anastomotic leak or whether the total hip replacement will loosen. They are not concerned with whether they have contributed to a clinical trial.

Surgery is becoming ever more complex. It is paradoxical that, as the number of techniques, team processes, tools, and equipment needed to provide accepted standards of care in 2015 rises exponentially, the time allocated to teaching them falls. The development of minimally invasive practice in all subdisciplines of surgery, whether it be endoscopic, laparoscopic, robotic, or similar, has vastly increased the number of patients who can be treated safely, with less morbidity and mortality than with open repair. This, however, is true only if these procedures are performed by well trained surgeons and their multidisciplinary teams. Rather than reducing trainees' chances to gain these unique skills we need to find ways to increase exposure to their craft.

The aim of training, we must all agree, is not one dimensional. An ability to critically read and

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sure these complex questions are considered in an effective manner.

The Royal College of Surgeons of England (RCS) and the National Institute of Academic Anaesthesia are already working closely to develop these multidisciplinary research teams.[8] Translation of these developments for the benefit of patients will require the participation of hundreds of specialist units. The leaders of these clinical units (consultants) will need to have been trained.

Advances in surgical care

The past two decades have seen common procedures transformed by minimal access techniques, robotics, and surgery guided by imaging; all of these require careful, controlled evaluation before their safe introduction. An even greater advance in care may be seen at the interface between novel targeted therapies for chronic disease and traditional surgical treatments. The introduction of these therapies will necessarily change the role, and in some cases reduce the size and scope, of surgical interventions for many common conditions, from cancer[9 10] to inflammatory bowel disease and degenerative joint disease.

It is difficult to see how such substantial changes will be implemented without clinical trials and the wide engagement of the surgical community. We would not countenance a new drug being introduced without formal assessment within a multicentre trial. The same standards should be applied in surgery.

One consistent criticism of surgical trials is the protracted time to completion, with results seeming outdated. This is probably overstated because, more often than not, doing the trial has overseen the safe and effective dissemination of the new intervention. New institutions, such as the UK National Institute for Health Research, have started to change this landscape by enabling large multicentre trials to be established and recruited to quickly. In addition, as we develop better routine data sets,[11] many studies will be conducted from within large population based cohorts, simplifying recruitment and improving generalisability.

Audit isn't enough

Surgery has tended to focus on audit as a way of evaluating and maintaining standards. As a method of verifying minimum standards of care this is essential, but audit is not designed to safely develop and introduce new treatment pathways or operations. Clinical audit is designed to eradicate poor practice, but clinical research is essential to determine and disseminate best practice.

To their credit, surgical trainees have themselves already recognised the importance of clinical research to patients. In the past five years, trainee research collaboratives have sprung up nationwide, and the United Kingdom can rightly consider itself world leading in this arena.[12]

Major multicentre trials led by trainees are already influencing clinical practice.[13 14] Trainers are responding to this. The RCS has proposed clinical research as a central activity of any consultant surgeon; UK orthopaedic surgeons have introduced mandatory trainee participation in multicentre clinical trials; and at least one regional deanery (West Midlands) has introduced mandatory training for core surgical trainees. The consultants of tomorrow are already voting with their feet.

Surgeons are under increasing time pressures to complete training, and any addition to the curriculum must be considered in this context. Participation in clinical research provides the tools for continued education throughout a consultant's career and should be seen as essential to continued professional development.

appraise clinical research is indeed mandatory.[16] This should be taught and examined, but this does not mandate involvement in a clinical trial.

Useful skills can be learnt elsewhere

Trainees would learn useful skills during their involvement in trials—ethics, good clinical practice, consent processes, recruitment, reporting, and governance all spring to mind. To say that participation should be compulsory, however, we would have to provide effective training in these domains by ensuring the quality of trial methodology and prove that these skills could not be learnt as effectively elsewhere.

If there were time out of the clinical arena to participate in clinical trials, we would need to be sure that this is high quality training. We need to define what we mean by clinical trial in this context. The World Health Organization defines clinical trials precisely, stating, "For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc."[17]

It places no restrictions on quality, type, or size of these trials. Pertinent questions arise from this. Who would quality control the standard of trial needed? Is a 20 patient randomised trial enough? Without proper governance the standard of trials in which trainees are included will vary considerably, likely perpetuating the common assumption that surgeons can't do effective trials, and failing to teach trainees the rigour required for high quality, reliable research. Although it could be argued that a trainee surgeon's involvement in trials will advance the evidence base for new procedures or techniques, and that these trials will disseminate best practice, it is more likely that such involvement will generate a host of poorly run trials.

Trials aren't the only research

It seems a tall order to expect the trainee to be involved in all stages of a well conducted trial. There are not enough high quality clinical trials for all surgical trainees to be part of the study management team. In all likelihood the trainee will join a multicentre trial that is already set up at their site, recruit a few patients, and leave the site again before the reporting phase. Insistence on involvement may not always turn out in favour of the trainee.

Lastly, we must ask whether involvement in a trial is the only way to teach the skills that are required. The problem and limits of clinical trials in surgery have long been known: non-blinded studies, poorly defined control groups, highly selected patient groups, and conscious and unconscious bias cast doubt over many trials.[18] Equally important could be participation in a registry based study or similar large scale research that may teach the same skills; surgery often most effectively learns from other methods of investigation.[19]

Asking all surgical trainees to be involved in a clinical trial would mean they learn vital skills and would encourage best practice, but it will take the trainee further away from the operating theatre. These non-clinical skills can be learnt elsewhere or later, and we should not be fixated on trainee involvement in clinical trials that may well vary in quality.

Competing interests: Both authors have read and understood BMJ policy on declaration of interests and declare the following interests: MD is director of clinical research at the RCS England.

Provenance and peer review: Commissioned; not externally peer reviewed.

References are in the version on themj.com.

Cite this as: *BMJ* 2014;350:h2045