Future of Surgery Workshop 1 Report

“Trials are only as credible as their endpoints”: Defining the future outcomes of surgical research

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On Wednesday 4 May the first of five Future of Surgery workshops took place, led by Mr Angus McNair, University of Bristol, and hosted by the Royal College of Surgeons of England. NCRI has launched the Future of Surgery workshop series to bring together experts to deal with challenging, cross-specialty topics and influence the future of surgery research in cancer. The series takes up actions identified in the 2012 NCRI Report "Challenges and opportunities in surgical cancer research in the UK", in order to support and develop surgical research in the UK.

Each workshop will take the form of an expert working meeting, drawing on the expertise of all those attending to inform and advance surgery research in cancer. The first workshop, on outcome measures in surgery studies, involved a diverse group of surgeons, consumers[1], clinical academics and methodologists, representing a range of cancer sites and disciplines.

Around 80 delegates discussed challenges and opportunities in surgical research between short talks on exemplar studies and methodology (see agenda). The participants shared their expertise and identified gaps in knowledge on outcome measures in surgery studies.

The workshop discussion built consensus on themes around selecting, measuring and reporting outcomes, which will be used to set the research agenda for surgical trials and to improve the quality of future surgical randomised controlled trials (RCTs). The themes highlighted as important to pursue are as follows.

PROMs and patients

Patient Reported Outcome Measures (PROMs) were the focus of the first group discussion, after hearing from methodologist Kristian Brock, University of Bristol, and Terry Jones, University of Liverpool, who spoke about the PATHOS trial. Simon Bach, University of Birmingham, chaired a discussion which centred on maximising consumer involvement in outcome selection and measurement.

There is work to be done on developing and validating meaningful PROMs. During the workshop, it was recommended that core outcome sets in surgical cancer trials should include PROMs, building on the COMET initiative.

There was a strong consumer voice in the discussion around how to define minimally important differences, and on the future of involving consumers: it was noted that the FDA now requires consumer involvement for PROMs development.

Pilot and Feasibility studies

Pilot and feasibility (P&F) work is key for surgical trials. Adele Francis, University Hospital Birmingham, spoke about the LORIS trial, and Jane Blazeby, University of Bristol, on Pilot and Feasibility trials (e.g. ROMIO and Bluebelle respectively). The speakers argued that the difficulty of recruitment for surgical trials is often addressed through P&F studies. Furthermore, in pilot studies it is possible to model outcome selection and measurement in preparation for the main trial. Pilots can even provide the opportunity for surgeons to improve their skills, for example if the surgery is filmed. Which raises the issue of Quality Assurance.

[1] Patients, carers and others affected by cancer

Surgical Quality Assurance (QA)

From the floor, the fact that QA is not about the 'best' surgeon was raised. It was stated that QA is rather about clear protocols for surgical intervention which are consistently adhered to, so that the variance of surgical outcomes can be measured, therefore selection of those outcomes is key. But how surgeons' learning curve should be addressed is a topic for further thought. Pilots may give the opportunity for surgeons to improve but there is more work needed on defining QA outcomes.

Early phase trials

In comparing early phase surgical trials with those of drug trials, process outcomes are particularly important – unlike drug trials, there is not a systematic path for evaluation of surgical interventions. If the purpose of a Phase I drug trial is safety, should minimum safety concerns be addressed in Phase I trials in all sectors, including surgery? Or should costs and training also be addressed at this stage?

Conclusion and next steps

The delegates identified challenges and priorities for future areas of research in selecting, measuring and reporting surgical outcomes, to improve surgical RCTs. An aim of the workshop had been to develop consensus for guidelines on selecting and measuring meaningful outcomes for surgical trials. From the workshop discussion, it was clear that more work needs to be done in defining surgical outcomes research before a set of guidelines can be produced.

1. As a result of the workshop, the above themes – PROMS, P&F studies, QA and early phase trials – were agreed as key areas for future research.
2. **The key recommendation was that work on QA should be scoped with a view to formulate a programme on QA to ensure outcomes from surgical research are defined, and ultimately to produce guidelines.**
3. It was recommended that core outcome sets in surgical cancer trials should include PROMs.
4. The group recommended that the Future of Surgery steering committee's networks take this research agenda forward through education, networking events and engaging surgeons who were not at the workshop.
5. Delegates will present on the research agenda for surgical outcomes at key conferences in the coming year, and will recommend that research efforts are focused in these areas to improve the quality of future surgical RCTs.
6. Delegates will publish journal articles building on this workshop topic, and defining a research agenda for outcomes of surgical RCTs.

The NCRI will be linking these recommendations with those from the other Future of Surgery workshops.

For more on the Future of Surgery visit the NCRI website: www.ncri.org.uk/initiatives/surgery

» See presenters' slides from the workshop

Please email Victoria Murphy with any queries or to find out more about future work in this area.