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Improving early phase surgical studies to inform main trials and evidence-based practice

It's unusual for innovations in surgery to be introduced in a phased, controlled way. It's difficult to design studies of changing, complex surgical techniques. Selecting something appropriate to compare with the innovation is often challenging, particularly when a placebo (where a fake treatment is used) is needed.

What translational research was done?

We developed methods to improve early phase studies of new surgical techniques, to inform the design and running of main trials.

With international colleagues, we designed and updated the IDEAL framework[1] and produced guidance for pilot studies and trials using placebos[2]. We also contributed to a new framework for developing and evaluating complex healthcare interventions, updating MRC guidance to be relevant to surgery[3].

We developed systems for designing surgical and placebo treatments in trials, and new methods for undertaking research in the operating theatre.

We piloted our new system to breakdown and classify the steps in complex surgical procedures and applied it to studies evaluating innovative procedures.

Using digital imaging we extended this work to develop ways to check whether surgeons adhere to the surgical technique being evaluated. We tested this in an IDEAL phase 2 study of novel surgery for oesophagus cancer.

We piloted our new methods for undertaking research in the operating theatre in a study of a novel device to assist birth, and identified important design and technique features to optimise the device's use.

Translation into later phase research, clinical practice and patient benefit

Our novel methods are being used by surgeon innovators and **12 trials** have been funded using our system for designing surgical interventions.

Working with surgeon innovators, we led studies in minimally invasive lung and oesophagus cancer surgery, novel weight loss surgery and gallbladder surgery.

We also supported studies in new treatments for Dupuytren's disease and appendix removal in children.

Our NIHR ROMIO study in oesophagus cancer surgery is the **world's largest trial in this field**. The embedded IDEAL phase 2 study of totally minimally invasive surgery is the **first of its kind**.

Our pioneering work allows surgical innovators to conduct high quality trials of new procedures informed by earlier pilot work. This leads to evidence which informs better, safer patient care, shared decision-making and effective health policies.

References

1. Hirst et al., Ann Surg, 2019;DOI:10.1097/SLA.0000000000002794
2. Beard et al., Lancet, 2020;DOI:10.1016/S0140-6736(19)33137-X
3. Skivington et al., BMJ, 2021;DOI:10.1136/bmj.n2061