

# DEVELOPING SURGICAL RESEARCH IN THE MODERN NHS: A CALL TO ARMS

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Change is an everyday occurrence in the modern NHS and many new initiatives apparently conspire to make the surgeon's life ever more difficult. Many surgeons wish to take part in clinical research but either do not know how to get involved or lack support. This article describes recent developments that promise to make the participation of surgeons in clinical research easier.

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## Abbreviations and jargon

A government white paper entitled, *Best Research for Best Health*, signalled a change in the research culture of the NHS.<sup>1</sup> The paper outlined the strategy for the further development of the UK Clinical Research Network (UKCRN) that is made up of four groups, one for each of the devolved nations (Figure 1). In order to facilitate the development of a research culture within the NHS, the Department of Health in England established the National Institute for Health Research (NIHR) with a budget of around £1 billion per annum.

The NIHR Clinical Research Network (NIHR CRN) is the network for England and is made up of six topic-specific CRNs

(cancer, stroke, diabetes, medicine for children, dementia and neurodegenerative diseases, and mental health), a primary care research network and a comprehensive clinical research network (CCRN). The CCRN covers all areas of clinical research not covered by the other NIHR networks. Expertise in the various topics that fall within the remit of the CCRN is captured through 26 national specialty groups, of which surgery is one. Gastroenterology, cardiovascular disease, and injuries and emergency care are other examples.

The NIHR CCRN covers the whole of England and comprises 25 comprehensive local research networks (CLRNs), some of which have identified surgery as a

**FIGURE 1**

THE PLACE OF SURGERY IN THE UK CRN

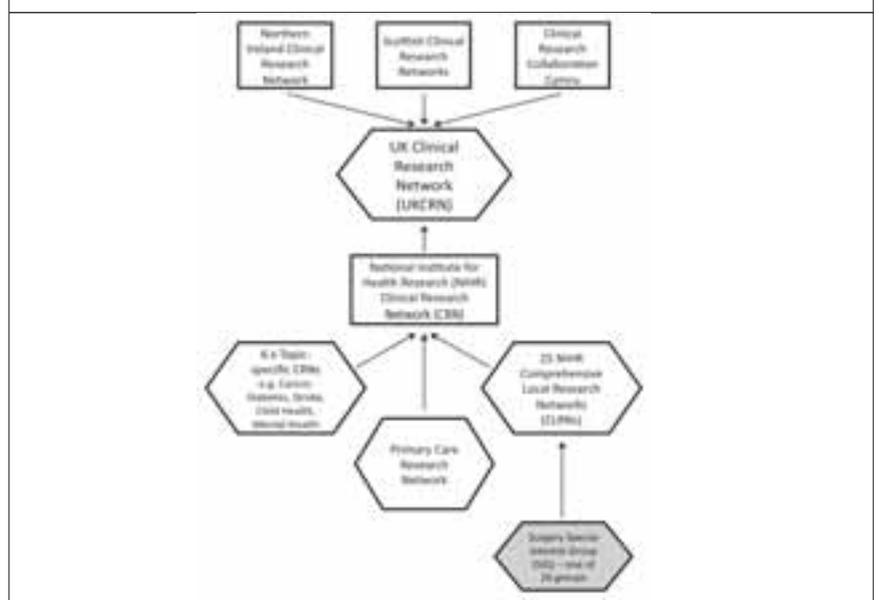


FIGURE 2

SURGERY SPECIALTY GROUP MEMBERSHIP WITH LOCAL LEADS (MARCH 2010)



priority area and have designated a local research lead for surgery (Figure 2). The local leads are members of the national surgery specialty group that facilitates recruitment to the trials in our portfolio.

The CLRNs provide service support elements (eg pharmacy and radiology) of funded research projects. This includes the provision of research nurses and other health professionals to facilitate recruitment, follow-up and completion of trial documentation. The CLRNs can also remunerate investigators for dedicated research time. In order to qualify for support from your local CLRN a research study must be 'adopted' on to the NIHR CRN portfolio. The portfolio can be accessed and searched online through the NIHR portal (<http://public.ukcrn.org.uk/search/>).

Academic studies and trials funded by NIHR partner organisations are automatically eligible for adoption on to the NIHR CRN portfolio and then become eligible for CLRN support. Partner organisations are those that allocate research grants in open national competition, have high-quality peer-review processes and fund research that is of direct relevance to the NHS.

Partner organisations include the Medical Research Council, Cancer Research UK, the Wellcome Trust and the British Heart Foundation. The NIHR is also funding a number of studies through several new schemes including the Research for Patient Benefit grants as well as schemes that predate the NIHR, such as the health technology assessment programme. Industry-led studies that have not yet commenced are also eligible for the

NIHR portfolio and, if successful, will qualify for CLRN support. Information on this process can be obtained from the NIHR CRN coordinating centre's website (<http://www.ukcrn.org.uk/index.html>).

### A new beginning for surgery

Not every CLRN has a local research lead for surgery but the national specialty groups are working hard to provide national coverage. It is a decision for each CLRN whether to have a research lead in a particular specialty. Whether or not you have a surgical lead in your CLRN, you are still entitled to access research support if you are involved in a portfolio study. If a study interests you and you want to participate, you should contact your local CLRN lead or national specialty group chair.

The CCRN can help surgeons with the following:

- > bureaucracy through access to research management and governance staff;
- > provision of a research nurse (or a share thereof); and
- > CLRN support proportionate to the number of studies in which you participate.

Participation in NIHR CRN portfolio studies looks good on Career Enhancement Award applications. As surgeons we must engage in this process as it provides an unparalleled opportunity for NHS surgeons to take an interest in developing their specialty and to help their patients by developing and participating in the evaluation of new treatments.

### Problems and solutions

Surgery is one of 26 specialty groups in the CCRN and has the remit to deliver surgical research. Each specialty group has a portfolio of studies: the surgery portfolio is particularly weak for a number of reasons. These reasons and possible solutions are outlined below:

- > Many surgical trials are cancer-based and therefore appear in the National Cancer Research Network portfolio.
- > Surgery is often an intervention that forms part of a patient's treatment and many studies that involve surgical input are being led by the disease-specific

specialty groups, such as the cardiovascular and gastroenterology groups, both of which have large portfolios of trials.

Co-adoption of studies on to the surgery portfolio is now being used to resolve both these issues and to provide a comprehensive picture of the research activity in which surgeons are involved.

- > Surgery is a complex intervention, far removed from a simple drug trial of drug A vs drug B. Surgical trials, therefore, require careful design but this can be resolved with appropriate advice and specialist help from one of the large clinical trials centres or one of the regional research design services.
- > Surgeons often have difficulty with the concept of 'equipoise', which is necessary to allow randomisation between two surgical treatments. The evidence base and clinical trials centre running the trial will be able to assist in this.
- > Surgeons are busy seeing urgent cases, meeting cancer targets, etc.

Many surgeons would like to recruit patients into trials but simply do not have the time. This is being addressed by providing dedicated research nurses supported by the local CLRN to recruit patients into surgical trials. These nurses should be able to take on much of the paperwork for trial participation and follow-up. Many surgeons are not trained in Good Clinical Practice (GCP) to the standard required by Pharma Consult and based on the Helsinki agreement. Increasingly doctors recruiting patients into clinical trials will be required to have received GCP training. The NIHR is looking at ways of providing this training to large numbers of surgeons at once, for example by tagging on an additional session at national surgical meetings, which will lead to GCP certification.

The NIHR is very keen to look at blocks to recruitment and surgical research is no exception. The CLRNs have systems in place for streamlining the approvals process to facilitate the rapid start-up of clinical trials, such as the Coordinated System for Gaining NHS Permissions. The research passport scheme allows researchers to use their ethics and research and development approvals (gained in their own institutions) in other institutions thereby facilitating multicentre data collection.

### The future

The expansion of the response mode and commissioned funding streams from the NIHR has already started to generate new surgical trials. The Human Tissue Authority scheme has recently funded two major trials in colorectal surgery, which have ambitious recruitment targets: FIAT 500, a trial of the anal fistula plug; and a trial of stapled versus conventional haemorrhoidectomy.

The NIHR is sympathetic to the difficulties of recruiting to surgical trials and have shown a willingness to help by funding up to 30 part-time research nurses specifically to work in surgical clinics to assist in recruiting patients to clinical trials.

A good example of how CLRN resources can be used to help recruitment to a surgical trial is outlined in a paper by Carr *et al.*<sup>2</sup> which highlights the use of CLRN resources to increase recruitment to a multicentre trial of treatment for rotator cuff tears in 58 centres and involving over 100 surgeons. Sites supported by their local CLRN recruited patients to the trial at almost double the rate at unsupported sites. The authors are hoping that a similar level of assistance from local CLRNs can facilitate recruitment to the anal fistula plug trial, among others.

Although much of the above focuses on recruitment to clinical trials, the NIHR is acutely aware that methodologies other than randomised clinical trials may be appropriate for evaluating new surgical technologies and NIHR is willing to facilitate discussions between individuals or groups of surgeons and commercial partners or trials centres to obtain suitable alternatives for evaluating new technologies.

### Conclusions

Surgeons are by nature investigators but surgery is a multi-faceted intervention that does not fit easily into the clinical trials category. This has put many surgeons off recruiting patients into clinical trials. However, the development of the CLRNs and the new appetite for research in the NHS means that there is now a fresh impetus to encourage surgeons to recruit to clinical trials. This provides a new opportunity for interested surgeons to recruit patients to an expanding portfolio of existing clinical trials led by surgeons and also allows surgeons to bid for a new pot of money that may allow them to become principal investigators in their own right.

**Interested readers can find out more about the surgery specialty group's research portfolio by logging on to the NIHR CRN coordinating centre's web pages at [http://www.ukcrn.org.uk/index/networks/comprehensive/spec\\_groups.html](http://www.ukcrn.org.uk/index/networks/comprehensive/spec_groups.html).**

### References

1. Department of Health Research and Development Directorate, Department of Health. *Best Research for Best Health – A New national health research strategy*. London: DH; January 2006.
2. Carr A, Cooper C. The UKUFF trial and the NIHR comprehensive local research networks. *Shoulder & Elbow* 2009; 1: 63–64.