Undertaking Research in Paediatric Anaesthesia

The current requirements and legislation governing research in paediatrics has presented challenges for clinicians wishing to undertake research projects. This is a particular hurdle to those trainees or new consultants approaching this for the first time. This short article aims to give a brief framework provide links to important reference websites and suggest contacts that may be of help. The key elements to undertake adequately governed and funded research are:

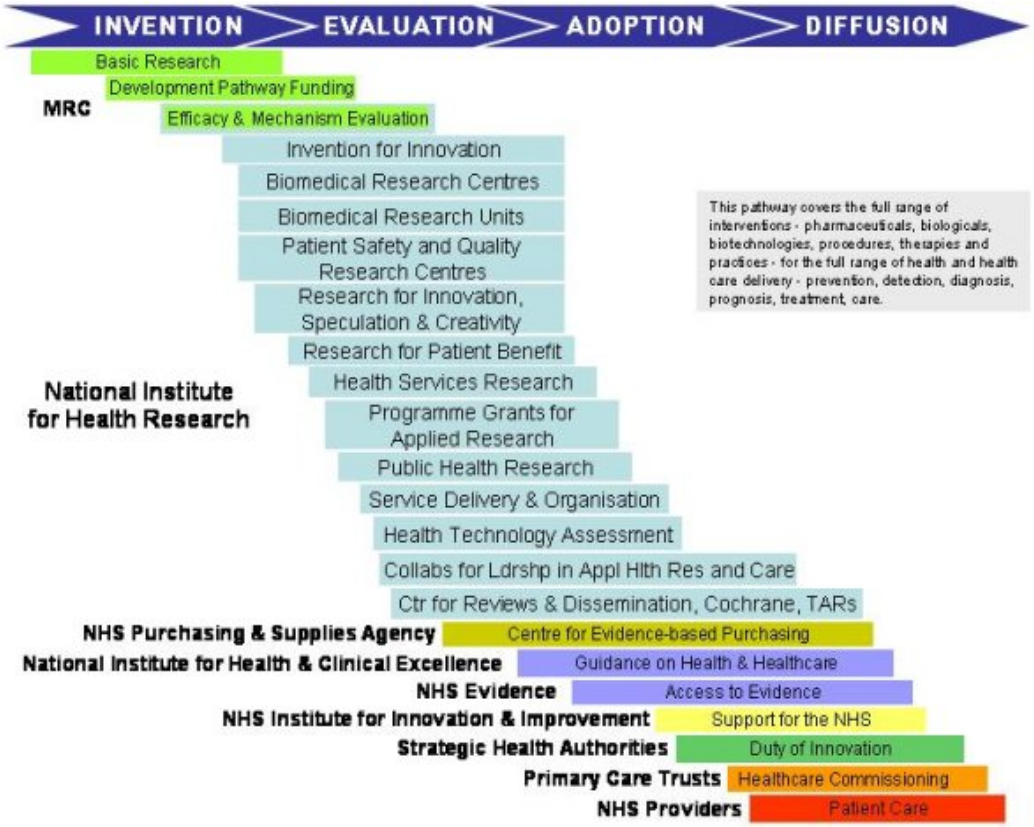
1. Understanding the current UK Research Infrastructure and the researchers obligations to undertake research (for example mandatory training in good clinical practice; see http://www.crncc.nihr.ac.uk/index/training/gcp.html)
2. Developing a good idea that can then lead to a research study. This could be a descriptive study (collecting data in a particular setting), a retrospective cohort study or may involve a prospective trial of equipment or drugs.
3. Understanding the legislative "hoops" required to allow research to take place. Such as ethics permissions, local research and development approvals and issues relating to the studies of drugs and the role of the Medicines and Healthcare products Regulatory Agency (MHRA)
4. Finding where you can get help with your project via groups such as the National Institute for Academic Anaesthesia, the Medicines for Children Research Network Clinical Studies Group (MCRN CSG) etc.
5. Knowing how to apply for Grant funding

Each of these individual steps can be daunting, but money is available for good research and with adequate mentorship good clinical research is feasible even to those approaching this for the first time. This brief article is not comprehensive, but is an overview that will assist in understanding the overall steps that need to be undertaken. It also gives some references to the organisations that help to support the research

1. Research Infrastructure

In the last few years, medicine based research has been centralised with a view to produce coordinated efforts on important themes that will improve patient care and provide value for the research investment. A central body, the National Institute for Health Research (NIHR) coordinates this care from basic science through to patient care (fig 1). The link to their website is:http://www.nihr.ac.uk

The NIHR has set up Biomedical Research Units and Biomedical Research Centres that have funds available to drive translational (from lab to patient) research which in turn is supported by other grant giving bodies such as the Wellcome Institute and other Charitable Institutions; whereas some sections of the Wellcome Institute Medical Research Council (MRC) and others fund basic science research. The NIHR also commissions clinical research and makes calls for research proposals via the Health Technology Assessment Programme (HTA) which advertises at regular intervals for Grant submissions four times each year. In addition the HTA make occasional calls for specific themed proposals. Their website is:
http://www.hta.ac.uk/funding/index.shtml



Within the NIHR infrastructure are the Clinical Research Networks that aim to further co-ordinate the research efforts. Key networks that interface with paediatric anaesthesia are:
The Medicines for Children Research Network (MCRN)
The CRN Anaesthesia Networks www.ukcrn.org.uk
The Comprehensive Local Research Networks
www.ukcrn.org.uk/index/networks/comprehensive.clrns.html

2. Who can help me with the initial research idea?
The idea will need to be discussed with your colleagues or trainers. If you work within a teaching hospital with an academic department of anaesthesia, further help and advice may be obtained here. Contacting the local research network and talking to your local Research and Development Department will be of help in preparing the Research protocol. The APA Scientific Committee will also be happy to give advice on suggested research proposals. In the future, we hope to be able to offer more substantial support in terms of advice via a Paediatric Anaesthesia research network.

3. Legislative "Hoops"

Once a feasible protocol is in place then the key steps will include:

Funding

See below

Sponsorship of the study

The study sponsor is the organisation who will administer the study according to GCP standards, hold and distribute the grant, and be responsible for underwriting the liabilities of the trial. It is important to identify a sponsor as soon as possible as many funding bodies require that the Sponsor be identified prior to a funding application.

Trial Adoption

Adoption of the study into the NIHR portfolio is crucial to the success of the study. In order to gain access to network resources all the regulatory requirements and consents must be completed. This can be an arduous task that the appropriate network can help you with. Contacting the MCRN and getting the study discussed by the relevant experts within the MCRN CSG's or Anaesthesia network groups can help the study reach a standard whereby it can be adopted into the network. Once a trial/study has been adopted then help with the on-going regulatory tasks will be provided through the coordinating centre.

Ethical Approval/ Research and Development Approvals/ Regulatory Approvals

If your trial is a clinical trial then you will need to apply for a EudraCT number before you apply for any approvals (http://eudract.emea.europa.eu/) as this reference number needs to be quoted on the applications.

All trials require ethical approval and Research and Development (R&D) approvals before they are able to open. If the trial involves an investigational medicinal product or a medical device then you may also require approval from the MHRA. To check if you need to apply to the MHRA for a trial involving a medicine refer to the following website:
http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Isaclinicaltrialauthorisationrequired/index.htm
To check if you need to apply to the MHRA for a trial involving a medical device refer to the following link
http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm

The essential approvals that consider the ethical and regulatory aspects of the study and the impact of this work within the NHS have recently been streamlined into a combined application. The Integrated Research Application System
https://www.myresearchproject.org.uk/

The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health care research in the UK. It enables the applicant to enter the information about the project once instead of duplicating information in separate application forms. IRAS captures the information needed for the relevant approvals from the following relevant review bodies:

- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC R&D offices
- NRES/ NHS / HSC Research Ethics Committees
- National Information Governance Board (NIGB)

4. Funding

Most research requires significant grant money to enable the work to take place. In the past this might be incorporated within a departmental fund and the costs to the NHS were not adequately costed. The process of research is now carefully regulated to ensure research is undertaken with adequate funds and the administration needed to comply with good clinical practice. Help can be obtained via the local research and development office in preparing the budgetary requirements for a research proposal.

If you have a good idea that generates a research question you will eventually need some money to take it further. There is a limit to what can be achieved in your SPA time, your own time and with the resources available within the hospital. The scale of grant bodies varies as indicated. I (JHS) have used my own contacts as examples but it is likely that similar resources are available in your hospital / University.

Local:

1. Speciality related charitable funds. These are usually administered at Trust level. The funds are usually small and the trustees will be chaired or advised by a colleague. This has the advantage that you can take informal soundings as to the likelihood of your request being successful and perhaps the amount of money you might get. The trustees might want you to have ethics approval in place before the money is released. Usually < £10,000 but might be more.
   http://www.newcastle-hospitals.org.uk/services/14461.aspx

2. Hospital / University held charitable funds. These are administered at Trust level but will usually be chaired by some one with a research interest; they may have both university and Trust people on the board and be more distant from you than the first group. The assessment will be more stringent, the application more testing but one could get up to £50,000 from this source. Ethics would be expected and this group, in Newcastle, meets twice a year. http://www.newcastle-hospitals.org.uk/patient-guides/charity-matters_applications-for-research-grants.aspx

3. Locally administered NIHR funds, Research Capability Funding (previously termed flexibility and sustainability grants). These locally administered funds are usually obtained via application to the research office of your organisation. They are advertised three times each year and are directed at allowing clinical researchers to devote more time to research, in the hope that they may make sufficient headway to allow them to apply for larger grants from national bodies. Up to £50,000 or more can be obtained, the application is usually brief and the turnaround time is s relatively quick.
   http://www.nihr.ac.uk/infrastructure/Pages/research_capability_funding.aspx

National grants:

1. NIAA (http://www.niaa.org.uk/NIAA_home). The national institute of academic anaesthesia provides grants in two rounds each year. As well as being a potential source of funding, is also a major resource for linking an idea through the regional network system The National Institute for Academic Anaesthesia (NIAA) has been awarded Partnership status by the NIHR. This means that many studies funded by the NIAA Research Council grants are adopted onto the NIHR portfolio and are eligible for support from the NIHR Comprehensive Local Research Networks. The application process is more detailed than those listed above but not exhausting, from application to results might take about three months. The website should be reviewed regularly for new calls and some of the smaller grants are open at the time of writing.
2. NIHR (http://www.nihr.ac.uk/Pages/default.aspx) This funds the Medicine for Children Research Network and believes it has contributed to the expansion of research in paediatrics in recent years. The headings for the main programmes are Programme grants for applied research (you can only qualify for one of these with a good track record in research), Research for patient benefit, i4i (device innovation) and the Health Technology Assessment programme. Complicated applications, some specifically themed with a longer turnaround time. You will need help in applying for these from your University, Trust Finance and your local research development office. Getting a research experienced person to referee your application pre- submission

may also be useful. They may award large amounts and would expect to the recipients to be collaborative groups with a good deal of research experience. A track record in the subject that you are applying for would be very helpful.

3. EPSRC (http://www.epsrc.ac.uk/Pages/default.aspx) Highly competitive and usually science or engineering projects but can make calls for innovative engineering solutions to clinical problems. All the help specified above will be required. Has begun to ask for pre-submissions for vetting and then invite full applications and this may save some time and effort.

Charitable Funds (both local and national i.e. British Heart Foundation (http://www.bhf.org.uk/), Action Research (http://www.action.org.uk/our_research/latest_research), SPARKS (http://www.sparks.org.uk/research/)

Useful Links:

General Medical Council Research Guidance
http://www.gmc-uk.org/guidance/research_guidance

NIHR Evaluation, Trials and Studies Coordinating Centre
http://www.netscc.ac.uk/

NIHR Health Technology Assessment Programme
http://.hta.ac.uk/

National Institute for Academic Anaesthesia
http://www.niaa.org.uk/

NIHR Medicines for Children Research Network
www.mcrn.org.uk

National Research Ethics Service
http://www.nres.nhs.uk/

Clinical Trials Toolkit
www.ct-toolkit.ac.uk

The Medicines for Human Use (Clinical Trials) Regulations 2004
http://www.uk-legislation.hmso.gov.uk/si/si2004/20041031.htm

Andy Wolf, Jon H Smith
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