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Improving recruitment in neonatal research trials — A practical guide

K. Willoughby, Clinical Trial Manager[a,c,*], J. May, Clinical Research Nurse[c,d], A. Curley, Consultant Neonatologist[b,c]

[a] *University of Cambridge, Cambridge, United Kingdom*
[b] *National Maternity Hospital, Dublin, Ireland*
[c] *UK NHS Blood and Transplant (NHSBT), United Kingdom*
[d] *Neonatal Unit, Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Cambridge, United Kingdom*

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Abstract Clinical research brings potential benefits to patients in the form of improved treatments and therapies. Using evidence to challenge existing practice will make current methods of working safer and more effective. The NHS Constitution pledges to inform patients of relevant clinical trials in which they may participate and it appears that the overwhelming majority of the population would like to be so informed. However, there are many challenges to running successful programmes of clinical research. The role of the Clinical Research Nurse (CRN) is crucial to delivering successful clinical research studies, but very often these specialist nurses work in isolation making sharing of ideas difficult.

In this paper we examine practical ways in which research staff can improve recruitment to studies and overcome some of the barriers to success.

Introduction

In 2006 clinical research came to the forefront of the NHS agenda when the Labour government invested money through the Department of Health to establish the National Institute of Health Research (NIHR). This institute was designed to combat barriers to effective research and allow faster transition of the findings from the laboratory to the clinical setting. Not only could this potentially result in new treatments, but it might be possible to demonstrate that existing practice could be

* Corresponding author. University of Cambridge, Cambridge, United Kingdom.
E-mail address: kw369@medschl.cam.ac.uk (K. Willoughby).

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undertaken more effectively and safely. The results of clinical research could then influence policy in an informed way and new successful developments in the life sciences industry might potentially boost employment in this area. The patient would ultimately benefit from new developments in translational cutting edge work. By ensuring that existing clinical practice was founded on evidence based research the safety, efficiency and effectiveness of treatments would be improved.

The potential benefits to patients were again reinforced by the inclusion of research in the NHS Constitution (legally underpinned by The Health Act 2009) which stated that there was also a duty to 'promote research on matters relevant to the health service, and the use in the health service of evidence obtained from research'. The Constitution goes further to state that "The NHS commits to inform you of research studies in which you may be eligible to participate."

It appears that the public agreed with the policy makers on this occasion as according to a poll conducted by Ipsos Mori in 2011 (Ipsos MORI), 97% of the public believe it is important for the NHS to support research into new treatments, 93% want their local NHS to be encouraged or required to support research and 72% would like to be offered opportunities to be involved in trials of new medicines or treatments, if they suffered from a health condition that affects their day-to-day life.

If clinical research is central to the NHS, then the cornerstone is the clinical research nurse (CRN). The success or failure of many trials rests almost entirely with research staff and clinical engagement. In the setting of neonatal research the role of the CRN is vital. We present our experience of running an international multicentre neonatal randomised controlled trial and the lessons that we have learnt and applied to improve recruitment, communication and data collection. Many of these advances are shared learning points garnered from our research nurses in over 40 centres. We would like to share our common experience in order to promote and develop research within a UK setting so that the true aim of the NHS constitution can be achieved.

Developing a blueprint for successful research

Let people visiting your unit know that you value research

It is important to consider who you are trying to deliver this message to. The aim is to inform people and raise interest and awareness about research. In our experience units that are unapologetic about their involvement in clinical research are generally better recruiting sites. As clinicians we need to be able to talk openly and honestly to patients and relatives about research. Morley et al. (2005) demonstrated for example, that in a neonatal setting, parents like to be given the choice whether or not to allow their baby to participate in a trial. Even if parents refuse consent the decision should be theirs and not a clinician adopting a paternalistic view.

Involve parents locally in the design of studies

In the early stages of developing a protocol it is essential to involve parent/patient representatives when designing material aimed at getting their involvement. What is clear to clinicians may not be quite so clear to the lay person. To help improve communication between researchers/clinicians and the public, the NIHR Clinical Research Network is developing a Patient Research Ambassador (PRA) Initiative. The aim of the PRA is to further embed research within healthcare by giving a more patient centred perspective. PRAs can be involved in a number of activities from checking literature aimed at public engagement in research to being actively involved in training days. More information about Patient Ambassadors can be found at: nihr.ac.uk/involvement4access/home/patient-research-ambassadors.

Local Clinical Research Networks are currently working on embedding PRAs within Trusts.

The power of marketing

There is considerable variation in the use of promotional material for research in the NICU. All posters/leaflets and other materials that are available for non-staff to view must have ethics approval. The NIHR have developed generic leaflets such as 'Understanding Clinical Trials' which are useful for parents/caregivers and staff. The pamphlets are written in a clear and concise manner (awarded a 'Crystal Mark' by the Plain English Campaign) and provide a good starting point for discussions surrounding research (nihrcrn). Position the information where parents can easily access it. This allows parents to read at a time when they are more able to take in information rather than seeing it for the first time at a time of acute stress.