Processes in recruitment to randomised controlled trials of medicines for children (RECRUIT): a qualitative study

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Executive summary

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Executive summary

Background

Recruiting children to clinical trials is reported to be difficult. Interventions to optimise recruitment and its conduct must be consistent with the values of families and the perspectives of practitioners. Existing evidence has focused on parents' understanding of trial information to ensure informed consent. While relevant, such research does not address what parents and practitioners consider important about the way that trial recruitment is conducted. Existing evidence also lacks cohesion because it neglects or provides limited coverage regarding:

- Convergences and divergences between (1) the perspectives of the three stakeholder groups – young people, parents and practitioners; (2) the experience of trial recruitment and the actual conduct of trial discussions; and (3) the views of those who participate in a trial and those who do not.
- The experiences of (1) families making decisions about entering a real trial rather than a hypothetical one and (2) trials outside oncology and neonatology.

Objectives

This study investigated recruitment processes across a range of trials and from the perspective of the three stakeholder groups to identify strategies to improve recruitment and its conduct across the spectrum of trials of medicines for children.

Specifically, the objectives were to:

- describe how recruitment consultations (trial discussions) between families and trial recruiters (practitioners) are conducted and how information about trials is exchanged during these encounters
- describe, from the perspective of families, the experience of trial recruitment and the communication needs and other priorities that are served or thwarted by recruitment consultations
- describe, from the perspective of trial recruiters, the goals of recruitment consultations, the functions of these goals, how they interface with the conduct of the consultation and families' communication needs, and other priorities.

Methods

This qualitative interview and observational study [processes in recruitment to randomised controlled trials of medicines for children – RECRUIT] ran alongside four diverse trials of medicines for children. RECRUIT data were verbatim transcripts of (1) audio-recorded trial recruitment discussions between practitioners and families ($n = 41$) and (2) semi-structured interviews exploring the experience of trial recruitment from the perspective of the three groups, parents (62 individuals from 60 families), young people ($n = 22$) and recruiting practitioners (19 doctors and 12 research nurses). Of the 60 families, 39 were randomised and on trial,

10 declined, three were randomised but withdrew and eight were ineligible. Interpretive analyses following the general principles of the constant comparative method were combined with descriptive summaries of recorded trial discussions comprising some quantitative measures.

Results

There was a marked divergence between parents and practitioners in how they regarded the trial approach. Many practitioners viewed the approach as a burden for parents, but, even in the most difficult situations, parents did not mind being asked about trials and they did not describe the approach as burdensome. Some viewed the trial approach as a positive or exciting opportunity.

Practitioners in all specialties were concerned to avoid overburdening parents with information and strove to find a balance between providing sufficient information, while not overwhelming them. Some practitioners' accounts indicated that they found approaching families about trials to be aversive, pointing to potential negative consequences for practitioner morale and future engagement in clinical trials.

Parents and young people took little active part in the trial discussions and asked few questions. They nevertheless felt involved and were highly satisfied about how they had been approached, which centred on feeling valued, cared for and comfortable to interject during the discussion if they wanted. However, our interviews with parents identified several cases in which parents had important misunderstandings about the trial. These could stem from the ways in which practitioners communicated, particularly their tendency to use closed rather than open questions in discussing the trial with parents.

Parents sometimes viewed the trial as an opportunity to receive an otherwise unavailable medication; some were inclined to see the trial medication as offering guaranteed benefits. This could stem from the way practitioners presented the trial arms.

There were few differences between parents who consented and those who declined a trial. Regardless of whether or not they consented, parents' decisions were influenced by their perceptions of the trial in relation to their child's safety and well-being, potential benefits to the child and family, potential benefits to others and the practicality of participation. Of these, parents' paramount consideration was their perception of the trial's safety. Parents would not consent if they had doubts about safety. Parents', young people's and practitioners' views on what is important when considering a trial were broadly convergent. This indicates that practitioners are well placed to structure their explanations according to families' priorities, although families gave greater importance to the practical requirements of the trial than practitioners did. All parties valued the face-to-face discussion more highly than the participant information leaflets (PILs), and wanted shorter, and less complex, written information.

Parents did not feel pressurised by the trial team to participate, but some described how their personal values made them reluctant to decline, and several parents who did decline described a passing sense of discomfort.

Parents felt it was important to involve their child in the decision-making, but some swayed their child's deliberations if they perceived these to be taking an unwise turn. Most young people described making a decision jointly with their parents, although they often relied on their parents for guidance.

Conclusions

Parents and young people said little during trial discussions. Despite this, they described the trial discussions in strongly positive terms. The concerns of some practitioners, that families would be overburdened, were unfounded and parents did not object to being asked about research, although all groups felt that the written information on trials could be shorter and more straightforward. These findings have important implications for practitioner training, current practice in recruitment conduct and trial design.

Implications

- Some practitioners described discomfort in approaching families for research. Ongoing 'moral support' or mentoring would allow practitioners to informally discuss their concerns and receive advice and feedback. Less experienced practitioners and those working in specialties in which families are under considerable emotional strain would benefit most from this.
- Families emphasised the 'feel' of the trial discussion more than its informational content. The social and emotional dynamics of the trial discussion should be considered in designing recruitment training; training should not focus exclusively on the procedural and informational aspects of informed consent.
- Practitioners and parents were dissatisfied with the current PILs, viewing them as too lengthy and complicated. A review of the current guidelines on PILs, taking into account parents', young people's and practitioners' perspectives, would enhance the value and usefulness of these documents for all groups.
- Clarity in the trial discussion could be enhanced if practitioners used open questions to elicit families' views of the trial before seeking consent, drew a distinction between routine care and that provided as part of the trial, and presented the trial arms in a neutral way. The use of simple educational aids may be helpful. Some families expressed discomfort in saying 'no' to research, which may be ameliorated if practitioners endorsed parents' decisions.
- Recruitment could be enhanced by considering the priorities of families at the design stage of trials so that a trial's design, particularly its practical requirements, does not deter participants. Increasing public knowledge about research may also help families by reducing the cognitive and emotional 'work' they have to do when approached about a trial. Similarly, this may also ease the burden of explanation for practitioners.

Recommendations for research

Further research is directly indicated by RECRUIT to:

1. identify the type of support that practitioners need and how to deliver it, particularly for those who find the trial approach difficult
2. further explore the views of parents and young people who decline trials, particularly those who have a negative disposition towards research, to inform our understanding of practitioners' difficulties when they approach such families and public education about research; specific research is warranted on how best to access this group and to explore reasons for declining at different stages of recruitment
3. explore the views of practitioners who choose not to be involved in clinical trial work, to identify ways to make this work more attractive to paediatric practitioners

4. investigate the impact for families of saying 'no' to research, including the potential problem of decisional discomfort and its management
5. investigate parents' knowledge and views about the use of unlicensed medicines in children and how they might be influenced by information about the role of trials in the licensing process.

RECRUIT has also shed light on several other topics, which, although less central to its main findings, are potential areas for further investigation:

1. While parents in this study did not indicate a preference to be approached about a trial by a known practitioner over one who was not responsible for their child's clinical care, other types of evidence are necessary to fully answer the complex question of who should approach families about trials.
2. Family, practitioner and public perspectives on trials with different designs and consent processes to those considered in this study, such as trials in emergency medicine.
3. Contrasts between the different support needs in approaching child versus adult patients about clinical trials.
4. Evaluation of the effectiveness of decision and educational aids in recruitment to trials with children.

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Publication

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NIHR Health Technology Assessment programme

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The research reported in this issue of the journal was commissioned by the National Coordinating Centre for Research Methodology (NCCRM), and was formally transferred to the HTA programme in April 2007 under the newly established NIHR Methodology Panel. The HTA programme project number is 05/516/08. The contractual start date was in December 2007. The draft report began editorial review in June 2010 and was accepted for publication in September 2010. The commissioning brief was devised by the NCCRM who specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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