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Patient and public involvement into the design of a paediatric surgical trial: the ninja study

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Background
Patient and Public Involvement (PPI) is increasingly important in the design of research and surgical trials. Evidence on PPI for paediatric trials appears is limited. Using a case study, the NINJA study, the potential impact of PPI on the design of a new paediatric surgical trial is highlighted.
NINJA study: Nail bed injury is the commonest hand-related cause of emergency paediatric consultation. After nailbed repair, there is debate whether the nail should be replaced or not. There is controversy and uncertainty around whether replacing the nail is beneficial in causing or preventing infection. A 60 patient pilot study (NINJA-P) was conducted to demonstrate the viability of a large multicentre paediatric surgical trial comparing infection rates in patients with replaced and discarded fingernails. Patients were recruited in just over 4 months at 4 sites and followed-up for 4 months. The paediatric population created some unique aspects and challenges, especially with retention and completion of patient-reported assessments.
Methods
The issues raised by the pilot were put to a youth group - the Young Person's Executive (YiPpEe) group based at Oxford University Hospitals NHS Foundation Trust and also to a focus group of parents (and one toddler). Information from both groups was collated to inform the development of the definitive study. The issues discussed were: Choice of the primary outcome measure and how to administer this; Retention of this study population; Presentation of study information.
Results
Regarding the outcome, the appearance of the nail was overwhelmingly the most important variable. This was in contrast to the clinicians' choice of outcome; the incidence of infection. The NINJA study now has co-primary outcome measures of appearance and infection rates. The groups shared ideas for how children (or parents) could measure their satisfaction with their nail appearance. A simple 3 point scale showing facial expressions was developed. This was favoured over the 5 point scale used in the pilot. Both groups were clear about the method of collection for follow up data. This population includes busy working parents. They suggested moving away from postal questionnaires and clinical visits, if not necessary, and employing mobile technology i.e.: 'apps' to upload photographs and complete questionnaires. The parent group felt the option to complete follow up requirements in this manner would improve the retention rate. Both groups had specific ideas regarding patient information presentation. The use of technology, videos, and comic-strips showing real people was supported. Collaboration with YiPpEe will continue to help develop information portals for the study.
Conclusions
Due to PPI involvement, the full NINJA study objectives were modified and a follow-up regime and content designed to suit this very specific patient population was developed. Our experience shows that solutions offered by children and parents can be incorporated into trial design at an early stage. The PPI exercise helped address and titrate issues raised in a pilot study and generated design and procedural elements that had not previously been discussed.

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Consent pathway options in trials of emergency interventions

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Background
In trials of emergency care interventions standardised pathways for obtaining participant consent can be inappropriate and alternative models are required. Unless specific approval is granted, obtaining participant consent is an essential prerequisite to research participation. OBS2 was a randomised trial evaluating the effectiveness of using early fibrinogen replacement in the management of complex postpartum haemorrhage. Reflecting the range of potential clinical scenarios in which recruitment could potentially occur, and to meet NHS ethics committee requirements, several consent pathways were identified, each requiring tailored patient information and consent forms.
Methods
All women booked to give birth at the six participating maternity units during the recruitment period, were provided with written information about the study during the antenatal period. Five consent pathways were developed: (1) for women at higher risk of postpartum haemorrhage, pre-event consent; (2) for women with controlled haemorrhage, written consent at the time of the bleed; (3) for women competent to provide assent during the bleed, but unable to provide written consent, verbal assent at the time of the bleed; and in the event of women lacking capacity to provide assent, pathways utilising a personal (4) or professional representatives (5). All women, regardless of the pathway followed, once well enough following their bleed were also required to provide written consent for use of their collected data.
Results
The study recruited 663 women who experienced a moderate to severe postpartum haemorrhage, with a minimum of 1,000 ml blood loss. Data relating to the mode of consent were captured on the site screening logs for 511 participants. No participants were recruited using the pathways developed for written consent provided at the time of the bleed, nor for the pathway utilising a professional legal representative. Antenatal (pre-bleed) consent was obtained from 15 (2.9%) recruited women; verbal assent was provided by 473 women (92.5%) during the haemorrhage, and for 23 women (4.5%) assent was provided by a personal representative, a relative or friend present. All women, once well enough following their bleed, provided written consent to the use of collected data.
Discussion
Appropriate recruitment and consent pathways are an essential component in the design of all trials. Trials of emergency intrapartum care bring particular challenges as they combine a known population, women booked to give birth at participating units, with unknown eligible potential participants, in the case of OBS2, women who went on to have a postpartum haemorrhage of >1,000 ml. The requirement to provide all potentially eligible women with antenatal information was intensive of professional time and resources. The pathways of consent available to staff in the recruitment of women were identified to have strengths and weaknesses, and these were reflected in the utilisation of each. Based on the experience of the OBS2 trial, the legal and logistic complexities of consent in emergency trial settings will be presented and discussed.

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How can incentives be designed and used to improve recruitment and retention in ways that are effective, efficient and ethical?

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Background
Recruitment and retention is critical for trials, yet both remain significant problems. Very little evidence exists on effective methods to boost recruitment and retention. There is increasing interest in exploring financial and non-financial incentives.