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Authors	O'Shea, Niamh;Doran, Kieran;Ryan, C. Anthony;Dempsey, Eugene M.
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Parental And Clinician Views Of Consent In Neonatal Research

O'Shea N[1,3], Doran K[2], Ryan C A[1,3], Dempsey E[1,3].

[1]Irish Centre for Fetal and Neonatal Translational Research (INFANT), University College Cork, Cork, Ireland

[2]School of Medicine, University College Cork, Cork, Ireland

[3]Department of Paediatrics and Child Health, Neonatal Intensive Care Unit, Wilton, Cork, Ireland

Abstract

Aim

To determine parental and clinician views of the informed consent process in neonatal research.

Methods

A questionnaire-based study on the informed consent process. Two questionnaires were developed and distributed to parents and clinicians over a four-month period.

Results

Thirty-four parents (79%) surveyed had consented their baby to a research study. The majority of clinicians (72%) had a preference for antenatal provision of information. A desire to help

future babies (97%, n=32) and a belief that their baby's healthcare would directly benefit (72%, n=28) were primary reasons for consenting. The majority (76% n=28) of parents were not in favour of a waiver of consent. However twenty clinicians (56%) agreed that a waiver of consent may be appropriate in neonatal research. Thirty-one (86%) clinicians rated GCP training as important.

Discussion

Parents are generally supportive of neonatal research. Good clinical practice training is essential for clinicians involved in neonatal research

Introduction

Informed consent is an obligatory requirement for research participation[1]. The process of informed consent states that certain measures must be followed to ensure a research participant has made an informed decision about their participation in a research study[2,3]. Consent for research should be voluntary, informed, and understood by the consenting individual who must also be competent to do so. In the case of neonatal research informed consent is acquired from parent(s)/guardian(s) of a patient.

Informed consent in neonatal research is a controversial subject. International studies conducted in this area have highlighted variability from country to country[4,5,6,7]. The Euricon study found that only 59 parents of a total of 200 had given a valid consent or refusal to participate in neonatal studies[8]. The vulnerability of parents during the neonatal setting has been noted[9]. Generally, parents are supportive of neonatal research and have expressed altruistic motives for consenting[10,11]. Studies have shown that, overall, consenting parents' understandings are that involvement in neonatal research studies should not cause harm and should be of direct benefit their baby's healthcare[12] and will help future generations of sick, newborn infants [13].

The primary aim of this study was to investigate the perceptions parents and clinicians had of the informed consent process in neonatal research. Specific objectives explored included parental recall, reasons for consenting or refusing consent, the role of parent information leaflets, antenatal consent and a waiver of consent.

Methods

Two questionnaires were developed. Questionnaire one was administered to parents of infants admitted to the neonatal intensive care unit (NICU) of the Cork University Maternity Hospital (CUMH) after birth and questionnaire two was administered to clinicians working in an Irish hospital setting. Parents completed their

questionnaire whilst attending a follow up appointment in the outpatient clinic in the CUMH. Clinicians completed their questionnaire whilst attending training seminars. An information leaflet detailing the rationale for the study was provided in conjunction with the questionnaire. The questionnaires incorporated questions and statements of a similar design and content. This included questions with yes/no answers, questions requiring free text answers and questions based on a Likert scale. Likert-type scale questions had two different five point scales; scale one asked respondents to rate their level of agreement to the importance of various statements (starting with "very important" and ending with "unimportant"), scale two rated the level of agreement respondents had to various statements starting with "strongly disagree" and ending with "strongly agree").

The parental questionnaire was divided into three sections; background information, parental experience of the informed consent process and information relating to the research study parents were asked to consent their baby to. The clinician questionnaire was divided into two sections; background demographic information and the clinician's views and experiences of the informed consent process.

Ethical approval for the study was granted by the Cork University Hospitals Research Ethics Committee in December 2014. Data analysis was performed using the statistical programme IBM SPSS statistics version 22.

Results

Parent Questionnaire

A total of 49 questionnaires were completed. Of these 6 were excluded from data analysis as they were completed by parents who did not fully satisfy the inclusion criteria. Of the 43 questionnaires analysed, 33 were completed by mothers independently, 8 were completed solely by fathers and two were completed by both parents together.

Clinician Questionnaire

A total of 36 clinician questionnaires were completed. Of these 7 were completed by Specialist Registrars, four were completed by Registrars and 25 were completed by Senior House Officers.

Study Recall

Parents gave brief descriptions of the studies in which they were asked to consent. Statements included 'brain activity', 'brain monitoring' and 'breast milk'. Although brief, the majority of explanations provided by parents reflected various studies that were on-going in the NICU at that time.

Consent to Neonatal Research

The majority of parents (79%, *n=43*) had consented their baby to a research study. Additionally, parents in the group whose questionnaires were excluded had also consented to a neonatal research study. When asked why they consented their baby to a research study the majority of parents (97%, *n=32)* agreed/strongly agreed with the

statement '*I want to help babies born in the future'* as motive for consenting. A total of 72% *(n=28)* of parents believed their baby's healthcare would directly benefit from taking part in a research study. When asked if they *'felt obligated to give consent to a study'* a total of 71% *(n=27)* of parents disagreed/strongly disagreed and when asked if they '*felt pressure to take part in the study'* 82% *(n=31)* disagreed/strongly disagreed. Thirty-two parents (78%) agreed/strongly agreed that being asked to participate in neonatal research studies whilst their baby was an inpatient in the NICU did not add extra stress to them at that time.

Reflections of the informed consenting experience

The majority of parents and clinicians objected to a consenting process where the conversation was audio recorded. Twenty six clinicians (73%) said they spend less than 20 minutes discussing the study with parents. Most clinicians (*75%, n=26*) believed that this was sufficient time spent with parents to obtain an informed consent.

Refusal of consent

Parents refused consent for a number of reasons including their perception of the severity of illness of the mother and/or baby and their concerns regarding the effect study procedures may have on a very premature baby.

Information Leaflets

The majority of parents (93%, *n=41*) could recall receiving an information leaflet during the consenting process with thirty-six (85%) stating a clear understanding of the information included in the leaflet. However 8 parents expressed difficulty in understanding the information received. Reasons included; language barriers, difficulty understanding the words used by the doctor when describing the study to them and difficulty understanding the information provided in the information leaflet.

Waiver of consent in neonatal research

Twenty-eight parents (76%) were opposed to the idea of a waiver of consent in a neonatal research study. Nine clinicans (25%) of clinicians agreed/strongly agreed that a waiver of consent was not appropriate in neonatal research. Twenty clinicians (56%) agreed/strongly agreed that a waiver of consent was appropriate in certain types of neonatal research.

Good Clinical Practice

Of those surveyed 38% of clinicians had received formal GCP training. While 85% of clinicians rated training in GCP as important, only 62% stated that they were familiar with it.

Randomised Trials

Fourteen clinicians (36%) believe parents do not fully understand randomisation when it is explained to them while ten (29%) believe parents do fully understand this process. When asked if they would allow parents' consent to a

research study, at the parents insistence despite concerns regarding parental comprehension of the randomisation process, 52% (n=15) of clinicians who answered the question would allow parents to consent.

Discussion

We found that parents were generally supportive of neonatal research. They chose to consent for altruistic reasons such as helping potentially sick babies in the future. As shown in other studies[12,13] parents expressed the belief that their baby's healthcare should benefit as a result of participating in a research study. Parental vulnerability during the informed consent process was highlighted. Examples of this include confusion surrounding the randomisation process and pressure some parents felt to consent to a study.

In terms of antenatal consultations, antenatal advice regarding neonatal research appeals to parents and doctors alike. Three-quarters (72%) of clinicians believe approaching parents antenatally leads to a greater uptake in consent while over half (57%) of parents preferred antenatal research consultations. When asked about a continuous consenting process the majority of clinicians said they did not continue to monitor consent for validity once obtained and did not make contemporaneous notes during the consenting process. This is an important point to highlight and one that may reflect the lack of GCP familiarity amongst the junior physician cohort studied.

One of our objectives was to explore parental recollection of the study for which they had previously consented. Many parents (70%) could not recall the study in which they participated and a number of parents expressed confusion with some of the content in the information leaflets they received. In relation to particular aspects of clinical trials, parents displayed a lack of understanding for certain study procedures, such as randomization. Many parents, who could recall taking part in a RCT, were unable to recall the concept of randomization. This may reflect the time-lag between the actual research study and the present follow-up questionnaire. It may highlight a lack of information provision to parents and a lack of a continuous consent process.

Parents made recommendations about the process for future studies. They felt strongly that clinicians should have set guidelines to follow which would advise them of when, and in what situation, they should or should not approach parents with information about a neonatal study. They also suggested that a consultant be present during all meetings between parents and clinicians regarding neonatal clinical trial participation. The amount of consultant support given during the consenting process should vary in respect of the type of research to which parents are asked to consent their newborn. For example it would be recommended that a consultant be available during the informed consenting discussions to a RCT involving preterm infants. However, for non-emergency observational research appropriately trained junior doctors would be suitable. It was also suggested that a liaison research nurse be made available during the consenting process to meet with parents where necessary. Parents also proposed that a separate room be made available for parents to engage in discussions about participation to research studies with research staff.

A number of limitations to this study merit consideration. Only parents who had been approached to participate in a newborn trial completed the questionnaire. However the time frame was variable between enrolment and completion of the questionnaire. The question relating to a waiver was in a select group who had all been approached to participate in a trial and so there was significant potential for selection bias. It is important to note that there are many areas of medical care where a waiver process is seen as a reasonable approach eg. emergency department research. A prospective study of antenatal patients may be a more suitable population to ask this question of. The clinician component involved junior doctors alone. We purposely chose this cohort. A lack of GCP awareness and knowledge was highlighted. A total of 12 clinicians had previously acquired consent for neonatal research from parents; only five had received training in GCP. It is recommended that clinicians involved in neonatal research attend mandatory informed consent training seminars hosted by senior consultants with expertise in the acquisition of informed consent.

The current study demonstrated the need for guidelines, which would assist clinicians during the consenting process in neonatal research. These guidelines should be made available to clinicians and researchers on a national level. Another recommendation is that mandatory training in GCP be introduced to hospitals nationwide to ensure clinicians involved in research have awareness of GCP and its applicable procedures. Further studies are required to explore parental perceptions of the various consent processes in future comparative studies.

Correspondence
Prof. Eugene Dempsey, Department of Paediatrics and Child Health, Neonatal Intensive Care Unit, Wilton, Cork, Ireland. Tel +353 87 052 4271
Email: gene.dempsey@gmail.com

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Conflict of Interest.

The authors have no conflict of interest to disclose.

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