

## ORIGINAL ARTICLE

# What do parents think about enrolling their premature babies in several research studies?

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**Objective:** To investigate parents' opinions about enrolling their premature baby into several research studies in the few days after birth.

**Methodology:** A questionnaire was given to parents of premature babies in the neonatal intensive care unit who had been invited to join several studies (two to seven).

**Results:** All 50 mothers and 42 of 48 fathers completed the questionnaire independently; 28% had been asked to join two studies, 32% three, 24% four, 14% five, and 2% six studies. There were 61 babies with mean (SD) gestational age 26.9 (1.6) weeks and birth weight 877 (249) g. Nearly three quarters (71%) of the parents thought it was very good for their baby to be in a hospital that was carrying out a lot of research. Most (93%) thought that their baby would get the same or better care in a study. Only 15% thought their baby was too small for research studies. Almost all (98%) wanted to be involved in the decision about their baby joining a study. Only 22% were worried about the number of studies; 10% would not enrol their baby in any studies, but 74% were willing for their baby to join two or more studies, and 10% would enrol in all the studies. Most (94%) believed that their baby's participation would improve care of future babies.

**Conclusions:** Most of these parents were willing to join several studies. The majority were not worried about their baby participating in the studies. The profession needs to be aware that parents are supportive of neonatal research and participation in multiple studies.

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Good neonatal research is essential if we are to improve the care and outcome of newborn premature babies. Some hospitals may have several research studies recruiting premature babies during the first weeks of life. This means parents may be asked to allow their baby to participate in more than one study. Having a very premature baby is stressful for parents,<sup>1-3</sup> and unfortunately consent often needs to be sought at an early stage and may add to the stress.<sup>4</sup>

Researchers and ethics committees sometimes consider it inappropriate for patients to be asked for consent to join more than one study. However, there are few reports about what parents think about their premature babies joining research studies; most are about the consent process<sup>5-8</sup> and none asked their opinions about enrolling premature infants in multiple studies. Brocklehurst<sup>9</sup> discussed the issues of recruiting pregnant women or their newborn infants to more than one trial. He pointed out several reasons why it is scientifically and ethically justifiable. He commented, "To restrict patients to only one trial will result in fewer interventions being evaluated because the number of potential participants is finite". Parents with infants receiving intensive care, who had recently agreed or declined consent to one of three trials, were interviewed by Zupancic *et al*<sup>10</sup> to determine the factors that influenced their decision to enrol their babies in the trials. They found that parents were influenced by risk benefits assessment, their attitude towards research, and the integrity of the consent process. They found that 32% of the parents preferred the doctors to advise them about whether to enrol their babies into clinical trials rather than make an independent decision. Stenson *et al*<sup>5</sup> investigated parents' recollections by post, 18 months after they had been entered into a randomised controlled trial, of the consent and information. Only 8% of the respondents were unhappy about giving consent to their infant being in a study, although 24% said that it made them

feel more anxious and 20% less anxious. Most (83%) did not want to forego the consent process.

The aim of our study was to investigate the opinions of parents about enrolling their premature baby in more than one research study. In particular, we sought their opinions about: their baby being cared for in a hospital that carries out research; how many studies they would allow their babies to join; whether having their baby in a research study caused anxiety; who they thought would benefit from the studies. In addition, we sought to determine parents' attitudes about the effect of research on their baby as well as future babies. In this study it was not the intention to investigate the parents' knowledge or thoughts about the consent or randomisation process.

## METHODS

During the time of the survey there were seven research studies in this 17 bed neonatal intensive care unit (NICU) with about 250 babies weighing <1500 g admitted every year. Parents were given written information about each study that they were asked to join, and then different trained medical or nursing research staff talked to them about individual studies at different times.

## Data collection

From December 1999 to January 2001, all parents with preterm infants in the NICU, who had been asked to join two or more studies, were invited to complete a questionnaire about each study that involved their baby. The questionnaire was developed for this survey and piloted on 10 sets of parents before final modification. There were two styles of question. Parents were either asked to circle the most appropriate answer to each question or to answer on a seven

**Abbreviations:** NICU, neonatal intensive care unit; RCT, randomised controlled trial

**Table 1** Profile of the parents

	Mother (n = 50)	Father (n = 48)
Age (years)	31 (5)	33 (6)
Not known	1	7
Marital status		
Married	42 (84%)	37 (77%)
Co-habiting	6 (12%)	5 (10%)
Single	2 (4%)	0 (0%)
Not known	0 (0%)	6 (13%)
Cultural background		
Australian	32 (64%)	33 (69%)
European	10 (20%)	5 (10%)
Other	8 (16%)	5 (7%)
Not known	0 (0%)	6 (13%)
Highest level of education		
Primary school	0 (0%)	2 (4%)
Secondary school	24 (48%)	15 (31%)
Trade/apprenticeship	4 (8%)	4 (8%)
Certificate/diploma	9 (18%)	9 (19%)
Bachelor/higher	12 (24%)	12 (25%)
Not known	1 (2%)	7 (13%)
Occupation		
Professional	14 (28%)	21 (44%)
Trades person	9 (18%)	14 (29%)
Clerical or service	13 (26%)	2 (4%)
Labourer	1 (2%)	1 (2%)
Home duties	12 (24%)	12 (4%)
Other	1 (2%)	1 (2%)
Not known	0 (0%)	7 (15%)

Values are number (%) except for age which is mean (SD).

**Table 2** Questions about the seven individual studies

I felt if my baby joined the study he/she would receive...	
Worse care	N = 83 5 (0-18)
The same care	78 (64-82)
Better care	15 (8-36)
I felt if my baby joined the study the care for the babies in the future would be...	
No different	N = 79 6 (0-21)
Better	17 (0-30)
Very much better	77 (0-92)
I thought my baby was too small to go in this study.	
Yes	N = 82 15 (0-27)
No	85 (73-100)
I would prefer to have the doctor or nurse caring for my baby decide whether or not my baby should join this study rather than to be asked for consent	
Doctor should decide	N = 68 2 (0-9)
Nurse should decide	0 (0-0)
I want to decide	98 (91-100)

Values are percentages with range in parentheses. Some questions were not answered, or the babies were not eligible for every study, so not all the results have the same number of participants.

point Likert scale. The parent could pick only one answer for each of the questions. There were separate questions about each study. The answers are presented as the median percentage and percentage range for each answer for the different trials. The research nurse invited parents to fill in the questionnaire during their baby's third week of life. They were asked to complete it independently of their partner and return it anonymously in a sealed envelope. Parents were approached for consent for each trial at different times, according to the trial protocol, and therefore the severity of each baby's illness may have differed at the time of consent. The Royal Women's Hospital research and ethics committees approved the study.

### Research studies

The seven research studies were:

- (1) A multicentre international randomised controlled trial (RCT) of elective nasal continuous positive airways pressure at birth in infants of 25-28 weeks gestation compared with intubation and ventilation. The outcome was survival free of chronic lung disease.
- (2) A multicentre international RCT to evaluate the safety and efficacy of caffeine compared with placebo in babies with a birth weight less than 1250 g. The outcome was survival and neurodevelopmental status at 18 months corrected age.
- (3) A multicentre RCT to determine whether dexamethasone given to infants born weighing <1000 g or <28 weeks gestation, who are ventilator dependent after 7 days of age, reduces the rates of ventilator dependence and chronic lung disease, without adversely affecting mortality or sensorineural impairments or disabilities at 2 years of age.
- (4) A single centre RCT of the use of the Florian lung function monitor (Acutronic Medical Systems AG, Zug, Switzerland) for infants ventilated with the Infant Star ventilator (Puritan Bennett, Pleasanton, California, USA) to determine whether medical and nursing staff seeing

the tidal volume, minute volume, and flow pattern altered the ventilator parameters.

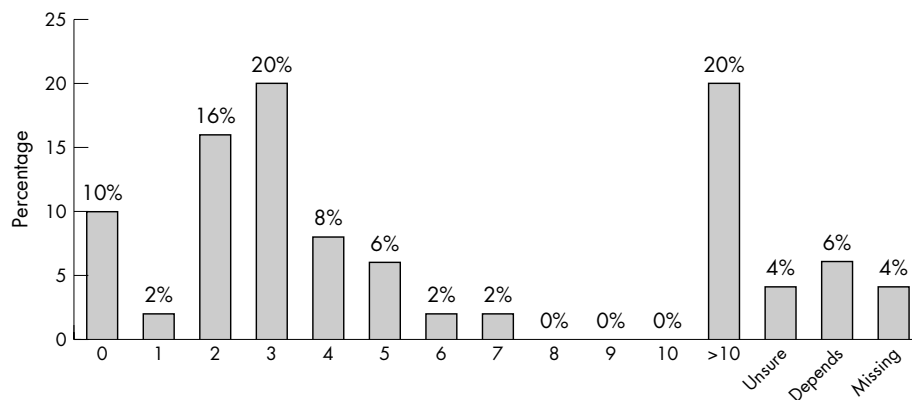
- (5) A single centre RCT to determine whether a toy placed outside a premature infant's incubator reduces the rate of infection compared with a toy placed in the incubator.
- (6) Crossover studies investigating different techniques of ventilating babies.
- (7) A multicentre international trial investigating the usefulness of interleukin 8 as a marker of neonatal bacterial infection.

### RESULTS

During the time of the study there were 50 mothers (two without partners) and 48 fathers who were given the questionnaire. All of the mothers and 42 (88%) fathers returned it. There were 61 babies including 11 sets of twins. The mean (SD) for gestation and birth weight was: 26.9 (1.6) weeks and 872 (249) g. Table 1 gives basic information on the parents. There were no evident differences between the answers given by the mothers and fathers, and their answers are amalgamated in table 2 and figs 1-4.

Of the 50 mothers, 14 (28%) were asked to join two studies, 16 (32%) three studies, 12 (24%) four studies, seven (14%) five studies, and one (2%) six studies. Altogether seven (14%) refused to join any studies, four (8%) joined one study, 16 (32%) joined two studies, 14 (28%) joined three studies, seven (14%) joined four studies, and two (4%) joined five studies.

The majority (93%) of the parents thought their baby would receive the same or better care if participating in a study. Only 15% did not join a study because they thought their baby was too small. Most (96%) of the parents thought that having their baby in a hospital that carries out research is either good for their baby or makes no difference to the outcome, with only 4% thinking it was bad for their baby. Only 10% said they did not want their baby to be in any studies. The majority were willing for their babies to be enrolled in several studies, with 58% willing for their baby to



**Figure 1** Percentage of the mothers who were prepared to let their babies join different numbers of studies.

be in three or more studies and 20% willing to join more than 10 studies. Ninety four percent of the parents thought that if their baby joined a research study the care of babies in the future would be either better or very much better.

Forty percent of the parents said they were happy or very happy about their baby being in several studies, 30% said they were neither happy nor distressed, although 22% were worried, and 8% did not answer.

When asked whether the doctors, nurses, or parents should decide about a baby being enrolled into a research study, almost all the parents (98%) wanted to decide and did not want the doctors or nurses to decide.

Some reports have suggested that parents do not remember that their child was enrolled in a research study, or, if they do remember, they may not remember the details of the study.<sup>4-7</sup> Those were not questions we specifically asked, but the parents surveyed here filled in their questionnaires within a few days of being approached for the different studies.

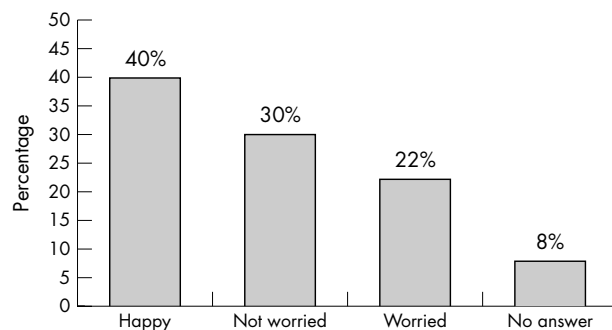
**DISCUSSION**

This study is the first to investigate parents’ views of their very premature babies being enrolled in several research studies in the first three weeks of life. Schmidt *et al*<sup>11</sup> and Lantos<sup>12</sup> have shown that patients in research studies have a better outcome than those not enrolled. It appears from our study that parents of sick infants appreciate the benefits of a hospital that carries out research.

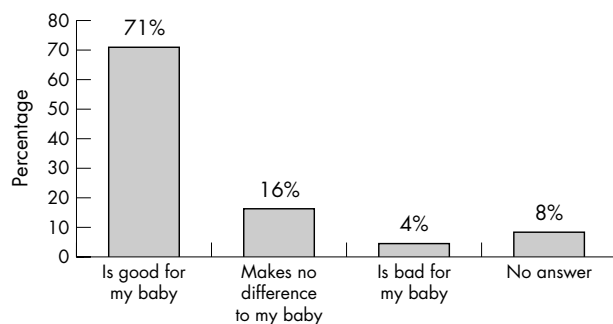
In this NICU, at the time of the questionnaire, parents could be asked to consent to their baby being enrolled in up to seven studies. It has been debated whether patients should be enrolled in more than one research study at a time.<sup>9, 13</sup> This study has concentrated on the parents who were approached for more than one study. Only 10% said they did not want their baby to be in any studies. Most were willing for their

babies to be enrolled in several studies, with the majority willing for their baby to be in three or more studies. Among parents of 200 babies asked to consent for neonatal trials and surveyed in the Euricon study,<sup>7</sup> 164 (82%) were asked to consent for a single trial, 16 for two trials, three for three, and for 17 the number was not known. Consent was obtained from 179 (90%), two agreed to one trial, but declined another, five did not remember, and one missed the randomisation deadline.

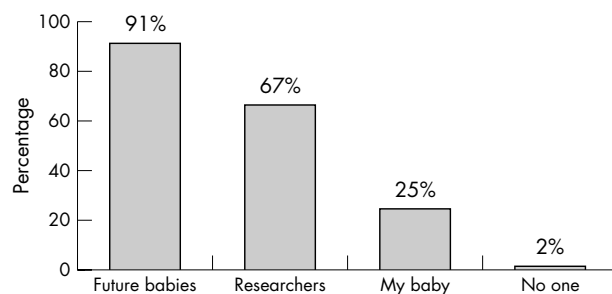
Do neonatal research studies cause the parents anxiety? The study of Stenson *et al*<sup>5</sup> suggested that 24% of parents felt anxious, and in our study a similar proportion said that they were worried. Due care has to be taken that parents are not worried by participation in research, but these data suggest that most are relatively unconcerned in this environment. One of the problems with questions on anxiety is that there is a high background level of parental anxiety when their baby is in an NICU. This study did not consider whether the



**Figure 3** Parents’ response to being asked how they felt about the number of studies?



**Figure 2** Parents’ response to being asked about having a baby in a hospital that does research.



**Figure 4** Parents’ response to being asked, ‘Who will benefit from these studies?’

parents weighed up the risks and benefits to their child from being in a research study. It is possible that the parents who did not give consent were concerned about the risks to their baby. Most parents of premature babies felt able to think about and join research studies, but some were preoccupied with their baby's welfare, and joining research studies was something they could not think about.

Our data suggest that investigators and committees should not put an arbitrary limit on the number of research studies in the belief that they are thereby protecting the babies or their parents. It appears that most parents think that their babies benefit and are not unduly concerned even about several studies. We would hope that parents would make an independent judgment about each study, although we have no evidence about this.

Truog *et al*<sup>14</sup> have argued for a waiver of informed consent and consider that, as with clinical care, participation in a RCT could be considered to be authorised by the general consent to treatment. This is because it is thought to be difficult to enrol babies in research at such a stressful and difficult time; the parents will not really understand and are not in a position to give informed consent. However, our study shows that almost all parents (98%) wanted to decide whether their baby should be in a research study. They did not want the doctors or nurses to decide. This differs a little from the findings of Zupancic *et al*<sup>10</sup> where 30% of the mothers said that they would prefer to have the doctors advise them whether their babies should be in the study or not. However, it is not clear whether advice is the same thing as deciding themselves. The Euricon study<sup>7</sup> also found that 97% of parents thought that they should be asked to give consent. The parents in our studies certainly did not appear to consider that being asked for consent is just a ritual.<sup>15</sup>

There may be concern that babies in multiple studies are being imposed upon or exploited. In Trevor Smith's book on *Medical ethics* he says, "It is hardly fair to impose upon children who already have many problems".<sup>16</sup> This is an area that we always consider very carefully when designing neonatal research. The studies being undertaken in the NICU at the time of the questionnaire would have caused little or no interference with the babies. They were comparing two established treatments, collecting data available without interference with the baby, or evaluating existing practices. Unfortunately, it is often just such sick babies where the best treatment needs to be defined by research studies. It appears that most parents do not want us to stop neonatal research.

This study did not consider parents' motives for allowing their baby to join research studies. However, the parents in this study appeared to be very altruistic. Although they appreciated that some studies were unlikely to benefit their babies and that the studies were being carried out to benefit future babies, most of them still allowed their baby to be enrolled in one or more studies. Many also appreciated that the researchers may benefit from doing the studies and yet they still allowed their baby to be enrolled.

The results of this study need to be interpreted in the context that the parents already had very premature babies cared for in a large teaching hospital NICU and they had been

approached to join two or more studies. The results may have been different with a different population.

In conclusion, this study has shown that parents who were approached for their premature baby to be enrolled in more than one research study think that it benefits their baby to be born in a hospital that carries out research. Although it was made clear to them that they were under no obligation to join the studies, most were willing for their baby to join studies, and more than half would let their babies join three studies or more. The majority were unconcerned about their baby participating in research, although a quarter were worried. This study suggests that parents appreciate that studies need to be performed to improve the outcome of ill and fragile babies. It is important to recognise this altruism. Although every care and consideration must be taken of the parents and baby when considering neonatal research studies, this report suggests that there should be no artificial ceiling on the number of studies undertaken.

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