

Factors influencing parental consent for participation in clinical research involving their children in Egypt

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العوامل التي تؤثر على موافقة الوالدين على الإسهام في البحوث السريرية التي يشارك فيها أطفالهم في مصر
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الخلاصة: لم تخضع العوامل التي تؤثر على موافقة الوالدين على إشراك أطفالهم في البحوث السريرية، للدراسة في جميع الخلفيات الثقافية. وهدف الباحثون إلى التعرف على المواقف والمعتقدات التي تؤثر على القرارات التي يتخذها الوالدان حول مشاركة أطفالهم في البحوث السريرية في المنصورة في مصر. وقد تواصل الباحثون مع 523 أسرة، استكملت الاستبيانات منها 357 أسرة، واتضح أن 98 من الوالدين (27.5%)، فقط قد وافقوا على مشاركة أطفالهم في البحوث السريرية، وأن متوسط أعمار الأطفال الذين وافق الوالدان على مشاركتهم بالبحوث وهو 8.6 عاماً (± 7.2) أكبر بمقدار يعتد به إحصائياً من متوسط أعمار الأطفال الذين رفض الوالدان مشاركتهم بها وهو 2.6 عاماً (± 1.2)، وأن العوامل التي ترجح الموافقة هي: البحوث التي تعود بالنفع على الطفل (84.7%) والشرح الوافي عن المنافع (40.8%)، والتعلم أكثر عن حالة الطفل (29.6%) أما العوامل التي ترجح رفض الموافقة فهي: استخدام أدوية أو لقاحات جديدة (89.6%)، والإجراءات الباضعة (84.2%). وكان هناك ترابطاً إيجابياً بين معدل موافقة الوالدين مع كون البحوث غير باضعة وكذلك مع الاعتقاد بأن البحوث نافعة لطفلهم، وكان هناك ترابط سلبي مع الاعتقاد بأن رفض المشاركة قد يؤثر سلباً على الرعاية التي تقدم لطفلهم.

ABSTRACT Factors affecting parents' decision to involve their children in clinical research have not been studied in all cultural backgrounds. We aimed to explore the attitudes and beliefs influencing parents' decision to involve their children in clinical research in Mansoura, Egypt. Of 523 families approached, 357 filled the questionnaire. Only 98 (27.5%) parents consented to involve their child in clinical research. The children of consenters were significantly older than refusers: 8.6 (SD 7.2) versus 2.6 (SD 1.2) years. Factors favouring consent were: research of benefit to child (84.7%), enough explanation about the benefits (40.8%) and to learn more about child's condition (29.6%). Factors favouring refusal were: use of new drugs or vaccines (89.6%) and invasive procedures (84.2%). Parents' rate of consent was positively correlated with the research being non-invasive and the belief that research was of benefit to their child and negatively correlated with belief that refusal may negatively affect the care provided to their child.

Facteurs d'influence sur le consentement parental à la participation de leur enfant à une étude de recherche clinique en Égypte

RÉSUMÉ Les facteurs influant sur la décision des parents de laisser leur enfant participer à une étude de recherche clinique n'ont pas été étudiés dans tous les contextes culturels. L'objectif de l'étude était d'examiner les attitudes et les croyances influant sur la décision des parents de laisser participer leur enfant à une étude de recherche à Mansoura (Égypte). Sur 523 familles contactées, 357 ont rempli le questionnaire. Seuls 98 parents (27,5 %) consentaient à laisser participer leur enfant à une recherche clinique. Les enfants des parents qui avaient donné leur consentement étaient nettement plus âgés que ceux dont les parents avaient refusé : 8,6 ans (ET 7,2) contre 2,6 ans (ET 1,2). Les facteurs favorisant le consentement étaient les suivants : une recherche bénéfique pour l'enfant (84,7 %), des explications suffisantes sur les avantages (40,8 %) et l'occasion de mieux connaître l'affection de leur enfant (29,6%). Les facteurs favorisant le refus étaient les suivants : l'utilisation de nouveaux médicaments ou vaccins (89,6 %) et des actes invasifs (84,2 %). Le taux de consentement des parents était positivement corrélé à une recherche non invasive et à la croyance que la recherche serait bénéfique pour leur enfant, et négativement corrélé à la croyance selon laquelle un refus pourrait négativement influencer sur les soins fournis à leur enfant.

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Received: 02/05/13; accepted: 25/09/13

Introduction

Informed consent prior to enrolment in research is a fundamental ethical prerequisite in the process of conducting clinical research. Obtaining consent involves informing subjects about their rights, the study purpose and procedures and the potential risks and benefits of participation [1]. Different barriers to obtaining informed consent have been identified, such as the content and readability of the consent form, language barriers, the subject's age and educational and socioeconomic status, the type and severity of illness, and the timing and amount of time allotted to the process of obtaining consent [2–4]. Subjects who are vulnerable due to their age or cognitive disability need a higher level of protection when included in clinical research [5,6]. Since children are considered incapable of giving informed consent to participate in research, regulations are required to obtain permission from parents or legally authorized representatives. The American Academy of Pediatrics published a policy statement in 1995 on the legal concept of informed consent in paediatric practice [7], and this has evolved over the years to become more formalized [8].

There are many factors that influence parents' response to consent for research involving their children. Identification of these factors is an important way of developing strategies to improve the manner in which study information is disclosed, to ensure that parents are truly informed, to increase the chances of parental acceptance and to avoid selection bias [9,10]. Previous studies have looked at the different motivations behind consent release, where the perception of the risks and benefits of a research study was the main important factor [11,12]. However, the influence of these factors varies considerably based on the ethnic and cultural background of subjects. We could identify no literature which addressed the issue

of clinical research participation and the opinion of parents as regard their child's participation in clinical trials in the Eastern Mediterranean Region (EMR). We therefore proposed a study in Mansoura, Egypt to determine the rate of parents' consent to participation in clinical research involving their child and to evaluate factors that influenced parents' consent.

Methods

Study design and sample

Parents or legally authorized representatives of children admitted to the inpatient departments of Mansoura University Children's Hospital, Mansoura, Egypt, between January 2009 and December 2011 were eligible for the study. To cover a range of factors that may influence parents' decisions no exclusion criteria were set. Parents or guardians were approached within 48 hours of the child's admission and were asked to complete a questionnaire exploring factors that would influence their decision to involve their child in clinical research. The primary nurse of the child was asked to inform the investigators of a suitable time to approach the family so that both parents were present. Of 523 families approached, 357 parents (68.3%) filled the questionnaire: 308 mothers and 49 fathers.

Questionnaire

The questionnaire was developed based on previous studies that addressed reasons for parental consent or refusal for children's participation in clinical research [11,13]. Baseline characteristics of the involved children were collected: age; sex; disease or reason for admission; disease status (acute versus recurrent or chronic illness); and disease severity (mild = one-day care, moderate = ward care, or severe = intensive care). General demographic data were collected about the parents: family socioeconomic status (low income <

US\$ 12 000 annually, middle income US\$ 12 000–24 000 annually or high income > US\$ 24 000 annually); level of parents' education (no education, primary school, secondary school, college or postgraduate); parents' marital status (married, divorced or widowed), previous bad experiences with the hospital or physicians; parental acquaintance with the involved physician; parents' conflicting views; and parental source of information regarding the child's illness.

Parents were asked if they would agree to their child's participation in scientific research (Yes/No). To explore their attitudes they were then given a list of conditions and asked to choose whether they would give consent under that condition (Yes/No): if no sampling was required; if a blood sample was required; if a urine sample was required; if taking a new drug was required (never; if the drug had been tried previously on other patients; if the benefits and side-effects were explained in detail; if there was no alternative treatment); and if there was a fee for the test.

To explore parents' beliefs they were given a list of statements about the research process and asked if they agreed or not (Yes/No): research might be of benefit to the child or similar cases; research will adversely affect child's health; doctors do not give enough explanation about the research; the research is only of personal benefit to the doctors; refusal to participate might affect child's medical care; and participation in clinical research is prohibited by religion.

Finally, the questionnaire explored possible factors influential in parents' consent or refusal. Parents who consented to participate were asked which of the following was the most important factor: to get access to better medical care; personal knowledge of the physician; to obtain sufficient information about the benefits and side-effects of the treatment; to gain more experience about the nature of the child's illness; to get a fee; or other. Parents who refused

participation were asked to indicate which of the following was the most important factor: research on a new drug or vaccine; research that required sampling from the child; research that has nothing to do with the child's illness; or other.

Data collection

After explanation of the purpose of the study, parents/guardians were given the questionnaire and an informed consent form and were asked to complete it at a convenient time. They were re-approached prior to their child's discharge in order to retrieve the questionnaire and discuss any unclear points with them. Parents/guardians who could not read or write but who were willing to participate in the study were provided with a research assistant to help them complete the questionnaire.

Statistical analysis

According to the parent's decision to consent or refuse to involve their child in research, all respondents were divided for analysis into 2 groups: consenters or refusers. Differences between the 2 study groups were assessed using Student t-test for continuous variables, and the chi-squared test with Fisher exact test for categorical variables. Spearman test was used to assess the correlation between parents' agreement and their baseline characteristics. Unless otherwise stated, values are expressed as mean and standard deviation (SD) or absolute numbers and percentages. Analysis was performed using SPSS statistical software, version 16. *P*-values of < 0.05 were considered statistically significant.

Results

Rate and reasons for consent or refusal

Of 357 parents who completed the questionnaire 98 (27.5%) would consent and 259 (72.5%) would

refuse for their child to participate in research. According to consenters the most important factors in favour of giving consent to participation were if the research was of benefit to the child (83/98, 84.7%); if they received enough explanation about the benefits of the research from the staff (e.g. expected benefits from the research; impact of the results on the disease status of the child; expected hazards and plans for monitoring/care of such hazards) (40/98, 40.8%); and if the research allowed for learning more about the child's disease (e.g. disease process and progress; effect and side-effects of the treatment) (29/98, 29.6%). Refusers' main reasons for refusal were if the research used new drugs or vaccines (previously only tested in animal trials) (232/259, 89.6%); and if it used invasive procedures (218/259, 84.2%). Among both consenters and refusers the strongest motives for parental consent were if the research was of benefit to the child (187/357, 52.4%) and if they had enough explanation about the research (179/357, 50.0%).

Patients' baseline characteristics

More of the mothers (82/308, 26.6%) were consenters than were the fathers (5/49, 10.2%). The children of consenters were significantly older in age compared with those of refuser parents [8.6 (SD 7.2) versus 2.6 (SD 1.2) years] ($P < 0.01$), while other demographic characteristics of the children were not significantly different (Table 1). None of the parental baseline characteristics were significantly different between the study groups, including: socioeconomic status, level of education, marital status, age, previous bad experience with the hospital or physicians (e.g. contracting infection in hospital; death or sickness of another child; having a conflict with hospital staff), acquaintance with the involved physician, conflicting opinions, and source of information the child's illness (Table 1).

Patients' attitudes and beliefs towards giving consent

Parents' attitudes and beliefs towards involving their child in clinical research are listed in Table 2. Most participants agreed to participate in a research if no samples were taken from their children (68.6%). Regarding trials using a drug, 39.8% would never consent to participate, 29.4% would consent if the drug was tested before and 17.1% if detailed explanations were offered to them. Fewer parents agreed to consent if they were given compensation or no other alternative treatment was available (7.8% and 7.6% respectively). Over 60% of participants believed that the research might be of benefit to the child or similar cases. About 50%–52% of parents believed that the research would negatively affect their child's health and doctors did not give enough explanation about their research. A high percentage of parents (43.3%) believed that the research was only of interest to the physician.

Correlations

We correlated the rate of consent of parents for involvement of their child in clinical research with various demographic characteristics and attitudes and beliefs. The factors most positively correlated with parental agreement were that the type of research was non-invasive and belief that the research was of benefit to their child (Table 3). On the other hand, the factor most negatively correlated with consent was the belief that refusal to participate in a research study proposed by the treating hospital may negatively affect the care provided to their child (Table 3).

Discussion

Obtaining informed consent for research that involves infants and children is a challenge for investigators since the subjects are incapable of giving consent and are legally represented by

Table 1 General characteristics of children and their parents who consented for their child to be involved in research and those who refused

Variable	Consenters (n = 98)		Refusers (n = 259)	
	No.	%	No.	%
Child's variables				
<i>Mean (SD) age (years)</i>	8.6 (7.2)		2.6 (1.2) ^a	
<i>Sex (male)</i>	58	59.2	127	49.0
<i>Disease severity</i>				
Mild	25	25.5	71	27.4
Moderate	52	53.1	134	51.7
Severe	21	21.4	54	20.8
<i>Disease/reason for admission</i>				
Central nervous system disease	7	7.1	18	6.9
Respiratory disease	24	24.5	65	25.1
Cardiovascular disease	15	15.3	32	12.4
Gastroenterology disease	10	10.2	41	15.8
Genitourinary disease	7	7.1	20	7.7
Haematology/oncology disease	13	13.3	20	7.7
Endocrine disease	11	11.2	26	10.0
Genetic disease	4	4.1	11	4.2
Other	7	7.1	26	10.0
Disease is recurrent	57	58.2	127	49.0
Parents' variables				
<i>Socioeconomic status</i>				
Low	52	53.1	109	42.1
Middle	39	39.8	127	49.0
High	7	7.1	23	8.9
<i>Education^b</i>				
None	12	12.2	38	14.7
Primary	25	25.5	47	18.1
Secondary	38	38.8	105	40.5
College	23	23.5	69	26.6
Postgraduate	0	0.0	0	0.0
<i>Marital status</i>				
Married	88	89.8	223	86.1
Divorced	10	10.2	34	13.1
Widowed	0	0.0	2	0.8
<i>Mean (SD) age (years)</i>				
Father	33.0 (7.0)		34.6 (8.0)	
Mother	29.3 (3.0)		30.4 (6.0)	
<i>Previous experience of care</i>				
Had bad experience with hospital/physicians	19	19.4	44	17.0
Acquainted with the involved physicians	23	23.5	45	17.4
Conflicting views between parents	19	19.4	54	20.8
<i>Source of information</i>				
Television	4	4.1	10	3.9
Friends	3	3.1	8	3.1
Other patients	3	3.1	6	2.3
Physician or nurse	71	72.4	205	79.2
Books or Internet	6	6.1	7	2.7
Other	11	11.2	23	8.9

^aP < 0.01 for child's age; no other significant differences were found between consenters and refusers by Student-t test or chi-squared test (Fisher exact).

^bLowest level of education among the parents.

Table 2 Items related to attitudes and beliefs of parents toward consenting to involve their child in clinical research (n = 357)

Items	Total (n = 357)		Consenters (n = 98)		Refusers (n = 259)	
	No.	%	No.	%	No.	%
Attitudes						
Agree to participate without any samples taken	245	68.6	98	100.0	147	56.7
Agree to participate with urine sampling	208	58.3	98	100.0	110	42.4
Never agree to drug trials	142	39.8	14	14.3	128	49.4
Agree to participate in a drug trial if drug is previously tested	105	29.4	55	56.1	50	19.3
Agree to participate in a drug trial if a detailed explanation is provided	61	17.1	38	38.8	23	8.8
Agree to participate with blood sampling	61	17.1	42	42.8	19	7.3
Agree to participate if compensated with incentives	28	7.8	8	8.1	20	7.7
Agree to participate in a drug trial if there is no alternative drug	27	7.6	8	8.1	19	7.3
Beliefs						
Believe that the research might be of benefit to the child or similar cases	217	60.8	98	100.0	119	45.9
Believe that the research may negatively affect child's health care	186	52.1	2	2.0	184	71.0
Believe that doctors do not give enough explanation about the research	179	50.1	44	44.9	135	52.1
Believe that the research is only of interest to the physician	155	43.4	8	8.1	147	56.7
Believe that refusal to participate might affect child's care	59	16.5	9	9.1	50	19.3
Believe that participation in clinical research is prohibited in religion	44	12.3	0	0.0	44	16.9

their parents or authorized guardians. This factor represents a pressure on the decision-makers due to the risks and hazards they may expose their dependants to through their decisions. Exploring the factors that may affect parents' or care-givers' decision-making has gained the interest of investigators in recent years. However, these factors may vary with on the cultural and ethnic background of the patients and their care-givers. Due to the paucity of studies addressing this issue in the EMR, we conducted this research to explore the demographic characteristics, attitudes and beliefs that may affect parents' decision to involve their children in clinical research in Mansoura, Egypt.

In our study we found a lower rate (27.5%) of parental consent to involving their child in research compared with previously reported rates. In a multi-centre study at 3 hospitals in France, where children were being treated for cancer or HIV infection, of 71 parents interviewed 89% consented to allow their child to participate in the clinical trial [14]. In a study in the United States where parents were approached for permission to allow their child to participate in a study of clinical anaesthesia or surgery, 81% of parents consented to participate [2]. The low rate of consent reported in our study further supports the value of this study in exploring parental beliefs and attitudes toward research that involves their children in

our Egyptian community as an example for other countries in the region.

We found that none of the baseline characteristics of parents and their children influenced parents' decision to consent or refuse to involve their child in clinical research, except for age. The children of consentor parents were significantly older compared with refuser parents, which may reflect a greater level of parental concern for the safety of younger children. In our sample the percentage of parents with a higher level of education (< 30%) was low compared with another study (> 70%) [11]. Indeed, we did not find any difference in the rate of parental acceptance among the sector of highly educated parents in our group. In a survey of Australian

Table 3 Correlation between rate of consent by parents for involvement of their child in clinical research with various demographic characteristics and beliefs

Studied parameters	Spearman correlation coefficient <i>r</i>	<i>P</i> -value
Income	0.041	0.45
Education	0.006	0.90
Source of knowledge about child's illness	-0.102	0.06
Previous bad experience	0.049	0.35
Receive enough explanation	-0.080	0.13
Acquainted with involved physicians	0.051	0.34
Non-invasive research	0.362	< 0.001
Given incentives	-0.003	0.96
Believe that refusal may affect child's care	-0.170	0.001
Believe that only physician benefits	-0.028	0.59
Believe that child benefits	0.296	< 0.001
Believe that child's care adversely affected	-0.053	0.32
Believe that religion prohibits	0.012	0.81

parents who consented to involve their child in a randomized, double-blind, placebo-controlled trial of a drug to treat asthma, consenters were less well educated, less likely to have professional or administrative jobs, had less social support and made more frequent visits to family doctor or clinic compared with refusers [15]. We observed that there was a uniformity in beliefs among parents of different demographic backgrounds towards refusal to involve their children in research.

In our group of parents, the factors most likely to favour consent to involve their child in research was if the research was of clear benefit to the child, getting enough explanation about the benefit of the research from the investigators and to learn more about the disease. In a survey in Denmark addressing parental preferences for consent procedures in neonatal resuscitation research, the most important factors for consent were: no pain or suffering to the infant; that doctors would act in the best interest of the infant; understanding the study purpose; clear explanation of the study steps; available written material about the study; studying a drug of help to the infant; and having sufficient time to think about the study

[16]. Jay et al. in France reported that the relationship between the research staff and the parents was the cornerstone for success in performing studies involving children [17]. Rothmier et al., in a survey of parents or guardians of children participating in clinical asthma research in the United States, identified that the most important factors in favour of parental acceptance were: learning more about the disease; helping medical knowledge; trials using new drugs; relationship with staff; financial benefits; free medications; encouragement by physician; and free visits [11]. Factors of less importance were: type of treatment; location of clinic; duration of study; influence of friends; social support; and gifts received. In contrast to this study, our parents listed the use of new drugs or vaccines and research using invasive procedure as the main reasons for refusal. This difference reflects a more sceptical nature of these Egyptian parents toward the safety and hazards of using a new drug or an invasive procedure on their children.

Overall we found that the most important factors increasing the chances of parental consent for involving their children in research were: research of clear benefit to the child; and getting

enough explanation of the research concept from the staff. Similar to our findings, previous studies found that most important motives for parents to consent for research on their children were: clear benefit to their child; detailed explanation on the research consent form; and the research adding to medical knowledge [11,12,18,19]. In a survey of parents of children with leukaemia, the most frequently suggested factors to improve informed consent were: giving parents more time to make their decision; the amount and type of information provided; organization of the consent conference; communication style; and providing additional information materials [20]. In another group of patients with asthma, parents' most important motives were learning more about their child's illness and helping medical knowledge [11].

Exploring not only factors that influence parents' decisions but also parents' attitudes and beliefs toward the research process is important. We found that although most parents had a positive attitude towards involving their children in non-invasive research, they had a negative attitude towards involving their children in research that involved new drugs or vaccines. Also, most of the parents surveyed in our study did not agree to participate when compensated with incentives. Morgan et al. in Australia found that the almost 60% of parents who consent for neuroimaging was due to its being a non-invasive research and that children in the future would benefit from this research [18]. Masiye et al. in Malawi found that a higher rate of parents' agreement to participation in malaria research was as a way of accessing better quality medical care and benefiting from the material and monetary incentives that were being given to participants for their participation [21].

In an attempt to understand the reasons behind the high rate of refusal by parents in this study, we found that most of our group of parents believed that research was of sole interest to the

physicians, that physicians did not give enough explanation about the research and that the research may negatively affect their child's health care. Other studies showed that inadequate explanation about the research and lack of awareness of the parents for specific procedures involved in a research study was a risk factor contributing to parents' complaints that they were not informed about research involving their children [22,23].

We acknowledge the limitations of our study, one of which was the low response rate the questionnaire (68.3%) compared with reported response rates

of 70%–90% in previous studies that addressed the same issue [13,24,25]. Another limitation was that we did not propose a specific type of research design to the parents or a specific pattern of patient disease, and this may have made our results more of a subjective parental opinion rather than an actual decision about consent or refusal.

In conclusion, we found a very low rate (27.5%) of parental consent to involve their child in research compared with previous reports. This finding represents a major challenge to researchers and investigators in our community. This finding needs to be

further evaluated in different locations with more standardized assessment tools. In this hospital in Egypt, minimally invasive research of clear benefit to the child and with a clear explanation of the research process by staff were the most important motives for parental consent to involve their children in clinical research. We recommend that better public education and information which addresses the community and individual benefits of research for the future treatment of diseases is needed to encourage patients and parents to participate in research.

Competing interests: None declared.

References

1. Ellis GB. Profile: Office for Protection from Research Risks (OPRR). *Politics and the Life Sciences*, 1994, 13:271–273.
2. Tait AR, Voepel-Lewis T, Malviya S. Do they understand? (part I): parental consent for children participating in clinical anesthesia and surgery research. *Anesthesiology*, 2003, 98:603–608.
3. Gallagher SM. Barriers to informed consent in clinical trials. *Ostomy/Wound Management*, 1999, 45:14–16.
4. Taylor HA. Barriers to informed consent. *Seminars in Oncology Nursing*, 1999, 15:89–95.
5. Rose RM. Informed consent: history, theory, and practice. *American Journal of Otolaryngology*, 1986, 7:82–85.
6. Additional protections for children involved as subjects in research—Department of Health and Human Services. Final rule. *Federal Register*, 1983, 48:9814–9820.
7. Committee on Bioethics, American Academy of Pediatrics. Informed consent, parental permission, and assent in pediatric practice. *Pediatrics*, 1995, 95:314–317.
8. Committee on Bioethics. Informed consent, parental permission, and assent in pediatric practice. *Journal of Child and Family Nursing*, 1998, 1:57–61.
9. Tait AR, Voepel-Lewis T, Malviya S. Participation of children in clinical research: factors that influence a parent's decision to consent. *Anesthesiology*, 2003, 99:819–825.
10. Goodman NW, Black AM. Refusal rates for clinical trials. *British Journal of Anaesthesia*, 1986, 58:938–939.
11. Rothmier JD, Lasley MV, Shapiro GG. Factors influencing parental consent in pediatric clinical research. *Pediatrics*, 2003, 111:1037–1041.
12. Franck LS, Winter I, Oulton K. The quality of parental consent for research with children: a prospective repeated measure self-report survey. *International Journal of Nursing Studies*, 2007, 44:525–533.
13. Tait AR, Voepel-Lewis T, Malviya S. Factors that influence parents' assessments of the risks and benefits of research involving their children. *Pediatrics*, 2004, 113:727–732.
14. Chappuy H et al. Parental consent in paediatric clinical research. *Archives of Disease in Childhood*, 2006, 91:112–116.
15. Harth SC, Thong YH. Sociodemographic and motivational characteristics of parents who volunteer their children for clinical research: a controlled study. *British Medical Journal*, 1990, 300:1372–1375.
16. Culbert A, Davis DJ. Parental preferences for neonatal resuscitation research consent: a pilot study. *Journal of Medical Ethics*, 2005, 31:721–726.
17. Jay F et al. Children's participation in vaccine research: parents' views. *Paediatric Nursing*, 2007, 19:14–18.
18. Morgan AT et al. Parental consent for neuroimaging in paediatric research. *Child: Care, Health and Development*, 2010, 36:241–248.
19. Maayan-Metzger A, Kedem-Friedrich P, Kuint J. Motivations of mothers to enroll their newborn infants in general clinical research on well-infant care and development. *Pediatrics*, 2008, 121:e590–e596.
20. Eder ML et al. Improving informed consent: suggestions from parents of children with leukemia. *Pediatrics*, 2007, 119:e849–e859.
21. Masiye F et al. Why mothers choose to enrol their children in malaria clinical studies and the involvement of relatives in decision making: evidence from Malawi. *Malawi Medical Journal*, 2008, 20:50–56.
22. Legge A. Hospital criticised for not obtaining proper consent. *British Medical Journal*, 2000, 320:1291.
23. Smith R. Babies and consent: yet another NHS scandal. *British Medical Journal*, 2000, 320:1285–1286.
24. Stolt UG et al. Information and informed consent in a longitudinal screening involving children: a questionnaire survey. *European Journal of Human Genetics*, 2005, 13:376–383.
25. Van Stuijvenberg M et al. Informed consent, parental awareness, and reasons for participating in a randomised controlled study. *Archives of Disease in Childhood*, 1998, 79:120–125.