TITLE OF RESEARCH

Issues in Informed Consent with Research in Children, Ibadan, Nigeria.

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SPONSORS:

Self

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SUMMARY OF PROPOSED INVESTIGATION

Introduction:

Scientific research should only be carried out with the prior, voluntary, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent at any time and for any reason without any disadvantage. Exceptions to informed consent include- emergencies, when giving information and obtaining consent could be detrimental, occasions when full disclosure could cause psychological harm, in those with lower levels of capacity who voluntarily waive the right to be informed and/or give consent, or when intervention can be legally ordered for societal/public health and lastly in "incompetent" participants.

Research in children is generally approved only if it offers direct benefit to the group studied and presents no greater than minimal risk to the children and when adequate provisions are made for soliciting the assent of the children and the consent of their parents or guardians, or, anticipated benefits are expected and the risks are at least as favourable as that provided by available alternative approaches.

Aim

To assess the understanding and concerns of parent /guardian's, about the informed consent obtained on children who are recruited for research in Out-patient clinics at the University College Hospital, (U.C.H.), Ibadan.

Methods and Materials

The study sites will be the Out-patient clinics of the University College Hospital, Ibadan. These include the General Out-patients' clinic, the Children Out-patients' clinic and the Institute of Child Health clinic. The study design will be a cross-sectional qualitative descriptive study. The study population will be groups of parents/guardians of the children eligible for and recruited into an on-going research in U.C.H.

SUPERVISOR'S ATTESTATION STATEMENT:

I, Dr. Olayemi O. Omotade hereby certify that I am the supervisor for this research. I attest that this work will be done by the researcher as part of the requirements for fulfilment of a Masters degree in Bioethics in the Department of Surgery, College of Medicine, University of Ibadan.

_____

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BACKGROUND OF STUDY

Scientific research should only be carried out with the prior, voluntary, expressed and informed consent of the participants. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent and further participation from the research. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage to the care received (Berg et al., 2001).

Exceptions to this principle should be made in accordance with ethical and legal standards adopted in the community. These occur in circumstances such as "emergency" situations when giving information and obtaining consent may be detrimental (Berg et al., 2001). The rationale is that reasonable persons would consent to treatment/intervention in an emergency if they were able and therefore consent is implied.

However, only reasonable intervention as necessary within the confines of the emergency is allowed. When there is strong evidence that the individual would not have consented even if informed, decisions should not override those wishes. The process of informed consent may also be withheld when disclosure could be upsetting and cause psychological harm which is detrimental to the person's best interest. This should only be permitted when disclosure would negatively affect the person's participation in the decision making process and not just to promote paternalistic attitudes of the researcher or physician as in "Therapeutic privilege."

Participants may voluntarily waive the rights to obtain disclosure and/or give consent; however they must know the rights which they are wavering. It is the duty of the researcher/physician to disclose relevant information and his responsibility not to render intervention without their consent. The person has the right to make decisions which may be consenting or refusing. This waiver must be given voluntarily without inducement or persuasion. It is the individual's decision to be protected from possible psychological harm that the process would bring.

Situations arise when it is legally required to intervene to protect the society as well as the individual. This is obtained by statute authorizing intervention or a valid court order when decisions to refuse intervention or treatment can have harmful effects on family members and society. Informed consent is also modified when it concerns the incompetent individual. The goals are pursued differently but the decision must still safeguard the incompetent individual's future autonomy.

Individuals “capacity” is determined by medical and mental health professional whilst “competence” is determined by law. Some are adjudicated to be incompetent only for specific tasks such as financial tasks yet are competent for health related tasks. The law states that children and the unconscious individual are temporarily incompetent. All decisions must safeguard their future autonomy and be in their best interest. The process of informed consent can be split into two processes, the disclosure and obtaining the consent. It can be argued that one can obtain disclosure and not give consent, or not want disclosure yet give consent, or both.

Protection of children is a universal principle derived from respect for persons and beneficence. Child development theories tend to emphasize children’s ignorance, inexperience and inability to make truly informed autonomous decisions (Alderson et al., 2006). Some opinions claim children respond with trusted compliance or suspicious resistance and have been traditionally assumed to lack autonomy and will (Alderson et al., 2006) Children are deemed incompetent by the fact that generally they have less background knowledge (especially of medical issues), and fewer life experiences to achieve adequate understanding or to judge the risks and benefits of a medical intervention and have also not reached the age of legal majority. This demarcates childhood from adulthood. The law considers adults legally responsible for the majority of their actions whilst children are considered legally responsible for only minority of their actions, their parents/guardians being legally responsible for majority of their actions. In most countries, the age of maturity~~majorit~~ falls between 18 and 21 years. In the United Kingdom and some states of America however, the age of criminal responsibility can be as low as 10 to 14 years (Ganes and Roger, 2007).

Apart from those who obviously cannot communicate, i.e. foetuses and infants, who by law are incompetent, it has been found that children above 14 years are generally capable of making informed decisions. Some below 14 years, especially those living with chronic conditions and those who are prematurely street-wise have also been found to have the capacity to make some decisions. Research in the very young child or in those not even born can be fruitful when interactions between genetic and environmental factors are being determined and their effect on childhood (Goodenough., 2003).

Practically, information-giving should not be by-passed and should be given to all and suspended only for those who are un-communicative or unconscious. If, during this process, the individual is still deemed incompetent, then a surrogate decision maker is required.

In some states in America, older children are allowed to autonomously authorize limited medical interventions such as related to pregnancy, sexually transmitted diseases, substance abuse and mental health for societal/public health rather than insisting on the process of parental consent, which may deter the child from participating in interventions that have health benefits. These are particular

exceptions promoting the welfare of minors and not based on any belief that the minor has greater competence with respect to those interventions (Berg et al., 2001).

The law generally holds that parents or guardians are surrogates and can make decisions about their children's medical interventions and/or participation in research. This is the alternative decision-making mechanism available for children assuming that the parent/guardian act in the best interest of the unborn or born child (Alderson, 1990). However, the researcher/physician must ascertain that the surrogate has the capacity to make an informed decision, otherwise the consent is invalid.

The process of giving an informed consent covers communication between the parties, understanding, appreciation of the risks and benefits, following the logical thought processes of comparing these risks and benefits and consideration of the nature and complexity of the decision. The cognitive domain of Bloom's taxonomy covering knowledge of terms and methods, comprehension, application to circumstances, analysis of elements of the knowledge, synthesis in proposing alternative solutions and evaluation by making judgments about the information must be seen to have been followed (Krathiwohi, 2002). Refusal to participate or allow one's child to participate may result from the content of the consent forms, the nature of the research, the timing and the length of the process, the manner the information is given and from the cultural inhibitions to the legal status of the forms when it comes to signing and thumb-printing.

Internationally, research in a vulnerable population such as children, is only justified if it offers direct benefit to the group studied and can be approved when the research presents no greater than minimal risk to the children and when adequate provisions are made for soliciting the assent of the children and the consent of their parents or guardians (Helgesson, 2005). Alternatively, the relation of the anticipated benefits to the risks presented by the study is at least as favourable to the participants as that provided by available alternative approaches (Alderson et al., 2006).

Sometimes, the risk of the research represents a minor increase over minimal risk; the intervention or procedure presents experiences to the child participants that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations and that the intervention or procedure is likely to yield general knowledge about the participant's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition in the child participants (Berg et al., 2001).

Arguments that claim that children should only participate if there is a treatment to be offered (therapeutic), or a preventive (non-therapeutic) action available, are based on the risks of "stigmatization just for participation" which may affect the child's development and future relationships. However, avoidance of the stigmatization can be incorporated into the study which may

provide motivational opportunities. It is believed that consequences matter and principles of benevolence are morally right, therefore the research which presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children and which will be conducted in accordance with sound ethical principles will benefit the child and/or provide considerable benefit for other children whilst having only minimal risks or inconvenience. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians (Berg et al., 2001).

In 1978, the National Commission for the protection of human subjects of biomedical and behavioural research published the Belmont report. This emphasized respect for persons, beneficence and justice. Research amongst vulnerable groups should be evaluated separately, avoided as much as possible and unreasonable risks should not be undertaken. The wishes of the vulnerable should be taken into account and a review board must ensure justice. However, the Helsinki Declaration appeared to have allowed physician's discretion by obtaining proxy consent or even waiver for clinical research that is combined with patient care, when the physician believes it is in the patient's best interest. (World Medical Association's Declaration of Helsinki and Nuremburg code, Oct 2008). This puts the responsibility on the Ethical Review Boards to painstakingly go through all the principles involved.

In adults, informed consent can be considered under sub themes (Alderson et al., 2006):

1. Understanding the purpose and nature of intervention and choices available

2. Showing sufficient comprehension.

3. Voluntary consent

4. Respect for Autonomy

5. Legal Capacity

1. Understanding the research process:

In children, a lot is based on trust and confidence in the parent/guardian and the researcher (Alderson, 1990). Considering "understanding" of the research process, it was found that children suffer less when they sense and trust in adults' benevolence. Children as young as four years showed they understood the general principle of a chronic illness such as Diabetes Mellitus, which is comprehension (Alderson et al., 2006).

2. Comprehension:

In an international genetic research work by Marshall and others, the factors associated with voluntariness and understandings of the study's genetic purpose were evaluated in adults. Most of the participants reported being told the study purpose; whilst less than half reported that they actually understood the purpose. Cultural and educational factors were implicated in this lack of understanding (Marshall et al., 2006). Therefore, the adults who give consent must have substantial understanding of the study and its implications. The child too should be given a clear explanation that would serve as the basis for trust. This explanation may be done through other means such as drawings, photographs, cartoons and movies, at the same time respecting that the child may only want limited information, especially about painful and inconvenient interventions and the overall outcome (Helgesson, 2005).

3. Voluntariness:

This is autonomy and free power of choice and is difficult to assess in children, however, this is a process that goes through emotions, reason, fear and uncertainty to hope, trust and confidence (Alderson, 1990). This process may not only occur when there is beneficial medical research as even successful medical treatment intervention sometimes requires encouragement or cajoling the individual to comply, especially if it is a painful process.

4. Respect for autonomy:

This is inter-related with protective care in children. However, there are conflicting theories concerning the rights and duties of the physician, (deontology), the consequences of any action, (consequentialism), and the use of a minority in research for the good of many, (libertarianism and Utilitarianism) (Berg et al., 2001).

5. Legal capacity:

The legal capacity of a young person differs. Different countries have varying "ages of consent" and therefore age limits can be contested. The "assent" concept and "mature minors" enable doctors to respect the agreement or refusal by children/minors (American Association of Paediatrics,1995; Rossi et al.,2003; Rosato J, 2000) Decisions should not be only what the doctors or parents regard as in "their best interest" especially as all decisions and consent are partly limited because they depend on what intervention is provided and to realistic and feasible alternatives which are available. Their "best interest" may also not always be considered by the parents (Alderson et al., 2006).

Protection by parents and adults has been acknowledged by law, but children should be associated with the process of consent even though the parent gives the consent. Assent refers to the child's agreement to participate in the intervention, after being provided with information appropriate for ages and cognitive abilities. Consent is however obtained from the parent/guardian. ~~a~~A court order may be

sought when there is no family member, or the family member's decision may be detrimental to the child, or there is a conflict between family members or when the decisions make the family members liable (Berg et al.,2001).

Researchers found that children's experience of chronic illness enables them develop understanding of interventions whereas healthy young children or those with acute condition may not be expected to demonstrate comparable skills. African, Asian and South American children show highly developed competences if they have been forced to live fairly independently and in the face of adversity (Liebel, 2004). This may be viewed as similar to long term challenges of chronic illness and is considered under "children's ability." Emphasis should be placed on respect and justice as regards children. What is the best decision and who makes that decision? Are adults always right and should they always retain control?

Consent in general should be viewed as a "process". In addition, some argue that older children's decisions should not be accepted over their parents in the interest of preventing family discord and sustaining family intimacy (Berg et al., 2001). However, family intimacy is better sustained if the child is involved in the decisions. As children mature they want, and should be allowed, to make decisions for themselves about their treatment interventions or otherwise, whilst continuing to look to the physician and their parents for support. Every opportunity must be given by health professionals and parents to nurture the development of a trusting relationship that is based on mutual respect in providing care for children. This helps promote the evolving autonomy of the child as they develop into responsible members of the society (Davis et al.,2004).

Factors such as age, level of maturity, body awareness and previous experience of interventions/treatment play an important role in enhancing the ability of children to consent to their own treatment or interventions. Health providers and parents should recognize that they have a duty to involve children in consenting to their treatment or interventions thus enhancing their decision-making abilities from an early age. The results from a study on dental interventions suggested that children wanted to be involved in the decision-making process and they wanted this to be in the form of a discussion between the dentist, their parents and themselves. Children wanted adults to recognize and help promote their evolving autonomy by listening to them and acknowledging their contribution in consenting to their care. This increases their understanding and satisfaction with their care and ensures compliance. Research that has no benefit to the child should be regarded as un-ethical. All research involving children should have strict guidelines, parental consent and child's assent and it must be monitored closely (Alderson et al., 2006).

Rationale for the Study

By law, the parents or guardians are in the best position to give consent for their children, who are presumed to be incompetent until a certain age. In Nigeria, 18 years is the legal age. However, the issue of adequate comprehension of the informed consent process for the best interest of the child, at that time and in the future, needs to be analysed. The relationship of the parent/guardian with the researchers, especially when the child is ill and the researcher is a physician, is also of concern. This relationship involves issues of paternalism, voluntariness, and trust. These shape the relationship which may be trust or anxiety laden. Since the informed consent process is an on-going issue till the end of the research and beyond, the parent/guardian is not always aware that he/she has the responsibility to keep asking questions about observations or worries.

Mere objection to the intervention without adequate comprehension may make the individual lose out on highly beneficial and relatively risk-free interventions. This asymmetry exists even when minimum risks are involved, and non-participation is a missed opportunity to benefit. In these circumstances, informed consent conflicts with the physicians desire to do good for the patient, which may also be interpreted to be medical paternalism. However, in applying "therapeutic privilege", the physician may only share information in so far as they believe it is in the best interest of the patient's health to participate, yet the physician should not be deceptive in depriving them of the necessary information to make an informed consent. The physicians are also obligated to facilitate the patients' opportunities to prevent ill-considered rational or irrational influences on their choices and not to view patients as means to one's ends. One does not do wrong for a child if what is done at the time is in the child's best interest, even if later that individual disagrees with the decision. It is wrong if the child's own good is insufficiently regarded.

Problem Statement

In Nigeria, older children are generally excluded from the disclosure and decision-making process in medical investigations. Their fears, feelings, ideas and expectations are not openly addressed. Decisions are obtained by law from the parents/guardians even if at variance with the child's wishes. Parents/guardians may also not comprehend the information given before giving consent due to various factors, believing that the physician researcher will do no harm (Helgesson et al., 2005)

Justification:

Knowledge from this study will help to change the attitude and behaviour of medical investigators when addressing the concerns of parents and children. It can be used to encourage the development of a trusting relationship between the parents, children and the investigators. The recommendations can be used to reduce the paternalistic effects when there is a conflict of interest in the primary physician who is also the investigator. There is also a paucity of data on issues of consent in research among children in this setting.

Aim of Study

To assess the understanding of the informed consent process amongst the parents and guardians of children recruited into research:

Specific Objectives

1. To determine the meaning of "randomization" to the parents/ guardian of the child.
2. To assess the parents/guardians understanding of benefits and risks to the children.
3. To evaluate the factors that influence the parent /guardian's comprehension of the process of informed consent.
4. To explore the concept of "assent" by the child.
5. To assess the parents' understanding of the available options for the child.

METHODOLOGY

Study Design

It will be a descriptive cross-sectional design. It will be qualitative and will involve the use of a Focus Group Discussion (FGD).

Description of the study location:

The study will be carried out at the Out-patients' Clinics of the University College Hospital (U.C.H.), Ibadan, Oyo State, Nigeria. Ibadan is one of the largest cities in West Africa, and has a population of 3 million people (Fed Rep of Nig. Gazette 2007). The people come from various walks of life, with various occupations such as civil servants, professionals, traders, students, artisans and farmers. Ibadan is also known as a student-town because of the many educational institutions such as the Universities, the Polytechnics, and the many primary and secondary schools in the city. The hospital was founded in 1957 as Nigeria's first Teaching Hospital. It has 850 beds and is a referral centre for many of the clinics and hospitals in the surrounding environment and even far beyond. As a tertiary training and service institution, a large volume of research is undertaken with children and adults, especially in children with malaria (Falade et al., 2008).

Study Population

The study population will be the parents or guardians of the children recruited into on-going research.

Inclusion Criteria: Parents/guardians over the age of 18years whose children have been recruited into research studies.

Exclusion Criteria: Parents/guardians not willing to participate.

Data Collection Technique

Instruments:

The instruments used will be a structured coded questionnaire to obtain background socio-demographic characteristics of the participants and an open ended discussion guide which will obtain information about the knowledge of research, understanding of informed consent and perceptions of assent by children recruited for research in children.

Focus Group Discussion

The FGD will comprise parents or guardians of children who have been recruited into a research study, grouped by their similar age groups. The participants will be allocated into three groups of 6 participants. To encourage free communication, discussions and expression of their experiences, each group will comprise adults of similar age groups and gender. If possible a group of fathers/male guardians would be included. Two Key Informants among the Parents and the Research Assistants will also be interviewed.

The following sequence of steps will be carried out:

1. After a brief introduction, the purpose and scope of the discussion will be explained to each group.

2. Participants will be given identification numbers and would be asked to give short background information about themselves.

4. The discussion will be structured around the key themes using the probe questions prepared in advance which will focus on their knowledge of health research in general and in children in particular. What are their expectations regarding information, benefits and risks of research? What type of research would they consent for their children to participate? What is understood by random selection? What are their responsibilities regarding giving consent on behalf of their children? Should their children be involved in the decision to agree to participate and in what way? What would be the consequences if they withdraw their children from the study?

5. During the discussion, all participants will be given the opportunity to give their comments and opinions.

A trained rapporteur will capture the discussion in writing and note the participants' nonverbal expressions. The discussion will also be tape-recorded. Refreshments and a monetary token to subsidize transport costs will be given after the session as a gesture of appreciation to the participants for having taken time off their work to participate.

Follow-up:

All children of parents' recruited will be followed up in the clinics or referred to appropriate specialty clinics.

Data Analysis and Presentation of Findings:

The data collected from the respondents will be analysed into themes, the simple Grounded Theory would be used to analyse the responses (Charmaz, 2006).

Plans for dissemination:

1. West African Bioethics Programme
2. The Department of Family Medicine, U.C.H., Ibadan.
3. The Department of Paediatrics, U.C.H., Ibadan.
4. The Institute of Child Health, COM, UI.
5. The general public.
6. Manuscripts will be sent to reputable journals for publication.

Ethical consideration:

The researcher will obtain approval from the Heads of the Departments of Family Medicine, Paediatrics and the Director of the Institute of Child Health, University College Hospital (U.C.H.), Ibadan. Ethical approval will also be sought from the Joint University of Ibadan (U.I.) / U.C.H. Ethical Review Board. In carrying out this study, the following ethical issues will be put into consideration:

Informed Consent: The purpose of the study will be explained to each of the potential participants, and their written consent obtained.

Right to decline: The parents/guardians will be informed of their freedom to withdraw or refusal to take part in the study without affecting their usual standard of care.

Confidentiality of data: All information, including results and recordings obtained from the respondents will be kept strictly confidential. The participants will be assured that their identity would be kept in confidence by the investigator.

Beneficence to participants: The benefits of the study in terms of how this study results will help in attitude of researchers to research in children will also be explained to the participants.

Non-Maleficence to the participants: No harm will be done intentionally to any of the participants.

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APPENDIX I

QUESTIONNAIRE

My name is Dr. Modupe Ladipo of the Family Medicine Department, University College Hospital, Ibadan. I am conducting a study to assess the knowledge and the concerns of parents about their children taking part in research. Your confidentiality will be guaranteed. You have the right to refuse to take part or withdraw at anytime and your child will still be attended to appropriately. There is no harm to you or your child except a few minutes of your time. The discussions will be of benefit and can be used to encourage the development of a trusting relationship between the parents, children and the investigators.

SECTION A: Socio-demographic

YOUR CHILD WAS RECRUITED INTO THIS STUDY

1. Serial No: ----------
2. Hospital No: ----------
3. What is the age of your child recruited? ----------
4. What is the gender? 1. Male ------2. Female----------
5. What is the parents/guardian's gender? 1. Male ------2. Female----------
6. What is the parent/guardian's age at the last birthday? ---------- years.
7. What is your nationality? ----------
8. If Nigerian, what geographical zone do you consider yourself to be from?
    a. South-west
    b. South-south
    c. South-east
    d. North-west
    e. North-east
    f. North-central
9. What is your highest educational level?
    a. Primary
    b. Secondary
    c. Some college/technical school
    d. Tertiary
    e. No formal education
10. What relationship do you have with the child you brought to the clinic today?
    a. Father
    b. Mother
    c. Grandparent

d. Aunt
e. Uncle
f. Sister
g. Brother
h. Guardian
i. Friend of the family
j. Supervisor from residential facility
k. Other (please specify) _____

SECTION B: Focus Group Discussion.

Questions (Themes)

1. What do you know about research in a hospital? - (Knowledge)
2. What do you know about research in children? - (Knowledge)
3. Who do you expect to inform you about the research that is going on? - (Knowledge)
4. What information do you expect to get? - (Knowledge)
5. Do you think it is advisable that the research and treatment should be explained to your child in a way he/she will understand? - (Assent)
6. At what age do you think a child can understand what is happening? - (Assent)
7. What do you think about research on unborn children or babies? (Knowledge)
8. Now that your child was recruited for this study, what information were you given? (Understanding)
9. Was the informed consent information adequate for you to understand? - (Understanding)
10. Are the children in this research exposed to benefits or risk? - (Understanding)
11. What are the benefits of children participating in the research? - (Understanding)
12. What are the risks of children participating in the research? - (Understanding)
13. What do you understand by “random” selection of patients? - (Understanding)

14. If not all the children recruited are given the same medication but picked randomly to be given Drug A or Drug B, would you still allow your child to participate?
    - (Understanding)
15. Are you aware that you could choose not to take part and your child would still be treated but not necessarily with the drugs used in a research?
    - (Understanding)
16. What do you think about the treatment that is being given in the research? (Understanding)
17. Should research be done only in adults and the same medicines used in children in smaller doses? - (Understanding)
18. What do you think about signing or thumb-printing of the informed consent forms?
    - (Understanding)
19. What should a parent consider when agreeing that their child should be recruited in a research? - (Knowledge)

Thank you for taking the time to discuss these issues.

KEY INFORMANTS.

The Key Informants will be guided along the themes of knowledge, randomization, risks, benefits, understanding, and the role of assent.