Informed Consent in Pediatric Research

By:

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1. Introduction

- 20'th century
  - Unethical medical experiment.
  - The Tuskegee syphilis study (1932-1972)→Afro-America with low socioeconomic were not effective antibiotic in order to follow the natural course of illness.
  - The US government-human exposure to radiation (1944-1974).
  - Nazi physicians to commit the most horrid of atrocities in human subject studies → prisoner (1939-1945).

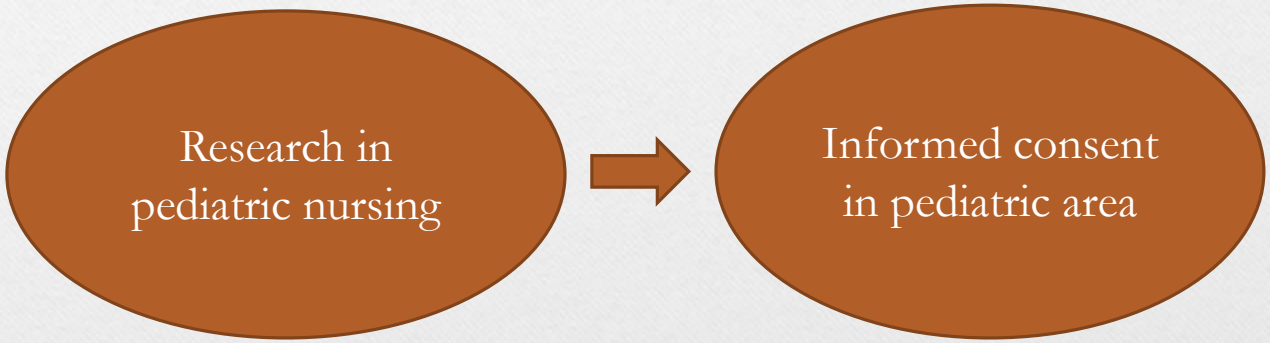
- The Nuremberg code military tribunal formed a code to prevent calamities.
  - All research subject→ informed consent (exclude minor, handicap, unconsciousness)→how about research in children?
- Helsinki declaration (1964)→permitted consent by the legally authorized representative of any potential research subject who incapable of giving informed consent.
  - i,e, children

- Consent from minor is complex.
  - Their vulnerability to exploitation and their maturity to grasp all relevant consequences from research.

2. Why conducting clinical trials (research) in pediatric?

- The Children's right to the highest attainable level of health.
  - It is not fair, if the children provided therapy based on study involved adult.
  - Children and adults differ in physiological capabilities, pharmacokinetic profile and pharmaco-dynamic characteristics.
  - The dose of medications is dependent on body weight or surface area.
  - Age influences the severity and type of disease, and pathological agents.

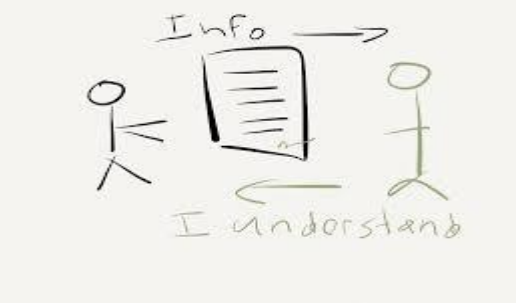
Bavdekar, 2013

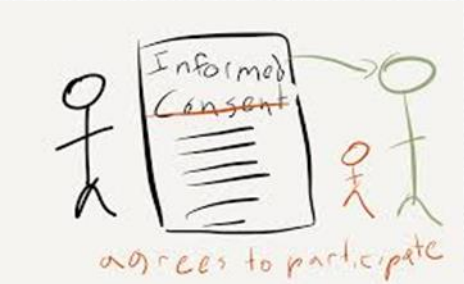

Research in pediatric nursing
Informed consent in pediatric area

3. Definition

- Informed consent is part of preferences of patients
  - The choices that persons make when they are faced with decision about health and medical treatment (also to be participate in research) .
  - The choices reflect the patient's own experiences, belief and value.

Johsen, Siegler & Winslade, 2015





- Informed consent in research:
  - A process for enabling individuals to make voluntary decisions about participating in research with an understanding of the purpose, procedures, risks, and benefits of the investigation, as well as alternatives to participating (Beskow, 2013).
- Components of informed consent are competence, disclosure, understanding, voluntariness, and consent (Johsen, Siegler & Winslade, 2015).

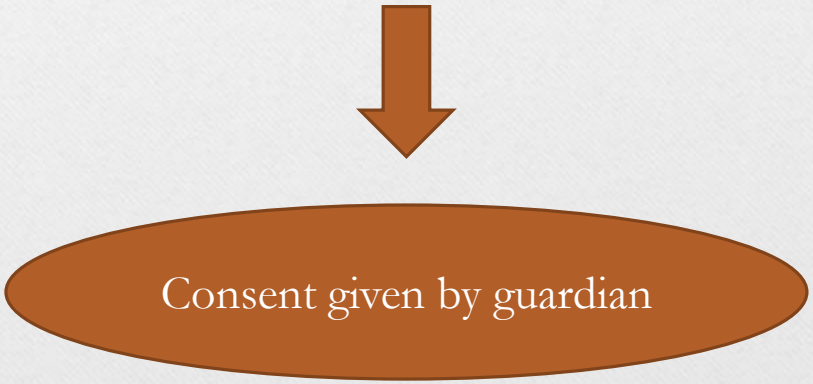
4. Measuring children's capacity to consent to research

- Study 1 (Lee, et al., 2013):
  - 123 adolescent (12-17 years, average 15 years) read a consent form and complete a comprehension test (Hepatitis B vaccine trial).
  - Result: Only 56% subjects demonstrated absolute comprehension.
  - Conclusion: Almost half subjects would have their decision on information, while they didn't fully understand.

- Study 2 (Ondrusek, et al., 1998 in Leibson & Koren, 2015)
  - 18 healthy children (5-15 years) agree participated in a nutrition study.
  - Respondent given explanation that this was research and not clinical, and they could withdrawn any time.
  - Result:
    - None of children < 9 years could explained the purpose of study.
    - Young children did not understand the planned procedures, potential harm, benefit and right to withdrawn.
  - Conclusion: Children <9 years cannot be expected to consent or assent in clinical research.

- Study 3 (Hein, et al., 2014 in Leibson & Koren, 2015)
  - 161 pediatric inpatient and outpatient (range 6-17 years, mean age 10,6 years).
  - Study proposed a standardized competence assessment instrument for children by modifying and existing tool: the MacArthur Competence Assessment Tool for Clinical Research.
  - Result: 37,9% of the children incompetence to give consent.

- From study 1,2,3:
- We learned that most of the children < 9 years lack capacity to consent for participation in clinical trials.



5. Proxy consent by guardian (still debate)

Pro

- If capable, child would consent in research and therefore proxy consent is valid (McCormick, 1974 in Leibson and Koren , 2015).
  - Children as members of a moral community.
  - They are obligate to the advance of health and welfare.

Cons

- from ethicists : one should not touch human being unless they can consent to be touched.

Pro

- Children tend to follow the course action that is recommended…by adults who are responsible for child's well being (Ackerman, 1979 in Leibson and Koren , 2015)
- Gaylin (1982 in Leibson and Koren , 2015): Parents have moral obligation to support their children's participation in research.

Cons

- Ramsey (1980) in Leibson and Koren (2015) claimed against any use in research of non-consenting subject such as child.

- This debate widened with the issue of enrolling healthy children in non-therapeutic drug research (Leibson and Koren, 2005).

6. Essential component informed consent in pediatric research

1. FREE CHOICE
   - Parent and children should be totally free to refuse to sign consent.
   - This freedom may be endangered by several factors:
     - Coercion→ fear quality of care their children receives.
     - Inducement of reward → avoid high reward may distort the concept of free choice.

2. COMPLETE AND UNDERSTAND INFORMATION

- The research plan should be clearly explained →purpose, benefit and risk, procedure, etc.
- Understanding the written information is extremely variable.
  - A single medical center in US has documented 25 % of the patient had inadequate health literacy (Carpenter, 2014 in Leibson & Koren, 2015).
  - Present information with different of multimedia→ to solve inability patient's to understand the written explanation (Tait, et al, 2011; O'Lonergan, et al., 2011 in Leibson & Koren, 2015).

- Participant does not understand protocol design and with randomization
    - Ashcroff, et al (2007)
- To ensure clarity, all information should be written
    - Informed consent consist of two parts: information sheet, consent form.

- How much information should be given for parents and children?
  - Many details information → may dilute the main issues should concern the parent.
  - The amount information that reasonable patient would want to know (in US, Canada, NZ).
- An area of continuous debate is how to inform parent and guardians on rare but serious effect of an experimental drug procedure.

3. CONFINDENTIALITY

- Documents should not contain the identifying details, unless the family/child agree.
- Securing confidentiality should state in the informed consent.
- Give information to family → If research reveal information which may be legally sought by child protection authorities.
- Confidentiality→ trust and cooperation for population.

4. ASSENT

- Agreement from children to be participate in the research.
- Additional parental agreement.
- Document that explains to the child in language, so child can understand the essence of study, as well as child say 'no'.
- It is contain purpose, benefit, and risk.
- AAP regards children with intellectual level 7 year or older capable of giving information.

- Evidence
  - Children < 9 years lack of capability to meaningful consent (Ondrusek et al., 1998; Hein, et al.,2014 in Leibson and Koren, 2015).
  - No children < 11 years were not aware that they stayed in hospital to research purposes (Schwartz, 1972 in Leibson and Koren, 2015).
  - Recent review→ children under certain circumstances the age of cut off (5-7 years) could be tailored, so their participation in the research truly represent intellectual ability (Waligora, et al., 2014 in Leibson and Koren, 2015).

5. CONSENT BY MINOR

- Consent given by children.
- British Medical Association:
  - where the minor can make decision for himself, it would be inadvisable to process without the approval of some one with parental responsibility
- Minor's ability consent to research is their capacity to understand, appreciate, reason, and free choice.

Leibson and Koren, 2015

- Consent by emancipated minors
  - Adolescent whose unique life (i.e. marriage, parenthood, self-support, military membership).
  - They able to give consent for research.

Leibson and Koren, 2015

- Consent by mature minors
  - This is for therapeutic decisions and not for research.
  - Mature minors capable to consent for medical treatment if treatment has a direct benefit to the minor.
  - Example: Seeking treatment for Sexual Transmitted Disease, drug abuse, pregnancy-related care.
  - Exception
    - Minors can participate in study with minimal risk and if research question only be answered in this population.
    - i.e. new antibiotic in gonorrhea.

Consent by parent

YES→ LAW

ISSUE: CHILDREN INTEREST

Children's age to give a consent

NOT CLEAR

COMPETENCY TEST

My opinion

Consent by minor

PROXY CONSENT BY GUARDIAN

YES → EMANCIPATED AND MATURE MINORS

Children Assent

YES, IF CAPABLE

ISSUE: INFANT, SICK INFANT

7. CONCLUSION

1. The special issues and process associated with consent are probably among the unique pediatric research.
2. Proxy consent by parent in pediatric research should involve the children's assent (if they capable to make agreement).
3. There is challenge societal judgment of the appropriate cut-off age affirmation for consent and assent.
4. Emancipated minors can give consent in therapeutic decision and research without parental approval.
5. Mature minors can give consent in therapeutic decision and specific research without parental approval
6. Increasing understanding the children maturity, it becomes apparent that regulatory, medical and public view on children's participation in the consent process will have to evolve continuously.

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Thank You