PERCEPTION OF SURROGATE CONSENT AMONG RELATIVES OF CHILDREN UNDERGOING SURGICAL PROCEDURES IN A TERTIARY CARE UNIVERSITY HOSPITAL IN EGYPT

Thesis Submitted for the Partial Fulfillment of the Master Degree in Anesthesiology

By

Ahmed Hazem Farouk

Supervised by

Prof. Dr. Maha Gamil Hanna, MD

Professor of Anesthesiology,
Faculty of Medicine, Cairo University.

Prof. Dr. Sherry Nabil Rizk, MD

Professor of Anesthesiology,
Faculty of Medicine, Cairo University.

Dr. Heba Mohamed Nassar, MD

Lecturer of Anesthesiology,
Faculty of Medicine, Cairo University.

Faculty of Medicine

Cairo University

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Abstract

This study demonstrated that the level of education was the main factor that significantly influenced a person's view about medical researching in general, and whether they would be willing to allow their children to participate in a health care research. This was a quantitative, exploratory, cross-sectional study with convenience sampling, undertaken from relatives of children who were admitted to pediatric hospital at Cairo University and scheduled to undergo a surgical procedure.

Keywords:- Competence- Voluntariness- Tertiary Care.

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Introduction

The basic rights of the individual are encompassed in the so-called *categorical imperative* as stated by Immanuel Kant in his formula of humanity (1): 'Act in such a way that you treat humanity, whether in your own person or in the person of any other, never merely as a means to an end, but always at the same time as an end.'

This implies that any human being possesses an inherent value and dignity and must be treated with respect. Several rights can be derived from this fundamental guiding principle, and in the context of medical research, these include the right to be protected from *harm*, *exploitation*, *coercion*, and *deception*. Research should therefore attain *beneficence*, *justice*, and *respect for persons*, and this is ensured through independent research ethical committees that review research protocols (2).

Justice requires that research 'does not prey on the vulnerable', vulnerable populations must not be exploited as easily accessible research subjects. They may only be used as research subjects if the research is designed specifically to benefit this particular group, and the research cannot be conducted on less vulnerable populations with a similar scientific gain (2).

Respect for persons requires that persons do not serve as research subjects against their will or knowledge, that is, they must not be coerced or deceived to participate in research; research subjects must therefore be treated as autonomous individuals and provide consent for research participation, and

vulnerable populations with diminished autonomy must be protected in a manner that reflects their vulnerability. In medical research on children, this protection will often be established by proxy consent (3).

So participation in medical research depends on participant willingness, and it has been reported by some studies that the desire to be involved in decisions concerning one's healthcare especially with regard to obtaining surrogate consent is related to educational status (4).

Aim of work:

1. To measure the response and perception of relatives of children undergoing surgical procedures toward providing surrogate consent about performing a medical research on their children.

2. To assess the factors, especially the educational status that influences the attitude of participants toward surrogate consent practice in Egypt.

Ethics for medical research (protecting patients, researchers and institutions)

Importance of medical research:

Medicine and social values are not static, Medicine is not an exact science in the way that mathematics and physics are. As every patient is different and there is no effective treatment for 100% of population Thus, medicine is inherently experimental. Even the most widely accepted treatments need to be monitored and evaluated to determine whether they are effective for specific patients and, for that matter, for patients in general (5).

Another, perhaps better known, function of medical research is the development of new treatments, especially drugs, medical devices and surgical techniques. Great progress has been made in this area over the past 50 years and today there is more medical research underway than ever before. Nevertheless, there are still many unanswered questions about the functioning of the human body, the causes of diseases (both familiar and novel ones) and the best ways to prevent or cure them. Medical research is the only means of answering these questions, In addition to seeking a better understanding of human physiology (6).

The basic principles of research ethics, The World Medical Association and code of Ethics, Declaration of Helsinki (DOH) 2013

It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject (7).

- **Scientific requirements, Research protocol and Research ethics committee:**

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects (8).

The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration. Medical research involving human

subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person (7).

- **Research Registration and Publication and Dissemination of Results:**

Scientists have a responsibility to gather data meticulously, to keep impeccable records with appropriate levels of privacy protections, to interpret results objectively and not force them into preconceived molds or models, to submit their work for peer review, and to report knowledge. All clinical trials must be registered and reporting of methodology and outcomes must be clear complete, and transparent (9).

Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication (6).

- **Risks, Burdens and Benefits (including social & personal value & scientific merits):**

One of the more controversial requirements of a medical research project is that it contributes to the wellbeing of society in general. It used to be widely agreed that advances in scientific knowledge were valuable in themselves and needed no further justification. However, as resources available for medical research are increasingly inadequate, social value has emerged as an important criterion for judging whether a project should be funded. According to the **DOH,** the importance of the project's objective, understood as both scientific and social importance, should outweigh the risks and burdens to research subjects (7).

A risk is the potential for an adverse outcome (harm) to occur. It has two components:

1. The likelihood of the occurrence of harm (from highly unlikely to very likely)
2. The severity of the harm (from trivial to permanent severe disability or death).

A highly unlikely risk of a trivial harm would not be problematic for a good research project. At the other end of the spectrum, a likely risk of a serious harm would be unacceptable unless the project provided the only hope of treatment for terminally ill research subjects. But if the risk is entirely unknown, then the researcher should not proceed with the project until some

reliable data are available, for example, from laboratory studies or experiments on animals (10).

Furthermore, the populations in which the research is carried out should benefit from the results of the research. The social worth of a research project is more difficult to determine than its scientific merit but that is not a good reason for ignoring it. So researchers, and ethics review committees, must ensure that patients are not subjected to tests that are unlikely to serve any useful social purpose. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results. The subjects must be volunteers and informed participants in the research project, the right of research subjects to safeguard their integrity must always be respected (11).

- **Privacy and Confedentiality:**

As with patients in clinical care, research subjects have a right to privacy with regard to their personal health information. In order to protect privacy, researchers must ensure that they obtain the informed consent of research subjects to use their personal health information for research purposes, which requires that the subjects are told in advance about the uses to which their information is going to be put, The potential impact on the patient's well-being; implications for family members; and the potential for adverse use of such information by employers, insurers, or other societal institutions

should be fully explored and understood. Commercial mail-order and other testing do not currently address the requirements of specificity, sensitivity, or scientific credibility. As a general rule, the information should be de-identified and should be stored and transmitted securely (12).

➢ Informed consent:

The first principle of the Nuremberg Code reads as follows: "The voluntary consent of the human subject is absolutely essential." (13). The explanatory paragraph attached to this principle requires, among other things, that the research subject "should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.", to protect and foster a patient's free, uncoerced choices (14)

In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed. While obtaining informed

consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship (4).

- **Vulnerable groups:**

For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons (15).

When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for