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Understanding Understood Consent

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While informed consent is a cornerstone of modern medical research practice, it is a relatively recent development. Prior to World War II, there were few universal guidelines concerning obtaining consent from patients prior to their undergoing a complex medical procedure or taking part in medical research. The postwar Nuremberg trials brought to light the atrocities committed by Nazi and Japanese researchers and led to the passing of The Nuremberg Code that established guidelines for consent for human subjects in clinical research.[1] The Declaration of Helsinki in 1964 established the first international ethical guidelines for research with human subjects.[2] In 1966, Beecher first brought to light many of the particular ethical issues involved with research studies involving children.[3] During the intervening 5 decades, ethical and legal frameworks for obtaining consent have evolved; guidelines have been created and are regularly revised.[4] Obtaining patient consent for medical treatment and procedures is now standard practice and is especially important when the proposed therapy is part of a research study. Ethically, obtaining consent demonstrates respect for patient autonomy and also may involve elements of the principles of nonmaleficence and beneficence. Modern research studies have detailed recommendations and requirements for obtaining informed consent. While a full discussion of the multiple ethical and legal issues concerning consent are beyond the scope of this essay, a key issue is whether informed consent should be our goal or whether we should strive for something better.

While various legal bodies and ethics and research consortiums have put forth different definitions and recommendations for informed consent, the recommendations have several universal components: the patient has been informed of the treatment and why it is being offered, has been presented with the potential benefits and risks, and has been presented with alternatives to the proposed therapy. In the case of entry onto a clinical trial, informed consent is more involved and should include the patient's rights in the study, key elements of the proposed research, potential risks and benefits, and the voluntary nature of participation, including the right to withdraw from the study. The challenges of informed consent are increased when dealing with children. Children are considered a vulnerable population, so extra care must be exercised when including children in clinical studies. The risks involved in the study must be carefully weighed against the potential benefits to the child, with the parents serving as legal surrogates in terms of providing consent, usually with assent being solicited from the minor child.

Undoubtedly, the development of universally agreed upon guidelines for patient consent has gone a long way toward promoting respect for patient autonomy, but have we gone far enough? Patient understanding of the procedure or study is an essential component of informed consent; however, common consenting practices may not be adequately achieving this goal. Current consenting practices often depend heavily on written documentation with a focus on the medico-legal aspects of consent and assent. Factors such as the length and complexity of the consent document,[5,6] language proficiency and reading and education levels of the patient,[7] parental and patient stress and anxiety,[8,9] and communication techniques of the person obtaining consent[9] have been shown to negatively impact the *informed* nature of informed consent. One study found that potential research participants understand only 30%-80% of the information in the provided consent package.[10] Another study looked at parental understanding of the randomization process involved in a pediatric oncology trial and found that fewer than half (49%) of parents understood the process despite it being addressed in 83% of the cases.[11] A 2017 study of oncology patients found that 80% incorrectly responded to key questions involved in the study.[12] Given that patient understanding of the therapy or clinical trial is essential if we are to demonstrate respect for patient autonomy, it appears that we may be failing that mandate.

During the last decade, the concept of *understood consent* has emerged as an alternative and perhaps superior goal. The difference between informed and understood consent is more than simply semantics. Understood consent addresses differences in patients' levels of understanding and switches the emphasis of the consent process from the person obtaining consent to facilitating understanding on the part of the patient. While accurately assessing patients' understanding of medical procedures or research studies is a difficult task, if we are to protect the autonomy of patients, it is essential. In a recent perspective paper, Isles argues that understood consent should be the new paradigm for pediatric research consent, and he offers suggestions for how to achieve this goal.[13] One technique to promote understood consent is to use oral communication as well as written documentation. The oral and written communications should be provided in the language in which the patient or guardian and minor are fluent, and the written communication must be at an appropriate reading level. Another technique that may enhance understood consent is providing written documentation in advance of the consent meeting, thus

providing time for the patient or guardian to review the documents and formulate questions. Yet another technique is the use of staged consents. These consents can break down the information about long or complex studies into smaller, more comprehensible, pieces. The current Children's Oncology Group Acute Lymphoblastic Leukemia studies are using this technique. The use of alternative media such as videos and computer- or cell phone–based applications may help to achieve understood consent. Having consenters trained in communication techniques also may facilitate understood consent. For example, the use of teach-back or repeat-back techniques, in which the consenter asks the patient or guardian to explain the information that has been presented, can be an effective means of gauging and ensuring patients' understanding of what they are actually consenting to.[14] Some of these techniques for improving the consenting process are being incorporated into the guidelines of several research bodies.

Medical treatments and research study designs are becoming more complex, thus increasing the challenges of translating this technical information into a comprehensible form for patient decision-making. Moving toward understood vs informed consent by using techniques that enhance patients' understanding of complex medical procedures and clinical trials is an ethically sound goal that demonstrates respect for patient autonomy and one that as healthcare providers and researchers we should be continually striving to attain.

REFERENCES

1. Shuster E. Fifty years later: the significance of the Nuremberg Code. *N Engl J Med*. 1997 Nov 13;337(20):1436-1440. doi: 10.1056/NEJM199711133372006.
2. World Medical Association. Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Revised October 19, 2013. www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects. Accessed August 17, 2017.
3. Beecher HK. Ethics and clinical research. *N Engl J Med*. 1966 Jun 16; 274(24):1354-1360.
4. Bhutta ZA. Beyond informed consent. *Bull World Health Organ*. 2004 Oct;82(10):771-777.
5. Sharp SM. Consent documentation for oncology trials: dose anybody read these things? *Am J Clin Oncol*. 2004 Dec;27(6):570-575.
6. Beardsley E, Jefford M, Mileshkin L. Longer consent forms for clinical trials compromise patient understanding: so why are they lengthening? *J Clin Oncol*. 2007 Mar 20;25(9):e13-e14.
7. Davis TC, Holcombe RF, Berkel HJ, Pramanik S, Divers SG. Informed consent for clinical trials: a comparative study of standard versus simplified forms. *J Natl Cancer Inst*. 1998 May 6;90(9):668-674.
8. Simon C, Eder M, Raiz P, Zyzanski S, Pentz R, Kodish ED. Informed consent for pediatric leukemia research: clinician perspectives. *Cancer*. 2001 Aug 1;92(3):691-700.
9. Miller VA, Drotar D, Burant C, Kodish E. Clinician-parent communication during informed consent for pediatric leukemia trials. *J Pediatr Psychol*. 2005 Apr-May;30(3):219-229.
10. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. *JAMA*. 2004 Oct 6;292(13):1593-1601.
11. Kodish E, Eder M, Noll RB, et al. Communication of randomization in childhood leukemia trials. *JAMA*. 2004 Jan;291(4):470-475.
12. Schumacher A, Sikov WM, Quesenberry MI, et al. Informed consent in oncology clinical trials: A Brown University Oncology Research Group prospective cross-sectional pilot study. *PLos One*. 2017 Feb 24;12(2):e0172957. 10.1371/journal.pone.0172957.
13. Isles AF. Understood consent versus informed consent: a new paradigm for obtaining consent for pediatric research studies. *Front Pediatr*. 2013 Nov 21;1:38. doi: 10.3389/fped. 2013.00038.
14. Fink AS, Prochazka AV, Henderson WG, et al. Enhancement of surgical informed consent by addition of repeat back: a multicenter, randomized controlled clinical trial. *Ann Surg*. 2010 Jul;252(1):27-36. doi: 10.1097/SLA.0b013e3181e3ec61.