

Improving health literacy: informed decision-making rather than informed consent for CT scans in children

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Health literacy is described as “The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions” [1].

In the paper titled “What physicians think about the need for informed consent for cancer risk with low-dose radiation,” the authors contend that physicians are aware of the risk of cancer with low-dose radiation examinations and that radiology departments should consider obtaining informed consent from patients undergoing radiation-based low-dose examinations [2]. The paper makes a compelling argument based on scientific reports from governmental agencies and multiple scientific papers that provide a strong rationale based on the extrapolated data using the linear nonthreshold theory of radiation-induced cancer from Hiroshima after the atomic bomb [3].

Although the authors’ intent of providing informed consent to patients prior to performance of CT scans is laudable, this approach might present more questions than answers for both the physician and the patient. As Frush asked in a letter to the editor, “Do we obtain consent from a 1-year-old, maybe a 40-year-old, but not an 80-year-old? Is the consent different for a child who has undergone CT once versus a child who has undergone 12 CT examinations? Do we begin to obtain consent after 50 chest radiographs?” [4]. Who would obtain the consent? The

referring physician who understands the indication for the medical imaging or the radiologist who performs the imaging? How do we measure cumulative dose or even track examinations in today’s mobile society?

With these problematic issues, we propose a different concept to foster informed participation of patients in their health care decisions: that is informed decision-making. Informed decision-making calls for “a meaningful dialogue between physician and patient instead of unidirectional, dutiful disclosure of alternatives, risks, and benefits by the physician” with informed consent [5]. The two concepts, informed consent and informed decision-making, can be quite different in their intent and outcome.

Informed consent is fraught with problems

Informed consent is defined as “consent by a patient to a surgical or medical procedure or participation in a clinical study after achieving an understanding of the relevant medical facts and the risks involved” [6]. Informed consent is a worthy goal but fraught with difficulty for the patient. As Cassileth et al. [7] ask in their paper on informed consent, “why are its goals imperfectly realized?” They report their study of 200 cancer patients who were asked to fill out informed consent for chemotherapy, radiation therapy or surgery. One day later, patients were asked to fill out a questionnaire based on their recall. Only 60% understood the nature of the procedure, and only 55% listed one potential complication. The forms were viewed as “legalistic” and an attempt to “protect the physician’s rights,” not the patient’s rights. Often these forms are difficult to comprehend and provide limited understanding of the procedure under consideration. In another study, consent forms from medical research studies were evaluated.

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A total of 114 websites of US medical schools were surveyed for Institutional Review Board (IRB) readability standards and it was found that the sample text of the consent forms provided by the IRBs fell short of their own standards [8]. The text of the consent forms was almost three school grade levels above the IRBs' recommendations and was too difficult for most people to truly understand, and fell short of helping the patient provide informed consent about participating in research.

Informed choice is a better option

Informed choice or informed decision-making uses a different approach that portrays the decision issues in more depth and uses individual risk estimates. It provides the patient with a context, where everyday risks such as "accidents from driving in a car" are related to the theoretical risk of the procedure. It provides several different formats or examples with enough flexibility that patients better comprehend the information [9]. This approach addresses the range of information needed for individuals of varied educational and health literacy background. The tenets of informed decision-making begin to fulfill the Institute of Medicine's (IOM) goal of improved health literacy [1]. The IOM stress the variable education levels and needs of US citizens when receiving health information and caution health-care providers to be flexible in presenting medical information. A study evaluating the amount of information that patients with cancer want to receive prior to instituting radiotherapy found that information needs varied widely among participants [10]. In this study, 28% of participants wanted to be informed of mild side effects if the risk of the side effects was deemed small (0.1%), whereas 31% wanted to be informed if there were either a 50% or a 100% risk. For severe side effects, 44% wanted to be informed of a 0.1% risk, whereas 16% wanted to be informed if the risk was 50% or 100% [10]. Younger patients were more likely to want more information than older patients.

The strategy of informed choice promotes the use of "decision aids" such as booklets, video, interactive computer programs and charts. These educational tools may be provided in advance of the procedure or at the time of the procedure [9]. This approach provides a framework for a meaningful discussion for informed decision-making and a truly "shared decision-making" model of patient care [11]. An example of communication of risk from radiologic examinations is provided by Picano [12]. He displays a graphical representation of cancer risk and radiation dose in multiples of dose from a chest radiograph for common radiologic procedures. He places these examinations in categories from zero to low in a

simple color-coded graph. Informed choice places the emphasis on the "decision-making process as a meaningful path toward fostering patient involvement" rather than satisfying an administrative requirement or protecting oneself from liability [5].

Discussion of risk from medical radiation is a complex topic

The discussion of risk is a complex topic. Risk is defined by the National Council on Radiation Protection and Measurement as "the probability of harm, combined with potential severity of that harm" [13]. In the case of medical radiation, the risk is real, but assessing the probability of harm and the potential severity of that harm is difficult to quantify. As Mezrich [14] points out, the circumstances of radiation exposure in Hiroshima are different from exposure to medical radiation from CT scans.

The discussion of medical radiation is a controversial topic. Patients cannot see radiation. We cannot measure it easily at the time of the CT scan. We can only estimate the radiation dose to the patient [15]. The effects may not be seen for years, if ever, as the latency for radiation-induced cancer is 10–20 years [3]. The theoretical risk from radiation-induced cancer is projected onto a background of a frequent disease (nonfatal cancer) in the general population with a life-time risk of almost 40% in both men and women [3]. To further complicate the discussion, the risk of radiation-induced cancer is based on population risk, not risk to individual patients. Yet the question asked by families is "does the CT scan ordered for *my* child cause cancer?"

We are asking parents to navigate a very complex and emotional topic. Experimental evidence on patients' understanding of the risk of medical treatment found that people's decision-making is not strictly rational but rather subject to systematic bias. Lloyd [16] demonstrated that people use shortcuts to simplify decision-making and this can lead to bias. Such shortcuts are referred to as *heuristics* [16]. This can lead people to treat risk on a simple level and categorize it as either "dangerous" or "safe." For example when there seemed to be evidence in a public health scare in the United Kingdom that birth control pills increase the risk of venous thrombosis, people reclassified the pill from safe to dangerous [17]. The authors emphasized that there was little evidence that people considered that the risk of pregnancy far outweighed the risk associated with the birth control pill and that individuals "rarely considered the relatively small increase in absolute risk associated with the pill when making a decision to stop taking it" [18]. The concern is that patients may begin to view imaging tests that use medical radiation as "dangerous" and

disregard the valuable role these modalities play in medical decision-making.

So *what is our ethical and professional obligation to our patients and their families?* We agree with the authors that reliable, understandable and available information is the responsibility of the medical profession and the right of the patient. We believe that radiologists have a strong obligation to perform examinations involving radiation using the ALARA principles. We have a responsibility to inform physicians involved in the ordering of examinations of the potential risks of medical radiation so appropriate risk-to-benefit strategies are considered. Patients should be made aware of how risk-versus-benefit decisions are being made, but this information might not be adequately addressed by a simple informed consent. We would argue that informed consent might not be necessary, not because it is too burdensome, but rather because *it does not provide enough information* for patients in a context that is understandable to them. According to the ACR guidelines on communication for patients undergoing a radiologic procedure: “There are other forms of communication that provide documentation of receipt which may also suffice to demonstrate that the communication has been delivered and acknowledged” [19].

We advocate that educational materials be provided to every parent or patient prior to the performance of every CT scan as part of medical safety and practice quality improvement and that receipt of this information be documented in PACS or the electronic medical record. This action promotes medical literacy as advocated by the IOM’s report. The widespread use of educational materials for patients, as advocated by Bulas et al. [20] (www.imagegently.org) and Larson et al. [21] prior to the performance of a CT scan and given within the radiology setting, provides parents with ready access to the answers to their questions and can reduce anxiety.

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