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**Informed Consent in Computed Tomography: A Case for Standardization**

Casey Rentmeester, PhD, Mark Bake, DBA, R.T.(R)(CT) & Christina Smith, MS, R.T.(R)(M)

Abstract

Informed consent has become the most obvious instantiation of patient autonomy in contemporary medicine, though as a practice it does not encompass all spheres of medicine. While diagnostic radiological procedures carry some risk due to the use of radiation, there is no standardized practice of informed consent in the United States. The authors describe the ethical justification of informed consent, the legal background surrounding it, and a brief history of radiology and radiological protection. They ultimately argue that informed consent should become a common practice in computed tomography given the risks involved due to radiation exposure, especially considering the overuse of this technology, since it respects patient autonomy.

 Informed consent has been described succinctly in the following way: “when *information* is disclosed by a physician to a *competent* person, that person will *understand* the information and *voluntarily* make a *decision* to accept or refuse the recommended medical procedure.”[[1]](#endnote-1) Typically speaking, the information disclosed will include the risks, benefits, and alternatives to the recommended treatment. While informed consent is standard practice in many sectors of the medical field, it has yet to be standardized in the field of diagnostic radiology in the United States. While this is appropriate for some diagnostic radiological procedures due to the small risk as compared with the potential benefit, it is not appropriate for computed tomography scans, which carry a far more significant amount of risk, especially given the overuse of this technology. Given the ethical justification of informed consent, the legal history of informed consent, and the risks involved in computed tomography scans, the authors argue that institutions should implement informed consent protocol for computed tomography scans.

**Philosophical Background**

Informed consent has become commonplace in most sectors of the medical field. The primary purpose of informed consent is to promote the autonomy of the individual in medical decision making.[[2]](#endnote-2) The philosophical foundations of autonomy are most clearly found in Immanuel Kant’s deontological ethics, but can also be seen in the works of John Stuart Mill and Aristotle, who represent the ethical theories of utilitarianism and virtue ethics, respectively. Thus, autonomy is an aspect of all three main ethical theories. Kant famously made the distinction between persons and things in his *Groundwork for the Metaphysics of Morals*. While persons are rational beings and must thus be regarded as “ends in themselves,” things only have “relative worth as a means.”[[3]](#endnote-3) Therefore, things are appropriately designated with a price, while persons are priceless and should rather be understood as having dignity. Since persons have dignity, they have the right to autonomy, which is sometimes also referred to as the right to self-determination.[[4]](#endnote-4) While Mill explicitly argues against Kant’s ethical theory in espousing his own theory of utilitarianism,[[5]](#endnote-5) his philosophical conception of freedom is consistent with Kant’s conception of autonomy. In his treatise, *On Liberty*,Mill stated, “The only freedom which deserves the name, is that of pursuing our own good in our own way, so long as we do not attempt to deprive others of theirs, or impede their efforts to obtain it. Each is the proper guardian of his own health, whether bodily, or mental or spiritual.”[[6]](#endnote-6) In other words, as long as one’s actions do not affect others, one is free to self-determine one’s own life. While decisions regarding one’s health do often affect others, Mill’s claim that the individual is the appropriate guardian of one’s own health is a philosophical justification of informed consent. Indeed, Dax Cowart, who was the champion of the “right to die” movement in the United States in the 1980s, has utilized Mill’s idea of freedom to support his cause.[[7]](#endnote-7) Finally Aristotle, who famously defined the human being as “the rational animal,” argued that “we are masters of actions from the beginning right to the end, if we know the particular facts.”[[8]](#endnote-8) Informed consent, of course, is all about providing individuals with the particular facts that are relevant to the recommended treatment. From the perspective of virtue ethics, which emphasizes the cultivation of character in a social setting, “autonomy becomes something not merely to be respected or honored but rather an element of human welfare and relationships to be nurtured, restored, or empowered.”[[9]](#endnote-9) Whether one’s ethical commitments lie in performing one’s duty for duty’s sake (deontology), maximizing happiness for the greatest number of individuals (utilitarianism), or cultivating virtues in order to attain the good life (virtue ethics), autonomy plays a role in accomplishing such commitments.

Autonomy has become progressively more important in medicine in the United States.[[10]](#endnote-10) The most obvious outcome of the emphasis on autonomy in the field of medicine is the doctrine of informed consent in which the risks, benefits, and alternative treatments are explained to the patient before treatment. In order to understand the importance of this concept, a brief understanding of the legal background surrounding informed consent is helpful.

**Legal Background**

 The legal background of informed consent in the United States has its initial basis in two court cases from the early 1900s. In Mohr v. Williams of 1905, a patient had given consent to a surgeon to perform an operation on her right ear, but the surgeon decided that her left ear was more in need of the surgery while the patient was unconscious and therefore performed the operation on the left ear, as opposed to the right one.[[11]](#endnote-11) Since both were diseased, the surgeon argued that he was providing optimal treatment, given the circumstances. The patient argued, however, that she never consented to any operation of the left ear and won the case. A year later, the case of Pratt v. Davis had a similar conclusion.[[12]](#endnote-12) Here, a surgeon excised a patient’s uterus and ovaries to treat her epilepsy.[[13]](#endnote-13) While the surgeon did obtain consent from the patient’s husband, no such consent was given by the patient herself and the court decided that this violated her right to bodily integrity. In the Schoendorff v. Society of New York Hospital case nearly a decade later, this sentiment was made explicit in a famous ruling by Justice Benjamin Cardozo, who stated, “every human being of adult years in sound mind has a right to determine what shall be done with his own body.”[[14]](#endnote-14)

While such cases do highlight aspects of informed consent, as Katz has noted, in the early 1900s, there was no sense of “a patient’s right to ‘thoroughgoing self-determination’ in medical decision making.”[[15]](#endnote-15) One could say that the law demonstrated a respect for consent but not *informed* consent. The court case that many point to as changing the paradigm from consent to informed consent is Canterbury v. Spence of 1972 in which a surgeon failed to inform a patient of the risks of paralysis related to a back surgery.[[16]](#endnote-16) The patient fell out of bed after the surgery and became paralyzed, which was a known risk of the procedure that was not conveyed to the patient by the doctor. The court ruled that informed consent must consist not only of the patient agreeing to receive the treatment but also of a description of the procedure, the risks involved, and any alternative methods of treatment. In other words, patients must be given all relevant information pertaining to a procedure if they are truly able to provide informed consent.

As can be gleaned from the court cases, informed consent has its history in medicine in the realm of surgery. This makes sense, given the risks involved in many surgical procedures. The concept of informed consent, though, has spread to other sectors of medicine, as informed consent is now a common practice before some non-surgical treatments and before the administration of some drugs. There is, however, no federally standardized list of treatments that require informed consent. The law simply requires disclosure of so-called “material risks,” that is, ones that a reasonable person would want to consider in order to make a decision rather than trivial risks.[[17]](#endnote-17)

Typically, when one thinks of risks associated with medical procedures, one thinks of the development of side effects or the chance that something will go wrong with the procedure. Some procedures, however, carry *inherent* risks. The imaging procedures in diagnostic radiology all carry some level of risk since “even the smallest dose [of radiation] has a finite probability of producing a deleterious effect.”[[18]](#endnote-18) Some individuals, such as fetuses and infants, are more radiosensitive, and some body parts, such as the gonads and the eyes, are more sensitive than other parts. Thus, there is variance as to just how radiosensitive any given individual or body part may be. Above and beyond this, particular diagnostic tests use different doses of radiation. For instance, a simple chest x-ray contains very little radiation, while certain computed tomography (CT) scans utilize significant amounts of radiation. A brief history of radiology will provide a background as to the risks involved in diagnostic radiology.

**History of Radiology and Radiological Protection**

 X-rays were discovered by Wilhelm Conrad Röntgen in 1895 and he is thus considered the father of diagnostic radiology. Röntgen’s discovery was so influential that he was awarded the Nobel Prize in Physics in 1901. At the time of his discovery, the dangerous effects of exposure to what was then dubbed as a “strange new force” was unknown; indeed Röntgen himself declined to classify the rays definitively as a new kind of light or a new form of energy.[[19]](#endnote-19) What was known was that Röntgen had come upon a powerful way to examine the inner structure of the human body as x-rays provided accurate images of aspects of the bodily interior in a seemingly non-invasive fashion. Upon hearing of Röntgen’s discovery, Thomas Edison experimented with x-rays but very soon found them to be dangerous as he himself suffered an inability to focus in one of his eyes after being exposed to radiation and one of his assistants, Clarence Dally, developed cancer and eventually died as a result of his exposure, prompting Edison to call him a “martyr to science.”[[20]](#endnote-20) In 1995, the *American Journal of Roentgenology* published an issue dedicated to the American martyrs to radiology, which featured Dally and others whose lives were cut short due to radiation exposure.

 As more information became known about the dangers of radiation, early pioneers using radiation implemented safety measures to protect themselves and patients from radiation, including shields and lower doses of radiation when possible. William Rollins was the first pioneer in radiation protection. In the early 1900s, Rollins was publishing papers warning of the hazards of overexposure.[[21]](#endnote-21) However, the advice of early pioneers like Rollins were not heeded on a general scale. Indeed, even as late as the 1970s, one could find shoe-fitting fluoroscopes in shoe stores that utilized x-ray technology as a way of ensuring a perfect fit for shoes.[[22]](#endnote-22)

The notion of protecting the public from unnecessary radiation exposure began in 1968 when the US Congress passed the Radiation Control for Health and Safety Act. In 1974, a code of standards for diagnostic x-ray equipment went into effect, which further reiterated the importance of consistency amongst healthcare institutions specifically regarding equipment. The awareness regarding the use of ionizing radiation continued, as did the practice of protecting the public. Educational institutions developed robust teaching practices for radiographers in relation to the safe operation of radiographic equipment while healthcare institutions established procedures for utilizing protective devices whenever possible. Furthermore, various medical societies developed partnerships in an attempt to reduce radiation doses. The Alliance for Radiation Safety in Pediatric Imaging formed in 2007; one year later, the Image Gently Campaign was initiated, which raised awareness of radiation doses in diagnostic radiology.[[23]](#endnote-23) The introduction of such programs created a network for individuals working in the field of radiology to disseminate information related to patient safety.

 The standard that maximizes patient safety is known as the ALARA principle, which stands for “as low as reasonably achievable.” This standard ensures that “all reasonable actions that will reduce doses to patients and personnel … have been considered.”[[24]](#endnote-24) Since there are various factors that come into play when determining the amount of radiation for each procedure, including the body mass index of the patient, the machine being used, and others, some of this is a matter of professional opinion. There are, however, standardized measurements for radiation, and a common way to understand radiation doses is through the background equivalent radiation time (BERT) method. Humans are exposed to radiation simply by living on this planet, and radiographers are able to estimate how much radiation a patient is receiving in comparison to the natural background equivalent. For instance, the average US resident is exposed to roughly 3 millisieverts (mSv) per year from natural background sources such as radon and thoron gases. A chest x-ray exposes a patient to 0.08 mSV of radiation, which is roughly the equivalent of 10 days of BERT.[[25]](#endnote-25) If there is a suspected problem with the heart or lungs, a chest x-ray can reveal fractures, calcium deposits, aortic aneurysms, congenital heart disease, heart valve problems, fluid in the lungs, emphysema, among others. Thus, given the small risk involved with the procedure as compared to the benefits, there is no need for a formal informed consent process when it comes to chest x-rays. Any such process may cause patients to undergo unnecessary anxiety or even lead patients to forgo diagnostic procedures that could have otherwise led to crucial diagnoses.

**Computed Tomography**

 Computed Tomography (CT) is the most significant development in diagnostic radiology, and is certainly one of the most significant developments in contemporary medicine as such. As opposed to one image, a CT scan takes multiple images and stacks them to create a cross-sectional image of a section of the body with the aid of computers. This technique provides far more information than simple x-rays and is far more detailed. The downside, however, is that the patient is exposed to far more radiation. One single CT scan of the chest exposes a patient to an average dose of 8 mSv of radiation, which is 100 times more than a chest x-ray, and the equivalent of 3.6 years of BERT.

 The higher dosage of radiation has led many to worry about the increase in cancer risks in CT scans, as opposed to simple x-rays. Brenner and Hall argued that 1.5% to 2% of all cancers diagnosed in the U.S. were the result of CT scans.[[26]](#endnote-26) Roughly the same estimates were corroborated by another study.[[27]](#endnote-27) Given the high risk involved in this procedure, radiographers are trained to reduce the radiation dose as long as it does not compromise the needed quality of the image.[[28]](#endnote-28) Even with such precautions in place, by the very nature of the procedure, CT scans involve higher doses of radiation than simple x-rays. Moreover, given their superiority in terms of detail and accuracy, CT scans are sometimes ordered by physicians when alternative procedures that involve no radiation (e.g., ultrasound or magnetic resonance imaging) may have been sufficient. Indeed, “CT is too often performed when its use is unlikely to enhance patient health or change clinical care.”[[29]](#endnote-29) The seventh assembly of the Committee on Biologic Effects of Ionizing Radiation (BEIR) report stated that 10 mSv of radiation exposure carries with it a 1 in 1000 risk of a future malignancy in a 40-year-old adult.[[30]](#endnote-30) This risk is even higher for other individuals, especially young children, given their increased radiosensitivity. Despite the inherent risk, very few healthcare institutions in the United States inform patients about the radiation risks of CT scans.[[31]](#endnote-31) Since the informed consent process has been primarily the responsibility of physicians, and many physicians may not know the information related to the risks of radiation, a formal process has not been implemented.

 Given the overuse of CT and the risk involved in CT scans, we argue that there should be an informed consent process in place that discusses the benefits, risks, including risks pertaining to radiation, and alternatives to CT scans in order to support patient autonomy. Moreover, since physicians may not be the most informed regarding these risks,[[32]](#endnote-32) we argue that radiographers should be responsible for informing the patients of the risks. In order for this process to be meaningful and practical, we offer a few guidelines in creating such a protocol: 1) risks should be presented in a way that reduces fear; 2) the radiographer should provide clear and concise instructions to optimize quality and reduce the risk of repeating the exam; 3) patients should be informed of best practices consistent with ALARA; and 4) radiation doses should be recorded on patients’ medical records.

 One of the standing concerns surrounding informed consent procedures is that if one is too descriptive of the risks, patients may become anxious or will opt out of treatments that they really need. When it comes to CT scans, the BERT method provides a useful approach to allay patient concerns. We recommend informing the patient of the risk of radiation using the BERT method since it emphasizes that radiation is already a part of one’s environmental surroundings and couches the risk in language that the patient can understand. There is evidence that using language that a patient can understand, as opposed to medical jargon, leads to more fruitful communication between medical professionals and patients.[[33]](#endnote-33) The BERT method allows for the most straightforward way to communicate information, thus respecting the patient and informing the patient in a way he or she can understand.

 Regarding the second guideline, the way in which a radiographer instructs a patient can optimize image quality and reduce the chance of repeating the image. Upon discussing the risks, the patient should realize the importance of obtaining the best possible image using as little radiation as possible. In order to achieve this goal, the radiographer should be clear and concise in his or her instructions and answer any and all questions related to the procedure. Clear instructions can help avoid the need for repeating exams in order to attain multiple images due to poor image quality from, for instance, movement on the part of the patient.

 If the patient has consented to the CT scan but is still concerned about the radiation, the radiographer should inform the patient as to the institution’s compliance with ALARA. As Adler and Carlton state, “The radiographer has the responsibility of maximizing the quality of the radiograph while minimizing the risk to the patient.”[[34]](#endnote-34) Protective devices, including shields, should be not only used by the radiographer when necessary, but also explained to the patient. Notifying the patient of compliance with ALARA will help to stave off concerns since the patient will know that the procedure will be utilizing the minimal amount of radiation possible.

Some patients undergo multiple CT scans as their condition changes. Since every dose of radiation carries a risk, radiation doses should be recorded on patients’ medical records. Some have proposed “smart cards” that track a patient’s radiation exposure history, which may be a viable option.[[35]](#endnote-35) In this way, the parents of a child who has already undergone multiple CT scans can make an informed decision as to whether or not they want to go through with another one, given the risks involved. The radiologist should be responsible for ensuring that the amount of radiation has been reported since he or she is the person best able to determine the amount with the most accuracy.

**Objections and Replies**

We have argued that patients deserve the right to informed consent if they are to undergo a computed tomography scan due to the risks related to radiation exposure and that radiographers are the most fitting medical professionals to complete the informed consent process in this sphere. This view may elicit some objections, which we will do our best to anticipate and reply.

First, one may argue that drawing the line at CT is arbitrary since other radiologic diagnostic tests or nuclear medicine examinations expose patients to just as much radiation, if not more, as CT scans. Semelka, Armao, Elias, Jr., and Picano have suggested that any test that exposes patients to 1 mSv or more of radiation should include an informed consent process.[[36]](#endnote-36) The problem with this position is that radiographers sometimes do not know the exact dose of radiation a patient will receive until *after* the examination. Thus, from a practical standpoint, it makes more sense to draw the line at CT scans, especially given their generally higher radiation dosage. This does not rule out arguments for informed consent for other medical examinations that involve radiation, of course. We simply argue that CT scans are fitting candidates for an informed consent process.

Second, one may argue that there is too much uncertainty surrounding the risks of radiation to warrant an informed consent process. Much of our understanding of the risk stems from studies involving the survivors of the atomic bombs in Hiroshima and Nagasaki.[[37]](#endnote-37) One may argue that it is scientifically suspect to extrapolate such data to medical imaging.[[38]](#endnote-38) While this is a legitimate concern, it is clear that there is risk involved in exposing patients to radiation, and that this risk is not insignificant in CT scans. Therefore, we should err on the side of caution and inform patients that there is a causal link between radiation exposure and health defects in order to respect their autonomy.

Third, since the level of radiation for each individual procedure varies due to the adjustments that must be made for each individual patient, one might argue that a separate informed consent form would really need to be created for each patient. Of course, this would be impractical. To overcome this difficulty, the informed consent forms can be made to be general and the details of the specific procedure, including the amount of radiation, can be explained by the radiographer.

Fourth, since the deleterious effects of radiation often take years, if not decades, to produce, one may argue that informed consent for, say, an 80-year-old patient would be a waste of time. Frush poses the question thusly: “when is someone too old to get consent for an imaging procedure?”[[39]](#endnote-39) The answer to this question, it seems, is “never.” To draw a line and say “at this age, there is no need for consent” is to make assumptions as to how old the individual will live naturally. Radiation still presents a risk to the elderly, and they still have the right to informed consent given this risk.

Fifth, one may argue that radiologists or the ordering physicians should be responsible for the informed consent process, as opposed to radiographers. Nievelstein, for instance, argues that it should be the joint responsibility of the ordering physician and radiologist.[[40]](#endnote-40) This may be because radiologists and physicians are more educated or, if the preference is the ordering physician, because they are familiar with the informed consent process. We have already shown how the ordering physician is often not aware of the risks involved with CT scans, which means they would not be the appropriate person to talk through these risks with the patient. As for radiologists, there are not necessarily radiologists on site when CT scans are being performed. Thus, it would be impractical to designate this duty to radiologists. Radiographers should be responsible for the informed consent process since they spend the most time with the patients and have the most expertise in terms of radiation dosage.

Finally, some have argued that informed decision-making is more appropriate than a formal process of informed consent in the realm of CT. Brink, Goske, and Patti, for instance, argue that educational materials should be provided to patients, as opposed to a formal informed consent process.[[41]](#endnote-41) One reason for their argument is that they think the informed consent process fails to actually inform the patient and serves more as legal documentation. True informed consent, of course, is far more than legal documentation. Meisel and Kuczewski have argued, in fact, that thinking informed consent is simply a legal matter is a myth, since informed consent reflects at its core an *ethical* relationship between the patient and the medical professional.[[42]](#endnote-42) If we are to relegate the information surrounding the risks of radiation to educational materials like pamphlets or videos, we are simply propagating the tendency to decrease the amount of actual communication that occurs between medical professionals and their patients. We owe it to our patients to educate them, which may include pamphlets and videos, but this cannot replace actual dialog between medical professionals and patients, which, after all, forms the heart of the medical professional-patient relationship.[[43]](#endnote-43) Thus, informed consent must be a formalized process, as opposed to relying primarily upon educational materials.

**Conclusion**

 If we are to respect patient autonomy, we should require informed consent for CT scans, given the radiation risks and the fact that this technology is overused in the United States. This will require more training on the part of the radiographer and more time spent with the patient, but this additional training and time is well worth it given the supreme importance of respect for patients.

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