Informed Consent for Genetic Testing in Autopsy

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As next-generation sequencing, whole exome sequencing, and other genetic tests become cheaper and more prevalent, pathologists will likely incorporate genetic testing into routine autopsies. Such testing has great promise for helping diagnose and treat living and future family members, but also raises questions about whether current consenting practices for autopsy are adequate. How is informed consent in the autopsy context different from informed consent in the typical clinical setting? Should we require specific consent for genetic autopsy testing?

Before discussing issues of consent for private autopsies, a review of autopsies performed under authority of a state's law governing medical examiners or coroners (MEs/Cs) is instructive because it shows the importance of how genetic information raises new issues and impacts the decedent's family. These autopsies, also called public or medicolegal autopsies, do not typically require consent and results are often, at least in part, public information. State law typically authorizes an ME/C to undertake an autopsy in enumerated circumstances, including doing an autopsy to investigate unexplained causes of death. The public health and policing powers and interests of the state justify foregoing next-of-kin consent.

Although consent is not required for these public autopsies, commentators recommend that ME/C offices take reasonable efforts to tell family members about genetic testing. Genetic testing is often performed or recommended in cases of ME/C investigation of sudden death of the young. The National Association of Medical Examiners (NAME) position paper on genetic testing acknowledges that informed consent can present "unique challenges" in sudden cardiac death cases, such as the necessity of a multidisciplinary approach that includes genetic counseling and the possibility of additional consent for testing family members.[1] If genetic testing isn't undertaken but there is a potential for genetic disease, NAME recommends that family members should be alerted. Other recommendations include offering family members the opportunity to opt out of receiving genetic test results.[2] Underlying these recommendations is an acknowledgement that genetic testing produces results that impact family members, that these family members should know that someone is doing the testing, and that they be able to have some control over the results.

Medical examiners/coroners do not have unlimited discretion to override next of kin's wishes to not perform an autopsy. Several state cases, as well as federal and state statutes, recognize a Constitutional first amendment interest of family members to not have an autopsy done.[3–5] A family member's objection does not completely preclude a public autopsy, recall the ME/C's important public health or criminal law objectives, but a family's religious or philosophical objections may raise the bar for an ME/C to show a compelling need to conduct an autopsy and take steps to limit the autopsy as much as possible. Even in public autopsies the family's interests in whether and how an autopsy is performed are legally recognized.

Private autopsies require consent from next of kin. State statutes require consent and typically name next of kin in list order beginning with the decedent's spouse, then adult children, then a parent, etc. Many states require that the consent be given on a written consent form and that the consent make clear that the person giving consent can limit the autopsy. Consents should, therefore, be specific about the scope of the autopsy and the use or retention of tissue.

There are many legal cases about informed consent. Two of the best known are the early 20th century case written by the Justice Cordozo, *Schloendorff v Society of New York Hospital*,[6] and the 1970s case, *Canterbury v Spence*.[7]

Justice Cordozo's opinion in *Schloendorff* places the foundation of informed consent on the patient's right to autonomy. Mary Schloendorff consented to an ether examination at the New York Hospital, but indicated that she did not want an operation. While unconscious during the ether examination her fibroid tumor was removed. After the operation her arm become gangrenous and she had some fingers removed. She sued the charitable hospital, which by state law was not liable for the negligence of its doctors or nurses. The case made its way to the highest New York court and Justice Cardozo explained in his ruling opinion: "In the case at hand, the wrong complained of is not merely negligence. It is trespass. Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages."

Over the years, informed consent has remained based on autonomy but evaluated by the laws of negligence rather than assault. For a long time the content of what information should be shared with the patient was

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determined by the medical standard of care. In other words, the standard was what information would the reasonable and prudent physician tell a patient. This professional standard was criticized because some people thought physicians were not telling patients enough about the risks, benefits, and options. The criticism was that the consent was not adequately informed. This began to shift in the 1970s with *Canterbury v Spence*,[7] a case about a patient who had complications after an operation for an injured vertebral disc. Commentators argued that informed consent is unlike medical malpractice negligence cases because there is no need for experts to explain the complexities of medicine. Instead, informed consent cases are less complex and should be judged from the patient's perspective, since the right is based on the patient's autonomy. The judge in Canterbury reasoned, "it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests lie." Informed consent must be about the patient being able to make decisions and "that right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need." *Canterbury* concluded that a professional standard of care does not determine the substance of informed consent. Instead, the *Canterbury* standard is that the adequacy of the substantive content is determined from the patient's perspective; it is what the patient would want to know and not what a doctor customarily discloses.

Informed consent law is governed by state law and there is variability across the states. Some states use a more "professional standard," others use a "patient standard" similar to *Canterbury*, and a few take a hybrid approach.

Consent in autopsies is, however, different from routine clinical consent. In a typical clinical context, the patient gives consent for a procedure done to them. In the autopsy setting, however, the decedent cannot give consent because they are no longer capable of making choices or exercising the rights of a live person. The decedent does not have the same legal rights as the consenting patient. Autopsy consent is intended to protect a different set of legal rights, namely the interests of the decedent's family. Autopsy consent is needed to protect a common law right of burial that belongs to the decedent's next of kin.[8] It isn't the family as a surrogate decision maker for the deceased trying to figure out what the deceased would have wanted or what might be in the decedent's best interest. Instead, the right belongs to the family member, who has a legal right to have a body as it was at the time of death to bury or otherwise dispose of according to their beliefs and wishes, within some constraints.[9] Courts have routinely acknowledged that an unconsented autopsy gives rise to a tort claim for "damage to the next of kin by infringement of . . . [the] right to have the body delivered . . . for burial."[10] The right belongs to the next of kin, with most states incorporating a hierarchy of family interests by placing the decedent's spouse in the primary position and creating a statutory list of priorities for various family members.

Of note, the decision-making process for organ and tissue donation differs from the autopsy consent process. In the United States, organ and tissue recovery at the time of death for potential transplant organs is governed by state law and generally follows the Uniform Anatomical Gift Act (UAGA), which relies on the legal framework of gift law rather than informed consent.[11] Donations under the UAGA do not consider the deceased's donation a health care decision. Under the UAGA, the lifetime decisions made by the decedent are generally followed, even over the objection of family members who have authority to consent for an autopsy. Notwithstanding, most organ procurement organizations defer to the family's decision about the deceased's organ and tissue donation.[12]

How then is consent for genetic testing different from autopsy consent? First, genetic testing impacts a greater number and extent of family members than interference with the right to burial. Disposition of the body is typically handled by a spouse or a few close relatives, but genetic information may affect more distant relatives. Second, the right to burial ends after the body is buried,[13] but genetic information impacts far into the future. Third, autopsy consent isn't based on the decedent's autonomy interest. Instead, consenting for genetic testing in autopsy involves the autonomy interests of family members. Consenting to do genetic testing is similar to the consent required for medical procedures and is typically performed by a physician or genetic counselor with the focus on the patient's understanding enough so that he/she can make an autonomous decision. For example, the National Institutes of Health (NIH) Web site explains that before a person has a genetic test they should understand the benefits, limitations, and possible consequences.[14]

Although there is no case law about genetic consenting in an autopsy, there is some instruction in the setting of conventional informed consenting that emphasizes the impact on family members of the person tested.[15] There is debate about the duties and roles of physicians and patients to inform family members about genetic information that may impact relatives. In *Pate v Threlkel*, the Florida Supreme Court recognized that a physician has a duty to warn a patient's children of a higher risk of cancer due to their mother's inheritable condition, but the court recognized conflicting duties of confidentiality and held that this duty to warn could be met by the physician telling their patient that her children may have a higher risk.[16] A subsequent case, *Safer v Estate of Pack*, showed a New Jersey court extending the physician's responsibility a bit further by acknowledging that the duty will not always be satisfied by telling the patient of their genetic condition and its potential to affect family members.[17] The court thought that in certain conditions a physician has a legal duty to warn a patient's immediate family. Most discussions about the ethical considerations around a duty to warn about genetic conditions recognize some duty by both physicians and families, but understand that physicians' duties of confidentiality and patients' rights of privacy mean that physicians are limited in what they can tell family members. The onus, therefore, is typically on the patient to tell family members of potential genetic conditions that may affect them and for which they may want testing.

The discussion about genetic testing in the nonautopsy setting shows the importance of including information about genetic testing in autopsy consent. The person consenting to an autopsy should know that genetic testing will be performed and may lead to information that will directly impact them and other family members. This is especially important since genetic information may be wanted or unwanted by family members. Genetic information indicating a higher cancer risk may encourage testing by family members, and genetic information obtained in a neonatal autopsy may guide parents' future decisions about

pregnancy. On the other hand, not all family members may want to know about an increased risk of untreatable neurodegenerative disease.

Another difference is that genetic and autopsy information also involve privacy interests in a way different from typical informed consent. For example, in a Freedom of Information Request for autopsy photographs, the US Supreme Court recognized surviving family members' privacy interest in preventing release of their loved ones' death-scene images. The Court noted that the family's privacy right in the body and images of the decedent has been "long recognized in our common law."[18] This recognition of a family's privacy right in the decedent's autopsy information includes the decedent's autopsy genetic information. Some states, similarly recognizing the extent of a family's privacy rights, have passed statutes protecting a family's privacy right in autopsy photographs.[19] The federal statute, the Health Insurance Portability and Accountability Act (HIPAA), also recognizes a dead person's privacy right for 50 years after death by requiring written HIPAA authorization for disclosure of private information. A privacy right exists, therefore, for the decedent and the decedent's family.

The interests and legal rights at stake in an autopsy-consenting process are different from those in a conventional consenting process, which means the analysis of what constitutes adequate informed consent differs. The decedent in an autopsy is not the same as a patient in a medical procedure. The standard for the person giving consent in a private autopsy, especially in a private autopsy that includes genetic testing, is not the decedent's best interest. Instead, they are representing themselves and the decedent's family. If genetic testing will be done as part of the autopsy, separate consent should be obtained. Just like an autopsy can specify that it is restricted to the "chest only," an autopsy can be restricted to not include genetic testing. The person giving informed consent for the autopsy needs to know, understand the benefits, limitations, and alternatives of genetic testing, including that other family members may be impacted, and the consenter should have the ability to refuse genetic testing in a private autopsy. Incorporating genetic testing into autopsies can have significant benefit for living and future family members. The details of how to best consent for genetic testing in autopsies is a needed area for future discussion and clarification in our profession.

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