
Ethical and Legal Challenges Associated with Public Molecular Autopsies

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There is a national movement supporting the retention and use of bio-specimens from deceased individuals for the purpose of genetic testing.¹ Studies have identified mutations that scientists believe can cause sudden unexpected death, and funding for a national registry for sudden death in the young (SDY) has been granted to several states to promote investigation into the causes of and risk factors for SDY.² Medico-legal death investigators, particularly Medical Examiners (ME),³ are being called upon to develop systematic protocols to collect and retain bio-specimens for future use, and some ME offices are going further by performing postmortem genetic testing themselves.⁴

MEs have a legal duty to investigate the cause and manner of death in cases within their jurisdiction. Each state has its own statutory guidance on when a

ME investigation is warranted. Generally, all the statutes are similar in granting jurisdiction when the death occurs in a suspicious or unusual manner or when the death involves a child, as defined by that particular state.⁵ Additionally, some states specifically grant MEs jurisdiction in the identification of human remains.⁶ Unlike postmortem genetic testing for research purposes or postmortem genetic testing requested by a family (i.e., private autopsy), postmortem genetic testing performed by MEs (hereafter, “public molecular autopsies”) raises issues that are not adequately addressed by current ethical and legal frameworks. For example, informed consent is not legally required for a ME to perform an autopsy and related laboratory analysis because of the distinct characteristics of death investigations.⁷ Additionally, in many states publish autopsy findings in an autopsy report that is accessible by the public through the operation of state open government laws. Thus, despite regulatory efforts to maintain the confidentiality of genetic information, even after death, genetic information can become public knowledge if obtained during the course of a death investigation via an autopsy report. Since genetic information is familial⁸ in nature, private health information about family members can also be revealed via the autopsy report.⁹

Risk of harm to living family members raises questions about whether informed consent should be obtained for postmortem genetic testing when carried out by MEs, whether existing confidentiality protections for genetic information are sufficient, and what obligations are owed to families regarding return of results. Conversations surrounding issues of consent, confidentiality, and return of results are not new in genetic testing,¹⁰ but the context of genetic testing in death determination introduces new concerns into

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these conversations. Pausing to consider the implications of such practices is crucial to ensuring that the benefits of postmortem genetic testing are maximized and harms are minimized. Further, as states develop protocols for bio-specimen collection and retention for state SDY registries, standard policies are needed to adequately address the vital balance of protecting individual and family rights and interests while also promoting public interests.

The Nuremberg Code first drew international attention to the importance of informed consent in the research context, focusing primarily on the voluntariness aspect of informed consent.¹⁸ In 1979, the National Commission for the Protection of Human Subjects published the Belmont Report, which identified three basic ethical principles relevant to research involving human subjects: respect for persons, beneficence, and justice.¹⁹ Application of these principles

Pausing to consider the implications of such practices is crucial to ensuring that the benefits of postmortem genetic testing are maximized and harms are minimized. Further, as states develop protocols for bio-specimen collection and retention for state SDY registries, standard policies are needed to adequately address the vital balance of protecting individual and family rights and interests while also promoting public interests.

Informed Consent

The concept of informed consent is rooted in principles of respect for autonomy and protection of individuals' property and bodies¹¹ from unauthorized invasion. Informed consent has influences that originate in tort law,¹² in international declarations,¹³ and in basic bioethical principles.¹⁴ An individual's informed consent must be knowledgeable and voluntary, and it conveys a decision in favor of a proposed course and the authorization to proceed.¹⁵

In the medical field, the requirement for informed consent evolved through the court system in tort and malpractice suits. In *Bang v. Miller Hospital*, a state court gave a rather broad instruction concerning the duty of a physician to disclose to the patient "all the facts which mutually affect his rights and interests and surgical risk, hazard and danger, if any."¹⁶ Unlike the many other laboratory tests considered as part of standard clinical evaluation covered under a general consent to medical treatment, because clinical genetic testing is thought to "affect the rights and interests" of patients, some states (thirteen as of 2012) require specific informed consent.¹⁷ Although family members are often part of the discussions, and potential harms to family members may be disclosed as a risk during consent discussions with the individual, ultimately the right to authorize genetic testing (or not) lies with the living person whose biological sample is being tested. Concerns of family members are treated as secondary to the autonomous rights of the individual desiring (or not desiring) testing.

reinforced the ethical requirement of informed consent. Regulations encompassing those bioethical principles were promulgated, making informed consent a legal requirement for research carried out or supported by federal agencies, such as the Department of Health and Human Services, subject to limited but significant exceptions.²⁰ Most salient here, regulatory requirements for informed consent do not currently apply to the deceased, or to research involving de-identified (or coded) bio-specimens.²¹ Proposed changes to the regulations would require consent for research on bio-specimens, based on the fact that DNA is inherently identifiable²², but those proposed changes do not mention the research use of bio-specimens from the deceased.²³ While an individual is living, his or her biological relatives generally have no legal standing to interfere with her decision to obtain a clinical genetic test or to participate in genetic research. However, upon death the deceased no longer has the same rights.²⁴ The family is thought to protect interests continuing after death, including interests in having one's body treated with respect and in having one's ante-mortem wishes upheld.²⁵ Thus, the law generally relies on the family to make decisions or manage matters within any constraints created by prior expressions of decedent wishes (for example, via a will or organ donor card). In the event of no prior designation, families can decide on the decedent's behalf. Biological relatives also have a personal privacy interest in the decedent's bio-specimens, since DNA is familial by its very nature.²⁶

Postmortem genetic testing may occur for the clinical benefit of family members, for research, or as part of an autopsy to aid in death determination. Clinically, postmortem genetic testing for the benefit of family members may be conducted to find a previously undiagnosed arrhythmia.²⁷ In research, although not required by federal regulation, the ethical and professional recommendations are to obtain informed consent from next-of-kin to conduct research on the newly dead, including genetic research. For instance, advisors to the National Institutes of Health's Genotype-Tissue Expression (GTEx) program recommend obtaining informed consent from the next-of-kin and review of research protocols by multidisciplinary panels to identify and address ethical issues, even though deceased individuals are not considered human subjects under federal regulations, and therefore not subject to the legal requirement of informed consent as described above.²⁸ The National Association of Medical Examiners (NAME) also states that bio-specimens should not be used for research without permission from appropriate family representatives.²⁹

A private autopsy requires family consent and can be performed when requested by the family, treating physician, or hospital.³⁰ There is variation amongst states in who has the legal authority to consent to a private autopsy.³¹ In most states, e.g., Iowa, North Carolina, and Texas, the surviving spouse (if one exists) is first in the list of persons with legal authority to consent to an autopsy.³² Without consent from an authorized party, it is illegal to perform an autopsy, unless the autopsy was ordered by the ME or other medico-legal death investigator. Thus, in private autopsies, consent should be obtained, and the scope of the autopsy, including genetic testing, should be part of the disclosures that are made when obtaining informed consent. Even if families consent to the autopsy, in most states they have a right to limit the scope of the autopsy and the retention of organs or tissues for later use.³³ Only in a few states, such as Nebraska³⁴ and Hawaii³⁵, is the consent to autopsy treated as an implicit authorization to retain and use tissues for scientific investigation. The ME office is not required to obtain informed consent to retain or perform testing on samples during the course of a public molecular autopsy.³⁶ For public molecular autopsies, the ME has a statutory duty to determine the cause and manner of death and broad authority to meet that end. ME offices generally have jurisdiction in suspicious deaths and child deaths. Each state has its own specific language regarding the kinds of deaths that would grant a ME office jurisdiction over the body. For instance, Massachusetts specifically grants the ME jurisdiction when a death occurs with diagnostic or therapeutic procedures, or if death occurs following an

unlawful abortion.³⁷ Other states, such as Utah, grant jurisdiction to the ME in deaths due to sudden infant death syndrome, or resulting from poisoning or overdose of drugs.³⁸

Rationales for granting MEs the authority to conduct public autopsies without consent could include states' interest in determining cause of death, seeking justice, and protecting public health, which seemingly outweigh arguments for requiring informed consent from families before proceeding with molecular autopsies. MEs need the authority to investigate suspicious deaths without interference from family members, who may be unable to use substituted judgment because of their own self-interest or if they were involved in the death. However, the public and state's interest in death determination is arguably not as strong in deaths that are thought to be natural and could have been caused by genetic mutations. No justice can be exacted where a genetic cause of death is identified. Therefore, the question arises as to whether an ME should contact potentially affected family members to request informed consent for genetic testing in these cases. On the one hand, genetic testing is being done for the purposes of identifying the cause and manner of death as part of the autopsy, which is the statutory duty of the ME. Similar to any other toxicology testing, this would not require informed consent. Further, NAME affirms that MEs may carry out postmortem genetic testing where crucial for death determination and encourages routine sample collection to facilitate postmortem genetic testing for other purposes in their role as stewards of public health promotion and monitoring.³⁹ On the other hand, families have expectations of control and consultation related to handling of the deceased as described above. Postmortem genetic testing could benefit biological relatives by identifying mutations that could put them at risk for sudden death. A causative genetic mutation found in the decedent could also have negative implications for surviving biological relatives, potentially exposing them to risks.⁴⁰ Informed consent is an established mechanism by which we allow individuals to either accept or reject such risks.

Public health justifications for postmortem genetic testing are important, but there needs to be a robust, thoughtful discussion regarding when public health concerns outweigh the rights and interests of family members. The Alder Hey controversy in the United Kingdom (UK) is a cautionary tale. In that situation, tissues and organs obtained from child autopsies were retained and stored by pathologists without parental knowledge or consent.⁴¹ Later, some of those tissues were used in genetic research.⁴² The public outrage at the retention and testing of postmortem tissues

led to the overhaul of the UK's Human Tissue Act in 2004. It now requires authorization for genetic analysis performed on bodily material from a person who died after the law entered into force.⁴³ Consent is required for genetic analysis even if the material cannot be linked to the person from whom it came.⁴⁴ This aids in governmental transparency and fostering public trust. Performing postmortem genetic testing without consent, in any context, may undermine that transparency and trust. Thus, consideration should be given to creating a standard of at least notifying family members when a public molecular autopsy will be performed, except when doing so would interfere with the ME's ability to determine cause and manner of death. Similar considerations support a standard of obtaining informed consent for the retention of biospecimens for future research.

Confidentiality

There is a legal and ethical tradition of protecting privacy and confidentiality in medical care and in research. Privacy is a broad concept that often resonates with people as relating to their sense of well-being, personal space, choice, and control over the sharing of information.⁴⁵ Confidentiality is a narrower term, which relates to the obligations, in a professional, fiduciary, or contractual relationship, to not disclose private information to third parties.⁴⁶

In medicine, there is a long history of an ethical commitment to medical confidentiality, dating back to the Hippocratic Oath, grounded in ethical principles of respect (for individual's autonomous right to decide with whom to share personal information) and non-maleficence (protection from harm to individual from discrimination and stigma, as well as dignitary harms), and virtues of trust and fidelity.⁴⁷ Further, confidentiality of patient information is required through state confidentiality laws and the Health Insurance Portability and Accountability Act (HIPAA), which prohibits disclosure of certain protected health information, including genetic information of individuals and their family members.⁴⁸

In research, the Common Rule addresses privacy of information about persons as well as confidentiality of data.⁴⁹ Notably the Rule distinguishes privacy from confidentiality, defining privacy as an interest persons have in controlling access to themselves, and confidentiality as a right to control access to certain types of data.⁵⁰

In the context of state action, protection of confidentiality is rooted in the constitutional right to privacy, recognized by the Supreme Court and embodied in the word liberty under the 14th Amendment Due Process Clause.⁵¹ This right to privacy protects two

kinds of interests: an interest in avoiding the disclosure of certain personal matters, and an interest in making certain kinds of important decisions.⁵² Generally, however, a state's action does not conflict with an individual's constitutional right to privacy unless it restricts the individual's freedom in a sphere recognized to be a zone of privacy protected by the Constitution.⁵³ Recognized spheres are matters relating to marriage, procreation, contraception, family relationships, and child rearing and education.⁵⁴

Public molecular autopsies raise distinctive issues related to privacy and confidentiality. Specifically, genetic information, which under the Health Insurance Portability and Accountability Act (HIPAA) would otherwise be protected 50 years after death, could become public knowledge in some states if obtained or gathered by the ME's office.⁵⁵ Each state has its own state Freedom of Information Act (sFOIA), which serves the purpose of maintaining transparency and accountability in government through permitting public access to government records. In many cases, autopsy reports are subject to the sFOIA because they are records created by MEs, who are public officials, and maintained by government agencies. Thus, public molecular autopsies create a greater risk of loss of confidentiality of genetic information in states that have not exempted autopsy reports from the sFOIA.

After death, families retain some privacy rights. Recently, a federal appellate court held that the Constitutionally-protected right to privacy included a parent's right to control the physical remains, memory and images of a deceased child to protect against unwarranted exploitation by the government.⁵⁶ In *Marsh*, a mother sued the County of San Diego because the District Attorney disseminated the autopsy photos of her deceased two-year old son.⁵⁷ The Court held that releasing the autopsy photos of her deceased son violated Marsh's substantive due process right to family integrity because release of autopsy photos both a) shocked the conscience, and b) offended the community's sense of fair play and decency.⁵⁸ The court considered the profound grief caused by the public display of death images as sufficient evidence of "shocking the conscience."⁵⁹ Further, the Court found that the Constitution protects a parent's right to control the physical remains, memory and images of a deceased child against unwarranted public exploitation by the government.⁶⁰

The current federal and state statutory exception from disclosure of photographs taken during the autopsy also recognizes the common law right to privacy of the decedent's family. In *Favish*, a reporter requested death scene photographs of former White House deputy counsel, Vincent Foster, under the Free-

dom of Information Act.⁶¹ The Supreme Court noted that the well-established cultural tradition of acknowledging a family's control over the body and death images of the deceased has long been recognized at common law.⁶² The Court held that the family's right to exempt disclosure of the decedent's autopsy photos was grounded in common law, and therefore the Court did not determine whether this right was also grounded in the Constitution.⁶³ However, most states recognize that autopsy photographs are exempt from public disclosure, and those recognizing a strong privacy interest of family members have designated the entire autopsy report exempt from public disclosure.

State laws addressing public access to autopsy reports can be grouped into three main categories: 1) Autopsy records are treated as confidential, with limited exceptions; 2) Autopsy records are subject to the sFOIA generally, but privacy interests are considered; and 3) Autopsy records are subject to the sFOIA, with very few exceptions (Figure 1).

In states falling within category 1, such as Iowa,⁶⁴ New York,⁶⁵ and Washington,⁶⁶ protecting privacy is a policy priority, and autopsy reports are considered confidential. These states create special exceptions for law enforcement, next-of-kin, and public safety. Many states fall into category 2, combining a strong public policy favoring open access to government-maintained records with some attention to privacy interests. For instance, Texas explicitly states in its open records statute, "it is the policy of this state that each person is entitled, unless otherwise expressly provided by law, at all times to complete information about the affairs of government and the official acts of public officials and employees. The people insist on remaining informed so that they may retain control over the instruments they have created."⁶⁷ Autopsy reports are public information, yet autopsy photographs are not made public because of concerns about privacy and respect for the dead. Although the issue of releasing genetic information has not been addressed by category 2 state legislatures, it is likely that the same rationale used to maintain the confidentiality of autopsy photographs can be applied to the handling of genetic information in autopsy reports.⁶⁸ In the third category, states such as Colorado,⁶⁹ Louisiana,⁷⁰ and Mississippi,⁷¹ favor open access and have very few exemptions limiting access to autopsy reports.

Each category has its own public policy justification, however, differences amongst states create inconsistent privacy protections for genetic information obtained during the course of an autopsy. Category 1 state laws provide the same level of confidentiality protections that genetic or other sensitive medical information would have if obtained in any

other context, while still allowing limited disclosure to accommodate important public and private interests. The American Medical Association (AMA) supports maintaining confidentiality of all medical information related to deceased individuals.⁷² The AMA suggests that exceptions be based on weighing factors such as imminence of harm to an identifiable individual or to public health, the potential benefit to at-risk individuals or to public health, and the impact disclosure may have on the reputation of deceased patients.⁷³ As noted above, category 1 state laws include exceptions that take account of these kinds of factors.

Category 2 state laws have a greater policy interest in the accountability of public officials. Arguably, the public has an interest in medical evaluations conducted by public officials in the pursuit of public goals. Thus, proponents of these laws would argue that findings of public autopsies are legitimately treated differently than the findings of autopsies initiated for private purposes and conducted by non-governmental actors. Unless these states specifically exempt genetic information from disclosure, as has been done with autopsy photos, information that would otherwise be private could be accessed by the public. The likelihood of disclosure of genetic information is even greater in states with category 3 laws, which essentially provide no recognition of privacy interests.

In genetics, privacy is a significant issue because of identifiability of genomic data.⁷⁴ Permitting access to genetic information as part of the autopsy report in states with laws in categories 2 and 3 is concerning because genetic information is familial and there is a potential risk of harm from discrimination and stigmatization of biological relatives. The greater the validity and the tighter the causal link to death, the greater the risk of discrimination and stigmatization of potentially affected family members. Current law does not fully protect against these harms, although family members may have some protection against misuse of that information through the Genetic Information Nondiscrimination Act of 2008 (GINA).⁷⁵ GINA defines genetic information to include family history and genetic test results and prohibits discrimination in health coverage and employment on the basis of genetic information.⁷⁶ However, GINA is not comprehensive (e.g., does not address disability, life, or long term care insurance) and is challenging to enforce owing to the opaque nature of much employment and insurance-related decision-making. In addition, some protection may be available under the Americans with Disabilities Act.⁷⁷ States have also created genetic privacy and/or antidiscrimination laws, but similar to GINA, they offer incomplete protection.⁷⁸

tainty, greater hope for the future, and resolution of emotional burdens.⁸¹

In the clinical context, a legal duty exists in some states to take reasonable actions to warn third persons of harm when there is a serious and imminent threat to the third party.⁸² This duty to warn may be ethically justified in circumstances where the prevention of serious harm to third parties arguably outweighs risks associated with loss of confidentiality. In some states, there is a legal duty to warn about the risks of hereditary disease. For example, in *Pate v. Threlkel*, Heidi Pate filed suit against her mother's physician because he failed to warn her mother of the risk of transmission of hereditary thyroid cancer, arguing that if Dr. Threlkel had warned her mother of this possibility her thyroid cancer could have been detected earlier.⁸³ The Supreme Court of Florida concluded that "when the prevailing standard of care creates a duty that is obviously for the benefit of certain identified third parties and the physician knows of the existence of those third parties, then the physician's duty runs to those third parties."⁸⁴ Similarly, in *Safer v. Pack*, the Supreme Court of New Jersey ruled that "reasonable steps" need to be taken to ensure appropriate family members are warned of their risk of a hereditary disease, though the Court felt this could be best accomplished by informing the patient of the risk of inheritance.⁸⁵

In the research context, there is a growing consensus that investigators should offer study participants research results of high clinical significance and actionability (typically defined as having the potential to lead to an improved health outcome).⁸⁶ In fact, some argue there is an obligation to return clinically significant and actionable genetic results under common law principles of duty to warn or duty to rescue.⁸⁷ This duty to warn is asserted to arise out of the relationship between the researcher and the participant. For example, a researcher's duty to warn was found because of a "special relationship" between researchers and study participants in a case involving lead poisoning research where both the harm and the family's identity were known.⁸⁸ Even though there is not a current legal obligation to return genetic research results, some have argued that there is an ethical obligation to do so.⁸⁹ In an ideal scenario, results would only be returned to research participants if they have given their informed consent. Obtaining informed consent to return results respects study participants' autonomy and the right to decide what information they want (and don't want) to know.⁹⁰ Also, offering to disclose results to participants' family members can be addressed as part of the informed consent process. However, many instances exist in the research context where the option to return research results to family

members was not discussed with or consented to by the study participant, much less the family members. In those instances, particularly when the participant is deceased, there is disagreement about whether to offer families the decedent's genetic results. Some argue that if there was a duty to return the results to the participant, that duty extends to the family members.⁹¹ In those cases, the discussion centers around the expectations created through the informed consent process engaged in by family members, as well as the weight of the aforementioned ethical justifications for disclosure of clinically significant and actionable results. Others have argued that the burden of contacting family members and deciding which relatives to contact is too great for researchers.⁹² The issue of returning results is complex when the research was conducted on samples from participants who were already deceased at the time of enrollment and when the families of these decedents cannot be found.

The rationale for disclosing serious and actionable genetic results to family members in the clinical and research contexts can be extended to public molecular autopsies.⁹³ MEs have a different role than clinicians and researchers in that the conduct of a public molecular autopsy for death determination is statutorily authorized. MEs have a statutory duty to do what is necessary to determine the cause and manner of death but do not have a special relationship to the decedent. Thus MEs, as public agents, are charged with identifying societal harms (environmental toxins, murderers, drowning hazards, etc.) through autopsies, which may create a duty to warn the public of possible harms. MEs also go beyond their statutory duties and customarily notify family members of the cause of death of their loved ones, so disclosure to families is not unfamiliar to most MEs.

Still, public molecular autopsies present uncommon challenges to MEs. First, interpretation of genetic test results requires more specialized knowledge than most MEs possess. Often, it is not clear whether a genetic test result is significant, and expertise in clinical genetics is required to make that determination. Also, the Clinical Laboratories Improvement Act (CLIA) requires that laboratories that report patient-specific results "for the diagnosis, prevention or treatment of any disease, impairment or health assessment" be CLIA-certified.⁹⁴ Most ME offices are not affiliated with a CLIA-certified lab. Because MEs may perform and release public molecular autopsy results, national standards should be developed to ensure families are receiving valid and reliable results, which will minimize the harms of worry, anxiety and healthcare costs associated with invalid results.

Second, several states such as Kansas,⁹⁵ North Dakota,⁹⁶ and Arkansas,⁹⁷ have enacted laws that create an affirmative duty in Sudden Infant Death Syndrome (SIDS) cases for MEs to notify parents of autopsy results. The statutes do not specifically address genetic testing, but if genetic results are part of the autopsy report, then an affirmative duty to disclose results would exist in SIDS cases. Again, as discussed above, there are challenges with the interpretation and disclosure of genetic test results from a public

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molecular autopsy, and an affirmative duty would increase the number of families who would potentially be affected by invalid results absent national standards. Clinical geneticists are the most appropriately trained to interpret genetic test results and their clinical utility, and genetic counselors are trained in psychosocial assessments of families and in communicating genetic information back to families.⁹⁸ A robust discussion regarding what, when and how to return results from public molecular autopsies, and whether these matters should be addressed via professional guidelines or statutory mandates, is needed as post-mortem genetic testing becomes integrated into ME practice. Standards for return of results need to be agreed upon, and resources should be made available to support ME offices in developing and implementing these standards. For example, ME offices need additional resources to engage genetic counselors in facilitating disclosures to families and connecting families with clinical services.⁹⁹

Conclusion

The issues of informed consent, confidentiality, and return of results are not new in the legal and ethical conversation surrounding genetic testing. However, the use of genetic testing by MEs in death determination raises concerns that have not previously been addressed. The issue of return of results is related to consent and could be addressed through an informed consent process, in that families would have an

opportunity to weigh the risks and benefits of molecular autopsies. However, MEs are not required by law to obtain consent, and obtaining consent may be inappropriate in circumstances where doing so would impede the death investigation. Further, in some states MEs are required to disclose autopsy results to the parents of children with suspected SIDS, although MEs may have inadequate training in both the analysis and disclosure of genetic test results and lack the resources to engage professionals with appropriate

expertise. Options such as a notification process in which reasonably available family members are given an opportunity to accept or reject return of results, and the necessity of allocating resources to the development and implementation of standards for return of results, have not received adequate attention. In addition, as public officials, MEs are subject to sFIOAs, which result in their work product, autopsy reports, being potentially accessible to the public in a significant number of states. If genetic information is part of the autopsy report, information that would have otherwise been deemed confidential

by other federal and state laws could become public knowledge. The concerns created by public access, and the potential for confusion associated with the significant state-to-state variation, suggest a law reform effort in this area may be warranted.

The excitement surrounding the use of public molecular autopsies to prevent sudden death in relatives is not without justification. Likewise, efforts to engage MEs in generating genomic information to advance public health are generally laudable. However, before public molecular autopsies become widespread, thoughtful consideration should be given to the distinctive ethical and legal concerns associated with genetic testing in the context of death determination.

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