

Using Biomedical Ethics Model to Explore Use of Postmortem Specimens in Tissue Research

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Abstract: Researchers often have a need to conduct human tissue research using postmortem specimens. Medicolegal death investigation organizations are untapped areas for obtaining postmortem human tissues. Because death investigation organizations are not required by law to conduct or support research, an ethical dilemma exists in whether or not researchers should use cadaver tissues for research purposes. This paper analyzes the ethical issues of using human tissues through discussion of principles of biomedical ethics, respect for autonomy, nonmaleficence, beneficence, and justice. Policy makers, organ and tissue procurement organizations, medicolegal death investigation organizations, and scientists should be aware of these principles when considering researchers requests. The authors conclude that with Institutional Review Board approval and next of kin consent, there are prevailing reasons for using postmortem tissue for research.

Keywords: Ethics, Forensic pathology, Medicolegal death investigation, Postmortem tissue research.

INTRODUCTION

Based on the premise that tissue research contributes to more accurate prevention, diagnosis, and treatment, a need exists for access to postmortem tissues. However, ethical considerations arise out of using human tissues in nursing clinical research [1]. Although the human genome research project and innovations in biotechnology have advanced the need for tissue research [2 - 4], using stored tissue samples poses some concerns. Researchers normally obtain consent for tissue from living donors prior to surgery or medical procedures. Consent for tissue research from patients that have expired in a clinical setting is typically obtained at the time of the clinical autopsy or when organ/tissue donation consent is requested.

Unfortunately, clinical autopsies in the United States are performed on less than 10% of deceased patients. However, approximately 20%-40% of all deaths fall under the jurisdiction of medicolegal death investigation agencies [5]. Of those deaths under jurisdiction of the medicolegal death investigation system approximately 80% require a forensic autopsy. A forensic autopsy theoretically presents an opportunity for obtaining needed tissues [6, 7]. Use of postmortem tissue collected to determine cause of death is not necessarily tissue that can be used for research purposes. Although researchers have a need to use postmortem biological specimens obtained in a forensic autopsy, this use poses an ethical dilemma [8].

DISCUSSION

To deal with the dilemma of ethical issues in regard to using postmortem forensic tissues from cadavers, this paper bases the discussion on Beauchamp and Childress' [9] major principles in biomedical ethics which are respect for

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autonomy, beneficence, nonmaleficence, and justice. The discussions in reference to use of postmortem tissue obtained through medicolegal death investigation are as follows:

- 1. **Respect for Autonomy.** The principle of respect for autonomy acknowledges the decision-making capacities of patients and patient's families and supports their right to make reasoned informed choices. Deaths within the jurisdiction of death investigation do not require next of kin consent for autopsy. However, the use of postmortem tissue for purposes of research becomes a consideration, especially when samples are linkable to phenotypical data. To carry through with autonomy, one should ask next of kin if the decedent, when living, expressed objections to organ and tissue donation or to research using the human body. Additional questions to be answered deal with informed consent. Is informed consent from legal next of kin required when tissues are collected and stored for possible research purposes? What is the procedure if no next of kin can be contacted?
- 2. Beneficence and Nonmaleficence. The principle of beneficence requires that part of the decision making process includes acknowledgment of benefits and any deficits or risks associated with that benefit, whereas nonmaleficence acknowledges doing no harm. Additionally, this acknowledgement addresses indicated versus non-indicated interventions as well as clinical judgment and clinical uncertainty [9]. Professional ethics, which notes that the interest of patients come first over those of the researcher and that patients should not exploited for increased reputation or financial gain, confounds the issue. Despite low medical risks regarding the collection of postmortem tissue, questions to be answered include the following. Who benefits from the tissue research? Will the research result in financial gain? What clinical uncertainty does the research attempt to answer? Will the research contribute or change the decedent's cause of death [10]?
- 3. Justice. The principle of justice addresses distribution, respect of rights, and laws that influence decisions, and, as such, relates to the complex relationships among patients, providers, and society that potentially create conflicts of interest and affect health policy [9]. For instance, whereas the law directs medicolegal death investigation organizations to determine cause and manner of death, the law does not deal with the use of forensic specimens for research [8].

Additional risks and benefits of using postmortem tissues for research include considerations regarding the identification of genetic disorders. Considerations include who has the right to that information and should the next of kin be notified when genetic concerns are identified. As there are ripple effects in the release of genetic information determined after death, the effects should be carefully considered before releasing information to any person or organization. It may be difficult for a decedent's family to grasp the effect of using tissues for research after death. In 1951, the researcher George Gey propagated the HeLa cell line [11] that has since been reproduced in countless numbers of laboratories, and the cell lines are widely available through biological companies throughout the world. No one had anticipated the remarkable number of research opportunities made available from this immortal cell line. However, the effect for the family, researcher, and society is apparent 60 years after the tissues were first harvested.



Human Tissue Research

Fig. (1). Beauchamp and Childress' four principles of biomedical ethics.

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Ethics additionally address the researcher being sensitive to a decedent's religious and cultural preferences, as these may influence decisions regarding tissue harvesting for research. For instance, a family may be against using the decedent's tissues to develop cell lines for stem cell or other genetic studies. Questions then arise as to how and who will store and maintain the genetic information and tissues [12], and how will genetic information affect a specific ethnic group or community as a whole.

Fig. (1) shows how one cycles through the four principles in considering ethical dilemmas. Fig. (1) is an adaptation of the Beauchamp and Childress' four principles of biomedical ethics.

CONCLUSION

Current federal laws mandate that the next of kin provide written consent for organ and tissue donation, regardless of the setting. The tissue procurement procedure could be modified for research purposes and as such, could be more acceptable and less costly than modifying state and local laws to incorporate tissue harvest for purpose of research. Given that the decedent's family consents and the researcher has obtained Institutional Review Board (IRB) permission, postmortem specimens could provide a needed resource for Medicolegal death investigation agency leaders should be encouraged to utilize the four principles of the bioethical model when researchers request permission to conduct postmortem tissue studies. Because few death investigative agencies have an IRB process in place, leaders should develop internal policies and procedures that clearly define the researchers' roles, responsibilities, and impacts to the decedent, families, and society. Studies are also needed to explore the publics' perception of using postmortem forensic tissues in research projects.

Advancements in technology for quickly and safely storing and processing tissues have expanded opportunities for genetic research. The use of postmortem tissues for research elicits ethical questions regarding providing tissues for purposes of research as well as subsequent discoveries that may occur after such research. Using the four principles of biomedical ethics gives a starting point for discussing the use of tissues obtained from forensic autopsies for research purposes other than determining the cause of death.

CONFLICT OF INTEREST

To the authors' knowledge, no conflict of interest, financial or otherwise, exists. The authors had no sponsors in concept, design, data collection, analysis or interpretation.

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REFERENCES

- Indech B. The international harmonization of human tissue regulation: regulatory control over human tissue use and tissue banking in select countries and the current state of international harmonization efforts. Food Drug Law J 2000; 55(3): 343-72.
 [PMID: 11824465]
- [2] Machling C, Pellegrino ED, Shimm DS, Spece RG. Emerging Policies for Biomedical Research, In: Kelley WN, Osterweis M, Rubin ER, Eds. Washington D.C.: Association for academic health centers. 1993; pp. 127-42.
- [3] National Institute of Health. National Human Genome Research Institute. http://www.genome.gov/10000925 [accessed August 22, 2011];
- Loescher LJ, Merkle CJ. The interface of genomic technologies and nursing. J Nurs Scholarsh 2005; 37(2): 111-9.
 [http://dx.doi.org/10.1111/j.1547-5069.2005.00022.x] [PMID: 15960054]
- [5] Hickman MJ, Hughes KA, Strom KJ, et al. Bureau of justice statistics special report 2007: Medical examiners and coroners' offices 2004. http://bjs.ojp.usdoj.gov/content/pub/pdf/meco04.pdf [Accessed August 22, 2011];
- [6] Nolte KB. Research issues in forensic pathology: a survey of academic institutions employing forensic pathologists. Hum Pathol 2004; 35(5): 532-5.

[http://dx.doi.org/10.1016/j.humpath.2004.01.010] [PMID: 15138925]

- [7] Roberts LW, Nolte KB, Warner TD, McCarty T, Rosenbaum LS, Zumwalt R. Perceptions of the ethical acceptability of using medical examiner autopsies for research and education: a survey of forensic pathologists. Arch Pathol Lab Med 2000; 124(10): 1485-95. [PMID: 11035581]
- [8] Grizzle WE, Woodruff KH, Trainer TD. The pathologist's role in the use of human tissues in research--legal, ethical, and other issues. Arch Pathol Lab Med 1996; 120(10): 909-12. [PMID: 12046602]
- [9] Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 5th ed. New York: Oxford University Press 2001.

- [10] Rigaud JP, Quenot JP, Borel M, Plu I, Hervé C, Moutel G. Post mortem scientific sampling and the search for causes of death in intensive care: what information should be given and what consent should be obtained? J Med Ethics 2011; 37(3): 132-6. [http://dx.doi.org/10.1136/jme.2010.037739] [PMID: 21186206]
- [11] McGehee Harvey A. Johns Hopkins--the birthplace of tissue culture: the story of Ross G. Harrison, Warren H. Lewis and George O. Gey. Johns Hopkins Med J 1975; 136(3): 142-9.
 [PMID: 235032]
- Jones DG, Gear R, Galvin KA. Stored human tissue: an ethical perspective on the fate of anonymous, archival material. J Med Ethics 2003; 29(6): 343-7.
 [http://dx.doi.org/10.1126/imp.20.6.242] [DMID: 14662812]

[http://dx.doi.org/10.1136/jme.29.6.343] [PMID: 14662813]

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