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Consent for Autopsy Research for Unexpected Death in Early Life

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Abstract

Research in sudden death in fetuses (stillbirth) and infants (sudden infant death syndrome [SIDS]) is urgently needed, particularly in high-risk populations involving socioeconomic disadvantaged families. Essential to such research is the analysis of fetal and infant tissues at autopsy. Obtaining consent for donating autopsy tissues for research is especially problematic in socioeconomically disadvantaged populations in which mistrust of the medical establishment often exists. In this article, we present communication strategies for obtaining consent for research in autopsy tissues of stillbirth and SIDS cases in socioeconomically disadvantaged populations. Recommendations are provided about preparation for and the timing, setting, and content of the consent interview. The same lines of open and transparent communication delineated in this article are applicable to obtaining consent for the autopsy and autopsy research. Although the grief responses to the untimely death of the fetus or infant are universal and the recommendations of this essay are widely applicable to the general population, the expression of this grief and feelings toward autopsy-based research in socioeconomically disadvantaged populations may raise special issues that health care workers should be aware of when obtaining consent for research on autopsy-derived tissues.

The sudden and unexpected death of a fetus (stillbirth) or infant always comes as a great shock to the parents and family who were looking forward to the birth of the newborn or who are delighted by the activities and development of the infant. The death of a fetus or infant is an extraordinarily traumatic loss that often forces families to integrate the almost simultaneous experiences of birth and death. Under these difficult circumstances, health care workers request an autopsy to determine the cause of death, educate the physician and family about the underlying disorder, help ameliorate parental guilt about perceived wrongdoing, inform about the risk of recurrence in subsequent siblings, and provide vital statistics for public health records. In addition, parental consent to donate autopsy tissue for research

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can provide personal solace in the time of great loss by the recognition that the knowledge to be gained will help prevent similar deaths and grieving in the future.^{1,2} Sudden infant deaths with a negative autopsy and death scene investigation are classified as the sudden infant death syndrome (SIDS).³ Although SIDS and stillbirth (generally defined as fetal intrauterine demise at 20 gestational weeks or older) affect all socioeconomic groups, races, and ethnicities worldwide, they disproportionately afflict socioeconomically disadvantaged populations,^{4–6} thereby making autopsy-based research in these populations imperative to develop targeted preventive strategies. Each year, an astounding majority (99%) of the estimated 3.2 million stillbirths in the world occur in the setting of low-income families;⁵ the proportion of SIDS deaths in families living in poverty is as high as 74% in different communities worldwide.^{7,8} Although obtaining consent for donating autopsy tissues for research purposes is difficult under any circumstances, it is especially problematic in socioeconomically disadvantaged populations in which mistrust of the medical establishment often exists, particularly during this vulnerable period of great tragedy.

The following essay concerns communication strategies for obtaining consent for research in autopsy tissues of stillbirth and SIDS cases in socioeconomically disadvantaged populations. In virtually all health care systems today, obtaining consent for autopsy research is a separate process from obtaining consent for autopsy, the latter which is performed for diagnostic clinical purposes only. Nevertheless, the same lines of open and transparent communication, as delineated in this essay, are applicable to obtaining consent for the autopsy for autopsy research with additional considerations for research, which is our main focus. This essay is based on our collective experience in the Safe Passage Study of the Prenatal Alcohol in SIDS and Stillbirth Network, a federally funded, prospective study of 12,000 women and their infants to determine the relationship between prenatal alcohol exposure, stillbirth, and SIDS. The major (but not exclusive) populations in the Safe Passage Study are American Indians in the Northern Plains and multiracial South Africans located in Cape Town, which are two socioeconomically disadvantaged populations at high risk for prenatal alcohol exposure, stillbirth, and SIDS.^{9–12} In the Safe Passage Study, we are faced regularly with obtaining consent from acutely grieving mothers, who are oftentimes separated from their families or the fathers of the infants or both. The mothers are more often from socioeconomically disadvantaged communities and are young, with limited schooling. In this study to date (2003–2009), we have been confronted with 46 stillbirths and sudden infant deaths, and we have obtained consent for research using donated tissues, including brain tissue, in 27 (59%) of these cases. Figures concerning autopsy consent for research for comparison in moderate- to high-income families are not available, but our rate exceeds the recent neonatal autopsy rates (with or without permission for autopsy) in the United States of less than 54%.¹³ The goal of this essay is to provide guidelines in communication in the hope that investigators who are in similar situations worldwide may benefit. Whereas the grief responses to the untimely death of the fetus or infant are universal and the recommendations of this essay are widely applicable to the general population, the expression of this grief and feelings toward autopsy-based research in socioeconomically disadvantaged populations may raise special issues that health care workers should be aware of when obtaining consent for research on autopsy-derived tissues.

APPROVAL OR REFUSAL FOR AUTOPSY-RELATED CONSENTS IN THE SOCIOECONOMICALLY DISADVANTAGED

In the Safe Passage Study, the major reasons given for acceptance of autopsy research are universal and include the desire to know the exact cause of death and to help others in the community. Little information is available, specifically about the views and perceptions about autopsy research among the socioeconomically disadvantaged. The overall conclusion in studies of moderate-income and high-income populations, however, is that research

involving donated autopsy tissues is generally acceptable to families when they are sensitively approached and thoroughly informed by an experienced counselor from a familiar and supportive medical community.^{1,2} Parents feel it is critical, however, that they are involved in all decisions about tissue retention and that the medical community not “betray” them by performing research without their explicit consent, because they understandably feel protective of their children even after death.²

Barriers to autopsy consent for donated tissues generally include misconceptions or lack of knowledge about the autopsy and fear of mutilation of the body,¹⁴ concern about delay of burial,¹⁴ religious or cultural beliefs prohibiting the autopsy,¹⁴ and, in our experience, fear of what autopsy research may reveal, as well as the feeling that such research will not “bring back” the deceased. Suspicion of the medical establishment may also play a role, based on the family’s potential fear of being “used” for nonaltruistic purposes,^{15,16} a belief with firm historic precedent, eg, the use of poor blacks for syphilis research in Tuskegee, Alabama.¹⁷ The oppression of women among the socioeconomically disadvantaged populations likewise may play a role, because many multiracial women in the Western Cape in our experience are neither accustomed to giving their opinions nor are asked what they think. These women are oftentimes simply ignored by their family or community and thus are often hesitant to express their feelings. In some cases, the mother may refuse to give consent to autopsy, because finding the cause of death may incriminate her lifestyle, eg, illicit drug use. Knowledge of cultural and religious views on death, autopsies, and research is necessary before approaching a family for research consent, including socioeconomically disadvantaged populations. Although no culture or religious views hold for all, a general understanding is helpful. Although not universal, some American Indians, for example, view the body as a sacred vessel that should not be desecrated in any way,¹⁸ believing that an individual will not proceed as a whole into the future or will be somehow maimed if the body is “tampered with” in any way.¹⁸ Parents and family members must weigh these often conflicting religious beliefs with the urgency and desire to help others through research.

GUIDELINES FOR ASKING WOMEN FOR CONSENT FOR AUTOPSY TISSUES FOR RESEARCH IN FETAL AND INFANT DEATH

The Circumstances of Consent

From the outset, no assumptions about the beliefs or desires of the parents or family should be made on the basis of their income, race, ethnicity, or religion, because each parent does not necessarily hold the view of the community as a whole. Moreover, it is vital for health care workers to stress that they are not trying to change the parent’s beliefs or to be disrespectful, but only to make sure that they have the same opportunity to help find answers and help future generations, and this is offered to others in the same situation. Throughout the whole consent interview, the health care worker must be attuned to how much the family would like to know, what they would like to ask, and what special concerns and needs they have. Approaching the mother, father, or family after the loss of a fetus or infant is difficult and stressful for the health care worker, and this is an impediment to consent itself. The worker is well-aware and worried that even a single “wrong” word or phrase can upset the mother or family and complicate an already devastating situation. We have found that, in particular, it is important to not refer to future pregnancies because mothers are focused on the special child they have just lost and cannot think about the future at this time. The individual asking for research consent should be aware that many religions determine burial practices, which may dictate how soon after death an autopsy needs to be performed.¹⁹

Determination of the Health Care Worker Obtaining Consent

Historically, the physician has asked for consent for autopsy and for use of donated tissues for research.²⁰ However, there is increasing awareness that this role may be well-filled by nonphysicians in the medical community who are specifically trained and skilled.²⁰ Whenever possible, a medical worker who has known the mother during her prenatal care should ask for consent in cases of stillbirth because that worker is more likely to have a relationship with rapport and trust. If possible, the health care worker who asks for consent should try to visit the mother before the delivery of the stillbirth, to express sympathy, and then promise to return for subsequent visits. In cases of SIDS, the mother interfaces directly with the forensic pathologists and investigators and almost certainly will be asked for consent from an individual she does not know. In these circumstances, utmost skill, experience, patience, and compassion are especially needed on the part of the individual asking for consent.

The Initiation of the Request for Consent

Families who do not provide consent often regret not participating in research many weeks or even months later; therefore, the request for consent must be performed with compassion and skillful communication at the outset. In addition, before approaching the parents for consent, the health care worker needs to prepare emotionally for a wide range of parental and family reactions. Pregnancy, the birth of the newborn, and the first postnatal year are life-changing events that fill parents with pride and happiness; during the duration of the pregnancy, parents visualize the birth and prepare for it, usually with joy. The feelings on loss of a fetus or infant were perhaps best expressed to us by a mother in the Safe Passage Study who said on delivering a stillbirth: "I was preparing myself for labor and birth, now I must prepare myself for a funeral. How is it possible to do this in less than 12 hours?"

After introductions, the health care workers obtaining research consent should let the mother, father, and family know that they know of their tragic loss and that they care by allowing them time to explain what has happened to them or prompt them to talk about the loss. A key part of the health care worker's role is to listen—and to use listening as a first step to assess the parents' perceptions about why the death happened, their feelings and experiences of the autopsy and research, and their spiritual beliefs that bear on their view of research. The quiet presence and willingness to listen by the health care worker may be therapeutic in and of itself. The health care worker should ascertain early in the conversation exactly what the parents know about the autopsy and the use of autopsy tissues for research, and if there have been any previous experiences with these issues. Moreover, it is imperative that the health care worker know the statutory provisions that regulate tissue donation in the region of practice.

Care should be taken to have this conversation in a quiet room with a closed door. If possible, it is best to be seated while asking for consent, because being seated is an indication that the health care worker has time to spend with the parents and respects them. It is important to ask whether the family already has a name for the baby in the case of stillbirth or the name of the infant in the SIDS case. This name should be used during all conversations with the family, rather than referring to "him/her/it" or the "body." The parents should be encouraged to have other family members present if they wish; in our populations, elders often are the leaders in the family and can provide comfort and advice. Time should be given to the family to hold private conversations and process the information together. If the parents are initially too distressed to complete the consent process, the health care worker should leave with the promise to return at a later time.

Explanation for the Importance of the Donation of Autopsy Tissues for Research

When the parents are ready, the next step is to explain the need for autopsy-based research. The main reason to consent for the donation of autopsy tissues is to perform basic research to better-understand diseases or to discover new conditions that cause fetal and infant death, leading to optimal interventions to prevent similar deaths and suffering in families in the future. In addition, it should be explained that knowledge of the cause of death will help the community at large because information about the common and potentially preventable causes of stillbirths and infant deaths would be obtained. It is important to tell the parents that they are part of the “team” to find the causes of fetal or infant death. We have also found it helpful to reference specific and understandable ways that research has helped advance medical and scientific knowledge, eg, the recognition that some unexpected infant deaths are attributable to previously unrecognized abnormalities in systemic metabolism, cardiac rhythms, or brainstem function.⁷ It should be emphasized by the health care worker that the tissues are always treated with the greatest respect and reverence and that the research is performed by researchers who are specially trained; moreover, these individuals care about and believe in the value of autopsy research and respect the family’s decision to consent. Furthermore, the health care worker should explain that small tissue samples are generally taken for research purposes and no tissue will be retained without informed consent. Moreover, it should be emphasized that no additional steps beyond the standard autopsy procedures for sampling tissues are used in obtaining research specimens. Families should be assured that autopsy usually will not delay preparations for the funeral and that, in cases of Muslim parents, it is performed on the same day of death. The parents need to be made aware they will not receive specific research information about their infant because this is standard procedure in research studies. If, however, an unexpected finding is detected that currently is known to affect clinical care directly, the parents should be reassured that this finding will be transmitted to the responsible clinicians for report back to them in the context of standard medical practice.

Time Needed for Consent

It is difficult to pinpoint beforehand how much time will be needed to obtain consent for research use of donated tissues because it differs considerably among families. In some circumstances, it is better to set up a second visit in a reasonable timeframe to continue the discussion. It may be helpful to leave a brochure explaining the research goals for the donated tissues with the family after the first visit. A brochure also can help to clarify and memorialize a family’s decision to donate tissue for research. Unfortunately, a decision about consent must be made quickly because of the rapid need to obtain tissues with short postmortem intervals for valid biochemical and molecular analysis.⁷

Ending the Meeting

If the mother declines to participate in the research, she should be thanked for her consideration and should be reassured that in no way will subsequent care be compromised because of her refusal. If consent is given, gratitude from the medical and scientific community should be given. In our experience, it is also helpful to thank the parents again for consent for autopsy research tissues in follow-up meetings.

CONCLUSIONS

Increased awareness of obtaining consent for donated tissues for fetal and infant death is needed for socioeconomically disadvantaged populations, because they are at greatest risk and scientific breakthroughs in diagnosis and prevention are dependent on research. Large-scale research into communication regarding autopsy research consent itself in socioeconomically disadvantaged communities is also needed. Based on our experience in

the Safe Passage Study in such communities, we have found that success in obtaining research consent is founded on the universal precepts of transparency, sensitivity, dedication, honesty, and respect.

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