RELEASE OF ORGANS AND TISSUES

National Association of Medical Examiners Position Paper: Medical Examiner Release of Organs and Tissues for Transplantation

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ABSTRACT: The National Association of Medical Examiners (NAME) endorsed a position paper on the medical examiner/coroner (ME/C) release of organs and tissues in cases falling under ME/C jurisdiction in 2007; this paper has now sunsetted. The goal of this paper is to provide an update on ME/C denials and to reaffirm NAME's position on this topic. In summary, it is the position of NAME that ME/Cs should permit the procurement of organs and tissues in cases falling under their jurisdiction, providing that there are cooperative agreements in place to ensure that ME/Cs are able to fulfill their legal mandates regarding determination of cause and manner of death and of appropriate collection and preservation of evidence.

KEYWORDS: Forensic pathology, Organ transplantation, Tissue transplantation, Autopsy

INTRODUCTION

Incredible advances in the science of recovery, processing, and transplantation, as well as improved immunosuppressive therapy, have vastly improved the outcomes and possibilities for transplantation medicine. The advantages of transplantation of human organs and tissues, or human derived cellular therapy products as first line treatment for a multitude of conditions have contributed to the shortage of these lifesaving and life enhancing gifts. Solid organ transplantation successes include five-year survival rates post transplantation of 54.4% for lung, 74.9% for heart, 73.8% for liver, and 69.3% for kidney as of May 2009 (1). Tissue transplantation is no less impressive, and far more common. Over six million musculoskeletal allografts have been safely transplanted in the last decade (2). Currently, over one million tissue transplants are performed annually (3). Reliably successful outcomes and continuing health problems in the population have led to perpetual shortages of organs and tissues for transplantation. As of this writing, over 123 972 people are on the waiting list for a life saving organ, and another person is added to that list every ten minutes (1, 4). On average, 18 people across the nation die every day while awaiting an organ that may have saved them (1).

Organ donation has grown in public support and awareness in the past decades due to the media coverage of its success stories and the amazing innovations in the transplantation world. Currently, there are more than 100 million people in the U.S. signed up to be donors (5). Many other countries have even greater percentages of their population registered as donors. The general public, lawmakers, politicians, and their lobbyists definitely support this magnanimous legacy of organ and tissue donation.

Children often have specialized organ and tissue transplantation needs and remain on waiting lists for a longer period of time. Their bodies cannot accommodate the size of adult organs. Allograft valves are preferred in valve replacement in children. Thus, the scarcity of donor organs is especially acute for children since organ size matters for liver, heart, and lung transplantation and there are relatively few size-matched deaths in younger children. Pediatric transplant programs are smaller than adult programs because fewer children require transplantation, and they must offer special expertise in children's health care. In addition, unlike for adults, children and adolescents cannot provide first-person consent for organ and tissue donation. Therefore, parents of young children usually must make a donation decision in the absence of any direct knowledge J. Keith Pinckard MD PhD is Deputy Chief Medical Investigator and Professor of Pathology at the University of New Mexico Office of the Medical Investigator.

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about their child's donation intentions during a time of great emotional stress.

It has been estimated that as many as 70% of potential donors fall under medical examiner/coroner (ME/C) jurisdiction (6). Therefore, ME/Cs frequently find themselves the gatekeepers of these valued organs and tissues for possible donation; they have the responsibility of determining cause and manner of death and of documenting and collecting appropriate evidence in cases falling under their jurisdiction. Organ/tissue procurement organizations (O/TPOs) must obtain consent from the ME/C in these cases before proceeding to organ and tissue procurement, regardless of the family's or decedent's prior consent or donation wishes. Predictably, ME/Cs across the United States are not uniform in their approach to making organs and tissues available to O/TPOs. This discrepancy, coupled with the lack of proof that organ and tissue donation actually impedes performance of a ME/C's statutory duties leads many O/TPOs to charge ME/Cs with unnecessarily withholding organs and tissues that could potentially be lifesaving (7). Both the public and lawmakers do not receive these allegations lightly. Indeed, court orders and legislation have been sought, advocated for, and passed to prevent such situations (8). Some of these recovery denials are due to the various methods of an individual ME/C, while others are due to attitudes of law enforcement and prosecutors in their respective jurisdictions, or poor communication between all parties involved (9, 10). Some states have passed legislation overriding the ME/C's concerns (11-15).

In 2007, the National Association of Medical Examiners (NAME) published a position paper on the topic of ME/C release of organs and tissues for transplantation (16). Since then, the Scientific Working Group for Medicolegal Death Investigation published a document with similar recommendations (17). The purpose of this manuscript is to update and reaffirm NAME's position on this important topic.

DISCUSSION

Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated as a human cell, tissue, and cellular and tissue-based product (HCT/P). The Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps. Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, veins, adipose tissue, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes, and semen. CBER does not regulate the transplantation

of vascularized human organ transplants such as kidney, liver, heart, lung or pancreas. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs.

Immediate Need vs. Stocking of Tissue

Donated tissues such as skin, bone, and heart valves can dramatically improve the quality of life for recipients and even save lives. Unlike organs, tissue can be processed and stored for extended periods of time for future use in burn cases, ligament repair, and bone replacement. However, the concept that tissues are "stocked" for protracted periods on inventory shelves is highly overstated. All donated tissues must go through a testing process for determination of suitability and a quarantine period before they are available to be distributed to waiting hospitals and surgeons.

Many tissues are of immediate need. Cardiac tissues such as valves or pulmonary/aortic conduits are life saving for patients with cardiovascular conditions. Certain musculoskeletal allografts such as ligaments and tendons are desperately needed. For example, a surgeon may have to cancel a scheduled surgery because a specifically sized Achilles tendon or patellar ligament is not currently available. Neurosurgical/orthopedic spacers and other bone grafts may remain "in stock" until a specific size/recipient is identified. In an engineered graft that is utilized to fit between vertebral bodies after disc removal, the sizing must be perfect. Surgeons are provided with a selection of grafts and insertion tools of various sizes to meet specific patient require-

Some "inventory" of other graft tissue is always maintained. Crushed bone material can be fashioned into bone packing material, bone "glue", or other grafts for future utilization.

Cardiac valve replacement is considered a life-saving transplant. A replacement heart valve is a device implanted into the heart of a patient with valvular heart disease. There are two main types of replacement heart valves: mechanical and biological. Biological valves are the valves of animals (xenograft) or humans (allograft), which are transplanted into recipients, and each tissue type has its own unique problems and complications. However, benefits of allograft heart valves include no need for long-term anticoagulation therapy (particularly beneficial in children and pregnant women) and better hemodynamic performance due to more natural function with the surrounding structures.

Reasons for Medical Examiner/Coroner Denials and Restrictions

Some ME/Cs deny procurement of organs and/or tissues for transplantation due to concerns of not being able to fulfill their legal mandate: to determine the cause and manner of death, and to ensure that appropriate evidence is collected. With appropriate communication and cooperation between ME/Cs and O/TPOs, this should not be the case in the vast majority of situations.

Some medicolegal death investigators express concerns regarding approval of organ and tissue donation for fear of compromising the investigation or subsequent prosecution. This is despite the lack of documentation of any medicolegal case having been negatively impacted by donation (18). We are aware of no more recent references regarding the impact donation may have on medical examiner cases, despite the decades of continued and increased recovery of tissues and organs from medical examiner cases. This fact seems to support the allegation that there is no significant negative impact on cause and manner of death determination, nor on the litigation of such cases. The vast majority of these concerns appear to be based in a reluctance to be blamed for compromising the case. Certainly there have been rare instances of individual prosecutors asserting that the prosecution of the case had been damaged by procurement (19). None of these alleged cases in which legal matters were not pursued or were dropped because of the alleged interference were ever published in support of this claim. Additionally, perceived possible failure should not be interpreted as true failure due to interference. However, the forensic pathologist/ ME/C has the responsibility to educate the attorneys about the procurement process and assure them that a complete and accurate examination can be accomplished and all necessary evidence and specimens will be able to be collected.

The important bottom line is that many ME/C offices have decades of zero or close to zero denials while still fulfilling their legal mandate and without having issues with subsequent legal proceedings. Because of this proof of concept, it is reasonable to conclude that this is possible in all jurisdictions.

Data about Medical Examiner/Coroner Denials

Most of the data regarding ME/C denials are between one and two decades old (20-22), and almost certainly do not represent current practices of approvals/denials. In these studies, overall denial rates were typically between six and ten per-

cent. Historically, nearly half of the requests to the ME/C concerning child donations were denied (21). There is often a concern surrounding donation of the heart (either as an organ, or for valves) because of a fear of the inability of diagnosing a cardiac abnormality. Currently, the rate of organ denials on all ME/C referrals is 2.6% (23), which is a substantial improvement over many years ago.

With regard to organ donation, there is a single published report of five cases (four infants and one adult) by Wolf et al. alleging that their cause and manner of death were unable to be determined because of the procurement of organs (24). An extensive analysis of this particular study is beyond the scope of this manuscript. In brief, four of these cases were infant deaths in which the medical examiner requested specific organs not be donated, but, in keeping with a Texas law (14), donation proceeded despite the medical examiner's request. In the fifth case, no denial was issued by the medical examiner, but release was thought to have been granted on what was alleged as incomplete or erroneous information. In this series of cases, all of the infants described were in the sudden unexpected infant death category, and, like many in this category, had initial circumstances suggesting a potential asphyxial mechanism. At worst, the allegation is that the undetermined cause/undetermined manner were the outcomes as a consequence of organ donation. That is not a reasonable assumption, as these were all cases in which a negative autopsy exam would not be unexpected. The finding of an occult natural condition in the heart, the kidneys, or the lungs (with clinically functioning heart, lungs, kidneys, liver, while ventilated) that would account for a cause of death is extremely unlikely.

The Uniform Anatomical Gift Act

The Uniform Anatomical Gift Act (UAGA) is one of the Uniform Acts drafted by the National Conference of Commissioners on Uniform State Laws (NCCUSL). For issues that are under state and not federal legislative control, each state must enact its own laws. For some issues (e.g., transplantation), it may be desirable for such laws to be relatively uniform and consistent from state to state. The intent of the NCCUSL is to draft acts with suggested language that states can either ratify as written, or modify in part (ideally, as little as possible) prior to passage. The 2006 revision of the anatomic gift act has been ratified in some form in almost all states (25). According to the NCCUSL version of the 2006 UAGA, if the ME/C anticipates a denial of procurement, he/she must attend the procurement procedure. Once there, if he/she still insists on denying the removal of an organ for transplantation after attending the procurement procedure, he/she must provide written documentation explaining the reasons for the denial (6). The precise definition of "attending" is open for interpretation, and could include photography, videos, or real time teleconferencing. A requirement to document denials can serve the ME/C community to clarify exactly what sorts of situations are faced and how those judgments might be improved, or perhaps shown to be justified. Additional data will also be beneficial to opening up dialogue between the ME/C communities and O/TPO agencies.

Regarding the potential denial of procurement by ME/Cs, the presence or extent of these legal requirements vary from state to state, as portions of the language of the NCCUSL 2006 UAGA were modified by several states prior to its passage.

Medical Examiner/Coroner and Organ Procurement Organization (OPO) Cooperation in Organ Procurement Cases

The collection of evidence on a case going to organ procurement can readily be performed while the patient is still in the hospital. This is the appropriate location for the collection of trace evidence and sexual assault kits, which need to be obtained as early as possible following a potential assault. This will also apply to the collection of gunshot residue kits if desired by law enforcement, although most jurisdictions have stopped collecting such kits in any circumstances due to lack of probative value. Organ donors will have had some period of hospitalization during which they will have been undressed and manipulated. Such trace evidence would thus have likely been compromised or lost well before the involvement of the OPO and the ME/C. Blood specimens also should be obtained as soon as possible and protocols can be formulated to allow the ME/C to secure specimens foremost, to satisfy what they need for toxicologic or diagnostic testing.

The external examination of the hospitalized patient by the ME/C may also occur before the patient goes to the operating room for organ procurement. If the medical examiner or coroner is unable to attend in person, an OPO or tissue bank representative can transmit real-time images of the body, organs, or recovery for the ME/C to evaluate. Proper photographic documentation can be obtained at this point by the ME/C or an agent acting on their behalf according to pre-established protocols or instructions. Specialized photos for each case can be requested as indicated by the history or video demonstration of the case. The ME/C may then choose to direct the medical team to avoid certain areas of the body that may have wounds that require further examination at autopsy. This also enables the ME/C to request ancillary testing such as computerized tomography, magnetic resonance imaging, bone scans, angiography, skeletal series, and retinal examination, which may be valuable in addressing future medicolegal questions. Such examinations can be performed at the expense of the OPO, allowing for a more complete examination, often with modalities that are unavailable to many ME/C offices, while at the same time offering cost savings to the ME/C system.

It is important that memoranda of understanding between the OPO and the ME/C be developed in advance. Such protocols should provide, at a minimum, for: a) an agreement by the OPO to provide high quality photographs of every step in the recovery procedure to include photos of the body prior to procurement, photos of any abnormal findings such as rib fractures or damage to internal organs, and photos of negative findings, such as the surfaces of normal organs that are recovered; b) an agreement that recovery will be immediately stopped and the ME/C contacted if any abnormal findings are encountered; c) the ability of the ME/C or their representative to be present in the recovery suite if desired; d) the willingness for the recovery team members to return at no cost to the jurisdiction for any future legal proceeding, if necessary; and e) an agreement that the ME/C has first rights to admission laboratory specimens. It should be recognized that in the majority of circumstances, prosecutors would much rather use their ME/C for any testimony. It is common practice for ME/Cs to testify as to the findings of other medical professionals who have been involved with a case prior to death. Organ and tissue procurement personnel should present no exception. The OPO should also be able to ensure that admission hospital specimens are properly retained and not discarded in the course of routine laboratory protocols. Part of the agreement between the OPO and the ME/C should also address the need for each agency to have access to such specimens. It is often possible for the OPO to ensure that the ME/C has enough admission blood for proper toxicology testing while simultaneously ensuring that they have sufficient sterile specimens to perform their needed serologic testing.

It should be noted that the OPO may also assist in the efforts of the ME/C by providing prompt notification to the ME/C office of a case which may become under their jurisdiction. If desired, the OPO may be able to notify the ME/C as soon as they become involved in a case. This will allow for more prompt investigation of the case. It is a tragedy for an OPO to follow a case for hours or days prior to a brain death pronouncement and then contact the ME/C when they are poised to proceed with recovery only to present the ME/C with the need to make a rapid and uninformed decision on donation. Many jurisdictions have found that such early notification of the ME/C

of the potential death provides for a much more complete investigation while simultaneously providing the ME/C the ability to contact other involved investigative agencies in an orderly manner to collect needed information. Although it is true that the ME/C does not have jurisdiction over the case until death is pronounced, forensic pathologists often have privileges at their local hospitals and can serve in the role of a forensic consultant performing what is termed as clinical forensics. They can consult with the physicians caring for the patient, gather information, and provide advice for steps which may be required prior to giving consent for recovery. This can allow the ME/C to ask for any additional information or testing before recovery and prepare them to offer an empiric and scientific basis for the decision to fully approve or approve with partial restriction. Another possibility is that the OPO could discuss the case in general with the ME/C without revealing any identifying information or protected health information.

Medical Examiner/Coroner and Tissue Procurement Organization (TPO) Cooperation in Tissue Procurement Cases

Recovery of tissues involves somewhat different issues than recovery of organs, although many similarities remain. With organs, it can always be argued that the surviving organ remaining fully functional in the recipient is the ultimate test of lack of injury or disease to that organ. This is not the case with tissues. But nor should it be assumed that tissue transplantation is not "lifesaving." Tissue transplantation is no longer just the provision of split thickness skin grafts for burn patients, although such skin can certainly be the deciding factor in their survival. Skin is also used in reconstructive surgeries. With recent advances in tissue transplantation, cells recovered from the descending thoracic aorta can be used to grow vascular grafts used in coronary artery bypass grafting and vascular shunts that are resistant to rejection and restenosis. Stem cells from adipose tissue are used to seed acellular donor bone matrix to improve graft acceptance, cell repopulation, and strength. They provide an allograft tissue with the benefits of autograft bone. Joint restoration (JR) with fresh articular tissues have been used to reconstruct entire joints in victims of devastating trauma, allowing for nearly full function of an extremity rather than the alternative of amputation. The ability of a young trauma or cancer victim to have a functional arm and interact with their child or spouse in a normal manner may literally save their life. Juvenile cartilage from 29 day to 12-year-old donors is processed and injected to restore articular surfaces in joint diseases and some forms of trauma. It is used to reduce defects in the cartilage and reduce pain. Corneas may be transplanted to provide clear vision for those blinded by cataracts.

Optimally, the ME/C should examine the patient prior to recovery. If this can be accomplished by means of the external examination and then allow the TPO to perform the recovery prior to the formal internal autopsy, it is of great advantage to the TPO. Tissue recovery must occur within a short period of time (usually 24 hours) following the last known alive (LKA) time. If the ME/C restricts the TPO to recovery post autopsy, this time window may be exceeded and the donation may be lost. It is also valuable to complete the recovery prior to autopsy for other reasons. The autopsy process will increase the biologic burden on the skin surfaces; post autopsy tissue culture rates, despite extensive surgical preparation at recovery, are known to be significantly higher. Additionally, incidental and easily modified autopsy incisions may destroy recovery potential of certain tissues.

During the external examination, the pathologist should ensure that they recover the specimens (blood) required by the TPO. The sample collection vials, and sterile needles could be provided by the TPO. If corneal recovery is anticipated, vitreous should not be drawn. An agreement should be in place that the TPO will obtain the vitreous for the ME at time of corneal recovery and return it to the ME/C following proper chain of custody procedures.

During the recovery process, it is important for the TPO to follow the same steps as outlined above for organ procurement. Extensive photography should be obtained, including photos of negative findings such as an unremarkable chest after reflection of the skin or an unremarkable heart lying in a pericardium without evidence of trauma. The recovery team should stop the procedure and contact the ME/C if unexpected findings are encountered. The expectations of the ME/C for recovery of specimens and adherence to any restrictions should be strictly adhered to if the specimens have not been obtained by the ME/C prior to recovery. The recovery personnel should be familiar with and strictly follow chain of custody procedures in obtaining the specimens and promptly transport them to the ME/C.

Procurement of the heart for valves is often a concern for ME/Cs, fearing that diagnostic information may be lost. Special protocols have been described in order to ensure that this does not happen (26, 27). Importantly, a large study was undertaken in the pediatric population to document what types of cardiac abnormalities are encountered; it was determined that with adherence to the protocols in place at that office, it would have been unlikely that any of these types of abnormalities would not have been diagnosed had procurement taken place (28).

If recovery is not or cannot be allowed prior to autopsy, simple variations in technique by the forensic pathologist can be very helpful to the tissue bank. The use of the "Y" incision, if extended completely up to the shoulder, may result in the tissue bank having to reject the recovery of the shoulder. Modification of the pathologist's technique may allow for recovery. During removal of viscera, if lower extremity skin or tissue recovery is planned, covering the legs with impervious drapes will reduce the bio-burden from transferring organs to the sink and autopsy station. The TPO could provide these drapes without charge. Additionally, if recovery is restricted to post autopsy, than no additional restrictions apply. Recovery of heart valves should not be restricted if only an external examination is planned.

Advantages for the ME/C in Cases with O/TPO involvement

There are advantages to the ME/C of a good relationship with their O/TPO that go beyond the earlier notification of cases and ability to obtain additional testing and safeguarding of hospital specimens discussed above. An agreement should be in place that hearts that are recovered for valves will be either returned to the ME/C for additional studies or sent to a qualified cardiovascular pathologist for complete examination, at no cost to the ME/C. Such testing, not infrequently, will disclose additional cardiovascular findings that may not have been documented by the ME/C, whether due to limited examination or cost saving measures in place that may restrict histological examination (29).

O/TPOs perform a very complete medical-social history interview on all of their cases during the assessment prior to recovery. This information may prove very useful in the death investigation and should be shared with the ME/C. Conversely, it is important that the ME/C share the information gathered in their death investigation with the O/TPO. O/TPO medical directors will review all of the documentation presented to them to determine suitability for transplantation. The ME/C report may prove to be very important in this process as the ME/C investigator may be the only one to learn certain aspects of the decedent's history. For example, although on the surface it may seem irrelevant to disclose that the decedent was participating in autoerotic activity at the time of their death, this may provide the medical director valuable information with regard to their lifestyle, and thus their suitability for transplantation.

Tissue banks routinely culture their recovered tissues for bacterial and fungal contamination. They also are required to test their patients serologically. It is recommended that the ME/C request these reports from the recovery agency.

Unexpected viral diseases or sepsis may be encountered and may prove useful in the death investigation.

Musculoskeletal recovery from lower extremities may occasionally disclose *in situ* thrombithat may have been missed or not looked for by the forensic pathologist. During recovery of the heart, the recovery team may find emboli. Protocols should be in place to properly document these findings, report them to the ME/C, and possibly retain the emboli. It is possible that such findings may not have been documented if the case otherwise did not require a full autopsy. Furthermore, additional injuries may be identified and documented through the process of tissue recovery in cases of trauma which may not be identified otherwise, in cases not autopsied, but only externally examined by the ME/C.

Difficult Cases

Two major classes of cases will pose the most difficult decisions for the ME/C to allow recovery: suspected or known homicides (especially suspected child abuse cases) and sudden infant death cases. The vast majority of homicide cases will remain candidates for at least "approval with restrictions," if not full approval. A homicide victim with a single gunshot wound to the head can readily be examined prior to recovery and approval given for recovery below the neck. Victims with penetrating or perforating wounds to the torso or extremities may be given approval for skin, musculoskeletal, adipose, or cardiac recovery following external examination by the forensic pathologist and appropriate radiographic examinations to document injuries and retained objects. Each case will need to be considered on its own merits. A uniform policy covering all situations is not appropriate.

Alleged child abuse cases require special scrutiny, as they are rarely simple in presentation. Pre-recovery examination by the forensic pathologist should be performed. Patients on life support may require multiple studies to exclude additional injuries (e.g., skeletal survey, computed tomography, magnetic resonance imaging, and/ or early retinal exam) prior to approval for recovery. If the clinical findings indicate isolated head injury, recovery of organs and tissues is appropriate. If studies indicate skeletal injury, the recovery team can be directed to avoid those areas. The O/TPO should be useful in obtaining special studies, as clinically indicated, to rule out occult or esoteric conditions in order to achieve permission for recovery. It is often the case that a more complete examination can be achieved using the resources of the O/TPO than might be possible from the ME/C alone. The O/TPO may be able to help facilitate the additional examinations even

on recently deceased patients in the hospital and on occasion on patients dying outside the hospital. For the patient who dies outside the hospital, it may be necessary for the pathologist to go to the recovery room and participate in the recovery of the heart after external examination. Once the pathologist confirms that the *in situ* vascular connections are appropriate, the heart may be recovered for valves and then sent for formal cardiovascular examination without loss of diagnostic ability (28). A negative skeletal survey and examination will allow permission for recovery of fresh joints. Skin and adipose recovery will not be requested in such small patients.

Sudden unexpected death in apparently healthy infants presents an additional challenge. But the challenge can be met by the forensic pathologists with some additional effort with the realization that a complete examination can be achieved with just a modicum of additional effort. As with the child abuse cases, the pathologist can examine the body before recovery and rule out injuries. Skeletal survey will exclude bony injury. The pathologist may desire to attend the recovery and exclude in situ cardiac abnormalities. Other options such as photos or videos may be considered depending on the comfort of the ME/C. The cardiovascular pathology examination will then address other cardiac issues. Subsequent recovery of juvenile cartilage/ fresh joints will not compromise the evaluation of sudden infant death. All of the other organs and tissues normally examined in such cases will still be available and uncompromised.

CONCLUSION: THE NAME POSITION

- 1. ME/Cs and O/TPOs should work cooperatively together and establish prospective agreements, protocols, or memoranda of understanding to ensure that both parties get what is needed and that procurement of organs and/or tissues from cases falling under ME/C jurisdiction can be maximized. The protocols described herein are suggestions regarding how ME/Cs and O/TPOs might interact. NAME recognizes that "one size" does not necessarily "fit all" and does not endorse or promote any specific protocols. Recognizing that each local jurisdiction and environment may have unique considerations, these agreements should be formulated between individual ME/C offices and the O/TPOs with which they interact.
- 2. NAME strongly opposes any existing or proposed legislation prohibiting ME/Cs from attempting to restrict and/or deny organ and/or tissue procurement in cases falling under their jurisdiction, and specifically, opposes the language regarding this topic in the 2006 UAGA. In states already having such legisla-

- tion, NAME encourages ME/Cs and O/TPOs to work cooperatively to avoid an adversarial relationship and to avoid the enforcement of such legislation and procuring of organs and/or tissues over the objections of the ME/C.
- 3. Expenses incurred by ME/C for additional work in cases involving procurement should be reimbursed by the O/TPO. These expenses should be "reasonable and customary" and not artificially inflated simply to discourage donation.
- 4. NAME contends that with proper communication and cooperation between ME/Cs and O/TPOs, the ME/C can allow for procurement of at least some, if not all, organs and/or tissues in cases falling under their jurisdiction and fulfill their legal mandates without detriment.
- 5. ME/Cs should permit the recovery of organs and/or tissues from decedents falling under their jurisdiction in virtually all cases, to include cases of suspected child abuse, other homicides, and sudden unexpected deaths in infants. It is recognized that blanket approvals may not be possible in every case, and may require an "approval with restriction(s)."
- 6. ME/C offices should refer all cases to be evaluated as potential donors, as any case not going thorough the hospital are not otherwise referred. ME/Cs should have a goal of 100% referral of out of hospital deaths investigated by ME/C offices where the last known alive time is within 24 hours.
- Some ME/C offices currently have "zero denials" and this should be the goal of every ME/C office.

DISCLOSURES

Dr. Pinckard is the Editor-In-Chief of Academic Forensic Pathology and a member of the Musculoskeletal Transplant Foundation's Medical Examiner and Coroner Advisory Committee. Dr. Moffatt is the co-chair of the Musculoskeletal Transplant Foundation's Medical Examiner and Coroner Advisory Committee. Dr. Schultz is the Medical Director/Vice President of Tissue Services for LifeLink Foundation and Chair-Elect of the American Association of Tissue Banks. Dr. Wetzler is the Assistant Medical Director of LifeNet Health and a member of the Physicians Council and Media Relations Council of the American Association of Tissue Banks.

The opinions and conclusions of this paper have been reviewed and approved by the National Association of Medical Examiners Board of Directors and as such are endorsed by NAME. These opinions and positions are based on a consensus of the current literature, knowledge, and prevailing theories on this topic. As Scientific knowledge and experience grow, NAME reserves the right to revise or update these opinions. The process by which NAME position papers are initiated, written, reviewed, and approved is publically available on the NAME website (www.thename. org). All scientific position papers endorsed by the National Association of Medical Examiners automatically expire five years after publication unless reaffirmed, revised, or retired at or before that time. This work is a product of NAME and as such, was not subjected to Academic Forensic Pathology editorial review.

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REFERENCES

- U.S. Government information on organ and tissue donation and transplantation [Internet]. Washington: U.S. Department of Health and Human Services; c2014. The need is real: data; [cited 2014 Jan 7]. Available from: http://www.organdonor.gov/about/data.html.
- Joyce MS, Greenwald AS, Boden S, et al. Musculoskeletal allograft tissue safety. Chicago: American Academy of Orthopaedic Surgeons; 2006. 6 p.
- 3) American Association of Tissue Banks [Internet]. McLean (VA): American Association of Tissue Banks; c2010. About us; [cited 2014 Jan 7]. Available from: http://www.aatb.org/About-AATB.
- United Network for Organ Sharing [Internet]. Richmond (VA): United Network for Organ Sharing; 2014 [cited 2014 Jan 7]. Available from: http://www.unos.org.
- 5) U.S. Government information on organ and tissue donation and transplantation [Internet]. Washington: U.S. Department of Health and Human Services; c2014. Becoming a donor; [cited 2014 Jan 7]. Available from: http://www.organdonor.gov/becomingdonor/index.html.
- Goldstein B, Shafer T, Greer D, Stephens BG. Medical examiner/coroner denial for organ donation in braindead victims of child abuse: controversies and solutions. Clin Intensive Care. 1997; 8(3):136-41.
- U.S. Government information on organ and tissue donation and transplantation [Internet]. Washington: U.S. Department of Health and Human Services; c2014. Advisory Committee on Organ Transplantation: U.S. Department of Health and Human Services recommendations 1-18; [cited 2014 January 7, 2014]. Available from:
 - http://www.organdonor.gov/legislation/acotrecs 118.html.
- WMSN Fox 47 [Internet]. Madison (WI): WMSN; c2014. Organ donation advocacy group weighs court intervention; 2013 Nov 21 [cited 2014 January 7, 2014]. Available from: http://wmsn.webtest.sbgnet.com/ newsroom/top_stories/videos/organ-donation-advocacy-groupweighs-court-intervention-8070.shtml.
- Jaynes CL, Springer JW. Decreasing the organ donor shortage by increasing communication between coroners, medical examiners and organ procurement organizations. Am J Forensic Med Pathol. 1994 Jun; 15(2): 156-9.
- 10) Sturner WQ. Can baby organs be donated in all forensic cases? Proposed guidelines for organ donation from

- infants under medical examiner jurisdiction. Am J Forensic Med Pathol. 1995 Sep; 16(3):215-8.
- 11) New York, County Law, art 17-A, §674-a, 1977.
- 12) Tennessee Code Ann 1993; §38-7-108-c (2).
- 13) New Jersey Stat Ann 1993; §52, Chap 17B §88 7.
- 14) Texas Health & Safety Code Ann 1995; §693:002.
- 15) California Health & Safety Code 2003; §7155:7.
- 16) Pinckard JK, Wetli CV, Graham MA, National Association of Medical Examiners. National Association of Medical Examiners position paper on the medical examiner release of organs and tissues for transplantation. Am J Forensic Med Pathol. 2007 Sep; 28(3):202-7.
- 17) Organ and Tissue Procurement Committee of the Scientific Working Group on Medicolegal Death Investigation (SWGMDI). SWGMDI's standards for interactions between medical examiner/coroner offices and organ and tissue procurement organizations and eye banks [Internet]. Scientific Working Group for Medicolegal Death Investigation; 2013 [updated 2013 Jun 20; cited 2013 Feb 2]. Available from: http://swgmdi.org/images/organ1.standardsforme.c.opo.eye bankinteractions.published6-20-13.pdf.
- 18) Strama BT, Burling-Hatcher S, Shafer TJ. Criminal investigations and prosecutions not adversely affected by organ donation. *Newsl Med Law Comm*. 1994; (Summer):15-21.
- 19) Ward PR. Allegheny County judge had to choose: Investigate child's death, or hurry to save another life? Pittsburgh Post-Gazette [Internet]. 2013 Nov 20 [cited 2014 Jan 7]; Health: [about 3 p.]. Available from: http://www.post-gazette.com/news/health/2013/11/21/ Judge-weighed-transplant-vs-investigation-Judge-weighedtransplant-vs-probe/stories/201311210241.
- Shafer T, Schkade LL, Warner HE, et al. Impact of medical examiner/coroner practices on organ recovery in the United States. *JAMA*. 1994 Nov 23-30; 272(20): 1607-13
- 21) Shafer TJ, Schkade LL, Evans RW, et al. Vital role of medical examiners and coroners in organ transplantation. Am J Transplant. 2004 Feb; 4(2):160-8.
- 22) Voelker R. Can forensic medicine and organ donation coexist for the public good? *JAMA*. 1994 Mar 23-30; 271(12):891-2.
- Unpublished 2013 data, Association of Organ Procurement Organizations.
- 24) Wolf DA, Derrick SM. Undetermined cause and manner of death after organ/tissue donation. Am J Forensic Med Pathol. 2010 Jun; 31(2):113-6.
- 25) Uniform Law Commission [Internet]. Chicago: National Conference of Commissioners on Uniform State Laws; c2014. Legislative enactment status, anatomical gift act (2006); [cited 2014 Jan 7]. Available from: http://www.uniformlaws.org/LegislativeMap.aspx?title=Anatomical Gift Act (2006).
- 26) Wetli CV, Kolovich RM, Dinhofer L. Modified cardiectomy: documenting sudden cardiac death in hearts selected for valve allograft procurement. Am J Forensic Med Pathol. 2002 Jun; 23(2):137-41.
- Gunther W. Pediatric heart valve donation: The Virginia protocol (FP05-6). ASCP Check Sample. 2005; 47:63-75.
- 28) Pinckard JK, Graham MA. Heart valve tissue donation does not preclude the diagnosis of clinically significant pediatric cardiac abnormalities. Am J Forensic Med Pathol. 2003 Sep; 24(3):248-53.
- 29) Centers for Disease Control and Prevention (CDC). Three sudden cardiac deaths associated with lyme carditis — United States, November 2012–July 2013. MMWR Morb Mortal Wkly Rep. 2013 Dec 13; 62(49): 993-6.