SCIENTIFIC WORKING GROUP FOR MEDICOLEGAL DEATH INVESTIGATION

PRC#4 Organ and Tissue Procurement Committee Standards and Best Practices for Interactions Between Medical Examiner/Coroner Offices and Organ and Tissue Procurement Organizations and Eye Banks

Public Comment Report 3

Created by SWGMDI's Organ and Tissue Procurement Committee
Open for Public Review and Comment December 2012 to February 2013
Total responses received= 24
21% endorsed the draft as is.

Comments Received from the American Academy of Forensic Sciences, American Association of Tissue Banks, Arkansas Regional Organ Recovery Agency, Association of Organ Procurement Organizations, Bryan College of Health Sciences, Charleston County Coroner's Office, DC Department of Forensic Sciences, East Tennessee State University, Iowa Office of the State Medical Examiner, Kenyon International Emergency Services, LifeLink of Florida, LifeLink of Georgia, Los Angeles Coroner, Maricopa County Office of the Medical Examiner, Nassau County Medical Examiner's Office, National Museum of Health and Medicine, New Jersey Organ & Tissue Sharing Network, OneLegacy, Pennsylvania State Coroners Association, South Bend Medical Foundation, Tarrant County Medical Examiner's Office, West Virginia University.

Commenter #1
Overall this draft is a vast improvement. Thank you for all your hard work. A couple minor suggestions/additions: Line 40 - Please clarify "Will provide a copy of the document". In our jurisdiction the organ procurement agency is obtaining verbal consent to donation. They are audio recording the conversation and consent. They are not getting any type of written documentation. As a result when we ask for a 'copy' of the authorization they tell us we can listen to it but may not have a copy. Please clarify that a 'copy' may be in written or audio form. As it is now they tell us they do not have any type of 'document'. They mean 'written'.
Response: This suggestion was incorporated in the revised document.
Lines 43-46: We need to clarify that this is an option for the "ME/C or their investigator" to conduct the external exam....not staff from the procurement agency. Again in our jurisdiction the procurement agency has taken it upon themselves to 'volunteer' in some smaller jurisdictions to conduct the exam, take photos, etc. This exam should be completed by the ME/C NOT the procurement agency. Maybe this should be listed under "Best Practice". I don't think we should as a profession, be deferring to the procurement agency to do those things nor should they be offering to 'volunteer' in that capacity. They are not investigators.

Response: The suggested clarification that the external examination shall be performed by the ME/C or their investigator was incorporated in the revised document.

Line 85: We may need to define "effort".

Response: The definition of "effort" as used in the document for allowing investigation prior to DCD pronouncement would vary markedly in each situation. Best effort can be defined in each situation if litigated.

Best Practice: (Referring to line 48) I think a best practice would be that the ME/C obtains their own samples for tox not the procurement agency. I understand that is some areas that may be difficult but the best practice is to limit the number in the chain and for the agency with the responsibility to obtain it and run it also collects it.

Response: This would require a trained representative from the ME/C be present at every harvesting of tissue and organs, which is possible under the law but wildly impractical for most offices.

Commenter #2

INTRODUCTION

Clear policies and procedures should guide regular communication between medical examiner/coroners and organ/eye/tissue procurement agencies and tissue processors in order to facilitate continued improvement of processes and to enhance mutual understanding. The following standards and best practices are suggested to ensure appropriate medicolegal investigation of death while at the same time ensuring the quality, safety, and availability of donated organs and tissues.

COMMENTS

The draft is based upon the fallacious assumption that taking away authority from a governmental agency can improve both evidence collection and organ and tissue donation at the same time. Both the recovery and transplantation of organs and tissues AND the forensic determination of the cause and manner of death can give meaning to the tragic loss of a life. The first can give life or improvement of life to others and the latter can tell the story of the dead so that justice can be served or epidemiological lessons can be learned. These differing missions both give meaning to death and mitigate the loss to survivors. BUT, realistically, the proper implementation of medical/legal investigations and organ/tissue procurement are neither symbiotic nor interchangeable. Increasing organ/tissue donation by destroying the ability of investigative bodies to preserve, document, collect and present forensic evidence in a legally appropriate manner is not an acceptable goal. Unfortunately this draft suffers from the same original bias in favor of organ donation and in opposition to the criminal justice system.

Response: The purpose of the Scientific Working Group on Medicolegal Investigation is to produce documents based upon recognized scientific principles that will improve medicolegal death investigation. The working group cannot and should not opine on policy issues. In our republican form of government that is the job of statutes and court decisions and is primarily a state not a federal issue.

It is the position of SWGMDI that the procurement of at least some organs and/or tissues for transplantation can occur in almost all cases without a negative impact to the goals of medicolegal death investigation.

COMMENTS

This is a conclusion for which no facts are given. It is therefore impossible to provide any

reasoned response thereto.

Response: This incorporates the opinion that there will be cases in which many or even most organs and/or tissues will not receive permission for donation by the ME/C but that almost all cases will allow some possibility of donation.

Definitions:Standards are a minimum level of acceptable performance.
Guidelines (or Principles) are a suggested level of performance, but not a standard.
Best practices are the most rigorous level of performance and are based on current knowledge without resource limitations.
In sections where the Guidelines and/or Best Practices are not listed, the Standards are the 24 24 Guidelines and/or Best Practices.
COMMENTS
No comment as the definitions of Standards, Guidelines, and Best Practices are a recitation of how SWGMDI has chosen to define those terms for purposes of the document. However, it should be noted that the clarification of Standards in lines 23-24 in essence render moot the need for any Guidelines or Best Practices.

Response: Lines 23-24 were deleted from the document in response to this observation.

STANDARDS
Medical examiners and coroners shall cooperate with procurement agencies to maximize the availability of donated organs and tissues to include prompt completion of all related reports.
COMMENTS
Coroners have no issue with allowing organ and tissue procurement to occur if the body is not required for investigation or autopsy, and if the next of kin agrees. However, it is not within their statutory scope, nor should it be, to maximize organ and tissue donation. It is axiomatic that organs will not survive an autopsy and not every autopsy or investigation will be completed within procurement timetables.

Response: The word "maximize" was changed to "facilitate" in response to this observation.

Organ and tissue procurement shall be allowed to take place as soon as appropriate after death, guided by any written agreements between the medical examiner/coroner and organ and tissue bank(s), the standards of the organ/tissue procurement and processing agencies, and any applicable regulatory authority.
COMMENTS
Greater specificity is needed. Define death, the "standards" of procurement, the processing agencies, and the regulatory authority. The document should be clear and not allow for a myriad of interpretations.

Response: Death is generally defined in state statutes or court decisions. The "standards" were enlarged to include those of NAME. The regulatory authority varies by jurisdiction and is not a scientific issue.

The procurement agency shall discuss the potential of tissue or organ donation with the medical examiner/coroner or their representative prior to approaching the legal next of kin of any case falling under the jurisdiction of the medical examiner/coroner. Any restrictions to procurement shall be delineated at that time. If an authorizing person makes the gift of organ or tissue donation, the medical examiner/coroner will be provided a copy of the document of authorization.
COMMENTS
It should be required to have the OPO or their representatives approach the coroner about

donation prior to approaching the next of kin. If the coroner does not indicate permission for donation, no further action by the OPO or their representatives should occur. (This rarely occurs this way. The hospital contacts the OPO, the OPO works the families long before the coroner is involved, and then the OPO uses the family decision against the coroner in talks to procure organs.) Multiple phone calls every few hours and inappropriate language to the coroner suggesting that his lack of permission is causing death to occur to the recipient must be prohibited. It is also important to note that in cases of SUIDIS or where the next of kin or other authorizing person is a person of interest in an investigation into the death, the OPO should carefully weigh its potential legal liabilities before attempting to rely on said donation authorization. Since most Organ Donation state laws refer to legal next of kin, as well as, agents who may authorize donation, this language should be broadened to include all persons from whom an OPO might seek authorization. In any areas where the OPO believes it can procure organs and tissues without consent of the individual, the coroner/ME must also be informed before procurement takes place or even begins as such actions may interfere with any coroner/ME investigation. Once vital body evidence is compromised it is lost forever. It should be noted that the Standard uses "legal next of kin" and "authorizing person". In the case of "legal next of kin" the coroner/ME is to be approached before seeking authorization for donation. In the case of an "authorizing person" the coroner/ME is to be given a copy of the authorization. These are two very distinct groupings with two opposite actions required of the OPO. There is no apparent reason for the distinction.

Response: The wording of the document was constructed precisely to answer the comment over the objection of OPO representatives.

For medical examiner/coroner cases, the option of performing an external examination shall be provided to the medical examiner/coroner prior to procurement when requested. Trace evidence may be collected at this time and fingerprints and/or photographs may be taken. Time limits for organ/eye/tissue shall be considered.

COMMENTS

Who will be conducting the external examination – the coroner/ME or his authorized representative or the OPO's agent? Who is collecting the trace evidence, the fingerprints, and the photographs? How is the chain of evidence being maintained? Several questions or concerns immediately arise, but are not meant to be an exhaustive list. If the body is in the hospital and waiting harvesting or procurement, the body has already been cleaned and, if so, what trace evidence can realistically be expected to be retrieved. Hair, fibers, bodily fluids will certainly have been eliminated by the cleaning. Many legal questions arise if the implication of this statement is that the OPO will retrieve the body and transport it prior to the coroner/ME seeing the body. At a minimum, the body will have been moved, and, therefore, any evidence of algor mortis, rigor mortis or livor mortis will have been compromised. Any evidence of sexual assault will likely have been lost or contaminated at this point. While fingerprints can be useful in determining identity, by itself it may not be conclusive. Photographs must be taken in accordance with specific scientific standards. SWGIT – Scientific Working Group on Imaging Technology has authored approximately two dozen documents providing for the proper collection, documentation and preservation of photographic evidence. Will these guidelines be adhered to by the OPO? What assurances are specified that will insure such full body photos will have relevance to any investigation of cause and manner of death and can be supported as evidence in any court proceeding? What are the image capture process, the image compression, the image integrity, the identification and handling of images, and the preservation and

archiving of images, to name a few requirements? Is the OPO taking the photographs properly trained and can he meet the legal standards for testifying in court? Generally, what types and frequencies of quality control checks are being recommended? No actual knowledge or understanding of the forensic investigation of cause and manner of death is conveyed by some superficial references to chain of custody or evidence recovery. Additionally, the Standard suggests that all of this may occur prior to procurement. However, in the cases of Donation after Cardiac Death or Donation after Circulatory Death (DCD) there already will have begun procedures to test the donor for suitability and maintenance of vital systems prior to procurement finally being begun. An explanation of how the appropriate recovery of the evidence and the preparation of the body for procurement can be accomplished simultaneously should be delineated.

Response: The myriad of complications listed is present with or without organ/tissue donation in cases in which a person is subject to life saving attempts. The issues involving DCD are handled below.

Samples for toxicological analysis may be collected by the procurement agency for the medical examiner/coroner. Such specimens shall be labeled in accordance with the medical examiner/coroner office's chain of custody procedure. All agreed upon body fluid samples shall be returned to the medical examiner/coroner. Blood and other body fluid samples from the earliest dates in the hospital laboratory shall be reserved for toxicological analysis by the medical examiner/coroner except for the minimal amount necessary for infectious disease testing by the procurement agencies. Procurement agencies shall share testing results to minimize the amount of blood needed for testing.

COMMENTS

The mere labeling of a blood sample does not equate to maintaining chain of custody. Chain of custody is a vital paper trail to ensure the integrity of a specimen to be tested. This paper trail must show seizure, custody, control, transfer, analysis and disposition of the evidence. Specimen integrity and the maintenance of HIPAA privacy rules are crucial. Additionally, a casual reference to "blood and other bodily fluids" is insufficient. According to the College of American Pathologists, forensic toxicology specimen testing routinely includes blood, urine, and tissue samples from the liver, brain, kidney, vitreous humor, and samples of stomach content and bile. Further, blood is routinely collected from the femoral vein and the heart to test for comparison of concentration of drugs. As written this section is woefully inadequate.

Response: Changes were made to address this issue.

At the time of procurement, detailed notes shall be taken and provided to the medical examiner/coroner describing any evidence of injury or disease encountered during the procedure. Any deep venous thrombi or pulmonary thromboemboli encountered should be 60 collected and returned with the body to the medical examiner/coroner. The procurement agency shall notify the medical examiner/coroner immediately if other abnormalities (such as hemopericardium) are found during the procurement procedure.

COMMENTS

Providing pieces of organs to the coroner is to serve what purpose? There is no chain of custody, there is no report written by a professional who is qualified to provide expert testimony before a court, there is no body. Is it being suggested that the OPO is going to assume legal responsibility for ascertaining whether there are any congenital abnormalities that need to be communicated to the family?

Response: Since the deep venous thrombi or pulmonary thromboemboli will be inside or

accompany the body, no chain of custody issue exists.

If the heart is procured for valves, the medical examiner/coroner shall be provided a report 65 describing the organ at the time of valve procurement. When requested, the entire remainder of the heart tissue shall be returned to the medical examiner/coroner for examination or, with the permission of the medical examiner/coroner, referred to a cardiac pathologist of the medical 68 examiner/coroner's choosing for complete assessment. All reports generated shall be routed to the medical examiner/coroner of record.

COMMENTS

Again, providing pieces of organs to the coroner is to serve what purpose? There is no chain of custody, there is no report written by a professional who is qualified to provide expert testimony before a court, there is no body.

Response: The purpose of allowing the ME/C to obtain the heart after the valves are harvested is to allow the forensic pathologist who examined the rest of the body to also examine as much of the heart as possible while allowing valve donation. The option of the use of a cardiac pathologist to examine the heart is included, who would be qualified to give an expert opinion.

If an organ is removed and subsequently not transplanted, the non-transplanted organ shall be returned to the medical examiner/coroner, when requested.

COMMENTS

If there is no such request, is the organ provided for research or education, is it cremated, or is it offered to the family of the donor for disposition?

Response: A sentence was added to require a written disclosure of the disposition of non-transplanted organs and/or tissues.

If a suspicious lesion for occult malignancy, infection or other conditions that may affect donation is discovered during postmortem examination these findings shall be communicated to the organ procurement/tissue agency immediately so that appropriate decisions can be made related to surveillance of organ recipients (as applicable) and to prevent release of unsuitable tissues.

COMMENTS

Legally OPOs are responsible for the quality of the donation. That legal responsibility should not be attempted to be shifted to the coroner/ME in hopes of lessening the OPOs liability.

Response: The wording was changed to remove any implication of legal responsibility of the ME/C for the quality of the donation.

In the special case of declaration of death by circulatory criteria (DCD) rather than by neurologic criteria, where arrangements are made for rapid procurement of organs after cardiac arrest, and where the death would come under medicolegal jurisdiction, the medical examiner/coroner or their representative shall be notified by the organ procurement organization upon authorization for donation so that efficient and timely medicolegal investigation can take place. An effort shall be made to allow the medical examiner/coroner 86 investigation prior to death pronouncement.

COMMENTS

What form of medicolegal death investigation is envisioned prior to the death pronouncement? It will have to be limited in scope and certainly be incompatible with a thorough investigation. It is also noted that coroners/MEs are only notified after authorization for donation has been secured and begun. Thus "DCD death" and "brain death" have now resulted in two very different means of OPO and coroner/ME communications being endorsed by SWGMDI in the

same document without any given rationale.

Response: It is envisioned that with notification of the ME/C at the same time the OPO is notified there will be sufficient time to investigate the circumstances of death to allow a reasoned decision on allow donation after cardiac death. A better solution is that found in the North Carolina law that permits the medical examiner to fully investigate such cases, including taking photographs and reviewing the chart, eliminating HIPAA privacy problems.

BEST PRACTICES
Tissue and eye procurement occurs at the medicolegal death investigation office.
COMMENTS
This is a statement which may or may not actually occur. In any event, the question must be asked regarding who is conducting this procurement, what are the sanitary conditions, who is transporting the body, at what hours will the procurement take place, how will this impact any arrangements for final disposition, why is this procurement occurring at a different location than other procurements? This is not meant to be an exhaustive list of potential questions.

Response: Best practices, as defined in the beginning of the document, assume no resource limitations. Having the donation take place at the ME/C facility would cut down on time spent transporting the remains and allow the ME/C staff to easily observe the harvest. However, considering the practical problems of creating and maintaining a properly sterile facility in a morgue as a generally applicable best practice convinces the Committee that this item should be deleted as a suggested best practice.

Commenter #3

In the section regarding collecting samples for toxicological analysis (lines 48-55), please add a statement requiring the procurement agency to actively attempt to limit any contamination to specimens collected to be submitted for analysis and for specimens to be taken at autopsy. For example, some procurement agencies use isopropanol to clean a decedent which can contaminate the vitreous.

Response: It is deemed unlikely that any meaningful contamination by isopropyl alcohol will occur under this scenario. In any case, the ME/C can specify that such a procedure will not be used if permission is to be given for donation.

Commenter #4

What happened to this document?
Please review the comments from Comment Report 1. Many of the changes that were introduced into the revision are now no-longer present (if you read through comment report 1, focusing on the "results" column...it is immediately apparent that many excellent changes that had been incorporated into the document are not longer present).
This new version again fails to make a distinction between organs and tissues. It also fails to emphasize the importance of evidence preservation, particularly with regard to tissue cases.

Response: No true philosophical distinction should be made between organ and tissue donation vis a vis medicolegal determination of the cause, manner and circumstances of death. The overwhelming majority of state laws give the medicolegal authority the right to limit or prohibit donation where it could interfere with their function. Furthermore, it is a policy issue, not a scientific one, and in our republican form of government must be left to the states' statutes and court decisions.

It mandates, in broad terms, action from ME/C, but very little (other than some specific items) from the organ/tissue agencies: "ME/C shall cooperate with..." Why not also include the following: "Organ and Tissue Procurement agencies shall cooperate with ME/Cs to ensure that all injuries are appropriately and sufficiently documented. Furthermore, procurement agencies shall maximize the preservation of all evidence."
Regarding the following... "Organ and tissue procurement shall be allowed to take place as soon as appropriate after death..." (lines 31+), why not include "the Autopsy Standards of the NAME," rather than just the standards of organ/tissue agencies? All the ME/C gets is "written agreements..." What if these don't exist and the two "sides" can't agree to make such written policies? This is absurd. Who determines what is "appropriate?" As written, I guess it's up to the procurement agency's standards. Where are the NAME standards? Come-on! Don't we have standards about collecting trace evidence, etc..., and we don't even reference them in this document? Besides inserting NAME standards, how about adding: "Regarding potential tissue procurement cases, the ME/C shall decide whether or not procurement can occur prior to body examination and evidence collection.
When body exam/evidence collection must occur prior to procurement, the ME/C will attempt to perform such procedures in a timely fashion; however, procurement agencies shall recognize that, in certain situations, evidence preservation and collection will take precedent and tissue collection will not be able to occur due to time constraints."

Response: The autopsy standards of NAME have been included.

Where did some of the requirements/mandates on the organ/tissue agencies go? No more requirements to document photographically or via imaging (at their expense), when requested to do so. No mention of allowing ME/C personnel to be in attendance at organ recovery. There's a requirement for "detailed notes" to be made. Yep, we already have that requirement here...never happens.

Response: The procurement agency representatives objected to photographing by their personnel, citing lack of training and equipment. It was realized that the procurement personnel are not trained to take meaningful and useful pictures. The ME/C can always attend the harvesting procedure and take whatever photographs they want, which also does away with the problem of admission into court proceedings of the images. As far as other imaging is concerned, that can be made a requirement prior to permission for donation being granted. Regarding the standard of detailed notes being taken, if that is not taking place when there already is a requirement, SWGMDI standards will not help.

This appears to be a somewhat watered-down version of the Revised Uniform Anatomic Gift Act from several years ago, where it was clear that an attempt was being made to make tissues equivalent to organs. The bottom line is that organs and tissues ARE NOT EQUIVALENT. Why must we, in the ME/C community continue to accept this type of language? This is not being done to "streamline" the language. It is being done so that the ME/C community will "bend over backwards" to do everything possible for tissue recovery...in a manner similar to what is being done to maximize organ recovery.

Response: While your opinion regarding the non-equivalence of organ and tissue donation is noted, as discussed above, it is not agreed to.

This is simply not acceptable as written. This needs to be re-worked, recognizing that the ultimate goal of the procurement agencies is to make tissues equivalent to organs. Right now, many of us in the ME/C community do absolutely everything possible to allow for organ

donation...this is appropriate. The way the current "standard" is written essentially makes tissues equivalent to organs. This is absolutely inappropriate. If this is the final version and it is implemented "as is," I guarantee that evidence will be lost in critical cases. It might be very easy for large offices (and maybe even medium-sized offices) to come in at all hours of the night to perform external exams (and maybe even complete autopsies) and collect trace evidence from bodies, but it's not remotely possible in smaller jurisdictions.
Please consider the "worst possible scenario" when writing this... Let's say that there is no written agreement between ME/C and procurement agency. Let's also say that the procurement agency's "standard" says that, when family gives consent, then tissue (skin, etc...) needs to be collected within 24 hours of death. Let's say that we have a death occurring at 10 am on Sunday morning. It can be any of a number of types of deaths where trace evidence must be collected, including but not necessarily, a sexual activity kit. There is no staffing in the ME/C office (other than body check-in) on Sundays. In fact, the day doesn't really get started on Monday at the office til 8 am. Since we are following only the "standards" set-forth by the procurement agencies, and totally ignoring any forensic standards for such cases, then we must either allow the procurement agency to collect their tissue, thus destroying/compromising any evidence collection, or we must somehow spring into action a pathologist as well as an autopsy assistant, and perhaps an investigating police agency as well. I guarantee that those of us "out in the sticks," and perhaps even many working in medium-sized offices, will not be able to do this. We currently jump through all sorts of hoops for organs, and we do this willingly because it's the right thing to do. Well, the right thing to do in tissue cases is to recognize that forensic issues should trump tissue collection issues.
I apologize for being a bit long-winded and repetitive here, but I feel that I absolutely must make my points heard. If we in the ME/C community signoff on this document, we do so at our own peril.

Response: The autopsy standards of NAME are now cited in the document.

Line 28 - "shall" should be deleted and replaced with "should," but more importantly if there is to be cooperation it should be from both parties such that the organ and procurement agency must also cooperate with the medical examiner/coroner.

Response: Standards require the use of shall rather than should, the latter being appropriate for guidelines.

Line 31 - Again "shall" should be deleted and replaced with "should when appropriate."
"Shall" is very strong language when placed into state law and that is the next place we will see much of the language used in this document. Those on the committee are not truly representative. Especially lacking is representation of medical examiners that work or have worked in different types of jurisdictions (county, city, and region) and specifically in state systems where this document could have major detrimental effects on budgets and staffing which are already in jeopardy.

Response: Standards require the use of shall rather than should, the latter being appropriate for guidelines.

Line 36 - Beginning with "shall discuss..." should be replaced with "shall discuss and obtain permission from the medical examiner/coroner or their representative the potential of tissue or organ donation prior to approaching the legal next of kin of any case falling under the jurisdiction of the medical examiner/coroner."

Response: If the ME/C has the legal right to refuse permission for donation, that will occur in response to the discussion. If the state law does not allow such refusal, as is the case in a small minority of jurisdictions, no SWGMDI standard can fix the situation. It is policy, not a scientific, issue.
Line 46 - delete "shall" and replace with "should."
Response: Standards require the use of shall rather than should, the latter being appropriate for guidelines.
Line 48 - This sentence should be re-written beginning with "May" and replaced with "shall be collected by the procurement agency for and when requested by the medical examiner/coroner."
Response: The ME/C always has the right to collect specimens by being present at the harvest. It is for the convenience of the ME/C that the document allows the procurement agency to collect the specimens.
Line 76 - The sentence should end with "agency." and the remainder of the sentence deleted and replaced with "This information is vital to those making decisions related to surveillance of organ recipients (as applicable) and to prevent release of unsuitable tissues." Written as it is currently could be construed by some to mean the responsibility of preventing the release of unsuitable tissue is that of the medical examiner. It should be the responsibility of the organ/tissue procurement agency to followup on the results of the autopsy prior to release of tissue or in doing surveillance.
Response: This change was made.

Commenter #6
Lines 74-78. I think it is a slippery slope to require the pathologist to inform the donation agency about conditions found at autopsy that could be detrimental to the recipient. The agencies have medical directors that review charts and autopsies for that purpose. I think it might open up the door for malpractice lawsuits against the forensic pathologist.
Response: Change made to remove implication of legal responsibility by the ME/C.

Commenter #7
Line 1. This document needs to be split into two documents; that is, completely re-written. There should be one document for vascular organ donation and one document for tissue and eye donation. With vascular donation, if the medical examiner refuses permission for a heart or liver donation, a specific patient may well die. The AAFS should promote a zero denial policy for vascular organ donation, while at the same time requiring the OPO to conduct any extra diagnostic testing on the donor that the medical examiner demands, e.g. coronary angiography. This has already been accomplished in Florida. For exemplary language, consult the Practice Guidelines of the Florida Association of Medical Examiners, available as a download from the web site of FAME, or from the Florida Medical Examiners Commission web site. Tissue donation, including valves, is an entirely different thing. Refusal to permit tissue donation does not put any one patient at risk of death. It merely alters the shelf inventory of the tissue bank. For example, because prosthetic heart valves are available, it is reasonable for a medical examiner to permit heart-for-valve donation only when the prospective donor has been in the hospital with a beating heart.
Response: The argument you give differentiating organ from tissue and corneal donation

oversimplifies the issues. Any particular organ donation may or may not increase the likelihood of a specific person's death. Not being able to determine the cause, manner or circumstances of death may lead to a defendant's long incarceration or even capital punishment. The ME/C, as someone without any personal interests in the matter, is in the best position to referee between a specific donation and the interests of justice in any particular case. No true philosophical distinction should be made between organ and tissue donation vis a vis medicolegal determination of the cause, manner and circumstances of death. The overwhelming majority of state laws give the medicolegal authority the right to limit or prohibit donation where it could interfere with their function. Furthermore, it is a policy issue, not a scientific one, and in our republican form of government must be left to the states' statutes and court decisions. Finally, the purpose of the Scientific Working Group on Medicolegal Investigation is to produce documents based upon recognized scientific principles that will improve medicolegal death investigation. The working group cannot and should not opine on policy issues. In our republican form of government that is the job of statutes and court decisions and is primarily a state not a federal issue.

Line 90.There is no reason to promote harvesting at the medical examiner office as a best practice. Best for whom? If the tissue bank has a super clean facility the interests of the prospective recipient patient are best served by having the harvest take place at that clean facility.

Response: Best practices, as defined in the beginning of the document, assume no resource limitations. Having the donation take place at the ME/C facility would cut down on time spent transporting the remains and allow the ME/C staff to easily observe the harvest. However, considering the practical problems of creating and maintaining a properly sterile facility in a morgue as a generally applicable best practice convinces the Committee that this item should be deleted as a suggested best practice.

Commenter #8

I appreciate the stated intent toward maximizing organ, eye, & tissue donation. However, I disagree with some of the standards or best practices in this document. For example: recovering tissues or corneas at an M.E./Coroner facility should only be done as a last choice due to lack of environmental controls, cross contamination issues, and the general quality of such facilities. Ideally all tissues and corneas should be recovered in an O.R. that has set up for environmental control (hepa filtered air, positive airflow systems, U.V. light, etc.)It is doubtful that such controls exist in the majority of morgues, coroner's facilities, and even autopsy labs.

Response: This is a best practice. Best practices, as defined in the beginning of the document, assume no resource limitations. Having the donation take place at the ME/C facility would cut down on time spent transporting the remains and allow the ME/C staff to easily observe the harvest. However, considering the practical problems of creating and maintaining a properly sterile facility in a morgue as a generally applicable best practice convinces the Committee that this item should be deleted as a suggested best practice.

Also: OTPO's should not be required to call the M.E./Coroner on every single case before talking with the family. This will result in inundating the M.E./Coroner's with unnecessary calls. There is also really no point in calling an M.E. or coroner if the family says no. I know for a fact that our local coroners do not want our agency to be calling them on every single case.

Response: Do they want to be called early on any cases? The arguments for earliest

notification of the ME/C are to allow the most time for investigation and to avoid the ME/C being seen as the reason donation already approved by a family and enthusiastically embraced is denied.

Commenter #9

While we appreciate that many of the changes requested have been made to the new draft Standards and Best Practices document, LifeLink of Florida can't support the draft as it is currently written. Lines 36 to 38 remain problematic for us in adhering to Federal and state guidelines that outline our responsibilities for those individuals who meet donation criteria. The draft is too prescriptive in requiring recovery agencies to discuss donation with medical examiners/coroners prior to approaching families. Additionally, many medical examiner/coroner offices do not have the resources to handle a huge influx of calls at all hours of the day and night prior to approaches for donation. Limiting or restricting hours of donation agency operations the hours the medical examiner/coroner offices have the most adequate staffing would result in many lost donation opportunities.

Response: Do they want to be called early on any cases? The arguments for earliest notification of the ME/C are to allow the most time for investigation and to avoid the ME/C being seen as the reason donation already approved by a family and enthusiastically embraced is denied.

Additionally line 90, noting recovery of tissue and eyes at Medical Examiner Offices as a best practice is problematic. We strongly believe determination of the most appropriate recovery location for tissue and eyes is the responsibility of the recovery agency. Tissue and eye donation must be accomplished within specific timeframes, which would preclude many donors if recovery agencies were required to work within the confines of medical examiner/coroner office hours. All of these points are best left to discussion and agreement between individual recovery agencies and the medical examiner/coroners they work with to best meet local needs and preferences.

Response: This is a best practice. Best practices, as defined in the beginning of the document, assume no resource limitations. Having the donation take place at the ME/C facility would cut down on time spent transporting the remains and allow the ME/C staff to easily observe the harvest. However, considering the practical problems of creating and maintaining a properly sterile facility in a morgue as a generally applicable best practice convinces the Committee that this item should be deleted as a suggested best practice

Lifelink of Florida is a not for profit, federally designated, Medicare certified organ procurement organization (OPO) serving 63 hospitals and 13 counties on the west coast of Florida. We are affiliated with the transplant centers located at Tampa General Hospital, All Children's hospital and Gulf Coast Medical Center. We also serve as the recovery agency for LifeLink tissue bank, and provide eye referrals to the Lions Eye Institute for Transplant and Research. OPO's have a duty to save lives and recover every organ deemed suitable for transplantation. We assist many more individuals in our community through our involvement with tissue and eye donation. Existing federal and state laws and regulations outline the duties for hospitals, OPO's and medical examiners to maximize organ and tissue donation. The draft document seems to ignore the existence of the federal and state laws, and does not adequately consider the considerable effort that medical examiners and recovery agencies have made on the local level to establish practices that work for their area. It is disappointing to us that this draft, which has great potential, fails to mention the most important best practice that should be

endorsed and replicated across the country – zero denials from medical examiners and coroners for all organs determined to be suitable for transplant.

Response: Except for less than a handful of offices, ME/C offices are also non-profit. If non-profit is equated with being good, ME/C's are just as good as organ and tissue procurement agencies.

Commenter #10

Again, we applaud the SWGMDI's attempts to balance the quality, safety, and maximum availability of donated organs and tissues with guidelines for the medico-legal investigation of death. However, once again we must state that the draft is unacceptable to our organizations. We cannot support the attempt to label certain suggested activities "Best Practices," "Standards," or even "Guidelines" when some appear to be at best, variations in national practice, and at worst, in opposition to our understanding of OPO federal and state obligations. However, we do truly appreciate your commitment to extend the SWGMDI review process to allow the donation community adequate opportunity to participate and provide feedback, and believe our shared goal of zero denials for donation is achievable with the further development of guidelines and agreements between Medical Examiner / Coroner offices and procurement agencies. We do not disagree with every suggestion. But as written, there are two areas of significant concern with the current draft, and as such we cannot support the document. These are noted below:

1.) As described on lines 36 – 38, there are legal and practical barriers, as well as Medical Examiner/Coroner preferences that do not support a documented Standard to discuss each potential organ, eye or tissue donor with the Medical Examiner/Coroner prior to communicating with the next of kin.

a. Federal (and certain State) laws and regulations require that recovery agencies communicate with the next of kin to offer the option of donation.

Response: As stated in the document, it is rare that no organ/tissue donation will be allowed even though some or even many will be justifiably denied. The procurement agency can then fulfill its required duty to offer what donation is possible.

b. Many states have Medical Examiner/Coroner laws that inhibit Medical Examiner/Coroners from restricting donation (as an example, by requiring the ME/Coroner to attend the recovery before restricting);

Response: This has nothing to do with the standard of requiring early discussion.

c. Virtually every state now also provides for (and federal and state agencies have endorsed and support) first person authorization, and the registries to document those decisions regarding donation. If a person has already made this legal and documented decision in advance of their death (currently more than 100 million people have already done so), then there is no "approach" for authorization for donation with the next of kin. This obviates the suggestion that an OPO/Tissue bank contact the Medical Examiner/Coroner before contacting a family.

Response: This does not obviate the requirement to discuss the potential donation with the ME/C as soon as the procurement agency is notified.

d. While the approach with the next of kin for donation is often a thought-out and collaborative process, there are situations where the dynamics of the case are such that there is not the opportunity to communicate with the Medical Examiner/Coroner prior to speaking with the next of kin –whether due to influences by the next of kin, hospital staff, legal staff, the physiologic

state of the potential donor, or other factors, or combinations of several of the above.

Response: If an effort is made, there should always be a way to contact a ME/C agency since deaths are generally immediately reportable.

e. There are medical examiner/coroner offices that either simply do not have the human, financial or physical resources to accommodate the volume. of calls that they might receive under this paradigm. In some areas this could amount to thousands of calls each month, arriving at all times of the day and week to a medical examiner/coroner's office. Many of our members' Medical Examiners/Coroners have stated they do not want this burden.

Response: Do they want to be called early on any cases? The arguments for earliest notification of the ME/C are to allow the most time for investigation and to avoid the ME/C being seen as the reason donation already approved by a family and enthusiastically embraced is denied.

2.) Line number 90 of the document can be a challenging standard for tissue and eye procurement organizations.

a. While it is understood that there are some medical examiner/coroner offices that have specifically designated facilities within their offices for the recovery of tissues, many medical examiner/coroners offices do not. Professional standards require tissue recovery site suitability parameters to be met so there is not an option to use sub-optimal facilities that could introduce contamination and promote cross-contamination of tissue recovered for transplantation.

b. There are specific time limitations for the recovery of tissues, particularly corneas, from a donor. Transporting a donor to the medical examiner/coroner's office, in conjunction with the other time consuming activities encountered by those working with the case, can preclude the donation and recovery.

Response: This is a best practice. Best practices, as defined in the beginning of the document, assume no resource limitations. Having the donation take place at the ME/C facility would cut down on time spent transporting the remains and allow the ME/C staff to easily observe the harvest. However, considering the practical problems of creating and maintaining a properly sterile facility in a morgue as a generally applicable best practice convinces the Committee that this item should be deleted as a suggested best practice.

We recognize that you and SWGMDI have invested honest energy and valuable time to negotiate a common vision. We appreciate that. We engaged in that process with you and SWGMDI fully expecting we could agree on a new document with your help. In fact you and the group made significant changes in some areas, and we appreciate that effort. All of us at AOPO, AATB, and EBAA also appreciate the ambitions of the SWGMDI to suggest practices that meet the requirements of national "Guidelines" "Standards" and "Best Practices." Unfortunately, this revised document still falls short of those ambitions, and AOPO (or AOPO, AATB. And EBAA) cannot support it."

Response: It is not understandable why your organization will not endorse the document due to the above minor disagreements.

Commenter #11

Lines 31-41: This suggested standard will pose a hardship for both the ME and for the organ procurement organization and should be deleted. Most cases do not fall under ME jurisdiction. In NJ, we have a law that states that the ME may restrict recovery of certain organs of they attend the recovery and visualize the organs and indicate that a specific organ may have a causal

or evidentiary relationship to the donor's death.
Line 90: this should be deleted. It is not possible due to lack of properly prepared recovery facilities at ME office to recommend this as a "best practice."

Response: The entire documents and this standard in particular apply only to cases falling under ME/C jurisdiction. The relationship between the standard on lines 31-41 and the NJ law is not at all clear. That standard reads, "Organ and tissue procurement shall be allowed to take place as soon as appropriate after death, guided by any written agreements between the medical examiner/coroner and organ and tissue bank(s), the standards of the organ/tissue procurement and processing agencies, and any applicable regulatory authority."

Commenter #12

Lines 36 to 38 remain problematic for us in adhering to Federal and state guidelines that outline our responsibilities for those individuals who meet donation criteria. The draft is too prescriptive in requiring recovery agencies to discuss donation with medical examiners/coroners prior to approaching families. Additionally, many medical examiner/coroner offices do not have the resources to handle a huge influx of calls at all hours of the day and night prior to approaches for donation. Limiting or restricting hours of donation agency operations the hours the medical examiner/coroner offices have the most adequate staffing would result in many lost donation opportunities.

Response: Do they want to be called early on any cases? The arguments for earliest notification of the ME/C are to allow the most time for investigation and to avoid the ME/C being seen as the reason donation already approved by a family and enthusiastically embraced is denied.

In addition, line 90, noting recovery of tissue and eyes at Medical Examiner Offices as a best practice is problematic. We strongly believe determination of the most appropriate recovery location for tissue and eyes is the responsibility of the recovery agency. Tissue and eye donation must be accomplished within specific timeframes, which would preclude many donors if recovery agencies were required to work within the confines of medical examiner/coroner office hours. All of these points are best left to discussion and agreement between individual recovery agencies and the medical examiner/coroners they work with to best meet local needs and preferences.

Response: This is a best practice. Best practices, as defined in the beginning of the document, assume no resource limitations. Having the donation take place at the ME/C facility would cut down on time spent transporting the remains and allow the ME/C staff to easily observe the harvest. However, considering the practical problems of creating and maintaining a properly sterile facility in a morgue as a generally applicable best practice convinces the Committee that this item should be deleted as a suggested best practice.

Commenter #13

As it pertains to lines 36-41 in the draft document, we cannot endorse this draft. Not requesting donation from a family will put an OPO or Tissue Bank at odds with federal regulations and state Uniform Anatomical Gift Acts, which stipulate that families of all potential organ and tissue donors must be asked to donate. Furthermore, there is no mention, for example, of the impact of direct, or first person authorization to organ and tissue donation, when a legally binding gift has been made prior to death under California law.

California Health and Safety Code Section 7151.20 (d) already addresses the mechanism by which a coroner or medical examiner office may restrict organs from being recovered for transplant. This process has worked well in our designated service area and is in compliance with California law.

Response: Do they want to be called early on any cases? The arguments for earliest notification of the ME/C are to allow the most time for investigation and to avoid the ME/C being seen as the reason donation already approved by a family and enthusiastically embraced is denied. As stated in the document, it is rare that no organ/tissue donation will be allowed even though some or even many will be justifiably denied. The procurement agency can then fulfill its required duty to offer what donation is possible.

Commenter #14

Specific needs of Medicolegal Death Investigators, who act as a link between procurement organizations and the Medical Examiners/Coroners (ME/Cs), should continue to be addressed, but questions remain from donation and transplantation stakeholders that should be answered by SWGMDI, such as:
•How will this document be used?
•Who will support it and will it be enforced?
•How will expectations be funded?
•What is the process for making future amendments to this document and is further public consultation a legal requirement?
Per expectations described as protocol on the SWGMDI website, see "Outcome of the Review and Comment Process," it asserts that:
•"All comments will be reviewed and addressed," and
•"Explanations will be provided for suggestions which are not incorporated in revisions of the document."
We have concerns that this protocol was not followed. The summary report documents published after the first comment period to PRC#4 described final decisions made that are not reflected in the updated draft. Additionally, public comments in these two documents were often paraphrased and not fully representative of the comment submitted, and it appears that not all comments were addressed. We suggest the process be followed as described on the SWGMDI website and optimized to clearly address each of the public comments submitted. For the reasons that follow, we cannot endorse this draft.
General concerns include:
•As stakeholders, [we are] concerned that the finalization of this draft document could render situations that negatively impact the safety of tissue recipients by imposing unacceptable protocols that not only compromise tissue quality but also increase contamination of tissue recovered for transplantation;

Response: No specific situations are described and the author of the standards knows of none.

To date, the organ, eye and tissue donation organizations have only been given one opportunity to comment on and discuss the first draft. This comment period allows one more opportunity to submit comments but more discussion may be warranted;
This draft continues to fail to consider individual needs of the local ME/C or the procurement agencies with whom they have developed successful protocols (LOCAL AGREEMENTS); and

Response: This is not true. A survey of all "Local Agreements" is impossible both because of the number of such agreements and the updating of them. It is not at all clear how the standards

conflict with any "Local Agreements".

To continuously improve communication and interaction, mutually agreeable training by the ME/C for personnel at procurement organizations should be encouraged.

Response: The primary duty of a ME/C is investigation and certification of those deaths falling under its jurisdiction, not organ/tissue donation. This document is meant to address the issues of medicolegal death investigation as it may involve organ/tissue donation. It is entirely unclear how the training mention is to be done and financed.

This document should recommend as a Guideline point:
•"A primary contact/liaison with each procurement program should be established to work with the ME/C to support local agreements." It should be understood there could be resource limitations that prohibit a procurement program from providing such a liaison.
Line 26:
Suggest "STANDARDS" be replaced with "GUIDELINES" and the title of the document be adjusted to read Guidelines for Interaction between Medical Examiner/Coroner Offices and Organ and Tissue Procurement Organizations and Eye Banks. This document would be acceptable to the majority of ALL stakeholders if most of the points are issued as "Guidelines" (see your own definition) that can be tailored to suit specific needs of local ME/Cs and their respective Organ Procurement Organization (OPO), Eye Bank and Tissue Bank. [We] previously submitted this concern and some points were adjusted in the revised draft but, if there remains preponderance for creating these points as "Standards," wording should be selected carefully by the Committee to allow consideration for LOCAL AGREEMENTS.

Response: It is the considered position of the SWGMDI that the document should propose standards rather than guidelines.

Lines 31 to 34:
This currently describes "Organ and tissue procurement shall be allowed to take place as soon as appropriate after death, guided by any written agreements between the medical examiner/coroner and organ and tissue bank(s), the standards of the organ/tissue procurement and processing agencies, and any applicable regulatory authority," but it lacks specificity to inform regarding the importance of time and contamination considerations that should influence decision making. The importance of time sensitivity and the potential for contamination for certain tissue allografts is not recognizable at this point due to the generality of the wording. In regard to maintaining "quality and safety" of tissues as ascribed to in the "Introduction" to the updated draft of PRC#4, consideration for eye/tissue recovery to occur before autopsy should be prioritized. Over a decade of experience supports that post-autopsy tissue recovery yields high contamination for tissue recovered for transplantation, and this can affect patient safety. The utility (clinical use for transplant) of the tissue can be adversely affected by delays when it is important to retain viable (living) cells in the tissue graft. Compromise is related to prolonged recovery time after death as well as the potential for increased microbial contamination if relegated to recover tissue post-autopsy. To address these quality and safety attributes, additional wording is suggested. It must be understood that to retain living cells in tissue grafts, recovery must occur soon after asystole and treatment methods (processing) of these tissues cannot include harsh chemicals, irradiation, or other risk mitigating steps to further control contamination. A reference to eye banking standards is also warranted. It should also be known that a point later in this revised draft of PRC#4, at lines 45 and 46, recognizes the importance of time to recovery where it states, "Time limits for organ/eye/tissue shall be considered." This is

described at the point that refers to the option of the ME/C to perform an external examination and to collect trace evidence.

Response: "As soon as appropriate after death" is a quick as one can envision. It is not at all clear how one can describe a quicker response.

Additionally, it is well known that some ME/Cs do not prefer to have LOCAL AGREEMENTS that are "written." To honor this difference, we suggest deleting "written" from this point where it describes "agreements." This is another reason to make this point a "Guideline" and not a "Standard."

Considering all of the important concerns above, this point should read:

"Organ and tissue procurement shall be allowed to take place as soon as appropriate after death, guided by any agreements between the medical examiner/coroner and local procurement agencies, the standards of the organ/eye/tissue procurement and processing agencies, and any applicable regulatory authority. This is especially important for time sensitive recoveries of ocular and tissue allografts where retention of living cells is important for transplantation (e.g., corneas, whole joints, stem cells). Whenever possible, recovery of tissue prior to autopsy should occur to reduce the potential for contamination of tissue to be recovered for transplantation."

Response: The word "written" has been deleted in the revised document.

Lines 36 to 41:

This currently describes "The procurement agency shall discuss the potential of tissue or organ donation with the medical examiner/coroner or their representative prior to approaching the legal next of kin of any case falling under the jurisdiction of the medical examiner/coroner. Any restrictions to procurement shall be delineated at that time. If an authorizing person makes the gift of organ or tissue donation, the medical examiner/coroner will be provided a copy of the document of authorization."

The Organ and Tissue Procurement Committee should be aware that some ME/Cs do not prefer to always be provided a copy of the document of authorization. LOCAL AGREEMENTS, as described previously, can differ and this is another reason to make this point a "Guideline" and not a "Standard."

Response: That some ME/Cs do not prefer to always be provided a copy of the document of authorization does not obviate the need for them to have them on file.

There are legal and practical barriers as well as LOCAL AGREEMENTS already in place that do not support the notion to discuss each potential organ, eye or tissue donor with the ME/C prior to communicating with the next of kin. For the Organ and Tissue Procurement Committee to label this point a "Standard" is problematic and this is another reason to make it a "Guideline." The following list was also supplied by AOPO in their comments but we emphasize the importance and common occurrence of "first person," legal registries for donation in the United States today.

•Federal (and certain State) laws and regulations require that recovery agencies communicate with the next of kin to offer the option of donation.

•Virtually every state now provides for (and federal and state agencies have endorsed and support) first person authorization, and the registries to document those decisions regarding donation. If a person has already made this legal and documented decision in advance of their death (currently more than 100 million people have already done so), then there is no "approach" to obtain authorization for donation with the next of kin. This obviates the suggestion that an OPO/Tissue bank contact the ME/C before contacting a family.

•Many states have ME/C laws that inhibit the ME/C from restricting donation (as an example,

by requiring the ME/C to attend the recovery before restricting).

•While the approach with the next of kin for donation is often a well thought-out and collaborative process, there are situations where the dynamics of the case are such that there is not the opportunity to communicate with the ME/C prior to speaking with the next of kin – whether due to influences by the next of kin, hospital staff, legal staff, the physiologic state of the potential donor, or other factors, or combinations of several of the above.

•There are ME/C offices that either simply do not have the human, financial or physical resources to accommodate the volume of calls they might receive under this paradigm. In some areas this could amount to thousands of calls each month, arriving at all times of the day and week to a ME/C's office. Many ME/Cs have stated they do not want this burden.

Considering all of the important concerns above, this point should read:

"A procurement agency representative shall discuss the potential of tissue or organ donation with the medical examiner/coroner or their representative for any case falling under the jurisdiction of the medical examiner/coroner. Any restrictions to procurement shall be delineated at that time. When applicable, the medical examiner/coroner will be provided a copy of the document of authorization."

Response: Do they want to be called early on any cases? The arguments for earliest notification of the ME/C are to allow the most time for investigation and to avoid the ME/C being seen as the reason donation already approved by a family and enthusiastically embraced is denied. As stated in the document, it is rare that no organ/tissue donation will be allowed even though some or even many will be justifiably denied. The procurement agency can then fulfill its required duty to offer what donation is possible.

Lines 57 to 62

This currently reads "At the time of procurement, detailed notes shall be taken and provided to the medical examiner/coroner describing any evidence of injury or disease encountered during the procedure. Any deep venous thrombi or pulmonary thromboemboli encountered should be collected and returned with the body to the medical examiner/coroner. The procurement agency shall notify the medical examiner/coroner immediately if other abnormalities (such as hemopericardium) are found during the procurement procedure."

LOCAL AGREEMENTS, as described previously, can differ in regard to actions desired when evidence of injury or disease are identified. This is another reason to make this point a "Guideline" and not a "Standard." For example, this point contains unrealistic global expectations of tissue recovery personnel. With this in mind, we suggest the removal of "any," it's used twice, and "encountered" should be replaced with "identified." To promote proper education and increase communication between the ME/C and their local procurement programs, we recommend this point contain a reference to training by the ME/C to increase the quality of the detailed notes described here. Additionally, LOCAL AGREEMENTS may dictate that thrombi or thromboemboli remain as found within the body (in situ) so "collection" does not actually occur. We advise that the word "collected" be deleted here. Considering all of the important concerns above, this point should read:

"At the time of procurement detailed notes shall be taken and provided to the medical examiner/coroner describing evidence of injury or disease identified during the procedure. To promote the quality of detailed notes, training should be provided by the medical examiner/coroner for procurement organization personnel. For example, deep venous thrombi or pulmonary thromboemboli encountered should be returned with the body to the medical examiner/coroner. The procurement agency shall notify the medical examiner/coroner

immediately if other abnormalities (such as hemopericardium) are found during the procurement procedure."

Response: The wording has been revised as follows: "At the time of procurement, detailed notes shall be taken and provided to the medical examiner/coroner describing any evidence of injury or disease encountered during the procedure. Any deep venous thrombi or pulmonary thromboemboli encountered shall either remain in situ or be collected and returned with the body to the medical examiner/coroner. The procurement agency shall notify the medical examiner/coroner immediately if other abnormalities (such as hemopericardium) are found during the procurement procedure."

Lines 64 to 69

This currently reads "If the heart is procured for valves, the medical examiner/coroner shall be provided a report describing the organ at the time of valve procurement. When requested, the entire remainder of the heart tissue shall be returned to the medical examiner/coroner for examination or, with the permission of the medical examiner/coroner, referred to a cardiac pathologist of the medical examiner/coroner's choosing for complete assessment. All reports generated shall be routed to the medical examiner/coroner of record." LOCAL AGREEMENTS, as described previously, can differ in regard to actions desired concerning the donation of the heart (for valve dissection). This is another reason to make this point a "Guideline" and not a "Standard."

In consideration of numerous LOCAL AGREEMENTS of which the Organ and Tissue Procurement Committee members may not be aware, the important concern above suggests this point should read: "Per local agreement, if the heart is procured for valves, the medical examiner/coroner may be provided a report describing the organ at the time of valve procurement. When requested, the entire remainder of the heart tissue may be returned to the medical examiner/coroner for examination or, with the permission of the medical examiner/coroner, referred to a cardiac pathologist for complete assessment. All reports generated shall be routed to the medical examiner/coroner of record."

Response: There may or may not be Local Agreements". The existence of current local agreements does not change the need for standards.

Line 90

This recommends "Tissue and eye procurement occurs at the medicolegal death investigation office."

This point must be removed and it cannot be listed as a "best practice" because it:

•may be pre-empted by local or state laws;

•may be in conflict with LOCAL AGREEMENTS already established;

•may be impossible because the "medicolegal death investigation office" does not meet cleanliness standards that are appropriate for a site where tissue recovery for transplantation can take place;

•assumes continuity in such facilities across the United States; and

•can cause time limits for tissue recovery to be compromised which can affect tissue quality, or time limits can be exceeded which aborts the donation.

While it is understood that there are some ME/C offices that have specifically designated facilities within their offices for the recovery of tissue, many offices do not have the space or the funding to provide it. Additionally, the Committee should be aware that coroners in different parts of the country use funeral homes to perform autopsies. This can pose a legal

problem because tissue recovery may not be allowed in a funeral home (e.g., New York) and funeral homes may not meet cleanliness standards for recovery of tissue for transplantation. The Committee is aware there are specific time limitations for the recovery of certain tissue for transplantation. This is especially important for time sensitive recoveries such as ocular and tissue allografts where retention of living (viable) cells is important for utility/transplantation (e.g., corneas, whole joints, stem cells). Transporting a donor to the ME/C's office, in conjunction with the other time consuming activities encountered by those working with the potential for donation, can preclude the possibility of donation and recovery.
Professional standards and federal regulations require certain tissue recovery site suitability parameters that must be met and there is not an option to use sub-optimal facilities that could introduce contamination and/or promote cross-contamination of tissue recovered for transplantation. To provide the Committee with expectations, see the last page of this AATB Guidance Document for parameters that must be met (Sample Tissue Donor Recovery Site Assessment Form) - http://www.aatb.org/aatb/files/ccLibraryFiles/Filename/000000000641/AATBGuidanceDocumentNo2v2May2907.pdf This expectation is also found in guidance to industry regarding Current Good Tissue Practice published by the U.S. Food and Drug Administration.
Access it here –
http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM285223.pdf
If this point is kept, the Committee may be promoting practice contrary to professional standards and federal guidance.

Response: This is a best practice. Best practices, as defined in the beginning of the document, assume no resource limitations. Having the donation take place at the ME/C facility would cut down on time spent transporting the remains and allow the ME/C staff to easily observe the harvest. However, considering the practical problems of creating and maintaining a properly sterile facility in a morgue as a generally applicable best practice convinces the Committee that this item should be deleted as a suggested best practice.

Commenter #15

Line 57. I see that previous comments have debated requiring photographs and/or radiographs be taken by procurement staff and that it is no longer in the final version and replaced by requiring written description. Given the ubiquity and ease of digital photography I do not see why this should be excluded. If under most circumstances the body is not to be touched by anyone once it is determined to be under ME/C jurisdiction then some meager effort to document injuries prior to organ procurement is warranted. The descriptions of procurement staff will be essentially meaningless since they will not have the same capacity for recognition of important details. Photos should also require use of scale and label in photo of date and name of patient or patient number. Radiology requirement would be unfeasible.

Response: Requirement for photography by the procurement agencies was deleted at the insistence of those agencies and with the realization that they are not trained or equipped to take accurate and acceptable photographs that would be helpful and admissible in court.

Commenter #16

Page 1, Line 14: "it is the position of SWGMDI"-redundant statement as this document is from

SWGMDI and by the group providing the standard, it is the endorsement of the group.
Response: This is a stylistic criticism. The change will not be made.
Page 1, Line 26: "Standards"-under this title, the subsequent information is in need of subheadings--SCOPE, TIMELINESS, COMMUNICATION, EXAMINATION, EVIDENCE, DOCUMENTATION.
Response: This stylistic change is not thought to help the reader better understand the document.
Page 2, Lines 64-72: This actually should be moved under the subheading of EXAMINATION Lines 43-46.
Response: If the subheadings are not used, this is moot.
Page 2, Lines 48-55: Information such as Vitreous sample being taken by the procurement agency needs to be void of any sort of facial cleaning products that possibly could contaminate the fluid to the eye. (isopropanol specifically containing products). Also the procurement agency needs to document and notify the lab if any type of drugs were used in the procurement process such as papaverine.
Response: It is unlikely that any topical use of isopropanol will confuse vitreous humor toxicological interpretation.
Page 3, line 90: Appears to be a single thought and might be better with an extension of the sentence such as "Tissue and eye procurement occurs at the medico legal death investigation office with direct communication and collaboration with the ME staff."
Response: Stylistic change not made.

Commenter #17
There is no mention of the optimal site to draw blood (femoral vein) in order to minimize Post-Mortem Redistribution, nor of the differences in drug concentrations between peripheral sites and cardiac blood. Also, that blood from different sides of the heart contain different concentrations of many drugs.
Response: This has been rectified in the revised version.
Also, no statement that questionable blood samples collected from the abdominal cavity often bear no resemblance to the concentration of drugs in femoral blood, the standard, and have little forensic reliability. These are important issues.
Response: The standards are not meant to be a textbook of forensic pathology. The inaccuracy of abdominal cavity blood is only one issue and probably not the most important one.

Commenter #18
Pg 2 line 49-50 "Samples for toxicological analysis may be collected by the procurement agency for the medical examiner/coroner. Such specimens shall be labeled in accordance with the medical examiner/coroner office's chain of custody procedure." Suggest procurement agency is unambiguously required to provide date, time and site (where appropriate) of collection. e.g. Knowledge of blood collection site (central v. peripheral)and time of collection may be valuable for evaluating PM redistribution on individual cases and could be useful for larger scale research purposes.
Response: Suggested change has been made.

Commenter #19
Perhaps tying in the need for autopsies to the CDC as an epidemiological reporting requirement would push the issue--maybe work politically to include ME offices in the LRN?
Response: The SWGMDI products have no force of law or regulation nor are they meant to.

Commenter #20
Concur with majority of comments on comment sheet 1 and 2, it is great progress in promoting cooperation between ME / C and donor procurement services and follows some of the European systems, which are ahead in some areas of this.
Response: Thank you.

Commenter #21
I head a research laboratory in a hospital/university setting and have interacted with MEs/coroners for 30 years in obtaining autopsied tissue (brain) for research purposes. My institution now requires the ME to sign off on a contract agreeing to indemnify my institution from all harm and pay unlimited legal etc. expenses should e.g., an error be made by ME in procuring the tissue (e.g., consent was improperly obtained). I have refused to permit this and recommend that as part of Best Practices there be a statement that it is inappropriate for ME, who is providing a helpful service only, to sign off on such indemnification clause.
Response: This is a legal not a scientific issue and is not the role of the SWGMDI.