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

After receiving the revised product, the Association of Organ Procurement Organizations submitted a critique of the product and asked for a telephonic meeting with the Organ and Tissue Procurement Committee of SWGMDI. This meeting was held on August 15, 2012.

Attendees present were:

John Fudenberg
Dr. Donald Jason
Dr. Steve Cina
Daniel Schultz

Elling Eidbo
Rich Luskin
Susan Gunderson
Jay Campbell
Scott Brubaker
Jennifer Dematio
Jean Davis
Dennis Hienricks
Susan Dunn

Before any discussion, Dr. Jason agreed to insert “and Eye Banks” at the end of the title of the product. Dr. Jason then stated that SWGMDI had received many public comments criticizing the product as being slanted towards the OPOs. He pointed out that the product is being created for the medicolegal community, has no force of law and must be approved by the Board of Directors of the SWGMDI before being published.

The various objections to the items in the product were discussed in order.

<table>
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<tr>
<th>Comment Type Received</th>
<th>Result</th>
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<tr>
<td>Suggested that the product should contain best practices rather than standards although they stated that they did not see a “meaningful difference between the two categories”.</td>
<td>All items were made best practices rather than standards.</td>
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<td>Replace the introduction with new wording that suggests written policies and procedures and that the product should delineate best practices rather than standards.</td>
<td>The introduction was replaced with the suggested wording except that the goal is not to produce “maximum availability” but rather availability. The reason maximizing availability was not set as the goal is that the needs of the public in determining the cause, manner and circumstances of unnatural and suspicious deaths must be balanced with the need to have organs and tissues available for transplantation.</td>
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<td>The speed at which tissues for transplantation should be guided by written agreements between the medicolegal authorities and tissue banks as well as applicable regulatory authority...</td>
<td>The wording suggested by the tissue procurement organizations was accepted except that written agreements were not assumed.</td>
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<td>The Organ and Tissue Procurement Organizations suggested that the authorization by the family be obtained before communication with the medicolegal authorities. The rationale was that this would decrease the workload of the medicolegal authorities.</td>
<td>This suggestion was not accepted. Only those potential donors whose deaths would come under official medicolegal investigation were involved. Furthermore, when notified the medicolegal authorities could define what organs or tissues could be donated without interfering with necessary investigation. It cannot be assumed that medicolegal authorities do not fully realize the impact of denying donation. It avoids giving the family the expectation of being able to donate certain organs or tissues when that would not be possible.</td>
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<td>Suggested that the option for external examination before procurement should only be when requested by the medicolegal authority and that “time limits for organ/eye/tissue should be considered.”</td>
<td>The option for allowing external examination before procurement should always be offered, so the addition of “when requested”, putting the need to request on the medicolegal authorities does not recognize that examination does not hamper donation but donation may hamper investigation. Photography at such examinations is mentioned. That “time limits for organ/eye/tissue should be considered”, as suggested, is included.</td>
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<td>Delete the requirement for full body photographs prior to procurement.</td>
<td>This is adopted and the paragraph deleted.</td>
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<tr>
<td>Delete the requirement for photography during the procurement.</td>
<td>This is adopted and the sentence deleted.</td>
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<td>The specification that any pulmonary emboli be placed in formalin before returning them with the body to the medicolegal authority was objected to because formalin is not generally available at organ harvest.</td>
<td>The requirement for placing possible pulmonary emboli in formalin was deleted both as an inconvenience to the organ or tissue procurers and because formalin fixation would make gross diagnosis more difficult and because the apparent emboli would be returned in a short time, refrigerated with the body and would not make diagnosis more difficult.</td>
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<td>Suggested new wording: “If the heart is procured for valves, and if requested by the medical examiner/coroner, the medical examiner/coroner shall be provided with a report describing the heart at the time of valve procurement. Mutually agreed upon written guidelines should define processes for final disposition of heart tissue.”</td>
<td>Good medical practice should require the OPO to create a report of the appearance of the heart taken for valve harvest and this is done currently. The medicolegal authority should not have to specially request this important piece of evidence. The medicolegal authority is free to not request return of the remainder of the heart, but a report should be generated at the expense of the OPO from a competent pathologist as to the appearance of the organ. The requirement for the “trimmings” to be returned with the remaining cardiac tissue is due to the experience of much of the atria being absent from returns hearts, the tissue apparently being discarded by those processing the hearts for valves as medical waste. The problem is that the sinoatrial nodal structure is situated in that discarded tissue as well as the proximal portions of the coronary arteries.</td>
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<td>New DCD practice paragraph suggested: “In cases under the medical examiner/coroner’s jurisdiction which may become organ donation cases after declaration of death by circulatory criteria (DCD) rather than by neurologic criteria, the medical examiner/coroner should be notified by the organ procurement organization upon authorization for donation so that efficient and timely medico-legal investigation can occur. An effort should be made to coordinate medical examiner/coroner involvement prior to death pronouncement when lawful and requested by the medical examiner/coroner.”</td>
<td>The best practice regarding DCD cases is changed, as suggested by the OPO, for notification by the OPO upon authorization for donation by next-of-kin rather than by the hospital upon notification of the OPO. It appears that, except for North Carolina, medicolegal jurisdiction does not attach until pronouncement of death. In the case of DCD, whose numbers are increasing steadily, it is impossible to make a meaningful investigation in the 5 to 10 minutes from cardiac arrest to the start of donation procedures. HIPAA precludes access to the medical record by the medicolegal authority before death in the absence of state law. The best practice calls for changes in state laws to allow such complete investigation as soon as DCD is contemplated in potentially medicolegal cases.</td>
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<td>Delete the requirement to freeze a piece of heart for genetic studies by the medicolegal authorities.</td>
<td>The paragraph is deleted.</td>
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