SCIENTIFIC WORKING GROUP FOR MEDICOLEGAL DEATH INVESTIGATION

PRC#9: A Report and Recommendations for Regional Medicolegal Autopsy and Death Investigation Centers - Construction, Staffing, and Costs

Public Comment Report

Created by SWGMDI's Systems Infrastructure Committee
Open for Public Review and Comment March 25, 2013 to May 25, 2013

Comments were received from twelve persons who reviewed the document. Excluding comments received from professional organizations (see below), specific comments were received from nine individuals, two from the viewpoint of tissue procurement organizations. Eleven persons indicated whether they endorsed the draft as is; four of the 11 endorsed the draft as it is. Four of the seven who did not endorse the draft as it is do not work directly in or for a death investigations system.

Title of Responder	Do you endorse this draft as is?
Chief Executive Officer (genomics)	No
Medical Examiner	No
Chief Medical Examiner	No
Forensic Death Investigator II	No
Forensic Pathologist	No
Chief Policy Officer (Tissue Bank)	No
Education Director (Transplant Foundation)	No
Autopsy Supervisor/Investigator	Yes
Director of Coroner Office	Yes
Associate College of Health Sciences Professor	Yes
Senior Deputy Medical Investigator	Yes
Coroner's pathologist	No response

General Response to Public Comments

The SWGMDI wishes to emphasize that the purpose of the PRC#9 document was to provide general guidance for the construction of an autopsy and death investigation facility that would include only the basic services required for case intake services, scene investigations, and forensic pathology services such as autopsies and histology. Most responders to the survey of perceived need for regional centers (PRC#7) indicated that regional centers in their area would probably not need more extensive facilities such as various crime lab services. Thus, SWGMDI feels that some of the reviewers did not realize why information for regional centers did not include guidance for more extensive services. In areas where more extensive services are needed, information in the PRC#9 document could certainly be modified to include cost and staffing projections for more extensive facilities. That being said, responses to individual comments are also included below.

Commenter #1
Our Office (30,000 sq. ft.) serves a similar population in SW Ohio. We review +/- 4500 deaths per year and perform over 1300 complete autopsies. In addition, we operate a complete criminalistics laboratory including Toxicology (accredited by NAME, ABFT, ASCLD-LAB).
Response: We assume this comment relates to the Appendix that presents some sample information from the Fulton County Medical Examiner (FMCE). The FCME facility could accommodate more cases than it currently manages, and it does have extra space that could be used as laboratory space, if needed. It does help to know that the SW Ohio location does seem to follow the general principles outlined in PRC#9 and that the space estimates are appropriate based on case load and services provided. No further comment is needed.
Line 148- I would recommend 8-9 (2 photographers and 6-7 autopsy assistants) to manage two or more examination rooms.
Response: We believe the numbers recommended in the report are a good minimum. This comment report will be maintained so readers will know that some feel slightly larger numbers are indicated.
Line 150- One FT Histologist is sufficient.
Response: We agree that one histologist is probably sufficient in a minimum size office and will change the recommendation to 1.
Line 152- I would recommend 8 FT investigators to cover 7/24 with days off/vacation and multiple scenes.
Response: We agree that 8 is probably a more reasonable workable staffing level and will change the recommendation. Again, SWGMDI was trying to establish a minimum level but we agree that 8 is a more appropriate minimum. Even a total of 9 including a Chief Investigator could cause occasional short staffing, but we feel that it is a workable minimum number.
Line 153- In a "paperless" Office, clerical staff will be reduced. Property clerk, receptionist, finance clerk and QA staff are sufficient (4-5 max)
Response: Our recommended number of 9 included a chief office manager, operations manager, payroll and purchasing personnel, transcriptionists, and other clerical persons. Thus, we feel 9 is an appropriate number to include all such positions. Even when an office is "paperless," there are documents that must be generated and processed (such as paper reports from outside agencies)
Add position for medical transcriptionist. (voice recognition software will reduce staff).
Response: Transcriptionist services were included in the Reception/Administrative/Clerical section as discussed above. Further, voice recognition software is still not without problems.
Line 155- One custodial staff is sufficient.
Response: Probably true if the autopsy assistants provide custodial services in their job duties. Custodians can also serve as "facility assistants" and "runners" for errands, deliveries etc., so we prefer to leave this number at 2.
Line 156- Chief Toxicologist.
Response: Our recommendations were for a center with no toxicology lab. No change needed. See general comment above on Page 1.
Line 156- Six Toxicologists.
Response: Our recommendations were for a center with no toxicology lab. No change needed. See general comment above on Page 1.
Line 156- One Executive operational Director- Manages the "business" of the organization. The above does not include +25 employees in Criminalistics Lab. Proposal looks great!"

Response: Our recommendations were for a center with no criminalistics lab. The Executive Operation Director is included in the Reception/Administrative/Clerical section. Our recommended number of 9 included a chief office manager, operations manager, payroll and purchasing personnel, transcriptionists, and other clerical persons. No change needed.

Commenter #2

I suggest there should be a reference in this document to a policy and requirement of facility for preserving biological evidence collected at the time of autopsy. In my experience as a DNA analyst, I did come across excellent evidence preservation (such as contamination free fingernail scraping, during autopsy, swabs from important area etc.) as well as loss of evidence during autopsy.

Response: We feel that this suggestion goes beyond the intended scope of the document. Publication of these comments will allow readers to consider this suggestion when planning a facility. No change needed.

Commenter #3

This document draft looks very thorough and well thought out. I do have one question though; page 3 line 120. When stating mileage is $1.47/mile...federal mileage for business is $.565/mile. Why the big difference?

Response: The $1.47 per mile was apparently an agreed upon fee between the parties that was not based on standard mileage rates. No change needed.

Commenter #4

Regarding lines 146-147, I believe this calculation needs some explanation or justification, as the anticipated # of autopsies (1,000) does not, on the surface, appear to justify the employment of 6 pathologists. If one considers that a Chief may perform only a fraction of the # of autopsies that other staff pathologists do; and if one considers that a 2nd tier of management may be needed (i.e., Deputy Chief) who also has reduced autopsy load; and if one considers coverage for vacations and leave, then one may be able to justify the proposed # of pathologists. It would be advantageous to have these factors used in the determination spelled-out in the text (as well as any other factors that were used).

Response: If the Chief indeed does have minimal autopsy duty, then having only 4 other forensic pathologists would put the case load at the recommended maximum of 250 per year. Especially in regional centers, travel demands on pathologists for court and other duties may require more time away from the office than in a typical county-based system. Thus, we feel the suggested numbers are reasonable, especially in view of the comments raised about other duties and management structure. Those planning a facility can consider this reviewer's comments when planning forensic pathology staffing. No change needed.

Commenter #5

P. 4 - I believe that the proposed investigator staffing is inadequate. In our county, population 1 million, we have 1 chief investigator and 11 investigators. This is usually adequate; at times, due to illness, injury, vacation, and so forth, it is a stretch, and overtime is a large portion of our budget. I should note that we staff the office 24/7/365; the number of investigators in the office varies with shift and we do not do "home call."

Response: This is the same concern expressed by Commenter #1. We agree that 8 is probably a more reasonable workable staffing level and will change the recommendation. Again, SWGMDI was trying to establish a minimum level but we agree that 8 is a more appropriate minimum. Even a total of 9 including a Chief Investigator could cause occasional short staffing, but we feel that it is a workable minimum number.

Commenter #6

Lines 84-87: I would include toxicology and fingerprint verification (lifescan or similar) as part of the standard regional location. Verifying identification is paramount to locating family and obtaining medical, social, and psychiatric history which has been known to impact the autopsy results. Also, having quick access to toxicology lab could expedite the likely or suspected drug cases.

Response: These suggestions go beyond the purpose of the PRC#9 document. They are services that need to be available, however. No change needed.

Commenter #7

Line 86: Histology (and Toxicology) services.

Response: See general comment on Page 1. No change needed.

Line 99: An autopsy rate of 1 per 100 population might be considered as (an optimal) formula.

Response: We are not sure about the basis for this comment. If this ratio were followed an office serving one million people would need to perform 10,000 autopsies per year. Perhaps the ratio is "optimal" for monitoring the health of a population, but it exceeds the level needed for medicolegal death investigation purposes. No change needed.

Line 110: population, recognizing that (the) smaller population...

Response: This typographical error will be corrected.

1- I really appreciate, as a Forensic Pathologist, the idea and the planning for the Regional Medico-legal Autopsy and Death investigation Centers; the need is the mother of the innovation.
2- I believe according to my experience that, the inclusion of the Toxicological Lab within the regional centers is more practical and also more scientific. That is because, having the Toxicological lab in another destination, means either to fulfill the requirements for preservation (- 20 Celsius) and transportation (freeze) for drug analysis which are unfortunately commonly missed, underestimated and neglected especially in the budget oriented and less organized places, so my recommendations disagree with the principles in the line 171 to consider the toxicology analyses as an additional staff.
3- It is a very good and promising sign to announce and anticipate for the concept represented in lines 217 and 230; considering the future request for the CT and MRI. Indeed, it has to be a here and now request.
4- It is a very promising SWGMDI `s report and recommendations.

Response: These concerns have been addressed above and in the General Comment on Page 1. They are good thoughts but go beyond the purpose of this document. The SWGMDI assumes that if a location needing a regional center is also in need of toxicology (or other) labs, they could be included in the plans and the cost estimates adjusted accordingly using information available elsewhere regarding laboratory construction costs. Otherwise, these comments are supportive. No change needed.

Commenter #8

Thank you for the opportunity to submit these comments.
Regarding the overall document, the American Association of Tissue Banks (AATB) appreciates very much that facilities for tissue procurement are proposed as a consideration when designing an autopsy building. We feel it is our duty to inform you that, to meet regulatory expectations of the United States Food and Drug Administration (FDA) within § 21 CFR Part 1271, you should be aware that a site where tissue recovery takes place must meet certain controls to prevent contamination and cross-contamination of tissue being recovered for transplantation into humans. To offer guidelines to meet these regulations, the AATB membership developed Guidance Document No. 2 - Prevention of Contamination and Cross-contamination at Recovery: Practices and Culture Results. It's available at this link:
http://www.aatb.org/aatb/files/ccLibraryFiles/Filename/000000000641/AATBGuidanceDocumentNo2v2May2907.pdf

Additionally, the following AATB standard is found in current Standards for Tissue Banking and can also be used as an easy reference:
D5.501 Recovery Site Suitability Parameters
These must address the control of:
1) size/space;
2) lighting;
3) plumbing and drainage for the intended use;
4) the physical state of the facility (i.e., state of repair);
5) ventilation;
6) cleanliness of room and furniture surfaces;
7) pests;
8) traffic;
9) location;
10) other activities occurring simultaneously;
11) sources of contamination; and
12) the ability to appropriately dispose of biohazardous waste and handle contaminated equipment.

Regarding lines 258 to 261 at listing 6) in the Summary of Recommendations, there is mention of inclusion of space for tissue procurement in the autopsy building design. The AATB proposes the new listing (x) that follows be added in this section to clarify the controls expected by FDA and AATB to prevent contamination and cross-contamination at tissue procurement:

"x) Specific features of the tissue procurement area should be included in the design to prevention contamination and cross-contamination: the tissue procurement area should be dedicated for tissue donation procedures only and not used to perform autopsies; there should be adequate space for proper performance of recovery procedures; it should be located in a separate area (or building) from the space designated for handling isolation cases; and there should be airflow controls (placement of doors and windows, HVAC systems and vents, fans, air filtration systems); adequate plumbing, drains and lighting; cleanable walls and floors; and a separate area next to the procurement site where a surgical scrub can be performed, the body can be assessed and prepared, and where procurement-related supplies can be appropriately stored."

At line 361 in Appendix I – A Sample Facility, a "tissue procurement "room" is listed. We recommend changing "tissue procurement room" to "tissue procurement area" since use of the word room could be misinterpreted that a simple room is all that is necessary to recover tissues under controlled conditions. A well-designed area for facilitating control of contamination at recovery should also allow for the isolation of tissue recovery procedures from other procurement-related functions such as performing a surgical scrub, evaluation/preparation of the decedent's body for donation, and storage of supplies, without significantly increasing necessary space or resources.

At line 326 in the Comments section, we recommend the following advisement be added: "If a tissue/eye procurement area is being considered as part of the design of the autopsy building, discussion should first take place with the local tissue/eye procurement organization(s) to ascertain whether the tissue procurement space is needed and, if so, consideration is expected in regard to including the necessary features to prevent contamination."

Response: These suggestions are important to know, but including them in the document exceeds the basic purpose of the PRC#9. We will add a recommendation that there should be consultation with tissue procurement organizations to plan any needed space for tissue procurement.

Commenter #9

This brief comment was meant to be included in the AATB comments submitted Friday, May 24th as it relates to the topic of body storage in this draft document (mentioned on lines 251-253).

Since new facilities are incorporating technology such as RFID as it relates to the traceability of movement of decedents through the facility, and specifically into and out of body coolers, we wanted to highlight that this information is critical to determining the suitability of a tissue donor for transplantation. If decedent traceability technology is being considered as part of the design of a new autopsy facility, justification for such a system could include that this information is very important to local eye and tissue banks due to AATB standards regarding the cumulative cooling time of a donor and their transplantable tissues prior to surgical explant.

I would like to personally thank the SWGMDI committee for taking tissue procurement into consideration during the development of this document. Please do not hesitate to contact me if I can be of further assistance.

Response: Please see response to Commenter #8.

Commenters #10 – 12 Comments received from the National Association of Medical Examiners (NAME), American Society of Clinical Pathologists (ASCP), and the Association of Pathology Chairs (APC).

Lines 16-28 Executive summary

NAME would concur with the comments about forensic pathologists. While there is a shortage of forensic pathologists in the country redistribution into regional centers of excellence would maximize the efficiency and usage of this resource. In order to facilitate increased numbers of forensic pathologists to meet the staffing needs regional well-equipped forensic centers will act

as one means to attract pathologists into this specialty. Regional centers also provide for increased quality assurance programs and mutual teaching between forensic pathologists.

Response: Supportive comments. No changes needed.

Lines 95-112 Findings of study

NAME agrees with the assessment that one autopsy per thousand persons is an appropriate target level for autopsy performance in order to provide accurate medicolegal data as well as protect the public's health. The SWG uses pathologist per population as the basis for their model. It would be valuable if they could explore the weaknesses of that model. What if the needs for pathologists decrease with increased use of imaging technology? Perhaps, expensive equipment such as a CT scanner might be the variable that drives the model for scale?

Response: Even though pathologists per population are used in the model, the recommendations relate back to NAME recommendations for a 250 maximum autopsy load per pathologist per year, and recommendations are based on a the target of 1 autopsy per thousand population. Newer technology may result in modification of recommendations, but implementation of newer technology on a larger scale, especially in non-academic settings, may take many years. We believe addressing these concerns is premature.

Lines 113-130 Geographic catchment area.

In the discussion of the Geographic catchment area, the SWG assumes that investigators will travel from the central office to investigate cases and therefore the distance needs to be kept less than 100 miles. The SWG might want to discuss some other models that allow a centralized office with longer transport distances. For example, New Mexico and Maryland have investigators distributed throughout the state with response times typically less than 30-40 minutes (in MD 3 hours' drive from the central office). In addition, states are not homogeneous in terms of geography and population. It would be valuable for the SWG to discuss how these variables can influence catchment area and transportation distances rather than creating a one-size-fits-all solution of transport distances less than 100 miles. While transport costs can be significant this is usually mitigated by the economy of scale and having a single large facility serving a large catchment area. The numbers quoted above suggest that body transport costs are far more reasonable than trying to establish multiple small offices with the minimum number of staff in order to achieve an appropriate outcome.

Response: These are valid comments. However, any regional centers would need to be developed in the context of existing services in the state and factors such as those mentioned in this comment. We believe that publication of these comments will make people aware that one size does not necessarily fit all, and models like those in New Mexico and Maryland may be adaptable to other places.

Lines 140-174 Staffing

In the staffing model, the SWG assumes that staffing needs are linear and the slopes of the lines for all of the job categories are parallel. However, this is not true. For example, the need for security doesn't increase with case volume. Other staff increases in a step wise manner. It would be more valuable if the SWG paid close attention to all of the different job categories when attempting to scale the Fulton County model to larger jurisdictions. The NAME accreditation checklist and the NAME standards both indicate that a pathologist workload should not exceed 250 cases per year. For an office performing 1,000 autopsies the minimum number of pathologists if all were occupied in performing autopsies would be four. If these pathologists are then expected to undertake other duties such as child fatality review committees, educational, and research responsibilities etc., the numbers suggested above become more appropriate for

minimum staffing.
Response: Again these are valid comments. We will add a comment to address the issue of non-linearity.
Lines 175-200 Funding To assess funding, only offices that meet minimum accreditation requirements should be used in the formula to determine an appropriate funding level. While there may be offices that are not accredited, by their own choice, that function at an appropriate standard, those that have accreditation have undertaken the process to prove that they meet the minimum standards for an appropriate medicolegal death investigation office. Hence these offices will more realistically represent the appropriate financial needs to undertake this task.
Response: We are unclear about what is being suggested in this comment. We will add a statement that accreditation should be considered when funding need is addressed.
Lines 204-224 Facilities Since new facilities have a horizon of 30 years, what percentage of future growth should be created in the facility design? Historically many facilities are built that are marginal in size and within 10 to 15 years have exceeded their design capacity. In the planning for any office it is appropriate to look at a 30 year life span without significant renovations for a new facility. The plan should then assess both the current needs and review historical data indicating population changes in order to assess the needs of the new facility for its expected lifespan. This is even more critical if the facility is to be built in an urban situation with little opportunity to do additions to the facility to supplement space requirements. The other choice would be to provide some undeveloped space within the existing facility which has been done in several medical examiner facilities with a view to the later development as needed. The SWGMDI report focuses on the present but fails to discuss the medical examiner office of the future. New facilities usually have a horizon of 30 years. The committee should discuss in detail the role of BSL-3 autopsy capacity (partial like Maryland or complete like NM), advanced imaging modalities (CT and MR), digital image technology (photographs and histology), telemedicine (subspecialty support, radiology, videoconferencing and video testimony) and a completely electronic medical record and how these changes and other changes will affect staffing needs and facility needs. For example, will we still need medical record rooms?
Response: The need to design for the future will be mentioned. Getting into more specifics goes beyond the purpose of this document. New Mexico and Maryland are in somewhat unique positions and do not reflect the typical areas where even basic death investigation services are needed.
Lines 225-234 Construction Costs Construction costs can be misleading and it should be clear that the construction costs include all aspects of land acquisition, design, construction, and equipment. The new facility in Maryland construction costs were $366 per Sq. Ft. If the equipment, design and other costs are included then this cost is $450 per Sq. Ft.
Response: We will add a statement that land acquisition costs may need to be considered separately from the basic costs of facility construction and equipment.
Lines 236-267 Summary of Recommendations Consideration to including a toxicology laboratory in the facility to support the death investigation responsibilities should be discussed. A toxicology laboratory exclusively supporting the needs of the office results in a very efficient and cost effective system. In the summary, the SWG also states that new facility should have at least 2 buildings. This

statement is not true and is not supported by the literature. Two recently opened facilities are single buildings. Autopsy rooms need to have separate air handling from the rest of the facility and a separate building is only one method to achieve this. It would be valuable if the SWG could provide a more complete discussion of biosafety needs.
Response: Whether or not to include toxicology is something that individual states need to consider when designing a regional center, and our reasons for not including this recommendation are discussed above. Does the literature show that a single building facility is as safe as two buildings, or that odors are as well-controlled? We will mention that a single building may be workable and that biosafety issues need to be thoroughly considered.