SCIENTIFIC WORKING GROUP FOR MEDICOLEGAL DEATH INVESTIGATION

PRC#11 Research in Forensic Pathology/Medicolegal Death Investigation

Public Comment Report

Created by SWGMDI's Research Committee
Open for Public Review and Comment May 29, 2013 to August 21, 2013
Total responses received = 21 (Counts NAME/ASCP/CAP comments as 1 response)
37% endorsed draft as is [7 of 19, as 2 comments related to a different SWGMDI document].

Comments Received from the National Association of Medical Examiners (NAME), American Society of Clinical Pathology (ASCP), and College of American Pathologists (CAP):

Commenter #1

We agree generally with the points that are made in the SWGMDI report and with the research initiatives that are mentioned. Whether the cause of death is known or not, there is much to be learned, in general, and with new technologies that can be applied across the specialty to enhance our understanding of medical examiner caseload and its ramifications, for all of the reasons mentioned in the report. We are concerned that the literature evidence that is used as a platform for this report seems scanty.

Response: Most of the document is philosophical and involves the presentation of survey data. There is not much literature on this subject; a few references have been added as suggested by the commenting organizations.

"Acceptance" of research as being part of the death investigation mandate is more complicated, when medical examiner's office budgets are marginal at best and are predicated entirely on case investigations as defined by statute. While it may be possible to make the point that research is an integral part of the investigative process in individual cases, it would seem unlikely as a general proposition.

More to the point, it would be valuable if the SWGMDI could explore in greater detail the relationship between academic medicine and the practice of forensic pathology. The majority of health research takes place in academic health centers, where there is a variety of research assets, including administrative (e.g., offices of sponsored research) and compliance support (e.g., human and animal subjects protection, conflict of interest reviews). In addition, depending on research interests at the time, there may be investigators who would be interested in collaborating on projects of a basic, clinical and translational nature. In this regard, the SWGMDI might want to review Nolte KB, Research issues in forensic pathology: a survey of academic institutions employing

forensic pathologists, Hum Pathol, 2004;35:532-535.

Response: A brief discussion of this topic, as well as the suggested reference, has been added.

The most interesting and valuable research takes place at the intersection of disciplines. It would be useful for the SWGMDI to discuss some of these intersections, such as epidemiology and public health and safety, the development of possible interventions (e.g., for youth suicide) and the evaluation of their effectiveness. To learn more about the intersection of forensic pathology and public health the SWGMDI might find it valuable to review Lathrop SL, Forensic Pathology and Epidemiology, Public Health and Population-Based Research, Acad Forensic Pathol 2011; 1(3):282-287. Other intersecting areas might include surveillance (e.g., firearm mortality) and translational projects that affect human health on a larger scale (e.g., using MR spectroscopy to address the biochemical basis of degenerative disc disease). These disciplines and technologies could then also be used collaboratively to address forensic pathology questions (e.g., the mechanism of abusive pediatric head trauma).

Response: A brief discussion of this topic, as well as the suggested reference, has been added.

The suggestion that "regional centers based in a university, large MDI system facilities or newly created geographical regional MDI research centers" would partner with universities/pathology departments and with medical examiners/coroners and other scientists for collaborative research seems a concept in need of further definition.

Response: This was simply a concept put forth for general consideration; it does not represent a detailed, outlined plan.

In terms of "research sabbaticals", it might be more realistic to suggest that federal support be given to career development, new investigator, pilot study, research mentoring, center development and other award mechanisms already in place at the NIH for other health disciplines that could be replicated for forensic pathology at NIJ.

The relatively small numbers of individuals in the specialty who have applied themselves to research over the years have done so largely because of personal interest in a particular subject and often through a collaborative relationship with a like-minded institution. We think this is where the emphasis should be placed. It would be valuable for the SWGMDI to discuss how the numbers of such individuals could be increased.

The SWGMDI report should be clarified to state that decedents are not considered human subjects, in the traditional sense, for the purposes of research and are not under the purview of Institutional Review Boards (IRB). Nevertheless, most IRBs also function as HIPPA privacy boards. If the research involves protected health information on decedents, the IRB functioning as the HIPAA privacy board does, indeed, have oversight. Regardless of the circumstance, it is useful and we would recommend discussing decedent projects with IRBs even if the project does not require IRB review and approval as human subjects research. Most IRB chairs are willing to give advice even when they grant an exemption. As written, the SWGMDI report should be amended with the above considerations in mind. To learn more about this complex topic the SWGMDI should consider reviewing Weedn VW, et. al., Legal and Ethical Considerations in Forensic Pathology Research, Acad Forensic Pathol, 2011; 1(3):288-301.

Response: A brief discussion of this topic, as well as the suggested reference, has been added.
The recommendation to align federal and state laws and regulations concerning the use of forensic tissue samples, records and images does not specify which laws are to be aligned, and, even if that were possible, how such an alignment might be accomplished. States have a variety of statutory regulations pertaining to decedent research, ranging from permissive to prohibitory. It would be helpful for the SWGMDI to summarize the spectrum of these regulations with recommendations for oversight that fit the current research compliance landscape. The oversight process may need to be different for projects that involve tissue as opposed to data and images.
Response: A review of all legislation covering this topic is far beyond the scope of this document. We introduced it only as a concept rather than intending it for a detailed analysis.
It would also be useful for the SWGMDI to discuss the difference in consent issues for the research use of tissues ordinarily saved at autopsy (e.g., paraffin blocks of major organs, for case reports) as opposed to that of tissues not ordinarily saved at autopsy (e.g., cartilage from glenoid bone, to look for proteoglycans). Perhaps the SWGMDI could suggest a process for how national consensus could be developed in this area. The SWGMDI should not be the arbiter in determining what consent processes should be applied to the use of forensic tissue samples, records and images. We believe that these processes should evolve from a larger and more diverse group of investigators, subject matter experts and stakeholders.
Response: We are confused by these comments. It is first stated that that SWGMDI should suggest a process, but then, that SWGMDI should not be the ones who suggest that process. It is not the intent of this document to suggest or promote specific procedures.
The SWGMDI definition of "vulnerable populations" does not match the standard IRB conception of vulnerable populations, which does not include drug addicts and the poor. Having this discussion in this report muddies the water because decedent subjects cannot be inappropriately coerced, as living subjects (e.g., prisoners) might be. Consequently, we recommend that this discussion be deleted.
Response: The point is well taken. We have removed the phrase.
The mention of violence surveillance would benefit from broadening the surveillance concept to include other categories (e.g., drug-related fatalities, epilepsy, infectious disease, premature fatal cardiovascular disease). Along those lines, the SWGMDI might want to examine data coding issues (SNOMED, ICD) that would make data more easily accessible for public health research purposes. Specific Changes Recommended: Line 15-16: "unexpected", not "unexplained" in SUDEP, SUID.
Response: Change made.
Lines 16-17: suggest deleting the phrase relating to SIDS as being redundant.
Response: We used both the terms, SUID and SIDS, as many in the community do not see them as equivalent.
Lines 74-75: should include promoting the public health and foster a research culture

among those to whom the forensic community reports, i.e., agency heads, legislators, and the like.
Response: We believe that this sentiment is covered under the first enumerated point in the sentence.
Line 103: comma after "data".
Response: Change made.
Line 100-107: Death investigation and forensic autopsy practice is the same as patient care in this regard; forensic pathologists can collect useful data while providing care tailored to the needs of a specific case.
Response: Commentary only; no changes suggested.
Line 356: suggest adding physiological changes caused by cocaine and opioid use that increase the likelihood of sudden death.
Response: While we do not disagree, the suggested research study topics were based on survey data.
Lines 432-433: Who will perform the biannual re-evaluation of research focus areas?
Response: We did not specify. We (SWGMDI) would certainly entertain the possibility, but that of course would not preclude any other group(s) from conducting similar analyses.

Other Public Comments:

Commenter #2
around 350- add research into doll reenactments.
Response: This section is referring to research into cause of death, rather than research about the usefulness of particular techniques. While we do not disagree in concept, it does not really fit here.

Commenter #3
The draft defines SUID as Sudden Unexplained Infant Death. This is not correct. (line 16) The U is unexpected not unexplained. The Centers for Disease Control's widely used definition of SUID is with the U as "unexpected" and includes all infants death regardless of cause the cause of death is not immediately obvious PRIOR TO investigation. http://www.cdc.gov/sids/index.htm.
Response: Change made.

Commenter #4
Great job on this. You have named so many of the obstacles that prevent us from facilitating research and truly making a difference in so many of the seemingly chronic or untreatable problems. There is such a waste of materials for potential research that might lead to medical therapy or interventions. Thank you!
Response: Thank you. No changes indicated.

Commenter #5
Excellent document.
Response: Thank you. No changes indicated.

Commenter #6

My expertise falls under the Section II.D. Postmortem changes. I think that this draft touches on a lot of issues that are important and relevant. I think that it would benefit the MDI community to keep forensic microbiology on the radar. The field of microbiology is currently undergoing massive evolution with the progress of the Human Microbiome Project. These advances have already progressed medical microbiology and will likely end up revolutionizing the field of postmortem microbiology, moving it from a culture-based field to establish cause of death to one that can contribute to all major goals of a death investigation including establishing the identity of the deceased. Incorporating microbiome studies into MDI might also facilitate external research funding because of the vast amounts of information that we are now able to acquire. For example, exploring the relationship between the human microbiome and SIDS. I do not think that this needs to be included in the draft. But the MDI community will benefit greatly from microbiome research over the next few decades. In fact, I think that the field of postmortem microbiology (probably to be evolved through forensic taphonomy) will be unrecognizable from what it is now within 10 years time.

Response: Your comments are noted and we agree. No specific change suggested.

Commenter #7

The draft was thorough and well written. The draft was clear and understandable. I suggest expanding training sections, but, currently, I do not have specific suggestions. I will have to get back with you on that.

Response: No changes indicated.

Commenter #8

line 25: the word "with" should be omitted.

Response: Change made.

Thorough review of the areas of future research. Potential addition: sudden death in anorexia nervosa.

Response: While we do not disagree, the suggested research study topics were based on survey data.

Commenter #9

I do not endorse the entire premise of the Executive Summary and challenge the need for research into the biomechanisms of death by the medicolegal death investigation community. Mechanism of death is not our concern; strictly speaking we investigate the cause and manner of death. Cause of death is etiology specific, and identifies underlying disease, not "cardiac arrest" but what it's due to. Better to leave research into mechanisms of disease, trauma, seizures, SIDS, drowning, etc., to the neuroscientific community.

Response: We respect your opinion. However, we believe that forensic pathologists (at least those who have the interest in doing so) are among the best individuals to participate, perhaps even with professionals from other specialties such as neuroscience,

in such research.

Commenter #10

Under the section entitled, "In Custody Deaths" on page 13, line 395, in section 4, I noted that the term excited delirium was in quotation marks. Obviously this seems to signify that the term is not an accepted term for some practitioners. If this is the case, perhaps more attention to this "disorder" or symptom needs to be addressed by not only the medical community, the psychological community, and especially the MDI community. A footnote in the document should explain why the term is in quotation marks.

Response: You are correct in that we put the term in quotation marks, since the term has been controversial. We think the easiest solution is to simply remove the quotation marks.

Commenter #11

I recommend revising the document so that it is far less specific in providing examples of content area for research. This listing of research topics can become an agenda for funding, and it is biased toward interest in pediatric research. The most acute need from ME offices is well documented normal human specimens for use as control tissues for all sorts of ongoing research, probably cancer research being the most widely accepted by the general public. Hospital autopsy services do not generate "normal" tissues, and the ME offices have the traffic mishaps and house fires that are the prime focus for these studies. The NIH GTex project has failed over the lack of access to control specimens from MEs. Organ procurement services could provide access, but only if the ME offices get the kind of public mandate outlined in this report. I support the mandate, but not the appearance of priorities for research topics.

Response: We respect your opinion, and generating a list of potential topics, as perceived as needed by our own forensic pathology community, was one of the main objectives of this project.

Commenter #12

It seems to me that we are once again building a bureaucracy. That is government at its best. We need research and bureaucrats. Research grants in the areas of interest can be given to universities and medical schools. The research can be published in forensic journals without the costly bureaucracy.

Response: Commentary only; no changes were suggested.

Commenter #13

A very well written draft. I was pleased to see the comments for more education on child abuse fatalities. Sadly the US is the worst of all industrialized countries for child maltreatment and very few nursing and medical professionals feel confident in diagnosing this in living or deceased infants and children. I feel very strongly that the forensic communities really push education in this area. I am glad to see this topic addressed in this document. I also like the recognition of the forensic nurse as an important person in both investigations as well as liaisons between hospitals, families, and medical examiners' offices. We need to be utilized in more than sex assault cases and

this is also something law enforcement and the forensic community need to be educated on (I am a little partial to this topic). I do have a suggestion and that is to increase your reference database to at least 20 at minimum. The more the better. It has been a pleasure reviewing this draft and thank you for the opportunity! Keep up the good work!

Response: We have added a few references.

Commenter #14

We are a Coroner's Office who contracts for Forensic Autopsy services from a university based forensic pathology department. As a Coroner's Office we have applied for many grants. The only grants we have been awarded are those that are for equipment/personnel etc. We have found being a government office, we do not 'qualify' for research grants as we are not part of a university, do not have tenured 'professors' etc. When we have tried to work with university settings they want to 'be in charge' of the research however the body 'belongs' to the Coroner. We are very interested in conducting research however have never met the qualifications for an applying agency. This needs to be changed for us to be able to conduct research.

Response: We agree. No specific changes to document suggested.

Commenter #15

Page 10 section I: D. Standardization including National guidelines for practices and mandatory accreditation for local agencies should be included.

Response: We added the word “accreditation” to the line item as suggested.

Commenter #16

L 13 "Oftimes within the indigent population" ?necessary comment and if substantiated in fact.

Response: Phrase was deleted.

L 224 "The poor" Indigent may be more appropriate in this case.

Response: Change made.

L 396 G 3 add "Availability and utilization of dental records"

Response: While we do not disagree, the suggested research study topics were based on survey data.

Commenter #17

It is really good and except for what I say below I do endorse everything else as is. I do not see in any reasonable spot where the ME is asked to document the perforations in clothing of pen/perf injuries. Besides lining up holes for gunshots and stabs (to make sure that victims real position is documented) there must be mention of at least looking for gunpowder residues on clothing of "indeterminate" entrance wounds on skin. Might also explain shored exit wounds under tight leather belt, etc. You probably have it in the document somewhere, but for best practice or even guidelines it should be mentioned in terms of injury description along with external and internal path(s).

Response: We are not sure where a suggested change would be; this is a document about research. This comment seems to be focused on practice guidelines, which is not the

intent of this document. We suspect that these comments might have been intended for a different SWGMDI document.

Commenter #18
I do agree that it is necessary with more research within the field, limitations and suggestions.
Response: No change indicated.

Commenter #19
Guidelines do not include interrogation of implanted devices.
Response: This is not a guidelines document, but rather, a research document. No changes suggested.
Line @130-131 may be more completely stated by including "or while serving in any branch of the military." Line @ 373 suggestion to add "PiercingsLine @ 507 may be more completely stated "physically collect and save such residue for analysis." Line @ 518 Measure wound "Dimensions." Line @ 547 Measure injury "Dimensions."
Response: It appears that these comments were intended for a different SWGMDI document rather than this one.

Commenter #20
Line 13...oftentimes could be replaced with "often."
Response: The entire phrase was deleted.
Line 25...(including with proteomics...."with" can be deleted.
Response: Change made.
Lines 92,93..."The bottom line is that the"....should be deleted(slang) ...start with a direct statement "Society must place"
Response: Change made.
Lines 102..."of the same quality" change to "of similar quality."
Response: Change made.
Line 141...change "In no way"(slang) to "Under no circumstances"...
Response: Change made.

Commenter #21
Brain Pathology is the challenge No. one for the forensic pathologists, so, the establishment of as much as possible of the advanced diagnostic tools is highly recommended to be standardized. I strongly support the contents of the lines 18-31. The diversity of death investigation systems, as mentioned in line (102) is a very unfortunate to that professions all over the world, not only a barrier for the research, but also for a good practice, so, global Standardization should an aim. One of the lines of standardization, which is absent in all Arab countries for example, is the interrelationship between the MDI from one side and the universities and pathology departments from the other side. I strongly recommend the Regional research centers (lines : 131-150) with the partnership protocols with the academic universities. It would impact, very positively, the research and development of the human capitals in MDI systems. It is so strange, yet still the majority, to take the marathon of the globalization with no quality assurance

programs in MDI, which is strongly recommended as in line (167). Training(316), Standardization (320), quality control of DI and autopsy (322) are the life saving concepts for a mission in danger. I strongly believe that the future could not handled with same way is was in the past decades. Giving help to public health(323-324), public education(325), Ethics of testimony (329), Accurate and detailed death certification helping the family and the MDI system (330), obtaining consent (331),to be done in the proper way are all could be an absent holly grill in the daily practice as it is always considered a secondary line of concern, so, it should be strongly considered in the training of MDI staff. As regard the consent, every one should have the voice of consent even the mentally ill patients (223-224) through the forensic instruments for assessment of the decision making capacity. The MDI staff and Forensic pathologist should, at least, know it is existed. Autopsy standards, especially Neuropathology (349), Toxicology research especially postmortem redistribution(356, 363) and more accurate estimation of postmortem interval (274); should be seriously considered as very critical yet basic points in practice. Autopsy alternatives (417) as PM-CT and MRI should be considered also, as an aid for autopsy best results. PM-CT is recommended for all cases of head trauma, brain pathology and sudden death. Post traumatic stress disorders in MD Investigators and Forensic Pathologists (327) could only be relieved after fulfilling the recommendation, above.

Response: Commentary only; no changes suggested.