



Research in Forensic Pathology/Medicolegal Death Investigation

A Report and Recommendations Prepared by the Research Committee of the
Scientific Working Group on Medicolegal Death Investigation (SWGMDI)

Executive Summary

The medicolegal death investigation system oversees the investigation of certain disorders that do not typically fall under the domain of academic hospitals, and thus are not generally autopsied in academic pathology departments in which research is not only permissible (with informed consent) but also strongly encouraged and fostered. The major category of such disorders is sudden and unexpected death. Disorders within the sudden and unexpected death category include suicide, including a population of those committing suicide with a variety of mental disorders, traumatic brain injury, and a variety of violent/homicidal deaths with frequently overlooked clinical behavioral manifestations, sudden unexplained death in epilepsy (SUDEP), sudden unexplained death in childhood (SUDC), sudden unexpected infant death (SUID), and deaths consistent with the definition of sudden infant death syndrome (SIDS).

In several of these disorders, the death remains unexplained after the autopsy and scene investigation and thus research is urgently needed. In virtually all of these disorders, the biological mechanisms, including brain pathology, are poorly understood. In order to develop treatment strategies and diagnostic biomarkers in living individuals with these afflictions or at risk for them, state-of-the-art research is needed. Moreover, this research must be critically based upon modern cellular, biochemical, and molecular techniques that are not routine autopsy practice and require special methods of tissue handling at the time of autopsy. In neuroscience, to name but one example, the stunning advances in tissue analysis (including proteomics, transcriptomics, western blotting, high performance liquid chromatography, and postmortem brain imaging with tractography) are now applicable to investigate the *human* brain at autopsy, and it is essential that these advances are translated to the investigation of deaths believed to be the result of sudden and unexpected neurological disorders. Furthermore, because there are no animal models for many of these disorders, research directly in human tissues at autopsy is imperative.

Research needs in medicolegal death investigation extend to areas in which the cause of death is known. Drugs and alcohol are often involved in deaths within the medicolegal death investigation system yet may not be fully examined due to fiscal limitations. Drug distributions are critically needed in pharmaceutical and toxicologic studies but require analysis from different

body systems and fluids, studies that may be limited by tissue restrictions or finances. Molecular pharmacogenomics is critically needed to understand the human responses to drugs and other substances. This applied research would advance understanding of drug metabolism in living patients as well as provide enhanced detection within the medicolegal system. Similarly, violence and injury is a leading cause of death in many age groups; these deaths are nearly the exclusive domain of medicolegal death investigation systems. Scientific studies of violence and injury are needed to understand and address this public health problem. This can only be done with rigorous scientific studies within medicolegal death investigation (MDI) system. These examples are not inclusive but rather a starting point for scientific investigation.

Finally, “systems” research is needed within the MDI community. These system needs encompass broad areas, from the identification of the most effective provision of MDI services within geographically different and demographically diverse communities to basic practice parameters involved in MDI, such as the ruling of manner of death, investigation needed in certain types of deaths or death scenes, etc.

In summary, there are diverse and collaborative research needs within the practice, system, and environment of medicolegal death investigation. Research in these areas would aid in addressing basic health, wellness, psychiatric, and public health needs of the United States and internationally. Furthermore, this information can then be translated to prevent these deaths and better diagnose and treat living patients as well as enhance the medicolegal community’s role in the courts and the criminal and civil justice systems.

This document addresses several key issues related to medicolegal death investigation research and is divided into corresponding parts. First, it identifies some of the barriers inhibiting research in the field of medicolegal death investigation. Second, it describes potential mechanisms to reduce those barriers. Third, it describes ways to promote research through access to study materials. Fourth, it describes ways to promote research through access to grant money. Finally, it presents a gap analysis based on survey studies and presents recommendations for research focus areas by the Scientific Working Group for Medicolegal Death Investigation (SWGMDI).

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Barriers to Medicolegal Death Investigation Research

The barriers to research in medicolegal death investigation (MDI), including forensic pathology, are diverse, widespread, and start at the local level and continue on up to the national and international levels.

In order to facilitate research in the medicolegal death investigation system, two fundamental changes are needed: 1) the development of acceptance of research in the forensic community by society such that research in death investigation agencies is not considered a conflict of interest, but rather an essential part of the mandate to determine the cause (and mechanism) of death; and 2) the fostering of a culture in the forensic community of support for and involvement in research, particularly in disorders that are the main purview of forensic medicine (e.g., sudden and unexplained death).

The medicolegal death investigation system has historically been mandated to determine the cause and manner of death on an individual level. This mandate should be broadened to advance basic knowledge of the disorders under investigation and therefore to include research. An example of this expansion in practice can be drawn from the state of California, whose infant autopsy law permits not only the determination of cause and manner of death, but also facilitates research for the general welfare in disorders suspected of causing death, particularly those that fall uniquely under the domain of the medicolegal death investigation system. Moreover, families should be given the opportunity to participate in research, which may impact other family members or populations of patients.

The cultural paradigm shift will ultimately require changes in state and federal laws, as pioneered in California for sudden and unexpected infant deaths. Nevertheless, these legislative changes are essential to better serve the welfare of society in general by performing state of the art research that will lead to the eradication or amelioration via treatment of disease. Society must place as much value upon research as it does upon the determination of an individual cause of death, and it must see research as part of the scientific investigation towards determining the cause of death. Effective policies need to end the barrier many medicolegal death investigation systems encounter (e.g., fear of litigation for fostering or performing forensic research). The policy change would support and allow for research as part of the fundamental mission of the forensic community.

Currently, “research” in the medicolegal death investigation system includes case presentations and descriptive case series. Research requires that the information being gathered and compared be of similar quality. Diverse death investigation systems do not have uniform resources and do not necessarily collect the same data, and the depth of detail varies. Uniform collection of information is essential for the research applications and in order to apply those findings toward a better interpretation of the circumstances surrounding a death as it relates to the public’s interests. However, the very nature of medicolegal death investigation precludes this from occurring in every case. Each death and each death investigation has its own focus and nuances. It should be noted that much valuable research potential involves the intersection of forensic pathology with other disciplines such as epidemiology and public health and safety (reviewed in 1).

The Research Committee has identified some of the barriers to research in medicolegal death investigation including forensic pathology and these include:

- **Time** constraints for those individuals who may have an interest;
- **Access** to appropriate study materials such as fluid specimens, tissue specimens and case file materials;
- **Legal** issues may include consent to obtain and use biological material and/or case information for research purposes, which may be beyond the scope of the usual statutory purposes of a death investigation to determine cause and manner of death in the public interest;
- **Skill**, aptitude and experience in research design, execution, and publication;
- **Funding** for personnel, materials and equipment;
- **Obstacles** encountered in writing grants to support research efforts;
- **Lack of interest** in conducting research at the local level by forensic pathologists, coroners and other medicolegal death investigators.

Ways to Reduce the Barriers to Medicolegal Death Investigation Research

It is anticipated that the final recommendations of the SWGMDI will contribute in large part to reducing barriers to research by achieving its goals of improving death investigation overall and advancing the scientific basis of MDI.

A consideration to reduce the barriers to research would include formation of regional centers based in a university, large MDI system facilities or newly created geographical regional MDI research centers. Regional centers could focus upon specific entities and utilize standard investigative and research protocols, the latter directed by hypotheses and specific aims. The centers should partner with local and regional academic universities and pathology departments to facilitate research collaborations; such regionalization allows for the standardization of autopsy protocols, ancillary studies, and classification schemes. Most research (on any topic)

takes place in academic medical centers, which have resources for both support of research and collaborations; this topic is reviewed elsewhere (2). In addition, regionalization would permit the researchers to have a larger and more uniform population to assess when addressing research questions. Standardization of autopsies and death scene protocols is also critical to research in order that the cases are consistently and comprehensively phenotyped for the particular entity under study. Under no circumstances should research sampling interfere with or impinge upon the determination of the cause of death for medicolegal purposes. In cases of suspected child abuse and homicide, for example, brain samples should not be donated for research if examination of the brain as a whole is needed to exclude intentional trauma. Finally, there are now established private and National Institutes of Health (NIH)-funded tissue and DNA banks that include disorders under the auspice of the medicolegal death investigation laws. Regional forensic research centers would be responsible for developing partnerships with forensic pathologists, coroners, medicolegal death investigators, and other scientists who have an interest, aptitude, and skill in conducting collaborative research and would allow for partnerships with other stakeholders such as law enforcement, clinical physicians, and prosecuting, plaintiff and defense attorneys.

The current time constraints imposed on those who do have such an interest in medicolegal death investigation systems or forensic pathology research should be alleviated by offering grant-funded research sabbaticals to conduct studies or to learn how to conduct research at the local level. Regional centers would provide for an infrastructure that would provide an opportunity for resolution of legal issues, and optimize funding while alleviating obstacles encountered in writing grants. Centralized, controlled access to appropriate study materials would also be optimized to support research efforts and improve collaboration.

Ways to Support Research through Access to Study Materials

Access to study materials is a critical component to further advancement of justice and knowledge within forensic sciences. Federal regulations currently encompass significant safeguards for individual privacy while allowing needed opportunities for knowledge, quality control, and advancement. State laws and local policies may severely restrict or entirely preclude use of materials, even anonymous specimens destined for disposal. This precludes meaningful advancement within forensic science and the quality assurance programs needed within the justice system. Furthermore, it often denies opportunities for families who may want to participate in research protocols from doing so. A critical step in supporting research is alignment of local and state regulations that recognizes the critical role of forensic research and use of research samples, records, images and other media in the advancement of justice and health.

Privacy

For research, all tissues and DNA should be de-identified to protect the privacy of the individual and family. Essentially all Institutional Review Boards (IRBs) recognize that in the course of research studies, certain findings may come to light that have diagnostic and known consequences (e.g., the discovery of a known genetic mutation in a research genetic study for postulated/candidate genes in a particular entity with whole genome sequencing). In these circumstances, mechanisms are generally stipulated for reporting back to the medical examiner such information, if a unique identifier for the decedent is available in the central research office.

Informed Consent

An IRB within the forensic community or regional forensic research center is needed for forensic research to include informed consent mechanisms. It is important to point out that decedents are generally not considered to be human subjects for the purposes of research, and therefore are not generally under the purview of IRBs (reviewed in 3). Most IRBs, however, are willing to give advice even when the proposed study is granted an exemption. It is also important to remember that decedents did not arrive at the MDI facility under consented circumstances and the MDI office does not own the body and research projects on bodies or tissues should be carefully considered. If a particular type of proposed testing or examination for research purposes is not being performed during the normal course of a medicolegal death investigation or autopsy, it would be prudent to consider obtaining consent from the next of kin even if not required by law.

Studies related to sudden unexpected death in infants have demonstrated that research involving donated autopsy tissues is generally acceptable to families when they are sensitively approached and thoroughly informed by an experienced counselor from a familiar and supportive medical community (4, 5). Parents feel it is critical, however, that they are involved in all decisions about tissue retention and that the medical communities not “betray” them by performing research without their explicit consent, because they understandably feel protective of their children even after death (5, 6).

The establishment of these mechanisms is essential to the performance of research in forensic offices, including with academic partners, and to the donation of autopsy tissue and DNA samples to national banks. There are several current informed consent models:

- 1) State law for research without direct parental consent in sudden and unexpected infant death in California with the infant autopsy law;
- 2) Delayed request for informed consent of parents of children dying suddenly and unexpectedly after tissue samples harvested for research at the time of autopsy with IRB approval, with research permitted when *consent obtained months after death*; and with the discard of saved tissues when consent not given, in New Jersey;

- 3) The request for parental consent for research tissues in sudden and unexpected death in infants in southern Florida by representatives of donor organ banks *at the time of autopsy*, in addition to request for organs, with submission of tissues to the national developmental tissue and brain bank at the University of Maryland according to its protocols (success rate, ~20% in first year of operation)(7);
- 4) The request for parental consent for research tissues in sudden and unexpected death *at the time of death* by study coordinators in specific catchment areas of the Northern Plains under the auspice of a NIH-funded study of infant mortality and SIDS (success rate, ~50%)(8).

State laws are the optimal mechanism because of the inherent difficulties in requesting tissues for research within hours of the death. This is particularly the situation in the medicolegal death investigation systems in which virtually all the deaths are sudden, unexpected, and under traumatic circumstances as in the suicide, homicide, or catastrophic accident of a loved one, and/or the sudden death of a seemingly healthy child. In addition to state laws, IRBs within the medicolegal death investigation system or their partnered academic institutions are needed to provide oversight concerning the need for and integrity of individual research projects. Issues related to research, for example, in socio-economically disadvantaged populations have been recently summarized (6). In this regard, IRBs serve as protectors of these populations in research and can be depended upon to do so in forensic research. The details of particular research in the medicolegal death investigation system need to be tailored for each system and research project.

In terms of who should ask for consent for research from families at the time of autopsy of their loved one, it is difficult for all, including trained health professionals, to ask for consent in a period of confusion and despair at the sudden loss. It has been suggested that parents who have experienced the death of a child be involved in the consent process, because they have experienced a similar loss.

Ways to Support Research through Access to Grant Funding

Investigations in MDI and forensic pathology (FP) are complicated by a paucity of funding sources and agencies compared to other medical and social research fields. This is compounded by the low appropriations to the few agencies, like the National Institute of Justice (NIJ), that do have a research portfolio in forensic science. Funding resources are critical to advancement. Several mechanisms could be utilized in promotion of research into areas of MDI and FP. First, funding within existing agencies, such as NIJ and Centers for Disease Control and Prevention (CDC) should be augmented, including previous public health and violence surveillance programs. Another key step is the recognition and incorporation of MDI and FP systems into existing research portfolios of federal agencies such as NIH, Department of Defense (DOD),

CDC, Health Resources and Services Administration (HRSA), Food & Drug Administration (FDA), Consumer Product Safety Commission (CPSC), Department of Transportation (DOT) and others. Sudden deaths from a variety of causes, such as substance abuse and violence, all have significant portfolios in existing federal programs. Integration of the clinical setting of forensic and MDI practices accomplishes goals of clinical translational research. The breadth of potential with genomics of sudden death, aging and pharmacogenomics would be greatly enhanced by rigorous inclusion of MDI systems.

Gap Analysis to Identify Research Priorities

SWGMDI recognizes the needs for specific focus areas of research for forensic pathology and the medicolegal death investigation profession to validate scientific methods, improve the accuracy of diagnoses, and improve the efficiency of death investigations.

The following recommendations were developed from data gathered from surveys conducted by National Association of Medical Examiners (NAME) in 2009 and SWGMDI in 2011.

Results Summary of the Two Surveys:

- The NAME Survey of 2009 received 94 respondents via NAME members identifying themselves as: Administrator (3), Full-time Forensic Pathologist (FP) (70), Part-time FP (13), Investigator (2), retired (5), no information (1). Their percentages of time devoted to research at the time of the survey were: None (31), less than 10% (44), 10-25% (8), 25-50% (2), 50-90% (3), information not available (6). The type of research activities of the respondents included: Basic science (7), Clinical (17), Translational (5), Descriptive Studies (33), not available or not applicable (32).

The NAME survey of 2009 reported the highest areas of research priority to be described as:

1. Child Abuse with head trauma 73/94 (78%)
 2. Postmortem toxicology 55/94 (59%)
 3. Genetic/Metabolic Abnormalities 50/94 (53%)
 4. Injury Aging/Dating 38/94 (40%)
 5. Pharmacogenomics 26/94 (28%)
 6. Child abuse without head trauma 26/94 (28%)
 7. Postmortem interval/time of death 24/94 (26%)
 8. Undetermined cause of death 18/94 (19%) and
 9. Emerging Issues 18/94 (19%)
- The SWGMDI Survey of 2011 received 121 respondents through an online survey distributed to NAME, International Association of Coroners and Medical Examiners (IAC&ME) and American Board of Medicolegal Death Investigators (ABMDI) memberships. Respondents were asked to list their top three priorities for areas requiring

research in the field of forensic pathology and medicolegal death investigations. This was a descriptive analysis.

1. Systems related 83/121 (69%)
2. Pediatric related 78/121 (64%)- of which 49% were related to pediatric trauma and 49% related to SIDS/SUID/Sudden death
3. Toxicology and Drug Related 53/121 (44%)- of which 49% were related to Drug Related Deaths and 51% related to Toxicology
4. Types of Death 27/121 (22%)- of which 63% were related to Sudden Death
5. Time of Death (TOD) Determination (slight overlap with post mortem changes) 27/121 (22%)
6. Molecular, genetic (also overlaps with sudden deaths, pediatric): 17/121 (14%)
7. Post-mortem changes (specific as opposed to TOD) 14/121 (12%)
8. In custody, restraint related deaths (also some comments in drug / toxicology related) 14/121 (12%)
9. Injury Aging / Dating of injuries 14/121 (12%)
10. Autopsy alternatives 8/121 (7%)
11. Identification (ID) Related and Mass Fatalities 8/121 (7%)
12. "Asphyxia" 6/121 (5%)
13. Elder related (also in toxicology and other deaths) 6/121 (5%)
14. Neuropathology related (also overlaps with trauma, pediatric) 6/121 (5%)
15. Suicides 3/121 (2%)
16. Image analysis 1/121 (0.8 %)
17. Bias 1/121 (0.8%)

SWGMDI's Recommendations for Prioritized Research Focus Areas

Based on these two surveys, the opinions of the SWGMDI Board, and public comment, we recommend the following to be considered for priority focus areas for research to improve the scientific merit of forensic pathology and medicolegal death investigation:

I. System Related Research (to improve the practice and management of medicolegal death investigation systems)

- A. Identification of funding resources to improve access for research into the MDI field
- B. Training of coroners and medicolegal death investigators
- C. The use of the forensic nurse profession in the field of MDI
- D. Standardization of death investigation/forensic pathology
- E. The use of dolls for infant death scene re-enactments
- F. Servicing remote areas, including underrepresented or minority populations
- G. Quality control for death investigation/autopsy
- H. Use of autopsy findings to reduce healthcare costs among the living and benefit public health
- I. Public education regarding the functions and missions of the medicolegal death investigation system
- J. Post-traumatic stress disorder (PTSD) in medicolegal death investigators and forensic pathologists
- K. Ethics of testimony by MDI professionals
- L. Death certification to improve accuracy of death statistics
- M. Determining optimal procedures for obtaining consent from next-of-kin for the use of autopsy tissues for research
- N. Standardization of Institutional Review Board review across death investigation systems

II. Scientific Related Research (to improve the accuracy of cause and manner of death determination by supporting the findings and analyses in MDI with evidence based research rather than opinion based unproven conclusions)

A. Pediatric forensic pathology research to improve the accuracy of cause and manner of death certification: Pediatric Forensic Pathology was rated as the second and top priority among the two surveys of MDI professionals assessing areas of critical research needs:

Unexplained deaths of infants and children represent the largest group of undetermined deaths in the field of MDI. Yet, given this overwhelming public health problem, the MDI community lacks evidence based research and standard practices for these investigations. This has likely resulted in inaccurate diagnoses and poor national statistics to address public health issues.

Specific areas in pediatric forensic pathology requiring additional focus are:

1. Autopsy standards and neuropathology
2. Sudden death
3. Child abuse
4. Cause of Death (COD) in unsafe sleep environments (e.g., bed sharing, soft bedding, etc.) and the diagnosis of asphyxia
5. Head and general trauma
6. Retinal hemorrhages

B. Toxicology/Drug research to better understand the contribution of toxic substances to pathology and death:

1. Marijuana/prescription drugs and driving
2. Rates of drug clearance
3. Interpreting toxic levels (especially with combinations)
4. Pediatric toxicology interpretation
5. Toxicology and natural disease interaction
6. Postmortem redistribution
7. Pharmacogenomics
8. Testing matrices
9. Alternative sample types

C. Molecular/Genetic studies research to evaluate the recent scientific advancements as they relate to the evaluation of genetic causes of sudden death and how the MDI community can, with improved accessibility, utilize these advances to benefit MDI's cause and manner of death determination and the protection of at-risk living blood relatives:

1. Cardiac channelopathies
2. Hypertrophic cardiomyopathies
3. Metabolic diseases

D. Postmortem changes research to more accurately estimate the postmortem interval:

1. Troponin-I
2. Body temperature at scene
3. Microclimatology
4. Taphonomy

E. Research to establish the diagnostic criteria for the accurate determination of cause of death:

1. Exsanguination
2. Starvation
3. Dehydration
4. Hypoglycemia
5. Anaphylaxis
6. Hypoxia/asphyxia
7. Acidosis
8. Sudden death with fatty liver
9. Drowning

F. In Custody Death research to understand the body's physiological responses to "restraint" as it relates to sudden death:

1. Physiologic stress of restraint
2. Conducted Electrical Device (CED) and mechanism of associated deaths
3. Restraint asphyxia
4. Excited Delirium

G. Mass fatalities and identification research to improve the efficient functioning of varied MDI systems in the event of a mass fatality with accurate and expedient identification and recovery of human remains:

1. Methods to expedite DNA identification
2. Field test for human vs. nonhuman remains

H. Elder death research to provide support for the protection of this vulnerable population with accurate cause and manner of death determinations:

1. Abuse
2. Hospice overdoses
3. Communication with adult protective services (APS)

I. Neuropathology research to accurately determine the source of brain and spinal cord trauma, disease, and congenital abnormalities, as well as to assess the validity and reliability of current methods used in MDI:

1. Chronic traumatic encephalopathy
2. Hypoxic encephalopathy
3. Source of bleeding in subdural hemorrhage
4. Dating of subdural hemorrhage
5. Sudden unexpected death in epilepsy (SUDEP)

J. Dating of injuries research to understand the temporal healing characteristics of antemortem, perimortem and postmortem injuries that is lacking in the current medical literature and limits the accurate analysis of autopsy findings

K. Autopsy alternatives research to evaluate new techniques and science that have the potential to improve accuracy and efficiency in MDI:

1. Postmortem computed tomography (CT) and magnetic resonance imaging (MRI)
 2. Laparoscopic procedures
- L. Bias research to evaluate the validity and reliability of MDI methods that are lacking (i.e., different observers coming to different conclusions despite using the same dataset)
- M. Image analysis research to understand how to apply modern image analysis and technology to support the field of MDI
- N. Suicide research to better understand its psychological aspects (i.e., the “psychological autopsy”)

SWGMDI recommends that these focus areas be utilized in allocating research funds to provide the most benefit to the field, as well as recognizing the areas in greatest need of evidence based research in MDI. SWGMDI also recommends these focus areas be reevaluated biannually to take into account scientific progress and emerging issues in the field.

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