

Report to the General Assembly
Workgroup Study on Testing Postmortem Specimens
on Occupational Exposures for First Responders
(HB 1943 of 2019)

Office of the Chief Medical Examiner
Virginia Department of Health

November 2019

Executive Summary

The 2019 House Committee on Health, Welfare and Institutions requested the Virginia Department of Health's Office of the Chief Medical Examiner (OCME) convene a work group to (1) study the Commonwealth's laws governing deemed consent for testing postmortem specimens on occupational exposures for first responders and (2) review and improve the current process for collection and testing of postmortem specimens for such cases. The Chief Medical Examiner and State Project Manager convened the Testing Postmortem Specimens on Occupational Exposure for First Responders Workgroup ("the workgroup") to review the current law and present options to improve the current process for collection and testing of postmortem specimens on occupational exposures for first responders.

There were two general meetings with all known stakeholders and several additional meetings with smaller groups of stakeholders to explore the pertinent problems and possible solutions. The workgroup agreed on the following list of options:

1. Amend the Code of Virginia to extend deemed consent for testing when a first responder has an occupational exposure to any patient whether living or dead.
2. Establish a statewide contract with a single designated laboratory capable of testing postmortem specimens for Human Immunodeficiency Virus, Hepatitis B, and Hepatitis C.
3. Assess and evaluate the need for a state exposure validation and coordination center. The roles of this center would be to validate exposures, provide guidance for specimen collection and testing, referrals for medical management if necessary, document exposures and outcomes including source status, antiviral use, patient outcome and cost, and provide specific training to Designated Infection Control Officers (DICOs).

Introduction

The Chief Medical Examiner and State Project Manager convened the Testing Postmortem Specimens on Occupational Exposure for First Responders Workgroup ("the workgroup") to make recommendations to improve the current process for collection and testing of postmortem specimens on occupational exposures for first responders. The workgroup members met twice to discuss and deliberate on these matters. A list of the workgroup members and organizations represented can be found in Appendix A.

Overview of Issues

The workgroup members identified and thoroughly discussed the below areas that pose issues to obtaining postmortem specimens for testing on occupational exposures for first responders.

1. Validity of an Exposure

Various perceived exposures are reported, but the event may not represent a valid exposure, which requires possible post exposure prophylaxis. For example, a first responder may get blood on the bottom of their shoe at the scene of a motor vehicle accident. This is not a valid exposure. However, a first responder may be exposed to a person's blood during resuscitation efforts either by getting blood in their mouth, eyes or an open wound or getting stuck by a needle, which would be considered a valid exposure.

Furthermore, it varies throughout the agencies and offices in the Commonwealth on who determines the validity of an exposure. Some agencies and offices have Designated Infectious Control Officers (DICO) that can be contacted when an exposure occurs. The DICO can provide input into the exposure and determine the validity and what should happen from there. However, the DICOs have varying levels of training and may not be the best resource in determining validity of exposures for all agencies throughout the Commonwealth. With consistent training, though, they could be a possible resource. Other offices have risk managers or infectious disease specialists that can provide insight into the validity of an exposure.

There is a varying scale on who determines the validity of an exposure and to the decision typically rests with the first responder's agency or office. The workgroup agreed professional guidance should be available for all agencies and offices throughout the Commonwealth regarding occupational exposures for first responders. When a first responder has a perceived exposure, the first responder or their agency/office can gather information regarding the exposure and make the appropriate inquiries in determining the validity of an exposure. Many times the exposure is not valid; therefore, a first responder will not need to take post exposure prophylaxis. Only true occupational exposures will need patient testing and/or post exposure prophylaxis.

2. Obtaining Specimens

The ability to obtain the specimens in an appropriate timeframe or if at all depends on the source of the exposure, whether they are living or deceased. If the source of the exposure is a patient within a facility, the patient can have their blood drawn easily within the facility. The more complicated specimen collection revolves around if the source of the exposure is a person who is not patient but may be in custody or is deceased. A person who is not a patient but may be in custody of law enforcement could be the source of an exposure. For this instance, a court order is required. This current process for obtaining a court order could exceed 48 hours and will still require post exposure prophylaxis for the first responder until a specimen can be collected and tested. Some members of the workgroup expressed that it can even take up to a month to obtain a court order.

If the source of the exposure is deceased, the process is more difficult (from collection to testing). Only 10% of all deaths in Virginia fall under the jurisdiction of the OCME; therefore, 90% are not OCME cases and never come under the jurisdiction of the Medical Examiner. The OCME has a short window in which they have custody of a decedent, which is typically for 24 hours after death. If the decedent is located at an OCME district office, OCME staff can collect the specimen and have it ready for the agency to pick up; however, next of kin permission is still required. The agency or office of the person exposed would have to obtain permission from the decedent's next of kin to collect and test the specimen.

Only half of the cases that fall under the jurisdiction of the OCME go into a district office. If the decedent is an OCME case but not at a district office but in a local funeral home or hospital, the local medical examiner (LME) could draw the specimen if they had the appropriate supplies. However, the LMEs currently do not have the appropriate tubes for blood collection for exposure testing; they collect specimens for toxicology testing to aid in determining the cause and manner of death. Therefore, if the OCME is notified after custody is transferred to a funeral home or crematory, then it is unclear who collects the specimen. Appropriate and timely notification is pertinent and causes issues for obtaining specimens. The OCME needs to be notified of the occupational exposure ideally as the death notification is made to the office, but at least, within 24

hours of death since the OCME should still have custody of the decedent. If the OCME knows that there was an exposure prior to an examination, a specimen can be collected and made available for testing. If the examination is complete, there is a chance that there will not be sufficient specimen for testing and that decedent is no longer in the custody of the OCME. Once the decedent is released to a funeral home, the decedent could potentially be embalmed and no appropriate specimen would be able to be collected for exposure testing.

Furthermore, it is unknown who is allowed and capable of collecting specimens on the 90% of decedents that are not OCME cases. The members of the Workgroup stated that their offices and agencies do not have designated personnel who currently draw postmortem specimens for occupational exposures. OEMS stated that some members within their agency have collected specimens at a funeral homes or hospitals in the past but this is not protocol.

It is unknown whether health care facilities have employees who are capable and willing to collect a specimen if a local medical examiner does not work at the hospital or if the case does not fall within the jurisdiction of the Medical Examiner. It is possible the OCME could provide training for Emergency Medical Service personnel on the collection of specimens on decedents if the OCME is unable to assist. Chiefs of Police throughout the Commonwealth have lists of EMS personnel who are called by law enforcement to collect specimens for Blood Alcohol Collection (BAC) Analysis. These specific individuals have been Operational Medical Director (OMD) approved at each agency as qualified, in the eyes of the courts, to draw laboratory specimens for determination of blood alcohol or toxicology. The training and approval process for these individuals occurs at the individual agency level. There are more than 600 licensed EMS agencies across the Commonwealth and these individual agencies know whom within their agency is capable of providing this service. Unfortunately, no master list of individuals who can perform this role exists throughout the Commonwealth. It is possible that not every licensed EMS agency throughout the Commonwealth provides this service or has trained personnel. These trained individuals could be a resource for collecting postmortem samples on non-OCME cases or cases that are located at a hospital or funeral home.

Tissue organ procurement organizations (OPOs) could be another resource for specimen collection or testing. LifeNet and Washington Regional Transplant Community are the two tissue OPOs most active within the Commonwealth of Virginia. Most OPOs collect specimens and do their own testing. The OPOs must complete testing, which is required by the FDA. If there is an occupational exposure on a decedent who is a donor for one of the tissue OPOs, the test results could be shared with the agency or office of the person who is exposed. The results and data would need to be received within a timely manner to prevent post exposure prophylaxis. Further discussion with tissue OPOs within the Commonwealth of Virginia could be explored as an option.

If a decedent is located at a funeral home and is already embalmed, there will be no blood for testing; therefore, the person who is exposed would have to take a full dose of the post exposure prophylaxis. However, if the decedent is at a funeral home and is not embalmed, the OCME could provide training on collection of specimens for EMS personnel and funeral home service members as stated previously. These cases would have to be identified and the specimens would need to be collected in a timely manner.

3. Permission for Testing for Occupational Exposures Involving Living Patients and Decedents Varies in Code of Virginia

The Code of Virginia pertaining to collecting specimens for occupational exposures varies depending on whether the source of the exposure is living or deceased. According to §32.1-45.1, if the person is alive and a patient, they have deemed to have consented to testing. However, if the person is alive and not a patient, a court order is required. Furthermore, according to §32.1-45.2, if the person is deceased, the custodian of the remains is required to preserve the blood and the agency must request the decedent's next of kin's consent for testing.

The current process for obtaining specimens is complicated and needs additional authorization for testing postmortem specimens, which prolongs the process and could exceed 48 hours, thereby requiring the exposed worker to start post exposure prophylaxis.

4. Laboratory – Testing of Specimens

Laboratory procedures and testing varies for clinical and postmortem specimen testing. There are plenty of methods available for testing for clinical patients; typically testing is completed within their hospital where they were admitted. However, that is not the case for postmortem blood. Once someone dies, the blood starts to breakdown and the testing of postmortem blood is not as “clean”. Laboratories state that postmortem blood wears down their machines. Furthermore, hospitals that used to complete postmortem testing on occupational exposures are no longer providing this service due to liability issues regarding false positives and negatives. Administrative personnel at hospitals are asking if there is a mandate that requires them to complete this testing. It raises liability concerns and there is a cost associated with completing the testing.

Rick Sikon with the Virginia State Anatomical Program (VSAP) explained that the program has postmortem specimen testing completed on all of their donors. He initially reached out to a few hospitals and labs within the Commonwealth of Virginia (VCU, UVA, DCLS, LabCorp); however, none of these labs test postmortem samples. To be able to test postmortem samples, specific equipment is needed for postmortem specimens, testing is needed to validate sample structures and approval by the FDA is also needed. Rick Sikon contacted other donor programs within the United States to see where they have their testing completed. It was determined that there are two existing commercial laboratories within the United States that can perform postmortem specimen testing, which are LabCorp in North Carolina (previously Viomed) and the Mayo Clinic in Minnesota. VSAP uses LabCorp in North Carolina to complete their postmortem specimen testing.

OEMS also stated that they are having a hard time finding a laboratory to complete postmortem specimen testing once they obtain a sample from an occupational exposure. The Division of Consolidated Laboratories (DCLS) does not perform complete postmortem specimen testing.

A single qualified laboratory for prompt testing of postmortem specimens should be available to support all Virginia agencies. This resource could be provided by a laboratory within the Commonwealth, or by a state contract available for agencies to utilize for postmortem specimen testing for occupational exposures.

Options

- 1. Amend the Code of Virginia to specify deemed consent for collection and testing of specimens if a decedent is the source of an exposure**

The existing statute for the collection and testing of specimens for occupational exposures contains varying provisions depending if the source of the exposure is alive or deceased. According to §32.1-45.1, if the person is alive and a patient, they have deemed to have consented to testing. However, if the person is alive but not a patient, a court order is required. According to §32.1-45.2, if the person is deceased, the custodian of the remains is required to preserve the blood and the agency must request the decedent's next of kin consent for testing. The Workgroup agreed that §32.1-45.2 of the Code of Virginia should be amended to specify that there is deemed consent for the collection and testing of specimens of decedents if they are the source of the exposure.

2. Designate a single laboratory resource for postmortem specimen testing

If the source of the exposure is alive, any clinical laboratory can complete the testing and provide the results.

There are few capable laboratories that can complete postmortem testing partially due to the interpretation of test results and licensing required for testing of postmortem specimens. There are two existing commercial laboratories within the United States that can perform postmortem testing, which are LabCorp in North Carolina (formerly Viomed) and the Mayo Clinic in Minnesota. LifeNet or other tissue OPOs could be a possible resource to assist with providing results on occupational exposures. LifeNet has their own testing and research lab in Virginia Beach and is accepted by the FDA.

DCLS is currently not conducting this testing, but DCLS has an existing foundation for testing and a courier system throughout the Commonwealth. Since there seems to be potential for postmortem specimen testing, the Workgroup is recommending a single state source or contract for agencies and offices within the Commonwealth of Virginia to utilize for testing of postmortem specimens for occupational exposures.

The Workgroup discussed the potential for DCLS to start postmortem testing; however, laboratory development for testing, including cost and the risk associated with the testing, will take time and money. Therefore, the Workgroup agreed that DCLS could oversee a state contract with a commercial lab initially to provide this resource to offices and agencies throughout the Commonwealth. DCLS would look into providing resources to develop in-state testing for occupational exposures on postmortem specimens.

3. Further Study Needed for Potential State Exposure Validation and Coordination Center and Reporting Requirements for First Responder Agencies on Occupational Exposures

Further assessment and evaluation will be needed to ensure the validity of an exposure, to collect data and to provide guidance to those offices and agencies that need it. The workgroup discussed the steps that need to take place once there is a perceived exposure, which is illustrated in Appendix C. The person exposed or the agency representing the person exposed will contact the Designated Infection Control Officer (DICO) or their equivalent. The DICO will determine if the exposure is valid. If it is not a valid exposure, the person exposed does not need to proceed with any post exposure prophylaxis (PEP) and no specimen will need to be collected from the source of the exposure.

The DICO or their equivalent plays a crucial role in this entire process because they will determine the validity of an exposure and provide further guidance after that determination. The DICO or

person who is the main source in determining validity of an exposure would require necessary knowledge and specific training. To accomplish this, the workgroup considered recommending the establishment of a State Exposure Validation and Coordination Center (“the center”). However, further assessment and evaluation will be needed in determining the office in charge of the center and the necessary resources that would be needed to provide this service. The roles of this center could be to validate exposures, provide guidance for specimen collection and testing, referrals for medical management if necessary, document exposures and outcomes including source status, antiviral use, patient outcome and cost, and provide specific training to the DICOs.

Such a center would assist the DICOs with validating the exposures. The center would provide specific situational guidance for specimen collection or medical management. If the agency/office who contacted the center has their own resource to retrieve the specimens, they can use it. However, if the agency/office does not have their own resource, the center will provide guidance on specimen collection. Not only will the center be a resource for agencies and offices within the Commonwealth regarding occupational exposures, they will also collect specific data elements that will be pertinent to each exposure. There currently is not a centralized data repository that collects information on occupational exposures throughout the Commonwealth. The Virginia Worker’s Compensation Commission has some data but it is not ideal. Therefore, the center will collect this information, which would include the number of occurrences, number of valid exposures, results and the cost associated with the valid exposures. This center would also provide ongoing training to the DICOs as information changes.

Furthermore, the workgroup suggested that agencies with first responders could report and track costs associated for all occupational exposures to the center. This suggestion is premised on establishment of the center. Agencies could be required to report this information annually. The costs associated with each exposure would include but not be limited to the time loss of the first responder from being away from work, prescription and medical costs, and testing and shipping of specimens.

The cost associated with each exposure may vary. If there is a valid exposure and test results are unknown by 48 hours post exposure, the first responder will start post exposure prophylaxis (PEP). If results are negative, the first responder can stop taking the PEP. However, there are instances where results a full course of PEP would be required, which are (1) the test results are positive so the first responder will need to complete the full course of PEP, (2) the test results are inconclusive due to the condition of the specimen, or (3) no specimen is available for testing. The cost associated with someone taking two days of PEP versus several months of PEP will vary. This information would be tracked by each individual agency and reported to the center.

Appendix A: Members of the Workgroup on Testing Decedent Specimens on Occupational Exposures for First Responders

Briant Atkins
Chief Safety Officer
Virginia Department of Fire Programs

Marilyn Bibbs Freeman
Director of Laboratory Operations
Division of Consolidated Laboratories

Julia Carlton
Division of Legislative Services

Gary Critzer
Chair
State EMS Advisory Board

William T. Gormley, MD, PhD
Chief Medical Examiner
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Virginia Department of Health

Jeremy Kaplan
Human Resource Director
Virginia State Police

George Lindbeck, MD
State Medical Director
Office of Emergency Medical Services

Vanessa Macleod
Office of the Attorney General

Valerie Quick
State EMS Advisory Board

Ron Passmore
Regulation & Compliance Manager
Office of Emergency Medical Services

Lynn Ramsey
Infection Control Officer
Virginia State Police

Michael Reilly
Executive Director
Virginia Department of Fire Programs

Brad Rinehimer
Representing Virginia Association of Chiefs
of Police

Richard Sikon
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Mark Sochor, MD
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Sarah Stanton
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Arkuie Williams
Administrative Deputy
Office of the Chief Medical Examiner
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Appendix B: Stakeholders who Attended Meetings Outside of the Workgroup Meetings

Shameera Carr
Operations Director
Community Health Services
Virginia Department of Health

Karen Owens
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Office of Emergency Medical Services
Virginia Department of Health

Lillian Peake, MD, MPH
State Epidemiologist
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Tim Powell
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Karen Shelton, MD
Health Director
Mount Rogers Health District

Denise Toney, PhD
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Division of Consolidated Laboratories

Melissa Viray, MD
Infectious Disease Specialist
Richmond City Health District

Appendix C: Process to Follow for Occupational Exposures

