Case Report

Quality Assurance Through Standard Operating Procedures Development and Deviation: A Medicolegal Death Investigation Systems Response to the COVID-19 Pandemic

Stacy A. Drake, PhD, MPH, RN, D-ABMDI, AFN-BC[1], Michal Pierce, MS, ASQ CMQ/OE[2], Parmod Gumpeni, MD[2], Eileen Giardino, PhD, RN, APRN[3], and Dwayne A. Wolf, MD, PhD[2]

ABSTRACT

Standard operating procedures drive everyday practice within any organization, including those within a forensic setting. In the event of unusual circumstances, organizations must respond rapidly to address the impact on operations while ensuring that the quality and safety outcomes of routine services are not affected. This case study illustrates how standard operating procedures can be newly developed or modified, and rapidly deployed and quickly revised, to address unusual circumstances. The response to the COVID-19 pandemic is used as an example in this case report.

KEY WORDS:

COVID-19; forensic nursing; medicolegal death investigation; quality assurance; standard operating procedures

Description of Situation

Standard operating procedures (SOPs) are important elements of a rigorous quality management system (Tsim et al., 2002). They ensure effective communication of expectations to employees, result in consistency of work product, reduce errors in day-to-day work, and ultimately assure courts, families, attorneys, and other stakeholders a minimum standard of integrity and reliability. An SOP serves to instruct how, when, and why techniques are implemented and facilitates uniformity of protocol among staff members. SOPs also provide forensic practitioners and other employees with all the necessary safety, health, and operational information to maintain quality and safety within the organization (ISO 9000, n.d.; Pearce, 2018).

The recent emergence of the COVID-19 pandemic brought to the forefront a number of barriers that medicolegal death investigation (MLDI) systems needed to rapidly address. The principal challenge faced by MLDI systems was the potential shortage of personal protective equipment (PPE; World Health Organization, 2020), coupled with an expected increase in reported deaths. These circumstances required proactive changes to workflow to maintain quality and safety. Moreover, the emergence of a novel disease such as COVID-19 required new procedures to examine, diagnose, and autopsy decedents suspected of the disease. The purpose of this case report was to describe how a large MLDI system utilized the quality management system to temporarily change existing SOPs ("SOP deviations") and developed a new SOP to address the emerging and novel disease while ensuring the health and safety of employees.

Case Report Editor: *Dr. Linda Starr, Flinders University, Adelaide, Australia. E-mail: linda.starr@flinders.edu.au.*

Author Affiliations: *[1]Texas A&M University, [2]Harris County Institute of Forensic Sciences, and [3]Rush University.*

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Correspondence: *Stacy A. Drake, PhD, MPH, RN, D-ABMDI, AFN-BC, Texas A&M University, 2121 W. Holcombe Blvd., # 1011A Houston, TX 77030. E-mail: sadrake@tamu.edu.*

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SOPs: Deviation

There are times when an SOP becomes either entirely outdated or simply inapplicable to a subset of cases because of their special circumstances. Upon identifying a difference between what is written in an approved procedure and what is required for current practice, the discrepancy should be rectified using one of the following two options. This first option is to revise the SOP permanently to bring it up to date. The second option is to issue an approved "deviation" from the SOP temporarily. The latter can be used when a change in normal practice applies to a special circumstance either affecting a small number of cases or thought to be short-lived.

As part of pandemic planning and response, each MLDI system is required to plan for the possibility of a large increase in caseload with simultaneous shortfalls of necessary PPE. Early in the COVID-19 pandemic, the Harris County Institute of Forensic Sciences (HCIFS) reviewed existing SOPs with the aim of identifying opportunities to reduce the number of personnel exposed and minimize PPE use while still maintaining adequate safety precautions. Specifically, on a daily basis, we wanted to know if it was possible to reduce the overall number of cases that required autopsy (i.e., a full internal examination) and could the required autopsies be performed using a smaller number of personnel. In summary, the HCIFS identified that the process of case assignment and the criteria for autopsy versus external examination were the two critical elements that could be temporarily modified, while maintaining quality and safety.

In the prepandemic era, the HCIFS followed a system of case assignment that ensured equitable work assignments, while minimizing the daily autopsy workload for individual personnel (i.e., pathologists and autopsy assistants). This process involved assigning the smallest number of cases to the largest number of pathologists available for a given day. However, in the pandemic setting, the assignment process resulted in an unsustainable use of PPE. In response to the concern of increased need for PPE, the decision was made to assign the maximum number of cases to the smallest number of pathologists and autopsy assistants in a given day, with the goal of using less PPE daily.

The second strategy implemented to conserve resources was to decrease the number of autopsies performed. The HCIFS had a long history of specific SOP protocols to determine when a full autopsy or external examination was required. For example, the HCIFS uniformly autopsied trauma scene deaths such as motor vehicle fatalities prepandemic. The threat of depletion of the reserves of PPE raised the question: Can this approach be changed, even temporarily, without significantly affecting the information provided to stakeholders? Consequently, an algorithm was developed from the collective staff expertise to support staff's decision making of when an autopsy or external examination was warranted. Staff considered the types of questions that surviving families as well as criminal and civil court authorities might ask, and after careful consideration, in light of the pandemic situation, staff decided that, on certain case types, the HCIFS could revert to external examination only. For example, a motor vehicle death could receive an external examination where the decedent was a passenger, provided there was evidence of external trauma (consistent with the facts of the crash) and no known evidence of road rage or other intentional elements (e.g., suicide or homicide).

Because changes in procedures were in contrast to the existing SOP that addressed examination type designation, it became necessary to either revise the SOP or issue a formal SOP deviation. An SOP revision is a permanent update to an SOP, based on a perceived change in best practice. An SOP deviation was the appropriate mechanism because of an anticipated temporary change. In other words, the change to the daily case assignment procedure was a response to the pandemic situation (i.e., an effort to conserve dwindling PPE levels), as opposed to a preferred method of operation. A temporary deviation to the existing SOP necessitated approval from management instead of formally revising the SOP (Mohan et al., 2016). Such an action emphasized to staff that the sudden change in procedures was temporary until conditions improved and that management did not, normally, endorse the practice of top-loading assignments on personnel or opting for external examinations in cases where full autopsies are more informative.

A SOP deviation must be documented and communicated to the appropriate personnel. There are a number of critical elements that should be included when documenting a SOP deviation. These elements include the rationale, the scope and details, and the time frame allowed for the deviation (Mohan et al., 2016). The specific format the SOP deviation is communicated in is less important than the critical elements. The HCIFS chose a memo format that included numerous examples of case scenarios. These scenarios had been discussed in person (via electronic real-time conference) with all pathology staff. Opportunities for questions were provided, and final consensus was established before implementation. The final memo was approved by executive management and distributed to all pathology staff.

New SOPs

The process of developing a new SOP should be carried out in a systematic manner (Nakagawa, 2005). First, all SOPs should be controlled through an agency's established document management system. The benefit of a document management system is that it permits a concise record of SOP approvals, activations, distributions, and staff acknowledgments, either manually or electronically. Subsequent revisions to an activated SOP must also be controlled and approved within that system. Second, although a new SOP should be approved by top management, it should be

developed with as much input from the involved personnel as possible. Even if a member of the management team develops the first draft of the SOP, the draft should be disseminated to the affected staff to have opportunity for input. The staff should verify that each step is clearly articulated and analyze for unintended consequences. Once input is solicited, the SOP is reviewed by quality personnel to ensure the required elements are included. Similar to the approval of SOP deviation, the new SOP should be disseminated to affected staff for acknowledgment.

The emergence of a new disease is not, of itself, a requirement to develop a new SOP. The HCIFS, similar to most MLDI systems, have SOPs to address the investigation of natural deaths. Because COVID-19 is a natural disease, the basic elements of the examination should fall within the appropriate SOP addressing natural deaths. However, what prompted the decision to develop a completely new SOP was the addition of ancillary tasks that were specific to the evolving disease.

The COVID-19 pandemic brought with it not only new tasks at the time of autopsy but also a whole array of requirements for external communications with multiple local health departments before and after the examination, the requirement to interface with multiple laboratories, and procedures for how to examine suspected COVID-19 decedents. Although the specifics of each new task are outside the scope of this article, the number of new tasks required the development of a new SOP, explicit to new tasks required for managing suspected COVID-19 deaths.

Evaluation

As with any change in SOP, whether permanent or temporary, it is important to provide adequate instruction on how the changes should be implemented. In addition, continuous evaluation of the change should occur to ensure that quality and safety are maintained during implementation and that the changes do not have a negative impact or unintended consequences on stakeholders.

As part of the Institute for Healthcare Improvement's Model for Improvement, the "Plan-Do-Check-Act" cycle is used to manage and evaluate any change initiative (Langley et al., 2009). Once an SOP is implemented, feedback should be solicited from employees on its practicality and effectiveness, so any necessary additions or modifications to the document can be completed. The COVID-19 pandemic was considered a unique experience in part because the knowledge of the disease and its virology, avenues of testing, and transmissibility (especially from contact with decedents) were all rapidly evolving. Therefore, the new SOP had to evolve along with that knowledge. Rapid cycle review and revisions to the COVID-19 SOP became an almost daily routine for the first few weeks after its initial implementation. A member of the pathology staff was designated to take the lead in assessing, revising, disseminating, and listening to end-user feedback for necessary SOP changes. As the scientific knowledge of this new disease reaches a plateau, the SOP will become a part of the arsenal of SOPs regularly maintained by the HCIFS that will require only an annual review.

Stakeholder Considerations

An initial unintended consequence became rapidly apparent related to the revised SOP addressing case assignment and postmortem examination operations. This predominately included the established involvement the HCIFS has within the academic settings extending to medical students, residents, interns, and nursing and nurse practitioner students, who frequently observe and learn from postmortem examinations. Such involvement prepandemic practice was not necessarily detailed in a formal SOP; rather, it was carried out either because of longstanding tradition or oral agreement with external stakeholders. However, once the pandemic threatened the PPE supply, it was decided to temporarily suspend these training programs to conserve PPE. Because assigning these trainees was never specified in the agency's SOPs, there was no need to include the decision to suspend training in either the SOP deviation memo or the new SOP. Instead, this decision was verbalized to both external stakeholders and staff during a virtual meeting, and ongoing discussions were held to assess the ideal time to resume this critical community engagement activity.

Forensic Nursing Implications

In a pandemic environment, the forensic nurse is at the forefront of events arising, providing both direct clinical care and administrative oversight to forensic organizations. Although this case report serves as an example of how one large medical examiner's office adapted to the rapidly evolving COVID-19 pandemic to ensure quality and safety outcomes, it illustrates the importance of the forensic nurses' role as an integral part of the MLDI systems worldwide (Lynch, 2011). The forensic nurse appreciates the importance of an SOP and often recognizes when quality and safety are jeopardized. This dictates that forensic nurses be involved with SOP development and are empowered to recognize when a current SOP does not meet the needs of current circumstances.

Forensic nurse leaders must have an essential skill set to not only recognize when existing SOPs are not meeting the current need but also be able to initiate an SOP deviation, develop a new SOP, and utilize the Plan-Do-Check-Act process to ensure continuous revision of the SOP. Above all else, the quality of service must be kept in mind when making a significant change to procedures. More specifically, during a state of emergency, any forensic patient, alive or dead, must still

be provided the level of service that satisfies statutory requirements, as well as practice standards, and meets the needs of next of kin, as well as the justice system.

Furthermore, the forensic nurse's role in MLDI within the context of a pandemic may extend beyond that of routine responsibilities. For example, the forensic nurse may be asked to provide the necessary training for those with nonmedical training on how to use infrared thermometers for temperature and symptom screening for employees' return to work. They may be asked to increase their role in case management by ensuring state laboratory values of COVID test results are identified and appropriately linked among decedents' cases.

Conclusion

This case report described an example of a rapidly changing situation, COVID-19 pandemic that necessitated reevaluation of SOPs within a large medical examiner office. Discussion of decisions and factors that determined whether a new SOP should be developed or a revision of an existing SOP or an SOP deviation was highlighted. The focus on SOPs is transferrable to other areas of forensic practice while highlighting the value of adhering to the structure of an established quality management system.

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