Insights into Risk Management

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CSI: Lifespan - S.A.V.E.D By The Evidence

– by Deborah Randall, RN, BSN, CPHRM

Preservation of evidence and litigation hold. Do these processes share anything in common? Are they relevant in the healthcare setting? Do they apply to all staff and providers?

The answer to each question is a resounding yes. To understand why, it is first necessary to understand what each is.

Evidence is that which furnishes proof through witnesses, documents, and concrete or material objects. In the context of a significant clinical event, evidence may include medical records, logs, disposables, equipment, devices and the like. Courts have established that the duty to preserve evidence exists not only during litigation, but when litigation is reasonably anticipated or it is known that evidence may be relevant to an anticipated legal action. A litigation hold is the notice to the involved parties that relevant evidence is to be preserved throughout this continuum.

When a significant event occurs, the first duty is to ensure the safety and wellbeing of the patient. Once the patient has been stabilized or the event has ended, staff and providers must shift focus and consider the physical surroundings in which the event occurred. In essence, they must respond as investigators at a crime scene and take steps to gather materials, whether known or suspected to have contributed to the event or not.

Yet, the most critical period in which to capture the evidence is often overlooked in the aftermath of an event. Whether it is for a lack of understanding or simply a lack of time, preserving all equipment involved in an event, especially disposable devices, the associated packaging, and identifying data is often neglected. In many instances, the suspect device, its related disposables and packaging are altered or discarded before the event is reported or investigated. Device settings may be changed or computer memories erased. The device might be sent for a safety check and even make its way back into service. These actions will hamper an effective investigation, placing patients at risk, as well as potentially compromising the ability to successfully defend a legal case. Further, it can also expose the hospital to a claim of spoliation of evidence in a lawsuit.

Spoliation is the willful or accidental loss, destruction, or unnecessary alteration of items that could become evidence in a civil or criminal suit. Although spoliation may frequently be thought of in terms of physical items, it can also involve information, such as electronic device logs or device settings. Electronic medical devices increasingly incorporate event logs, and it is important for users to be aware of the memory storage capability of the devices. To illustrate spoliation, consider the following:

- A physician alters medical records to cover-up a missed diagnosis.
- A hospital administrator instructs a medical records clerk to dispose of fetal monitor strips that indicate a medical error.
- An IV pump involved in a serious medication error was not identified and sequestered.
- A biopsy slide is lost.
- A medical instrument that was retained in a patient during surgery is discarded after the surgery to remove it.

A case that may have been defensible turns indefensible and the hospital or responsible party may face Court-imposed sanctions, such as expensive fines. For guidance and more information, turn to the special pull-out section, along with two relevant case studies that follow.

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Lifespan

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Preservation of Evidence - Case Study I

The purpose of this section is to share summaries of closed cases that have occurred in the New England area and represent real life issues that provide proactive risk management educational opportunities. The cases used may come from Lifespan affiliates, other institutions or practices, or may be composites of several cases with very similar fact patterns. We present these cases because we believe they have some relevance to situations that you may encounter.

PRESERVING EVIDENCE

ISSUE: **What is the duty to preserve information that could prove helpful in determining the cause of an unanticipated outcome involving patient harm?**

FACTS:

- The patient was intubated & general anesthesia induction begun.
- The anesthesiologist noted difficulty ventilating, reintubated & eventually manually ventilated with a bag mask.
- The anesthesiologist later unplugged the anesthesia machine & sent the breathing circuit to the biomedical department, stating there was a problem with it. It was examined & discarded.
- The event report indicated no problem with the anesthesia machine. Serial numbers were not recorded.
- The machine remained in use for several more months, then was replaced pursuant to a preexisting hospital agreement.

FINDINGS:

A lack of oxygen during the initial attempt to ventilate resulted in cardiac arrest and subsequent brain injury. The patient's family sued the anesthesiologist & hospital for medical negligence.

At trial, the plaintiff established the following:

The anesthesiologist had a duty to →

1) preserve the ventilator monitoring data & settings by not unplugging the machine
2) adhere to policies regarding standard chain of communication
3) provide information that the equipment had been involved in an event resulting in patient harm

These failures resulted in equipment being discarded, as well as not tested appropriately.

The OR staff had a duty to →

1) record identifying information for the ventilator on the event report
2) remove the ventilator from service
3) reinforce the standard chain of communication

These failures resulted in the equipment not being traceable for testing, as well as potentially placing other patients at risk.

The biomedical staff had a duty to →

1) respond to a deviation from standard operations by obtaining further information
2) save the equipment

These failures resulted in incomplete or no testing being performed.

- Whether any of the equipment caused the patient's injury was unable to be determined. The standard of care for preserving evidence was breached, resulting in grounds for imposing sanctions. The jury awarded more than $5 million to the plaintiff, who remained in a persistent vegetative state after being resuscitated.
- The trial judge's ruling was upheld on appeal, as was his jury instruction to infer that if the equipment been preserved & tested, it would have been found to be not operating properly. The high court noted that when a potential for litigation exists, there is a duty to preserve evidence that the potential defendant knows or reasonably should know is relevant to the action.

SUMMARY:

Following an event resulting in harm, equipment involved must be sequestered & not cleaned or tested. Chain-of-custody procedures must be adhered to & Risk Management notified immediately. If the device or equipment stores data electronically, the data must be downloaded in the course of an appropriate investigation by *an individual competent and skilled to perform this task.* In the event of a lawsuit, lost or compromised data could be construed as spoliation of evidence, resulting in court-ordered sanctions.

The Lifespan Loss Prevention Program

Who We Are:

The LRS Loss Prevention Program is a collection of services that take a proactive approach to mitigating risk in Lifespan-affiliated office practice, ambulatory and hospital settings.

The Program's primary focus is on identifying and eliminating threats to patient safety through a set of practices developed in response to past occurrence and claims data.

Who Are Our Customers?

The services offered through the Program are designed to serve the needs of physicians and staff of the entire Lifespan network.

What Services Do We Provide?

∗**Office Practice Risk Consulting and Site Survey**

Real-time risk management services for physician office practices and ambulatory settings, including onsite safety surveys with follow-up recommendations.

∗**The Physician Incentive Program**

A collection of risk focused activities intended to create a financial incentive for indemnified physicians who choose to participate.

∗**Risk Focused CME Presentations***

Educational programs addressing top areas of risk in healthcare, geared to each sub-specialty's specific malpractice threats. *See list on page 4

Meet The Loss Prevention Staff

LRS Loss Prevention Staff: (left to right)

Deb Randall, RN, BSN, CPHRM, Loss Prevention/Underwriting,
Suzanne Duni, JD, RN, BSN, Loss Prevention Program Manager,
Val Till, Executive Assistant (not pictured)

∗**The APOLLO Program**

Confidential and compassionate peer support provided by Lifespan physicians, for Lifespan-affiliated physicians involved in an adverse event, claim or lawsuit.

∗**Grant Programs**

Loss Prevention Grant Program: Offered to physicians and experienced grant recipients, this grant fund provides significant monetary awards for large-scale, multidisciplinary projects that focus on systems improvements such as team communication, patient satisfaction and competency training through simulation.

Risk Management Grant Program: Offered to all staff, this $125,000 grant program provides support for innovative education and research projects designed to reduce liability exposures. These grant projects have resulted in a significant improvement in patient safety, for example, difficult airway intubations, preventing central line infections and improving communication between providers.

RM Grant for Patient Safety in Nursing: Offered to front-line nursing staff, this $25,000 grant program was developed to support innovative ideas by direct caregivers while enhancing nursing professionalism. We are proud that Nursing Grant recipients have been invited to present the results of their successful projects at national professional organization conferences!

∗**Process Improvement**

Through participation on specialty committees, the Loss Prevention staff is able to provide risk management guidance regarding new ventures, policies and processes in a proactive manner, based on an awareness and analysis of past occurrence data.

∗**See our Website:**

For more information about Loss Prevention or the Risk Management Grant Program, please visit our website on the intranet at:

http://www.lifespan.org/centers-and-services/lifespan-risk-services/

Stay tuned for the next issue of Insights in which we introduce you to the staff of Business & Insurance

Device Control - Case Study II

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PRESERVING EVIDENCE

***ISSUE*: What is a nurse's duty to take devices and/or equipment out of circulation after an event leads to patient harm?**

FACTS:

- A 31 year old male patient returned from the O.R. with an order written by for IV Dilaudid to be administered via PCA (Patient Controlled Analgesia) technology. Following hospital policy, the RN taking care of the patient discussed PCA treatment with the patient's family who were at the bedside. The RN determined that the patient was likely opioid naïve and discussed the dosing with the PA and the resident present on the floor. The dosing was adjusted and again, per policy, the RN and her colleague performed a two-RN check when programming the PCA pump.
- The RN did a complete assessment on the patient's respiratory status and completed a sedation scale each hour for the first three hours the patient was on PCA Dilaudid. At shift change, the RN went to the patient's room with the oncoming RN, introduced her to the patient and his family, and did a face-to-face handoff of the patient's care.
- The family left the patient's room to go home for dinner at 6 pm. At that time, the evening shift RN realized she had not assessed the patient, and at 6:22 pm went into the patient's room. She found the patient unresponsive, not breathing, with fixed pupils. A code was called, but efforts to resuscitate failed and the code was discontinued.
- At the end of the code, it was noted that the IV bag containing the Dilaudid was empty.

FINDINGS:

- The patient's family brought a lawsuit against the hospital, alleging wrongful death, failure to monitor and failure to appropriately dose the patient with analgesic.
- The policy of the hospital involved instructed that a patient qualifier was to be determined prior to programming PCA pump settings. It was determined, through testimony of the PA, the resident and the oncoming RN that the day-shift RN correctly programmed the pump according to the patient's status as opioid naïve.
- During the discovery period, it was revealed that the model and series of the PCA pump used in this hospital had subsequently been recalled by the manufacturer for independently bypassing the programmed settings, and infusing boluses, sometimes infusing the entire bag of fluid.
- In this case, the pump was put back into circulation and used on subsequent patients. It was impossible to determine whether the pump was faulty, or whether indeed, the RN had not programmed the pump correctly.
- The case was settled for an undisclosed amount, finding the two day-shift RN's failed to appropriately program the pump, and finding the evening shift nurse failed to appropriately monitor the patient.

SUMMARY:

- All staff have a duty to preserve potential evidence, such as a device used in the care of the patient, anytime it is reasonably anticipated that a claim or suit may arise after an unexpected outcome.

Insights is published by Lifespan's Department of Risk Management. Submissions and ideas are welcome and may be submitted to **Suzanne Duni @ sduni@lifespan.org** or **Deborah Randall @ drandall1@lifespan.org**, or by fax to **401-444-8963.**

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Special Pull-Out Section For Posting

Focus on Preserving Evidence - *S.A.V.E.D.*

WHAT YOU NEED TO KNOW

What is considered a device?

As defined by federal statute: *an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar or related article, including any component, part or accessory.*

Examples include: *a simple tongue depressor to a sophisticated computed tomography scanner; also, specialty beds, catheters, implants, suture material, surgical drapes, wheelchairs & intravenous administration sets.*

What is *S.A.V.E.D.*? ~ *An effective tool to use as a prompt for evidence gathering & preservation following patient injury* ~

Using *S.A.V.E.D.* to preserve evidence in response to an incident includes saving:

***S*ettings: programmed parameters on pumps, ventilators, monitors**

***A*ccessories: non-disposable devices used with equipment such as cable, lead-wires, reusable probes & hand controls**

***V*aluable data and logs: equipment alarm printouts, recording strips or indicators activated during an incident, electronic event logs**

***E*quipment: equipment & initiation of chain-of-evidence documentation: equipment control number, manufacturer, model, serial number, & patient name. Includes chain-of-custody & associated documentation**

***D*isposables and packaging: items normally thrown away such as electrodes, pads, IV tubing and bag & their original packages (if available)**

In the event of patient injury:

Once the patient has been stabilized, **follow *S.A.V.E.D.*** making every attempt to preserve equipment, devices, other materials, electronic information, disposable items, packaging materials & associated serial numbers where applicable. Electronic data logs must be recovered from the equipment's event log.

Timing is critical. Please make these 2 calls immediately.

1st, call Risk Management. The Risk Manager may want to photograph the setting, equipment, & as applicable, the injury, as well as impound materials for further investigation.

If the event involves **medication, blood or blood products or other external agents,** remove items & associated equipment involved from the patient area. Keep in a secure place until retrieved or released by the Risk Manager.

2nd, call Medical Engineering. Specify that the equipment may have been involved in a patient event, and quarantine it & all accessories until Medical Engineering has arrived & assumed custody.

Do not change control settings on devices unless it is necessary to minimize injury at the time the event occurs.

Do not test, clean, send for reprocessing, nor release items to the manufacturer or patient without Risk Management approval.

For additional guidance: Refer to applicable policy & procedure as located in, for example, RIH, TMH, NH, EPBH Administrative Manuals: *Event Reporting, Management and Analysis Policy*, or other administrative or departmental policies.

@ RISK: Lifespan Risk Services Educational Offerings

The Loss Prevention Program provides valuable tools to manage risk through informative one hour presentations on a variety of risk-focused topics. Our team is able to customize a presentation to address risks specifically relevant to your field, work location or sub-specialty.

Programs include, but are not limited to, the following titles:

- **Anatomy of a Lawsuit**
- **Safe Documentation in the Healthcare Workplace**
- **@ Risk: Electronic Documentation**
- **Risk Management Strategies for the Subspecialist**
- **Conducting Meaningful Informed Consent**
- **Social Media, Telemedicine & Electronic Communication with Patients**
- **Risk Management in the Office Setting**
- **Navigating Risk in the Nursing Profession**
- **The Malpractice Claims Process**
- **Smart Strategies for the Consulting Physician**

To schedule a presentation, please contact Valerie Till at 444-4595 or vtill@lifespan.org

Coming This Fall in Insights: What is a Litigation Hold?

Preservation of Evidence. Litigation & Litigation Hold. Metadata. Discovery. Spoliation. Sanction.

What does all the *legal jargon* mean?

What does *S.A.V.E.D.* have to do with *Litigation Hold?*

Why *S.A.V.E.D.* can save more than *preserved evidence*.

Does Lifespan have a Litigation Hold *policy?*

Who is responsible to *initiate* a Litigation Hold?

Who is responsible to *respond* to a Litigation Hold?

***Litigation Hold Explained*:**
These questions & more will be answered in the Fall edition of Insights