EDUCATIONAL COMMENTARY – PATIENT SAFETY

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Learning Objectives

On completion of this exercise, the participant should be able to

- understand where the commitment to patient safety originated;
- discuss ways of preventing harm to the patient;
- recognize the organizations that have put forth initiatives and provide resources to help prevent patient harm; and
- identify where there is potential for harm in laboratory processes.

Today, patient safety is discussed in popular media and all areas and disciplines of health care. But what does it mean to practice patient safety? The commitment to patient safety is a core value expressed in the Hippocratic Oath, written in the 5th century BCE and sworn by physicians today. The most widely recognized tenet of the Hippocratic Oath is “First, do no harm.” The original Greek translates as “With regard to healing the sick, I will devise and order for them the best diet, according to my judgment and means; and I will take care that they suffer no hurt or damage.”

Concern for patient suffering and harm has increasingly been in the forefront of professional and popular discourse about medicine since the early 1980s. However, not until 1999 when the Institute of Medicine (IOM) published the report *To Err is Human: Building a Safer Health System* did the health care community and later the public realize the extent of preventable harm suffered by the people in the care of the medical profession. The IOM report stated that health care itself harmed 48,000 to 98,000 people each year. Since the IOM report, many research articles have concluded that health care practices are insufficiently safe and that provider errors are partially responsible. The harm suffered by patients ranges from no injury to death. Unsafe practices in health care contribute to morbidity and mortality. In addition, they add to the long-term care burden and cost.

Health Care Industry Efforts

Many organizations have accepted the challenge and have developed plans or guidelines to improve health care and decrease the risk for harm to patients. Hospitals accredited by one of the organizations that have been granted deemed status by CMS are considered to be in compliance with CMS and therefore eligible for Medicare/Medicaid payments. The need for compliance in order to receive
payments for services rendered is only one of the factors that has driven an increased focus on patient safety. Moving from a fee-for-service environment to a value-based-purchasing environment has shifted the focus from not just doing the right thing, but to auditing, measuring, and reporting the outcomes of doing the right thing. Four hospital-accrediting organizations that have deemed status from the Centers for Medicare Medicaid Services (CMS) have been key drivers of patient safety initiatives, as have other related organizations. Having deemed status from CMS indicates that the hospitals accredited by these organizations have met and are in compliance with CMS standards. The Healthcare Facilities Accreditation Program (HFAP) follows the criteria of the National Quality Forum in their patient safety initiatives and work. Det Norske Veritas (DNV) supports individual hospitals in developing patient safety initiatives for their own institutions and is based on ISO 9001 standards. The Center for Improvement in Healthcare Quality (CIHQ) improves and supports patient safety through their accreditation process, education, and other measures.

The Joint Commission (TJC) has also done a great deal to define safe patient practices. TJC’s National Patient Safety Goals (NPSGs) were developed as a living tool to focus on activities that ensure patient safety. The NPSGs were developed from confidential reports on sentinel events (defined as “unexpected occurrence[s] involving death or serious physical or psychological injury, or the risk thereof”), research on risk data, and other sources about forms of patient harm. The goals “focus on problems in health care safety and how to solve them.” These goals evolve over the years. As one goal is successful in effecting change and is retired, another takes its place. There are 15 specific goals for 2015.

The Agency for Healthcare Research and Quality (AHRQ) recommends the use of tools in health care that are developed through research/best practices, and evidence-based practices. These evidence-based recommendations focus on improvement of clinical practice in areas such as preventing health care–associated infections and reducing the risk for surgical site infections and central line–associated bloodstream infections. As well, AHRQ provides resources for patients, including 20 Tips to Help Prevent Medical Errors and Five Steps to Safer Health Care.

Table 1 summarizes the patient safety initiatives of a few health care organizations. The reader is encouraged to research each organization for in-depth information and details on safety initiatives. Aside from those mentioned in the table, other health organizations and laboratory accreditation organizations have patient safety initiatives to improve patient outcomes. Organizations such as the College of American Pathologists (CAP), COLA, and CMS have standards for performance and quality assurance that relate to patient safety.
Table 1 – Health Care Industry Safety Initiatives

<table>
<thead>
<tr>
<th>Organization</th>
<th>Type of Organization</th>
<th>Safety Initiative</th>
<th>Expectation</th>
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<tbody>
<tr>
<td>The Joint Commission (TJC)</td>
<td>Accreditation</td>
<td>National Patient Safety Goals</td>
<td>Decrease events that contribute to errors</td>
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<tr>
<td>Healthcare Facilities Accreditation Program (HFAP)</td>
<td>Accreditation</td>
<td>Person-centered care, safety culture, improve health care by analyzing risks</td>
<td>Establish standards, reduce variation, change culture to include safety, manage risk by proactive and predictive measures</td>
</tr>
<tr>
<td>Det Norske Veritas (DNV)</td>
<td>Accreditation</td>
<td>Safety culture</td>
<td>In a safety culture, the health care provider considers the patient safety implications when carrying out tasks</td>
</tr>
<tr>
<td>Center for Improvement in Healthcare Quality (CIHQ)</td>
<td>Accreditation</td>
<td>Standards</td>
<td>Establish standards, educate, and advise accredited institutions in delivering safe and high-quality care</td>
</tr>
<tr>
<td>Agency for Healthcare Research and Quality (AHRQ)</td>
<td>Research (part of US Department of Health and Human Services)</td>
<td>Develop measurement tools, surveys, report and recommend solutions</td>
<td>Recommend process improvement derived through research</td>
</tr>
<tr>
<td>Centers for Medicare &amp; Medicaid Services (CMS)</td>
<td>Federal agency</td>
<td>Conditions of participation</td>
<td>Base participation on compliance with 3 measures integrated into the accreditation process that the 4 deemed agencies establish.</td>
</tr>
<tr>
<td>National Quality Forum (NQF)</td>
<td>Research-based forum that brings members together and to endorse evidence-based best practices.</td>
<td>Patient-centered care based on defined measures</td>
<td>16 Measures, which include catheter-associated urinary tract infection, sepsis, anticoagulant safety, radiation dose in CT scans.</td>
</tr>
<tr>
<td>World Health Organization (WHO)</td>
<td>Directing and coordinating authority for health within the United Nations system</td>
<td>13 Action areas that include clinical best practices, education, classification of patient safety issues (for tracking), clean care (hand hygiene), safe surgery</td>
<td>Worldwide improvement in patient safety by coordinating and disseminating programs that promote improvements in systemic and technical aspects of care.</td>
</tr>
</tbody>
</table>

Many initiatives and measures related to patient safety and outcomes focus on improvements in clinical practice. The NPSGs are written globally to apply to any procedure, test, consultation, medication, or anything that impacts the patient. Surgery is often used as an example to demonstrate patient harm and patient safety measures, but the laboratory can just as easily be used. Among the many patient safety
initiatives from many organizations, are there specific initiatives that laboratory services need to adhere to? The answer is yes, even if the initiatives are general.

Laboratory Measures
System or process factors, environmental factors, and human factors affect the delivery of health care. Process factors that may affect each step of a patient’s diagnosis and treatment include treatment procedures, equipment used, coordination of patient care between care providers, and many more. Environmental factors that can affect care include layout of the facility, functionality of the building (working equipment, air flow, temperature, water), and even location. If the patient needs specialized care and there are no facilities in the vicinity, treatment may be delayed or forgone completely. Examples of human factors that affect the quality of laboratory results are communication in the laboratory, ensuring that reagents and supplies are viable, that storage of laboratory supplies is appropriate (e.g., blood products stored at 2 to 6°C), and that equipment is properly maintained. Two key precautions that are common to all of the guidelines are proper patient identification and hand hygiene. Both of these are critical to laboratory services and are deeply embedded in our daily functions.

Patient Identification
For the laboratory, the total testing process begins when the practitioner orders the test. As with any process or test, it starts with getting the right specimen. Proper patient identification is the first step in procuring the right specimen. The Joint Commission requires that two identifiers be used when identifying the patient. There are many tools for ensuring proper patient identification, but currently, barcoded patient ID bands have had the highest success rate.

In the transfusion service, there is no room for error in patient identification. The specimen has to be linked to the right patient all the time, otherwise serious consequences can follow, including death of the patient. Bar coded armbands and electronic nursing records have improved our ability to track both patients and blood products. In addition to testing specimens to match the correct blood product to the correct patient, the final disposition of the blood product must be documented. This is required for traceability: ultimately, where did the unit end up, transfused or discarded? Should there be a need in the future to contact the recipient, the documentation must be available and 100% correct.

When the laboratory receives a test requisition, entering the requisition into the laboratory information system (LIS) correctly is critical. The LIS database in large health delivery systems may have records of thousands, if not millions, of people. The likelihood of a similar or identical patient name is high, and a secondary unique identifier is needed. This should sound familiar since each action that touches a patient requires two patient identifiers. The identifiers used may vary, based on the action, location, and access to technology. Again, proper identification of the patient and the order is essential.
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The end of the total testing process is notifying the practitioner of the laboratory results. If the patient was not identified properly, the results may not be reported to the right person and care may be delayed. If this type of error is not caught by the practitioner, the wrong patient may be treated or given the wrong information, which can lead to serious harm. Aside from delaying patient care, reporting the results to the wrong practitioner is a violation of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA protects certain protected health information (PHI) in any communication setting. However, HIPAA is another commentary in itself!

Another laboratory activity that may cause harm is the manual manipulation part of testing. Any manual process, be it labeling, transfer of specimens, testing media, transcription of results, reporting of results, etc., introduces the potential for human error. For example, if there is a mix-up of patient identifiers on microbiology culture plates the consequences may be detrimental. The identified pathogen will be reported to the wrong provider(s), with consequences for all patients involved.

These examples of laboratory testing and reporting emphasize the role of patient identification as a key component of patient safety. If the patient information is entered incorrectly at any step along the way, the final report may be incorrect. The outcome from the incorrect result or information may cause harm not just physically, but emotionally and mentally, financially and socially. Laboratory reporting errors have wide-ranging ramifications.

Hand Hygiene

Hand hygiene, TJC’s NPSG (07.01.01), is another patient safety initiative that involves the laboratory. Everywhere you look, whether in a health care setting or public area, there are reminders about hand hygiene. Reminders to food handlers to wash their hands are visible in every restaurant and other places where food is prepared. The purpose of hand hygiene is to prevent infection, to ensure public health and safety. There are constant reminders in the media about “super bugs” like C diff (Clostridium difficile), CRE (carbapenem-resistant Enterobacteriaceae), VRE (vancomycin-resistant Enterococcus), and MRSA (methicillin-resistant Staphylococcus aureus). One way to help prevent infections in the hospital setting is to require proper hand hygiene.

Phlebotomists are the laboratory staff who have the most contact with patients. Proper hand hygiene requires that hands be washed prior to donning and again after removal of gloves. The goal is to prevent transmission of infection from one patient to another. Hospital-acquired (or nosocomial) infections are on the rise and have been linked to improper sanitizing of hands by care providers. Phlebotomists must do their part to decrease this risk and thereby harm to the patient. Phlebotomists represent the ‘face of the lab’ to most patients. It is important that they not only follow hygiene guidelines, but that they do so in a manner that is clear and transparent to the patient. This is one area where it is just as important for the patient to observe the action as it is for the phlebotomist to perform the action.
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**Turnaround Time**

Timely treatment of patients also has the potential to decrease harm. The turnaround time of laboratory tests is critical in many circumstances where the practitioner needs vital test results to determine the best treatment option. A delay in turnaround may cause serious harm, immediate or in the future. An example of the need for timely test results is the timely treatment of nonhemorrhagic, ischemic stroke. A number of agencies involved in patient safety, including CMS, TJC, and HFAP, have put forth stroke initiatives that are very similar. Ischemic strokes are caused by a clot, which is reversible when treatment is initiated within a certain window of time. Clinical research has established that treatment to remove the clot should be initiated within 3 hours of the ischemic attack. But before treatment is initiated, critical laboratory tests must be performed to check for possible bleeding disorders. Also, a CT scan or MRI of the brain must be performed to ensure there is no bleeding in the brain. Once those tests are cleared and the patient is determined to be a candidate for clot removal treatment, tPA (tissue plasminogen activator) is given.

One key component of the stroke initiatives is the timeliness of laboratory test results; a turnaround time of less than 45 minutes is mandated by most agencies. A delay in lab results may impact the 3-hour window for initiating tPA treatment. Accuracy of results is crucial as well. Successful tPA treatment dissolves the clot, decreasing and potentially resolving the effects of the stroke for better patient outcomes. The risk inherent in tPA treatment is the potential for hemorrhage in the brain that exacerbates the stroke.

As can be surmised, the laboratory, although not directly providing patient care, is a player in patient safety. In patient identification for specimen collection to testing processes, hand hygiene when contacting patients, or timeliness in reporting results, the laboratory can either help properly care for the patient or it can cause potential harm to the patient.

**Conclusion**

Safe patient care that does not expose patients to additional risk of harm is an ambitious goal. This commentary touches on just a few of the more obvious laboratory processes that impact patient safety. With the vast amount of data collected and generated by laboratories, they are in a unique position to contribute to the assessment of patient safety measures. When reviewing the, core measures, or other organization safety goals, be sure to evaluate each one for a link to the laboratory. Readers who are motivated to assess their own institutions for patient safety initiatives will find many more practices that ensure patient safety.
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References

1. Healthcare Facilities Accreditation Program: www.hfap.org

2. The Joint Commission: www.jointcommission.org


4. Center for Improvement in Healthcare Quality: https://www.cihq.org


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