Partnership Update
May 2019

Data Snapshot: Ensuring Correct Informed Consent for Surgical Procedures

Background

In addition to ethical and legal considerations, ensuring the capture and accuracy of informed consent prior to a surgical procedure and ensuring that the informed consent matches the scheduled procedure is paramount to ensuring patient safety. Wrong-patient, wrong-procedure, and wrong-site surgeries were the second most frequently reported sentinel events from 2014 to mid-2017 by the Joint Commission.\(^1\) The most effective way to avoid wrong-patient, wrong-procedure, or wrong-site surgeries is human verification of the consent form; it is more effective than a formal time-out in the operating room (OR).\(^2\) Centers for Medicare and Medicaid Services requires written informed consent in a patient's medical record prior to a surgical procedure.\(^3\) Healthcare organizations typically require that informed consent is verified against the scheduled procedure at multiple points along the continuum of care, including before transportation of the patient to the preoperative holding area, holding of the patient in the preoperative area, and before the procedure begins in the OR.

Despite this awareness, patient safety events involving missing or incorrect informed consent, or mismatched informed consent against the scheduled procedure, continue to occur. The case study below was submitted to ECRI Institute PSO for the purposes of sharing lessons learned and illustrates one such example.

Case Study Event

In the OR, a patient undergoing a surgical procedure was found to have signed a paper consent form for a procedure that differed from the procedure scheduled in the electronic health record (EHR) OR management system. The discrepancy was not caught while the patient was in preoperative holding prior to the surgery. Once the discrepancy of procedures between the consent form and what was listed in the OR management system was discovered, it was determined that the paper consent form indicated the correct procedure and the management system listed the wrong procedure. There was a delay in care.

Contributing Factors

To schedule a surgical procedure, an authorized individual enters the procedure into the OR scheduling system on behalf of the requesting surgeon. It is selected from a list of surgical procedures in the scheduling system, typically as a current procedural terminology code (CPT), each of which contains accompanying information that has downstream effects, such as the time estimate for the procedure for room scheduling purposes, and a materials list for stocking the OR with the necessary supplies prior to the procedure. On the day of the surgical procedure, the scheduling system displays critical information about the status of each patient's whereabouts, the surgical procedure to be performed, the involved surgical staff, and the status of the surgical procedure on a series of screens in the preoperative holding area, OR areas, and the postanesthesia care unit. Increasingly, these patient status boards are displaying a column for verification of informed consent.

In the case study above, the OR status board may not have had a column indicating verification of informed consent against the scheduled procedure. If the process for manual verification was performed outside of the system, there may have been gaps in the workflow, inadequate training on organizational policies, or miscommunication. The informed
consent was also in paper form, not within the EHR, where it could have contributed to the generation of an alert to staff that there was a mismatch.

Lessons Learned

A continual goal of utilizing health information technology (IT) for improving patient safety is to design safer systems and policies to reduce the likelihood of medical error. In the case discussed above, the OR in which this event occurred would have benefited from an improved EHR OR management system that could have verified the informed consent for this patient against the scheduled procedure, displayed this information clearly, and done so with an electronic version of informed consent contained within the patient’s EHR.

Preoperative tracking display boards should be in a convenient location and convey critical patient information in an easy-to-read format. Columns displaying the capture, verification, accuracy, and the consistency of informed consent with the scheduled procedure should be visible. If possible, there should be an alert generated for missing information, discrepancies, and if a staff member needs to take action.4

Consent forms are increasingly being stored in an electronic format with EHRs. They are not only scanned into the EHR, but generated, searchable, and actionable within the EHR. Discreet values within a structured query language database, such as the consent type (e.g., procedure), dates (e.g., created or signed), consent status (e.g., complete with all signatures), or procedure name, can contribute to generation of alerts due to mismatches. If possible, organizations should adopt and utilize such capabilities.

Conclusion

Using health IT to increase the assurance of captured and accurate informed consent that matches a scheduled surgical procedure will help reduce wrong-patient, wrong-procedure, and wrong-site events. This enhances patient safety, ensures patient autonomy, and enhances clinical efficiency.

References

Registration Open for 2019 Annual In-Person Meeting

Join us on September 12, 2019, at The Inn at Villanova for our annual meeting, Taking Action: Making Health IT Safety a Reality, to collaborate to improve and optimize health IT to assure patient safety. This meeting is an opportunity to:

- Prioritize health-IT-related issues and opportunities
- Gain knowledge from industry thought leaders
- Learn from the work the Partnership has completed through the year
- Identify new ways to achieve health IT safety

For more information and to register, click here.

Quarterly Meetings

The Quarterly Meeting held April 23rd is now available here on the Partnership website. The next Quarterly Meeting will be held on July 23rd, 2019.

Partnership News

Update: Closing the Loop Implementation Workgroup

The Closing the Loop on Testing Result Tracking Implementation Workgroup held its second meeting on May 14th. The workgroup is aimed at helping ambulatory clinics improve their test result tracking process by identifying each clinic's process; potential gaps in the process; and opportunities for implementing safe practice recommendations to better close the loop. The meeting on May 14th focused on how to map and analyze the clinics' test result tracking processes for opportunities for improvement. Future meetings will focus on implementing specific safe practice recommendations and monitoring for success. We look forward to sharing updates as the workgroup progresses.

Update: Prototype Project Workgroup

The prototype project is underway. Several participants have been recruited. The goal is to determine the best way for gathering information for prioritizing safety events and for sharing lessons learned. The project is using a measure endorsed by the National Quality Forum; the retract-and-reorder measure developed by Dr. Jason Adelman and his team of researchers. With the help of the EHR vendors, the implementation of the algorithm has gone smoothly. Most of the participating sites are going through the institutional review board process and have installed, tested, and verified the retract-and-reorder query. Using unique anonymous credentials, information and data will be submitted soon.

We Want to Hear from You

Not only is it important to develop safe practices, it is important to implement them. To assess and measure their effectiveness, we need your help in learning how these practices have enhanced safety within your organization.
If your organization has implemented any of the Partnership's health IT safe practice recommendations, we would like to hear from you. What has your experience been? Have you been successful? Did you have difficulty implementing these practices? How did you measure the outcomes? Start the conversation by emailing your responses and questions to hit@ecri.org.

Collaborating Organizations

The Partnership for Health IT Patient Safety is sponsored through funding from the Gordon and Betty Moore Foundation.

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