Potential Hazards of Clock Synchronization Errors

Erin Sparnon, MEng
Senior Patient Safety Analyst
Pennsylvania Patient Safety Authority

Clinical integration is intended to reduce errors by seamlessly porting information to and from diagnostic or therapeutic devices, ancillary information systems such as for laboratory and radiology departments, and electronic medical record (EMR) systems. However, this information transfer can raise new risks if there is disagreement between the clocks of medical devices, hospital systems, and watches or devices owned by clinicians and patients. Julian Goldman, MD, of Partners Healthcare presented original research to a National Science Foundation Cyber-Physical Systems symposium at the University of Pennsylvania in January 2012[1] that showed an average clock error of 24 minutes among 1,700 surveyed medical devices. Prompted by media reports related to this research, a reporter from the *Gray Sheet* contacted the Pennsylvania Patient Safety Authority in search of further information on clock synchronization issues for a recently published article.[2]

Authority analysts queried the Authority's Pennsylvania Patient Safety Reporting System database. Analysts searched for terms in the report narratives related to "synchronization" (and derivation thereof) or "internal clock." The time scope of the query ranged from the reporting program's inception in July 2004 through May 2012 and returned six reports. Upon reviewing of the reports, analysts determined that three were relevant to clock synchronization issues:

> An eight-minute difference [was noted] between the Epic [sic] computer and the cardiac monitor. This shows a delay in care where there is a patient issue (i.e., pain medications, blood pressure medications). (Accurate blood pressure does not correlate with time issue occurred.) Monitors and computers need to be synchronized. The patient was not harmed. System will be corrected immediately per [information technology department].

> Found out the clocks in the ICU [intensive care unit] and the lab are not synchronized, so [there were] two specimens for ionized calcium sent today that timed out before the test could be run. On the phone with lab personnel, I had them remain on the line as I drew the third specimen, marked the time on the tube that coincided with the lab clock, and received results for that specimen. This patient is critical and on ICU replacement therapy, so results are essential to provide effective treatment. We received results after third specimen was sent. [Lab staff state that] lab uses time displayed on [computers] as standard. Ionized calcium must be tested within 10 minutes of collection. Specimens received in lab after 10 minutes need to be re-collected for accurate results.

> [There was a] discrepancy [in] birth time due to unsynchronized time of clock on wall and time on fetal monitor.

The first report, regarding a time gap between a cardiac monitor and an EMR, is especially troubling due to the resulting discrepancy between patient care as recorded by caregivers in the EMR (i.e., delivery of pain and blood pressure medication) and patient status as automatically sent to the EMR by the cardiac monitor (e.g., blood pressure). For many short-acting vasoactive medications, caregivers need to titrate the medication to result, which means that they will administer the medication and assess the patient's physiologic response. If the monitor and EMR are not synchronized, two situations could occur:

1. A caregiver may use the EMR as a source of valid information for physiologic status, receive misleading information about a patient's condition, and give inappropriate therapy. For example, a caregiver may see an alert for low blood pressure, give a vasopressor, see another reading indicating the blood pressure is still low (because the monitor clock is eight minutes behind), think the blood pressure is still low, and give more vasopressor, resulting in high blood pressure,

which would not become apparent for another eight minutes.

2. A caregiver may notice the time discrepancy and use the cardiac monitor as the source of valid information for patient status, recording their actions in the EMR as they treat the patient. The EMR would then (incorrectly) show a delay in care between device-reported status and caregiver-reported actions, and the caregiver could face questions as to the reasons for delayed care.

Clock synchronization issues can pose hazards to both patients and staff, and the increasing integration of medical devices and information systems suggests that there may be significant growth in the frequency and severity of this issue. Authority analysts also noted that clock synchronization issues do not fit neatly into the Authority's event classification system, and narrative reports of these issues may not share the key terms used in the query. Therefore, the three relevant reports identified in this query may only represent a small portion of the actual clock synchronization events experienced in Pennsylvania hospitals.

Clock synchronization strategies may help reduce time discrepancies. As more medical devices connect to hospitals' wired or wireless networks, the use of Network Time Protocol (NTP) is an increasingly practical method of achieving clock synchronization. NTP is an Internet protocol used to synchronize computer clocks to the official standard for current time, Coordinated Universal Time (UTC).[3] Computers and servers typically set their clocks based on an incoming NTP signal from the networks to which they are connected, and networkable medical devices are increasingly able to accept an incoming NTP signal as well. If medical devices can accept the same NTP feed as the computers and information systems in a facility, time discrepancies should be minimized.

NTP is already used to provide clock synchronization of EMR systems, as noted in recent policy decisions. On August 23, 2012, the United States Department of Health and Human Services (HHS) released its meaningful use stage 2 requirements.[4] In this final rule, HHS requires that EMR and electronic health record systems use an NTP feed to stamp incoming data (whether entered manually or through integration):

> (g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC [request for comments] 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).

This ruling may spur adoption of NTP capabilities in networked medical devices as facilities look to comply with meaningful use requirements.

NOTES

1. Goldman JM. Medical device interoperability ecosystem updates: device clock time, value proposition, and the FDA regulatory pathway. Presented at: NSF CPS Large Site Visit PRECISE Center at Penn; 2012 Jan 31; Philadelphia. Presentation slides available at http://rtg.cis.upenn.edu/MDCPS/SiteVisit/MD%20CPS%20Meeting%20Goldman%20Jan%2031%202012.pdf.

2. Tahir D. Lack of device clock synchronization vexes physicians, hospitals. *Gray Sheet* 2012 Jul 2;38(27). Also available at http://www.elsevierbi.com/publications/the-gray-sheet/38/27/lack-of-device-clock-synchronization-vexes-physicians-hospitals.

3. The NTP Public Services Project [website]. Last modified 2011 Apr 4 [cited 2012 Aug 10]. http://support.ntp.org/bin/view/Main/WebHome.

4. US Department of Health and Human Services. Health information technology: standards, implementation specifications, and certification criteria for electronic health record technology, 2014 edition; revisions to the permanent certification program for health information technology (final rule to be codified at 45 CFR pt. 170) [online]. http://www.ofr.gov/OFRUpload/OFRData/2012-20982_PI.pdf.

PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

An Independent Agency of the Commonwealth of Pennsylvania

The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the Pennsylvania Patient Safety Authority, see the Authority's website at http://www.patientsafetyauthority.org.

ECRI Institute
The Discipline of Science. The Integrity of Independence.

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for more than 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures and drug technology.

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a nonpunitive approach and systems-based solutions.

Scan this code with your mobile device's QR reader to subscribe to receive the Advisory for free.