© Copyright AAMI 2014. Single user license only. Copying, networking, and distribution prohibited.

HTM NEWS & VIEWS

'No Problem Found' Service Calls—Keep Digging

Alan Lipschultz

About the Author

Alan Lipschultz, CCE, PE, CSP, is president of HealthCare Technology Consulting LLC in North Bethesda, MD. E-mail: alan@hctc.pro

No problem found (NPF), also known as "could not replicate problem" service calls often are problematic in healthcare technology management (HTM). For the purposes of this article, I am considering in-house service organizations, manufacturer field service personnel, and third-party service organizations as HTM groups. My goal is to sensitize members of HTM groups to realize that they have a responsibility to keep digging for the true problem(s) and cause(s) without taking the easy way out by simply saying NPF. In this article, I will first deal with generalities, give some examples to illustrate the real world, and summarize what should be the takeaway.

NPF is frequently assumed to be associated with user error; but, in reality, the situation is usually much more complicated. Any given NPF call may really be an intermittent problem (IP), involve an inadequate problem description, involve poor communication between the clinician reporting the problem and HTM, or entail some combination of these factors. Even if user error (preferably "use error") is suspected to be a cause, the real root cause often is inadequate human factors consideration in the design, or inadequate user training. Use error is a whole other subject—for more information, I highly recommend AAMI TIR50:2014, *Postmarket surveillance of use error management*.[1]

Many of the issues associated with NPF service calls also involve clinical education and/or risk management and/or patient safety issues. HTM groups in hospitals must have a strong working relationship with clinical educators, the risk management team, and those working on overall patient safety in the healthcare facility. The HTM team should be routinely collaborating with these groups in order to identify the real root cause of problems.

I find that simply telling the original problem reporter that HTM staff was unable to reproduce the problem often leads to additional clues.

When a clinician identifies a problem while using a medical device, a "resolution" of NPF does little to resolve the clinical problem when it reoccurs. I find that simply telling the original problem reporter that HTM staff was unable to reproduce the problem often leads to additional clues. My experience, particularly when working through nursing NPF issues, is to involve the clinical educators early; they know how users are "supposed" to use the devices and recognize other factors that HTM personnel normally is unaware of, such as a change in disposables or change in practice.

It is not uncommon for HTM staff to receive problem reports indirectly (for instance, the nurse to a unit clerk). Whenever

© Copyright AAMI 2014. Single user license only. Copying, networking, and distribution prohibited.

the person who had the problem tells someone else who writes up the problem, something is likely to be lost in translation. In addition, the clinician who experienced the problem may not know what details to include in the problem description to enable HTM to reproduce the problem. In the absence of an adequate problem description, HTM may be looking and testing in the wrong places. When communicating with the person who really experienced the problem, you will be able to ask follow-up questions to make sure that you clearly understand the symptoms observed. If these questions don't help replicate the reported problem, consider asking the problem reporter to show you exactly what they were doing at the time the problem occurred.

Medical devices are rarely used in isolation. Often they depend on accessories or disposables (for example, patient cables or IV tubing), and work in conjunction or proximity to other medical devices. The problem may manifest itself to the clinician on the medical device, while the real problem is elsewhere. As more and more medical devices become interconnected, the "real" problem device may not even be in close proximity. In searching for the solution to a NPF issue, expand your horizons; you will never find the real problem if looking in the wrong place.

Intermittent Problems

Even when the "real" problem is indeed in the medical device, HTM may be dealing with an intermittent problem (IP); often the most difficult type of problem to troubleshoot. I included IP in this NPF discussion because it may not be until after the second (or more) occurrence of the reported problem that HTM recognizes that they are dealing with an IP. If the technician working on the repair was unable to replicate the problem, despite all efforts, the assumption should be that it is likely IP.

I postulate that IPs come in at least three varieties that may overlap: 1) IP within one physical device; 2) IP within one group of physical devices, but showing up intermittently among different members of the same group (usually the same manufacturer/model); and 3) an IP that is transient and self-corrects with no apparent intervention. IP within one physical device may be caused by heat issues, but may also be caused by some characteristic that makes that device "different" from others of the same type (e.g., software version, features of the device that are not commonly used, practice variations). An IP should be suspected for a NPF if an experienced user gave a good description of the problem, especially if the user saw the problem and saw the problem resolve itself. Often intermittent problems are difficult to replicate and resolve themselves. HTM should consider the consequences of recurrence if they are unable to replicate and resolve the problem. The device manufacturer is likely to be a valuable resource, as they may have dealt with a similar problem.

As more and more medical devices become interconnected, the "real" problem device may not even be in close proximity. In searching for the solution to a NPF issue, expand your horizons; you will never find the real problem if looking in the wrong place.

When trying to solve an IP, a common strategy is to replace the portion of the device that is likely to have caused the symptoms reported. Nobody will know for sure that strategy worked until some time has passed without recurrence. HTM groups need to ensure that parts replaced under these circumstances do not end up back in the general parts pool or else the original problem may "migrate" to another device.

What Has Changed?

When searching for the cause of an NPF, a key question to be asked is "what has changed in the environment?" It may be that the problem being reported is the first problem report following a software upgrade, or a disposable problem, or a host of other factors. In my career, I can recall many times when some change in the clinical environment had unintended consequences that resulted in an HTM service call because the symptoms showed up on the medical device. If a new major system has just gone online, the connection often is obvious because everyone knows of the change; oftentimes

© Copyright AAMI 2014. Single user license only. Copying, networking, and distribution prohibited.

the change may not always be known to the parties directly involved. If you are the person trying to solve an NPF and are not aware of another change, you cannot connect the dots.

Documentation

Good documentation of an NPF (and IP) event is critical to enable others on the team to discern a pattern in the future.

If a recurrence of the NPF problem involves significant patient risk, HTM must share decision making responsibility regarding the NPF with their management chain, plus responsible clinician manager, plus risk management and/or patient safety. The collective group decision may be to return the suspect medical device to the manufacturer for analysis. Simply making others aware of the NPF may reveal that similar events have happened in the past, and/or enable staff to connect other events and to look for patterns. Sometimes when focusing a spotlight on one NPF (or IP), other staff members may suddenly remember prior events where they did not report the problem to HTM; either because they thought the symptoms pointed in a different direction, or the symptoms were transient, or they assumed that they had done something wrong.

If HTM personnel spend some additional time in the beginning to find the root cause, they may save future time and aggravation for both clinicians and HTM staff; they may also improve the patient and visitor experience.

Even if it appears that no patient risk is involved based on the problem description, good documentation will help eventually solve the real problem if similar reports surface in the future. Given that most HTM teams are resource challenged, there is a temptation for HTM to close an open work order with NPF when they can't replicate the problem and the device checks out. If HTM personnel spends some additional time in the beginning to find the root cause, they may save future time and aggravation for both clinicians and HTM staff; they may also improve the patient and visitor experience.

Examples

The purpose of these examples is to stimulate thinking by illustrating that complex problems often have a starting point; one never knows when the NPF problem you are working on today may turn out to be part of a bigger pattern.

Exapmple 1: Patient Monitor. I deliberately made the first example a relatively simple, common NPF that many have experienced. A clinician reports a problem with a noisy ECG signal on a patient monitor. HTM comes to the bedside and used a patient simulator to check out the monitor and the patient cable; everything seems to check out fine. The clinician explains to HTM that he/she has already tried replacing the electrode several times and still the ECG signal is noisy. Most BMETs have been in this situation many times; the problem is very likely to be in the patient cable or ECG electrodes. Because this scenario is such a common problem, I recommend that everyone who has dealt with this situation read this paper—*Electrocardiogram Interference: A Thing of the Past?*[2] With the knowledge gained, the frontline clinician may be able to solve an electrode application problem on his or her own without the frustration, expense, and pain (to the patient) of multiple electrode changes. In spite of all these efforts, the problem may not have been resolved. For a small percentage of cases, the root problem may be an intermittent connection where the patient cable connects to the monitor. For another small percentage of cases, the problem is a source of external interference in combination with poor electrode contact.

Example 2: Infusion Pumps. This example comes from my experience while I was director of clinical engineering for a hospital system. I will briefly summarize what happened over a period of a few years while the HTM team and others in the organization collectively tried to resolve the problems. This example will show how easy it is to miss the real root cause and incorrectly blame the problem on clinicians for an NPF call. It also shows that even once the real problem is identified, resolution may still take a significant amount of time.

The hospital system had a large (1,200) fleet consisting of one model of infusion pump with a digital keypad for nurses to input the infusion rate directly in millileters/hour (before smart pumps). For the first three years after we began using the pumps,

© Copyright AAMI 2014. Single user license only. Copying, networking, and distribution prohibited.

there were about a dozen service calls where nursing staff reported the pump running at a rate much greater than what they had programmed. In all cases, the pump's display showed a much higher incorrect rate. In all cases, the nurses were sure they had programmed the correct rate. In all cases, the pump logs recorded each individual key stroke and showed that the higher rate had been programmed. In all cases the pump log was shared with the nurse involved and his or her manager. The conclusion was that the nurse had mistakenly entered the wrong rate, and not double checked the digital display before pressing start. In all cases (luckily) there was no lasting patient harm. The nurses involved in these events accepted that they must have made a mistake; and they were much more careful in the future about double checking the display after doing a rate entry before walking away.

HTM logged each of these events as a near-miss event and kept a record. Before long, a puzzling pattern emerged. The bulk of the events of this nature occurred in Labor & Delivery (L&D). A hypothesis was that the nurses in that area did much more titration than other areas of the hospital with more frequent rate changes. Nursing staff in that area received special educational sessions about the events. The problem frequency decreased for a time, but reappeared periodically in that area. Other nursing areas continued to have occasional similar events. All occurrences were reported to the manufacturer as they happened, who agreed that they were caused by "user error."

One day, a staff nurse in L&D mentioned to a clinical educator that by pressing any of the digit keys on the pump slowly and lightly, one key press resulted in double entry on the pump. For example, by pressing the "3" key, the pump would register "33." The clinical educator immediately phoned me to come witness this demonstration. Once shown how to "incorrectly" press the key, I was soon able to replicate the problem on any pump in our fleet. This was clearly an OMG moment!

I called my customer service contact at the company and described what I had learned. He immediately pulled a new pump off the assembly line and reported he had replicated the problem with ease. He explained that this

Infusion pumps keypads and displays can pose a challenge to nurses. Healthcare technology management professionals can play a crucial role in determining the root cause of any problems.

phenomenon was called "key bounce" due to normal muscle tremor in the finger. It used to be a common problem when push button phones were first introduced until engineers learned to design in an a debounce circuit to filter out multiple presses too close together in time to be real. We both agreed that this was a major problem.

With identification of the key bounce phenomenon, I went back to the overall list of pump programming errors and realized that a majority (but not all) of programming errors were likely caused by key bounce (e.g. nurse intended to program 15 ml/hr and got a rate of 115 or 155 ml/hr). Each of these events ended up with a rate approximately 10 times the intended rate.

The hospital immediately began a massive education effort to make sure all nurses were aware of the situation. After the education, we did have a few staff nurses witness a key bounce in normal use, but they caught the wrong rate before pressing start.

Unfortunately, more senior management from the manufacturer later responded to us that they still regarded this issue as a human error that was unique to our institution. They said this pump was in common use for many

© Copyright AAMI 2014. Single user license only. Copying, networking, and distribution prohibited.

years around the world and that no other institutions were reporting this problem; in addition, the user manual clearly states the importance of checking the digital display before pressing start. The manufacturer also argued that there was no way to determine if any or all of overinfusion events in our list actually resulted from key bounce. We protested that it was likely that no other organizations were reporting the problem because they were also attributing similar reports to user error. We argued that if the key bounce issue with this pump were publicized with a warning letter, other institutions were likely to begin reporting examples. The manufacturer refused to publish a warning letter. After much more effort on our part to bring attention to the issue, the manufacturer eventually recalled all of their infusion pumps to install a software update to filter out these key bounces.[3]

Once the key bounce problem was identified, the hospital system debated extensively what to do until the problem could be resolved. We decided that we had no other viable choice besides continuing to use a product that we knew had a significant product defect. We later decided that the pumps needed to be replaced with a smart generation pump, but that trying to switch to another infusion pump in the interim or in haste might cause more patient risk than staying with a product that we knew and that worked correctly most of the time.

This example is one where both HTM and the manufacturer incorrectly concluded NPF with regard to the infusion pumps because of user error. This mistake was repeated through multiple repetitions until the real problem was finally identified. The example also illustrates that the lower overall patient safety risk may be to continue with a known problem in a technology instead of rushing in a different direction, which may introduce problems with greater risk to patient safety.

The lower overall patient safety risk may be to continue with a known problem in a technology instead of rushing in a different direction, which may introduce problems with greater risk to patient safety.

Example 3: Adult ventilators. This example is also a complicated one drawn from own experience while at the same hospital system. Once again I will summarize what happened over a period of a few years while the HTM team and others in the organization collectively tried to resolve the problem. This example was an intermittent problem over an entire fleet of equipment. Since nobody was able to replicate the problem, figuring out the root problem took quite some time.

The hospital system used one manufacturer/model combination for the bulk of the critical care ventilator fleet (about 70 ventilators). Because of the size of the hospital system and relatively small market share of the vendor, we had one of the largest fleets of this model ventilator in one organization. The ventilators had been used successfully in our system without major problems for about two years. One day a respiratory therapist (RT) reported that while they were adjusting the controls, the ventilator abruptly stopped cold. The display went blank as if it had been turned off; the ventilator alarmed with a "loss of power" alarm. The RT was present and bagged the patient until a replacement ventilator could be obtained. There was no adverse patient effect.

The ventilator started up normally when powered on after the event; it tested out perfectly, and the error log showed nothing abnormal. The wall power outlet used by the ventilator also tested OK. HTM consulted with the manufacturer and tried to reproduce the problem without success. The device was returned to service. HTM concluded that we were dealing with an IP with a potential for patient harm upon repetition and involved many others in the organization. While there was considerable concern, nobody was able to suggest anything more that could be done.

Within a week, the same exact symptoms and scenario played out with a different RT on a different ventilator in a different patient room. Again the RT was present, no patient harm resulted, and there was no added information to figure out what had gone wrong. This second ventilator was returned to the manufacturer, which also reported NPF. The same scenario occurred about four more times over the next two months, always with a different ventilator. Without any

© Copyright AAMI 2014. Single user license only. Copying, networking, and distribution prohibited.

intervention, the problems stopped and everyone hoped that this was all a fluke that would not return.

About nine months later, the same event occurred again. At this point we realized that the events were only occurring on really cold days or nights; presumably we were dealing with an electrostatic discharge (ESD) issue. Some of the RT involved remembered that the failure occurred when they first approached and touched the ventilator. The manufacturer did not deny that ESD might be a possibility, but stated that their product met all of relevant international standards for ESD protection. The manufacturer suggested that perhaps the hospital system had an abnormally severe static electricity problem since none of their other customers had reported similar problems.

HTM installed some dragging brass chains for the ventilators, purchased some test equipment for measuring static electricity voltage build up, worked with plant engineering on building humidification, and considered shoes/clothing worn by RT. The ventilator manufacturer also installed some added shielding and ground straps inside the ventilator. None of the efforts prevented additional recurrences until warmer weather arrived.

Debate as to how to address the problem within the hospital system remained split. Several leaders in the organization wanted to totally replace the fleet of ventilators without delay. Others felt that they couldn't justify this expense until it was determined definitively that ESD was the cause, and made sure that a replacement ventilator fleet might have the same issue if for some reason our institution truly was unique with regard to static electricity.

HTM located a test house company that did radio frequency interference (RFI) and ESD testing for the aircraft industry. Even though the company warned us that some of their testing might be destructive; we took one of the ventilators that had previously failed twice to the testing house. In order to help try and recreate the places where RT might initially touch the ventilator, we witnessed the testing. Since RFI had not been ruled out, they tested for RFI and ESD. The testing company found that that ESD in excess of the international standard, but not beyond what might be reasonably expected, did replicate the exact symptoms with the ventilator. Even RFI far in excess of international standards could not reproduce the problem. Their formal written opinion was that the root problem was ESD damage resulting from the manufacturer's design decision to use a plastic case for the ventilator. Subsequent efforts to add additional shielding or grounds couldn't overcome that basic design flaw. They pointed out that although we did not experience problem symptoms during the first couple of years of use, ESD was likely causing internal damage to insulation paths within the circuitry; this also is called a latent defect. Our symptoms likely started with subsequent ESD traveling directly through circuitry no longer protected by insulation paths damaged by previous ESD. I recommend *ESD Fundamentals*[4] for those desiring an introduction to this problem.

Simply meeting international standards with regard to some factors does not necessarily mean that they can afford to ignore the real world conditions that their product will be subject to.

The manufacturer was not willing to redesign their ventilator, but offered to take them back for a credit. Based on this opinion from the test house company, hospital leadership decided to replace the entire fleet. When this was done, the problems disappeared.

This example is meant to show the value of a large enough sample size and the value of persistence in the search for a solution. In an organization with a smaller fleet of these ventilators, or located in an area with higher humidity levels, the volume of similar problems may have precluded solving the problem. Indeed, we had contacted other customers utilizing this model of ventilator and they did not report having a similar problem. This example is also meant to illustrate to manufacturers that simply meeting international standards with regard to some factors does not necessarily mean that they can afford to ignore the real world conditions that their product will be subject to.

© Copyright AAMI 2014. Single user license only. Copying, networking, and distribution prohibited.

Conclusion

Each NPF case is different, but HTM groups are encouraged to dig deeper into NPF service events. Beyond a routine examination of the problem device, try to get back to the original person with the problem for a better description. Consider the possible patient safety consequences of a repetition of the problem. Particularly when there are patient safety consequences, dig a bit more, think outside of the routine examination, consider that the problem device reported by the user may not be the device with the actual problem. Ask what has changed in the environment and involve others in your problem analysis.

Good documentation is essential to spotting patterns and passing on messages to others. Keep in mind that the NPF or IP that you are working on today may be part of a larger pattern, and someone will be the first person to spot the pattern. One HTM technician in a team may not be the person to see other instances of the same problem. When faced with an NPF, document what you did very clearly for the benefit of the next person who is looking for clues. If the problem originally described by the user does not adequately describe the real problem, clarify the problem description.

HTM groups should work together to uniformly flag NPF issues and encourage members to look for patterns. HTM programs must be diligent about reporting device problems to manufacturers so that they, members of other HTM groups, regulators, and ECRI Institute can look for patterns across multiple institutions.

HTM groups should work together to uniformly flag NPF issues and encourage members to look for patterns. HTM programs must be diligent about reporting device problems to manufacturers so that they, members of other HTM groups, regulators, and ECRI Institute can look for patterns across multiple institutions.

HTM groups need to devote some resources and time to periodically looking at their records of NPF to look for patterns. Sometimes when you start consciously looking for patterns in data, they suddenly start appearing. While doing this analysis, also look for opportunities for improvement in the HTM documentation to make it easier to spot patterns.

When I was director of clinical engineering (for 38 years) I saw many NPF and IP scenarios similar to the ones discussed in the examples. Since I started being an expert testifying in legal cases in 2011, I have started to look at cases of this nature in a different light. Some of my cases have been on the side of the plaintiff and some on the side of the defendant; in either case, I try to objectively look at the evidence. When a bad event happens involving a medical device, sometimes it is simply because the device failed in an unpredictable (or even predictable) fashion. Following an adverse event, questions will be asked of both manufacturers and HTM to see if there were earlier failures that would have predicted the failure in question. If those earlier failures were reported to HTM and/or manufacturer, and the conclusion was NPF with superficial investigation or poor documentation; there was a missed opportunity to find the true root cause prior to the adverse event. In general, the greater the number of earlier instances of a similar problem without the responsible organization spotting a trend, the less defensible is the organization's position.

If all those solving service problems with medical devices look for additional opportunities when they are tempted to close a service call with NPF, there will be fewer NPF in the future, and our patients will be safer. ■

References

1. **AAMI News.** TIR Covers Postmarket Surveillance of Use Errors. April 2014. Available at www.aami.org/publications/AAMINews/Apr2014/TIR_Covers_Postmarket_Surveillance_Use_Errors.html. Accessed June 13, 2014.
2. Melendez LA, Pino RM. Electrocardiogram Interference: A Thing of the Past? *Biomed Instrum Technol.* 2012 Nov-Dec;46(6):470-7.
3. **FDA.** Safety Information about the Alaris Signature Edition Gold Infusion Pump Seizure. Available at www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm113268.htm. Accessed July 7, 2014.
4. **ESD Association.** *Fundamentals of Electrostatic Discharge: Part One—An Introduction to ESD.* 2013. Available at www.esda.org/documents/FundamentalsPart1.pdf. Accessed June 13, 2014.