

HEALTH DEVICES

July 2004, Volume 33, Number 7

Guidance Article

Failure Mode and Effects Analysis

A Hands-On Guide for Healthcare Facilities



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Featured in This Issue . . .

FMEA: Navigating the Process

In 2002, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) mandated that accredited hospitals conduct a risk analysis of a high-risk process each year. There are a number of approaches possible for this kind of analysis. One popular choice is failure mode and effects analysis (FMEA), a technique widely used in industry. Using FMEA, an organization breaks down a process into discrete steps and analyzes all the ways these steps can go wrong. For each possible failure mode, a mitigating strategy is identified and put into practice. The success of each mitigating strategy is then reviewed.

Although the principles underlying FMEA are simple, the execution takes time and thought and can be a challenge. That's one of the things we learned when, as an exercise, we conducted our own FMEA, focusing on the process of programming an infusion pump. Other lessons from the experience:

- It's important to take care when selecting the process you're going to analyze and defining how much of the process to cover. Narrow topics are preferable: They can be analyzed more quickly, more thoroughly, and with less confusion and debate.
- Your FMEA team should be diverse. Assemble staff from various areas of the hospital, and include some who are unfamiliar with your chosen process and so can provide an outsider's perspective.
- Be flexible. You may have to adjust your procedures as you go. Each facility's environment is different, and a cookie-cutter approach might not work.
- Document thoroughly from start to finish. This will allow you to review your actions as needed and demonstrate compliance to JCAHO.

An account of our experience, along with further conclusions we drew from it, begins on the next page.

JCAHO's New Equipment-Maintenance Requirements

On another JCAHO-related topic: This year, the Joint Commission revamped its accreditation process, with an initiative called "Shared Visions — New Pathways." Among the changes is a revised system for scoring equipment-maintenance programs. Hospitals are now scored more stringently

for their maintenance of life-support equipment than for maintenance of non-life-support equipment.

For the majority of healthcare facilities, the impact of this change should be small. Most facilities have effective equipment-management programs in place and will already be carrying out the necessary inspection and maintenance processes. They will, however, have to develop a specific (and preferably narrow) list of life-support equipment and demonstrate that the equipment on this list receives the appropriate priority for maintenance.

We emphasize, however, that developing a list of life-support equipment doesn't mean that you should change your prioritization of equipment that is *not* on that list. We believe that all *high-risk* equipment should be given a high priority for maintenance, regardless of whether it is used for life support or not. For further discussion of these issues, see the Guidance Article on page 244.

Maximizing BGM Accuracy

Blood glucose meters (BGMs) provide rapid glucose readings and are invaluable in caring for patients with diabetes. The accuracy of BGM results is essential, since they are used to adjust patients' insulin doses and to make other treatment decisions, some of them critical. In the Guidance Article on page 251, we describe how users can minimize erroneous BGM results. Our recommendations include conducting regular performance checks, confirming questionable results, following instructions for test-strip storage and handling, and using a large enough blood sample. We also provide some case histories of BGM problems and a discussion of physiologic factors that can affect results.

Problem Reports

This month's Problem Reporting section (page 257) describes a case in which a supplier provided a hospital with incorrect replacement casters for its video cart. The replacement casters could not support the load and failed prematurely, resulting in equipment damage and minor injury. Complicating matters is the fact that the supplier subsequently went out of business, making it impossible to determine if the problem could be widespread. Our report describes how you can ascertain whether you have an affected unit. Also in this section, we review what a pulse oximeter's accuracy specifications really mean. ♦

Failure Mode and Effects Analysis

A Hands-On Guide for Healthcare Facilities



Summary. Failure mode and effects analysis (FMEA) is one method hospitals can use to comply with the requirement by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) that they conduct at least one proactive risk assessment of a high-risk process each year. While it is not the only means of satisfying the requirement, FMEA is an established and widely used procedure and is the model suggested by JCAHO.

FMEA is not, however, a simple procedure. To help our readers better understand the challenges involved, ECRI conducted its own FMEA as an exercise. The high-risk process we analyzed was setting up and programming infusion pumps for intravenous delivery of medications. In this article, we describe each step we carried out, the principles underlying our decision making along the way, and the lessons we learned.

After reviewing our account, the reader should understand what an FMEA is and what it should accomplish, know how to choose and define a process for analysis, and grasp the key elements of a successful FMEA from start to finish.

Addressing JCAHO's Risk-Assessment Requirements

Failure mode and effects analysis (FMEA) is a formalized procedure used for risk assessment to anticipate the potential problems in a process and then eliminate or reduce the likelihood of an adverse outcome from those problems. Many U.S. healthcare facilities have become familiar with FMEA since the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) mandated, in 2002, that accredited facilities perform at least one “proactive risk assessment” of a high-risk process each year. FMEA is not the only means of conducting one of these risk assessments, and its use is not required by JCAHO. But it is an established process employed by numerous industries, and JCAHO has suggested it as a model to follow.

The goals of an FMEA are:

- Identify failure modes in a process
- Establish the risks and the consequences (called *effects*) of these failure modes
- Identify and implement mitigation strategies for the effects
- Assess the success of the mitigation strategies
- Implement modifications to hospital procedures as appropriate

Typically, FMEA — whether used in healthcare or elsewhere — is conducted by teams rather than individuals to ensure that a broad range of perspectives and experiences is brought to bear on the selected topic. Also key to FMEA is thorough documentation. This helps ensure that the analysis is complete and allows for future review of the findings and convenient tracking of progress.

As applied to healthcare, FMEA is intended to improve patient safety by identifying potential problems before accidents occur. It can also provide additional benefits, such as minimizing damage to facilities and reducing liability in the event of patient harm.

The FMEA process used by hospitals is generally simpler than those traditionally applied in industrial settings — for example, for product design or manufacturing. But even in a simplified form, FMEA can be confusing and difficult for those not familiar with it.

ECRI Does FMEA

Recently, we conducted an FMEA of our own so that we could describe our experiences to our readers. The high-risk process we chose to analyze was setting up and

programming infusion pumps for the intravenous (IV) delivery of medications.

The procedure we generally followed for our FMEA was based on one developed by the National Center for Patient Safety of the U.S. Department of Veterans Affairs (VA 2001). However, as we will describe, we departed from that procedure at certain points. Also, because our FMEA was conducted as an exercise, we were not able to carry out every step the way it would be done in a hospital. For example, although an FMEA team should include a

FMEA is intended to improve
patient safety by identifying
potential problems before
accidents occur.

hospital executive or other administrator (see Step 2), recruiting one for our team wasn't practical. As another example, when we developed our mitigating strategies (Step 6), we listed all possible mitigations for each critical failure, whereas in a real-life FMEA, such mitigations would be specific to the hospital conducting the analysis.

Step 1: Choose and Define a Process to Analyze

The first step in FMEA is to select the process that will be analyzed. Hospitals should start this step by reviewing their history of adverse events and situations in which patients were or could have been harmed, including past JCAHO Sentinel Events and “near misses,” to identify the most prevalent failures or the most susceptible processes in the hospital. Hospitals may also want to make use of JCAHO's Sentinel Event statistics (JCAHO 2004 Jan 29) to identify problematic processes they might wish to analyze.

We focused on infusion pump setup and programming for IV delivery for three main reasons: (1) it is a common practice in hospitals, (2) it is viewed as a major contributor to medication error, and (3) infusion medication errors have a great potential to result in patient harm and death.

Another consideration was that this topic allowed us to keep the focus of our analysis narrow. FMEA teams — especially those with little FMEA experience — should select a process that is not too broad and that has well-defined boundaries. There are several advantages to doing so: For one thing, selecting a narrow topic will help ensure that it is comprehensively analyzed. A narrow topic also

allows the FMEA to be completed in a reasonable amount of time. Furthermore, teams are less likely to miss failure modes in a limited process with well-defined boundaries; they are also more likely to have a good understanding of the entire process and less likely to experience confusion or disagreement over whether specific actions belong in the process. Finally, a narrow topic makes it easier to monitor the success of mitigating strategies.

Applying this reasoning to infusion therapy — which involves many steps from physician orders through administration and monitoring — we chose to narrow the scope of our FMEA to the medication administration tasks of the clinician inside the patient room. We included steps such as programming the dose error reduction system (DERS) and setting up the pump, but we excluded the ordering, filling, or distribution of infusion medications. (Although mistakes made during these latter steps are outside the scope of our FMEA, they are significant types of medication errors and would make a good topic for separate FMEAs.)

We formally defined the scope of our analysis as follows:

We will conduct an FMEA on clinicians' actions in setting up and programming a general-purpose infusion pump with a dose error reduction system for the delivery of intravenous medications, from taking the medication administration record and drug into the patient's room to beginning the infusion. For this analysis, we will assume that the correct drug has been dispensed for the patient and that the provider's orders are correct and appropriate.

Step 2: Assemble the Team

Our second step was to assemble a team to conduct the analysis. It's important that the team offer a breadth of experience and a variety of perspectives. To achieve this, the team should be drawn from three groups of hospital staff: people who are familiar with the selected process and the use environment, as well as with the causes and results of process failures; people who are not familiar with the process but have a background in a related field; and an executive or senior staff member. (Although we didn't do so for our FMEA, it may be useful in some cases to create a team with two "tiers" of members. One tier would consist of a core group that actually performs the analysis. The other would be a more peripheral group whose members are less directly involved day-by-day and function as advisors to the core members.)

People familiar with the process. This group should include staff from nursing (e.g., members of an infusion team, nurse practitioners, licensed practical nurses [LPNs],

nursing supervisors), medicine or pharmacy, risk management or patient safety, and clinical engineering. All those areas have staff who use and maintain infusion pumps, who develop guidelines for infusion therapy, and who are familiar with the consequences of medication errors. They will be able to identify common failure modes (including user errors) and ways to mitigate them. Since infusion practices may vary significantly among care areas within a hospital, we recommend involving nursing staff from two or three areas.

People unfamiliar with the process. This group should include team members who are not experienced in the process — in our case, with infusion pumps — but who have a breadth of other hospital and medical device experience. We found that these team members encourage the experts to explain and walk through common processes and mitigation strategies and thereby reexamine established procedures.

Administrative staff. Including a hospital executive or senior staff member establishes the importance of the FMEA program at the hospital and encourages staff "buy-in" by example. It also provides a sense of accountability and responsibility for those most affected by the decisions made, and allows hospital policy to change by executive sign-off on corrective actions.

Step 3: Describe the Process Step-by-Step

Once assembled, the team creates a step-by-step description of the process to be analyzed. Often, this description is graphical (e.g., a flowchart). By carefully walking through and documenting the process, the team can identify actual work practices. Indeed, much of the value of developing a process description is in the discussion between nurses and clinicians who can describe "what actually happens and when" and administrators who can

(continued on page 237)

Our FMEA Steps at a Glance

1. Choose and define a process to analyze
2. Assemble the team
3. Describe the process step-by-step
4. Define potential failure modes and effects
5. Identify critical effects for further study
6. Identify, implement, and evaluate mitigating strategies ♦

Programming an Infusion Pump



1. Patient and drug verified against order



2. Pump turned on



3. Set loaded and primed



4. Pump programmed



5. Programming verified against order



6. Delivery started

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For our FMEA, we identified these basic steps in the process of programming an infusion pump. Each step was then broken down into a series of substeps. (See page 237.) We then identified the possible failure modes for each substep, determined which failures were critical, and developed mitigating strategies for those critical failures.

(continued from page 235)

describe “what is *supposed* to happen and when” according to hospital policy. This step will encourage close scrutiny of both intended and actual practices, as well as the pros and cons of each. In some cases, the team may discover that the actual processes differ from intended hospital practice. It may also find that processes vary significantly from one care area to the next. Such scrutiny is a major benefit of FMEA, and the team should plan to conduct a lengthy discussion.

However, we found during our analysis that there is little guidance available on the best type of process description to use. Many of the examples we found started with a completed flowchart, for instance, and most of those were too complex or broad in scope (e.g., covering pumps from purchase to obsolescence, covering the whole medication administration process) or too hypothetical (e.g., driving to work) to be useful as guides. Therefore, we developed our own procedure for describing our infusion-pump processes:

First, we talked through the process of programming a pump to familiarize all team members with the different steps a clinician takes in interacting with the pump.

Next, we made a preliminary list describing each step in the process. We used a list rather than a diagram (flowchart) because infusion therapy is a linear process — for example, a pump’s programming cannot be verified before the pump is programmed — and a list was adequate to describe it. Flowcharts may be more useful when describing more complex processes with many decision points. Our preliminary outline is shown below and illustrated on page 236. (Note that our list may not correspond with every hospital’s infusion practices.)

1. Patient and drug verified against order
2. Pump turned on
3. Set loaded and primed
4. Pump programmed
5. Programming verified against order
6. Delivery started

Then we identified and numbered substeps for each step. For example, here are the substeps for step 4 (“Pump programmed”):

- 4.1. DERS mode selected
- 4.2. Drug name and clinical location identified and selected in DERS
- 4.3. Patient weight entered

- 4.4. Solution concentration or drug content and diluent volume entered
- 4.5. Rate or dose entered
- 4.6. VTBI [volume to be infused] entered

Step 4: Define Potential Failure Modes and Effects

This step consists of two main stages: determining possible failure modes — defined by the VA as “different ways that a process or a subprocess can fail to provide the anticipated result” (VA 2001) — and predicting their potential effects.

Identifying failure modes. Most process steps can fail in several ways, and many process steps share similar failure modes. At this stage, FMEA teams should strive for comprehensiveness and consider as many failure modes as possible. Failure modes that are unlikely to affect a patient, user, or equipment will be eliminated from consideration later on.*

At this point, the FMEA team will need to use a worksheet to organize its thoughts and decisions. This worksheet will serve as documentation of the FMEA process for future review. A portion of the worksheet we used is shown on page 238.

In our list, we defined and numbered failure modes for each process substep. For example, for substep 4.5 — “Rate or dose entered” — we identified the following possible failure modes:

- 4.5.1. Rate or dose cannot be located or read properly from MAR [medication administration record]/order
- 4.5.2. Wrong dose entered
- 4.5.3. Wrong units selected
- 4.5.4. Calculation error (e.g., when converting mcg/kg/min to mL/hr)
- 4.5.5. Rate or dose error detected and corrected but “enter” or “start” not pressed
- 4.5.6. Wrong order read (i.e., patient is on >1 IV drug)
- 4.5.7. No value entered

(continued on page 239)

* Note that FMEA makes a distinction between failure modes (*how* failures happen) and their underlying causes (*why* failures happen). These may sometimes seem to overlap but are in fact different. For example, in our analysis, failure mode 4.5.2, “Wrong dose entered,” may have more than one possible cause, including a staff member misreading written orders or simply having a slip of the finger when keying in the dose. In FMEA, causes are not specifically identified until the last step in the process, as part of developing remediations for failure modes. But the distinction between a failure mode and its cause can be subtle — a fact that needs to be kept in mind throughout the analysis.

Sample Worksheet for Infusion Pump FMEA Substep 4.5 ("Rate or Dose Entered")

Potential failure mode	Effects of failure: Description	Effects of failure: Severity	Effects of failure: Probability	Effects of failure: Detectability	Significant?	Causes of failure	Mitigating strategies
4.5.1. Rate or dose cannot be located or read properly from MAR/order	Can't program pump	Minor	Occasional	High	No*	—	—
4.5.2. Wrong dose entered	Incorrect dose to patient	Major	Occasional	Medium	Yes	Interpretation error (dose was read wrong), entry error	Revising DERS limits to match clinical use, double checks for high-alert drugs, automated programming (when it becomes available)
4.5.3. Wrong units selected	Incorrect dose to patient	Major	Occasional	Medium	Yes	Interpretation error (dose was read wrong), entry error	Revising DERS dosing units to match clinical use, standardizing on a few concentrations, user training, double checks for high-alert drugs, automated programming (when it becomes available)
4.5.4. Calculation error (e.g., when converting mcg/kg/min to mL/hr)	Incorrect dose to patient	Major	Occasional	Medium	Yes	Interpretation error (measurement was read wrong), clinician is rushed, clinician is interrupted	Revising DERS dosing limits to match clinical use, standardizing on a way to write concentrations, user training, double checks for high-alert drugs, automated programming (when it becomes available)
4.5.5. Rate or dose error detected and corrected but "enter" or "start" not pressed	Pump will not start and will alarm	Major	Occasional	High	No*	—	—
4.5.6. Wrong order read (i.e., patient is on >1 IV drug)	Incorrect dose to patient	Major	Occasional	Medium	Yes	Several IV bags used at once	User training, double checks for high-alert drugs, automated programming (when it becomes available)
4.5.7. No value entered	Pump will not start and will alarm	Minor	Occasional	High	No*	—	—

Abbreviations: DERS — dose error reduction system; IV — intravenous; MAR — medication administration record.
* For effects not considered significant, no identification of causes or mitigating strategies is required.

(continued from page 237)

We found that many failure modes fall into one or more of the following general categories:

- A step was performed incompletely or wrong. (In the preceding list, failure modes 4.5.2 through 4.5.6 might fit this category.)
- A step was attempted correctly, but some physical/material defect in a tool or accessory caused a problem (failure mode 4.5.1).
- A step was omitted (failure mode 4.5.7).

Extrapolating possible effects. Having identified possible failure modes, we then assigned effects, or likely results, to each one. These effects varied widely depending on the nature of the failure. Therefore, to simplify our analysis and ensure that each failure mode received adequate consideration, we decided to depart from the VA FMEA process and follow an alternate process described by JCAHO in its guide *Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction* (2002): Instead of listing every possible effect, we noted only the worst possible outcome of each failure mode. For example, the effects of failure mode 4.5.2. — “Wrong dose entered” — could range from no effect (if the erroneous dose is noticed before the drug is administered) to administering the wrong dose to the patient (if the error is not caught). We chose to assign the worst-case outcome, “Wrong dose administered.”

As with the failure modes, we found that the effects tended to fall into three categories:

- No effect because the failure (e.g., omitting turning on the pump) results in a stop to the process, which will be noticed
- Short-term delay in therapy without patient harm (e.g., if an order is incomplete or missing and the clinician must check with the pharmacy before proceeding)
- Likely harm to a patient (e.g., if the drug, concentration, dose, or administration route or time is wrong)

Note that the effects in the third category have the potential to seriously harm a patient, while those in the other two are essentially harmless — there are no “midlevel” risks associated with infusion pump use. That fact had a significant impact on the next step in our FMEA.

Step 5: Identify Critical Effects for Further Study

After identifying the effects of potential failure modes, FMEA teams must consider the severity, probability, and

detectability of each effect to objectively identify critical effects — that is, those that present the greatest risk and therefore most need to be reduced or eliminated.* This will help a hospital determine where to focus time, staff, and financial resources in order to provide the greatest impact on patient safety.

In *Failure Mode and Effects Analysis in Health Care*, JCAHO discusses several qualitative and quantitative methods of selecting critical effects. Here are some of the approaches you might choose from:

- Discuss each effect and rank it based on severity and probability, then select those effects that are critical enough to require further analysis.
- Using the VA procedure (VA 2001), assign probability and severity numbers to each effect. Then look up the resulting Hazard Score in the Hazard Scoring Matrix, and follow the detectability Decision Tree for effects with a Hazard Score over 8.
- Assign probability, severity, and detectability scores on a different scale — one of your own choosing. For each failure mode, you can assign a value either to all the effects or to one or more “most severe” effects. Then multiply the three scores to determine an effect’s Criticality Index, and select effects above a threshold value for further investigation.

We learned from our analysis
that successful FMEA requires a
flexible approach.

For our analysis, we initially attempted both the second and third approaches — that is, the two numerical scoring systems. But we found that, when dealing with a potentially life-threatening technology, assigning numerical severity scores is tricky. We couldn’t comfortably identify any effect as moderate. Instead, we wound up rating failures as having either (1) very severe effects (failures that create the potential for administering the wrong drug, concentration, or dose or for using the wrong administration route or administering at the wrong time) or (2) little or no effect (failures that halt the process or result in minor delays in therapy). Thus, there

* In the VA’s FMEA procedure (VA 2001), as well as in our own earlier article on FMEA (“An Introduction to FMEA,” *Health Devices* June 2002), this step is combined with Step 4. But because we found this step to be a particularly crucial component of FMEA, we have treated it as a separate element here.

was no advantage to using a numerical scale when scoring severity for this technology, since there were no gradations in criticality — it was essentially all or nothing.

In addition, this “polarity” in the severity scores made them difficult to combine with the scores for probability and detectability. In some cases, problems that we considered too remote to warrant further action nevertheless ended up being scored as critical because of their severity.

In other cases, effects we considered important received inappropriately low scores because they were likely to be infrequent — in other words, the probability score reduced the impact of the severity score, even though we knew that in fact the severity was the overriding consideration in those instances.

We think it’s possible that similar quandaries will face other FMEA teams trying to assess technologies for

Numerical versus Qualitative Effects Analysis

Figures Can Lie — Or at Least Shade the Truth

As we describe in the main article, we initially tried to use numerical scoring to gauge the criticality of failure mode effects. But we found that the nature of infusion pump failures made this kind of scoring impractical, and we finally resorted to a qualitative analysis instead. We also realized that there are other limitations to numerical analyses as well. Before we discuss those, we’ll briefly review how such analyses work.

THE NUMERICAL SCORING PROCESS

Each effect is given a score based on its severity, probability, and detectability. In our numerical analyses, we assigned numbers from 1 to 3 to each effect — 3 for the greatest risk, 1 for the least. The table below depicts these numerical ratings. (Note that detectability is graded inversely to the other two values: The greater the detectability, the lower the risk.) For the meaning of each of the ranking categories (“Major,” “Frequent,” etc.), see the table on page 241.

The three scores are then multiplied together to yield what’s called the Criticality Index. For example, an effect of moderate severity (a score of 2) that happens rarely (1) and is easy to detect (1) would have a CI of 2 ($2 \times 1 \times 1$). An effect that is minor (a score of 1) but that happens frequently (3) and is very difficult to detect (3) would have a CI of 9 ($1 \times 3 \times 3$).

Numerical Effects Scoring

Severity	Probability	Detectability
Major: 3	Frequent: 3	Low: 3
Moderate: 2	Occasional: 2	Medium: 2
Minor: 1	Rare: 1	High: 1

Criticality Index (CI) = Severity x probability x detectability

The FMEA team will establish a threshold value that determines whether an effect is critical enough to warrant further study — any score meeting or exceeding this value will be considered critical. So if a threshold value of 6 were used, any effect that had three moderate-risk scores, or that had one moderate-risk and one high-risk score, would be designated as critical and needing mitigation.

NOT ALWAYS WHAT IT SEEMS

Although the numerical approach can simplify decision making, there are times when it can be *too* simple. The ease with which a number can be assigned may detract from the in-depth analysis that effective FMEA requires, causing some critical effects to be missed and other effects to be given more attention than they need. For example, an effect that could — in theory — seriously injure or kill a patient, but that is so unlikely that remediation would be absurdly burdensome or even impossible, could receive a score that indicates the need for follow-up — which would be a waste of the hospital’s time. In some cases, a hospital may be better served by mitigating smaller everyday problems rather than trying to prevent a dire effect that is unlikely ever to occur.

While numerical tools may be very useful in some cases, they must be used as guidelines and indicators, not as a replacement for common sense and good decision making. If you’re going to use numerical analysis, don’t simply work up the numbers and move on. At least review each score and make sure that it makes practical, intuitive sense to everyone on the team.

The assessment process that we used is structured to allow, but not require, the assistance of numerical analysis. ♦

which certain failure modes have life-threatening effects. Those teams may wish to do what we did — find another approach. (There are other drawbacks to numerical scoring as well — see the supplementary article on page 240.)

We chose to pursue a qualitative analysis — though one that is somewhat analogous to the numerical approach outlined by JCAHO — that we based on ECRI’s experience with risk analysis. We discussed and assigned the severity, probability, and detectability of each effect and then decided whether each effect was critical based on our discussion of that effect. We developed the table at the bottom of this page for our analysis.

We learned two important lessons while carrying out this part of FMEA. First, FMEA teams should consider developing their own rules for assigning severity ratings based on their experience with the identified failure mode effects. For example, we categorically assigned the following ratings to infusion pump failure effects:

- A severity rating of “major” for any situation resulting in the administration (or potential for administration) of the wrong drug, to the wrong patient, at the wrong dose, by the wrong route, or at the wrong time. This was done to address the high risk of patient deaths and impairment caused by these situations.
- A severity rating of “minor” for short-term delays in treatment. This was done because short-term delays in infusion treatment, while not desirable, rarely result in harm to a patient.

Second, FMEA teams must be careful to assign probability, severity, and detectability scores separately and not allow one score to influence another before they are ultimately combined. In our case, for example, if a failure mode of “Start button is not pressed” occurred once a week but only resulted in the effect “no infusion takes place” a few times a year, we assigned probability based

on the frequency (once a week) alone, without considering the detectability (the fact that the failure is detected and corrected most of the time because infusion pumps will alarm if programming is entered but not started).

Step 6: Identify, Implement, and Evaluate Mitigating Strategies

After identifying the failure modes whose effects are critical, the team must develop strategies to minimize the likelihood that those failure modes will occur. To do this, they must first determine the likely underlying causes of the failures to prevent them from affecting the patient or to reduce the resulting harm if they do affect the patient. Most failure modes are the result of a complex interaction of failures. Therefore, FMEA teams must carefully analyze the components of each critical failure, drawing on experience gained from investigating prior adverse events related to the analyzed process.

Because we were conducting our FMEA as an exercise, we could not, of course, develop a list of likely causes specific to any one hospital. So instead, we listed all possible causes for each critical failure mode. For example, the failure mode 4.5.2, “Wrong dose entered,” might be caused by an interpretation error (e.g., clinician reading MAR/order incorrectly) or by an entry error (e.g., mistyping and double-pressing — clinician reads and understands dose as “10” but types in “110”).

Once they have determined the causes, FMEA teams can then identify a mitigating strategy, or action plan, to address each of these causes. There are several basic categories of mitigating strategies, which are listed in “Fixing the Problems” on page 242.

As with the likely causes, we did not attempt to identify mitigating strategies for specific hospitals — nor, for that matter, general strategies that could be used by all hospitals, since work practices and technology bases can vary

ECRI’s Qualitative Effects Analysis

Severity Level	Probability Level	Detectability Level
Major: Patient suffers unanticipated death or permanent loss of function,* or long-term loss or lessening of function	Frequent: Likely to occur immediately or within a short period (e.g., once a month)	Low: Detection by inexperienced users unlikely or difficult (e.g., problem will produce no or inadequate alarms or visible/audible cues)
Moderate: Patient or user has short-term loss or lessening of function, increased length of stay, or increased level of care	Occasional: Probably will occur over the long run (e.g., once every 1 to 5 years)	Medium: Probably will be detected by inexperienced users (e.g., problem will continue, but with obvious alarms or visible/audible cues)
Minor: No injury, no intervention required	Rare: Occurrence possible but not likely (e.g., once in 5 to 10 years)	High: Very likely to be detected by inexperienced users (e.g., this effect will halt the process until remedied)

* That is, the effect qualifies as a JCAHO Sentinel Event.

widely. Rather, we chose to identify as many mitigating strategies as possible for each failure mode.

For example, returning to failure mode 4.5.2, “Wrong dose entered,” the following mitigating strategies could be considered:

- Regularly reviewing the DERS alarm logs and optimizing dosing limits — for instance, using limits that are narrow enough to minimize the risk of patient harm but wide enough to allow for clinical judgment. (For more about the benefits of and requirements for a DERS, see our October 2002 and October 2003 *Health Devices* Evaluations of infusion pumps.)
- Instituting an independent double-check system for the programming of high-alert medications: One clinician programs the pump, and another clinician reads and verifies the dose before starting the pump.
- Using automated programming systems — once they become available — that automatically populate the pump with drug, concentration, and dose information from the medication order. (These systems are described in our October 2003 infusion pump Evaluation.)

Once an FMEA team has identified the potential mitigating strategies for its critical effects, it must develop a plan for deciding how and when each strategy will be implemented, as well as how and when the strategy will be judged to be either

a success or in need of modification (perhaps through future FMEA analysis). For each mitigating strategy, the hospital should develop a detailed description of the strategy, documenting the date by which the strategy will be implemented, the name and title of the person responsible for implementing the strategy, the criteria by which the strategy’s success will be evaluated, and the date on which the strategy’s initial success will be evaluated.

For mitigating strategies that are likely to significantly impact a hospital in terms of cost, time, or staff, the team should consider conducting a trial of the mitigating strategy on a limited basis to determine its effectiveness. For example, if one strategy is to replace pumps that lack a DERS with pumps that have one — which, if done hospitalwide, would be expensive and could significantly impact clinicians’ workflow — the hospital might plan a trial of the strategy. Documentation for the trial might look like this:

1. *Strategy:* We will conduct a trial of 20 infusion pumps with effective dose error reduction systems for our intensive care unit (ICU) and develop and implement dose limits for at least 50 of the most often used infusion medications in this unit.
2. *Trial date:* Pumps will be selected by November 2004. Pumps will be in use with dose error reduction system dose limits by March 2005.

Fixing the Problems

Types of Mitigating Strategies

A mitigating strategy entails a redesign of a process or its components to eliminate failure modes or to make their effects less serious or more easily detectable. There are several types of mitigating strategies; some are more effective than others. In order of descending effectiveness, mitigating strategies include the following:*

- Implementing procedures that “design out” the hazard by changing the workflow or process to eliminate the problematic step. (An example of this kind of strategy for infusion pumps is implementing automated checking of drugs against the MAR by using a bar-code point-of-care system in order to eliminate faulty manual checks.)
- Instituting fail-safe devices (for example, using set-based free-flow protection in infusion pumps to

prevent gravity flow when the set is removed from the pump).

- Implementing devices that warn users of failure modes (such as air-in-line detectors in infusion pumps that warn when air might enter the patient).
- Teaching users to be more aware of potential failure modes (for instance, familiarizing new or inexperienced clinicians with how to use the hospital’s infusion pumps).

Because many of these failure modes may share underlying causes, your FMEA team may find that one mitigating strategy can apply to several failure modes.♦

*Derived from: Bahr NJ. *System safety engineering and risk assessment: a practical approach*. New York: Taylor and Francis, 1997:14-7.

3. *Organizer:* Pat Smith, chief safety officer, will be responsible for gathering team members from medicine, nursing, clinical engineering, and pharmacy to select the pumps and work with the manufacturer in implementing the dose error reduction systems.
4. *Evaluation:* We will review nursing compliance (e.g., the percentage of infusions programmed using the dose error reduction system) two months after implementation by a two-day direct-observation study. Implementation will be considered successful if 60% compliance is achieved.
5. *Evaluation date:* The evaluation will be completed by May 2005.

ECRI Recommends . . .

Although FMEA is time-consuming, the information it yields can help a hospital improve the safety of both the specific process evaluated and other hospital processes. And while it won't identify every potential problem, it can help provide solutions that prevent a number of foreseeable difficulties.

Based on our own experiences, we found the following points to be particularly important:

First, take particular care at the start when defining both the topic to analyze and its scope. This may be one of the most important steps in the FMEA process: A well-defined topic and scope will make FMEA manageable and practical to complete in a reasonable time.

Assemble a diverse team. This will build staff morale and buy-in, increase communication between departments, and give staff "ownership" in patient safety issues. Even before failure modes are considered, having a variety of viewpoints draws attention to existing or potential workflow problems and differences in understanding of the process between work groups.

Don't lock yourself into a particular approach. As we discussed, successful FMEA depends heavily on flexibility. Because each FMEA process will be unique, FMEA teams may need to attempt several approaches to find one that fits.

Document your process meticulously. For each potential failure mode identified, this will provide the hospital with a clear record that the failure mode was considered and was judged as critical or noncritical, and that

mitigating strategies for critical failures were implemented and analyzed for their effectiveness. Such a record could prove vital in case of future legal or regulatory problems.

Remember that identifying mitigating strategies that are *not* effective is just as important as identifying ones that are. It will prevent a hospital from spending money on a flawed fix and allow the hospital to develop more useful approaches.

Finally, recognize that FMEA requires considerable time and effort from team members: It is not a one-day or even a one-week event. Plan to spend several hours thinking about, discussing, and carrying out each step in the FMEA process over the course of several meetings, with a few days between meetings to allow thought and (when necessary) literature searches for other instances of the problem. Not incidentally, this is another reason to choose your topic carefully: You need to make sure that the payoff will be worth the effort involved.

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Maintaining Life-Support and Non-Life-Support Equipment

What Do JCAHO's New Requirements Mean?



Summary. As part of its new “Shared Visions — New Pathways” initiative, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) now requires accredited healthcare facilities to demonstrate that life-support equipment receives a high priority in their equipment-maintenance programs. JCAHO has also revised its overall accreditation scoring system. Some of our member hospitals have asked ECRI for advice on how to deal with these changes.

JCAHO's intent, as we understand it, is not to impose burdensome new requirements on hospitals, but simply to ensure that life-support equipment receives the necessary equipment-maintenance priority. We believe that any facility that has been meeting JCAHO's requirements up to now won't need to significantly change its equipment-management program, though it will need to revise its documentation procedures.

In this article, we describe the changes to JCAHO's requirements and outline the steps that hospitals need to take to meet the requirements — as well as the steps they *don't* need to take.

What's New

At the beginning of 2004, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) formally launched a wholesale revision of its accreditation process under the name “Shared Visions — New Pathways.” As part of this initiative, JCAHO has divided its requirements for documenting medical equipment maintenance into two scoring categories: one covering life-support equipment and one covering non-life-support equipment. The upshot of this change is that facilities will have to specifically demonstrate that life-support equipment receives a high priority in their equipment-maintenance programs. JCAHO has also revised its overall scoring system. The changes are reflected in the 2004 edition of JCAHO’s *Comprehensive Accreditation Manual for Hospitals (CAMH)*. Some of our member hospitals have requested our advice on how to respond to these changes.

We believe that most facilities previously meeting JCAHO requirements should not need to make any major changes to their equipment-management programs, since most already address life-support equipment adequately. However, this category of equipment will now need to be defined in writing and specifically included in an appropriate maintenance program. In addition, this would be a good time for facilities to review their equipment-management policies and procedures in case minor updates are required.

Below, we explain JCAHO’s requirements and offer our recommendations for ensuring compliance in an efficient manner.

The Requirements in the CAMH

THEN

Earlier editions of the *CAMH* made no distinction between life-support and non-life-support equipment. And all requirements were scored on a five-point scale: One point indicated substantial compliance with the requirement, while five points indicated noncompliance. In addition, the elements within a standard were weighted during a survey so that scores for “minor” elements were capped at lower levels, meaning that they would contribute less to an adverse compliance decision. More significant elements, on the other hand, were allowed to generate higher maximum scores, meaning that failure to meet the requirements would contribute more toward an overall finding of noncompliance for the facility. (Hospitals that are judged noncompliant could receive provisional rather than full accreditation or, potentially, could lose accreditation completely if their non-compliance areas are not addressed.)

NOW

The 2004 *CAMH*, in Standard EC.6.20 (“Medical equipment is maintained, tested, and inspected”), sets out two separate requirements for documenting medical equipment

In a Nutshell . . .

To accommodate the changes to JCAHO’s requirements, most hospitals will likely need to do the following:

- Define and document a category of life-support equipment.
- Ensure that all equipment meeting that definition is identified and included in the equipment inventory.

In addition, they should review their equipment-management program to ensure the following:

- The program continues to be functional and adequately supported, and there are no gaps that allow key equipment to escape inclusion in the program.
- Appropriate strategies are in place to ensure effective, safe, and reliable operation of life-support

equipment. This will typically include monitoring completion of IPM procedures.

- These strategies are followed and compliance is documented.
- There is documentation of the corrective action plan and of the action taken for any deficiencies.

While life-support devices are singled out by JCAHO, ECRI recommends that these recommendations be applied to all equipment in your inventory, with a special emphasis on high-risk devices. Additionally, you should document annual review of the effectiveness of policies and procedures as part of the annual evaluation of your medical equipment-management program. ♦

maintenance. Both require that “Medical equipment is maintained, tested, and inspected.” And both call for the hospital to document maintenance of the equipment in a way “that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan.” But they also differ in significant ways.

EP 3: Life-support equipment. The first of the two requirements, Element of Performance 3 (EP 3),* applies to “equipment used for life support” and is classified as a category “A” requirement. Category “A” EPs are used to score hospitals on whether particular procedures are in place or not. In JCAHO’s words, “These EPs relate to structural requirements (for example, policies or plans) that either exist or do not exist” (JCAHO 2003). Under category “A,” facilities are generally scored on an all-or-nothing basis — they either meet the requirement to have a particular process in place or they don’t.

The equipment-management
strategies for any device
must be individualized to that
specific device.

A more important point — though one that is not explicitly stated in the *CAMH* — is that category “A” covers the most critical requirements. By putting its requirements for life-support equipment in category “A,” JCAHO is indicating that having and consistently following the appropriate policies and procedures is essential. JCAHO is also highlighting the need to give these devices priority when allocating equipment-management resources.

To give a sense of the significance of this categorization: During a survey, a single observation of a life-support device that has not been maintained according to hospital policy will raise concerns about compliance with EP 3. If the problem is the result of a failure either to document or to follow appropriate policies or procedures, the facility is likely to be found noncompliant for this EP and for the entire EC.6.20 standard. To maintain its Accredited status, the facility will have to address this noncompliance within 90 days. (The 90-day period will be reduced next year:

* Elements of Performance were called “intent statements” in previous editions of the *CAMH*; the EPs for a given standard provide more specific requirements for meeting that standard than are given in the standard itself.

After July 1, 2005, a facility will have only 45 days to address compliance problems.)

EP 4: Non-life-support equipment. The second requirement, EP 4, applies to “non-life-support equipment on the inventory.” It is otherwise worded identically to EP 3 but is classified as a category “C” requirement. That means that it is scored based on the number of times that the requirement is not met. If the facility has only one instance of noncompliance, it will still likely receive a score of 2 (satisfactory compliance). A second instance, however, will typically result in a score of 1 (partial compliance). With three or more instances of noncompliance, the hospital will likely be found noncompliant with the EP and with the EC.6.20 standard (score of 0). As with an EP 3 non-compliance, to maintain an Accredited status, an organization must address its noncompliance within a 90-day period (again, this will be reduced to 45 days next year).

ECRI Perspectives

THE OVERALL IMPACT

ECRI believes that it was not JCAHO’s intent to impose burdensome new requirements on healthcare facilities. Rather, JCAHO simply wants to ensure that hospitals are giving the necessary equipment-maintenance priority to devices used for life support. Most hospitals already do this and will not need to change their existing processes. They will only need to specifically document that they do have processes in place for giving life-support equipment the appropriate attention. However, JCAHO’s division of equipment into life-support and non-life-support categories could cause confusion for some facilities, since it is not consistent with the methodologies commonly used to categorize equipment for maintenance.

We don’t believe that JCAHO’s changes should be interpreted as meaning that *only* life-support equipment should be given high priority when considering maintenance strategies — including inspection and preventive maintenance (IPM) when appropriate — and when ensuring adherence to those strategies. We believe that most, if not all, *high-risk* devices (many of which are not life-support devices) should be given such priority. Lasers and electrosurgical units (ESUs), for example, are considered by ECRI to be high-risk devices because of the possibility of delivering excessive, harmful energy to the patient.

As ECRI has recommended for many decades, the equipment-management strategies for any device must be individualized to that specific device. And in fact, we believe that the new requirements do more clearly allow

hospitals to apply different maintenance policies to different types of devices. This may involve using different maintenance strategies (conducting periodic IPM on all devices in one category; conducting IPM on only a limited sample of devices that are then monitored for excessive failure rates; or performing repairs only) and permitting varying degrees of leeway in meeting maintenance goals. It is ECRI's understanding that the emphasis of JCAHO surveyors will be on seeing that the hospital uses an effective mechanism to monitor and react to problems in completing the work, rather than focusing on, for instance, the specific date on which the work was done (although hospitals must continue to strive to complete IPM tasks on time). If anything must be skipped, deferred, or done late, the equipment in question should *not* be from the life-support category (or, for that matter, from the broader high-risk category); it should be from the lower-risk categories.

In summary, we believe that hospitals should not over-react to the differentiation of life-support and non-life-support equipment in the *CAMH* — not because the equipment issues involved are unimportant, but because most hospitals will already have effective equipment maintenance programs in place. On the other hand, hospitals that do have major deficiencies in their equipment-maintenance programs should consider the revised requirements a wake-up call.

WHAT YOU NEED TO DO

The following recommendations will help you provide safe and effective equipment for patient care and comply with the JCAHO requirements in an efficient manner.

1. Define "life-support equipment." JCAHO has developed the following definition of life-support devices, which will appear in the 2005 *CAMH* and will be included in the quarterly update of the 2004 manual in September:

Devices intended to sustain life and whose failure to perform their primary function, when used according to the manufacturer's instructions and clinical protocol, is expected to result in imminent death in the absence of immediate intervention.

Note that the phrase "when used according to the manufacturer's instructions and clinical protocol" is included merely to stress the equipment-maintenance aspect of this definition. It should not be interpreted to mean that use error should be ignored by healthcare organizations or manufacturers as a primary concern in safe and correct use of devices.

After discussion with JCAHO, ECRI understands that the intent is to keep the scope of "life-support equipment" narrow, and that not all equipment used to sustain life

needs to be placed in this category. Further, we understand that the requirements would apply to those devices that warrant inclusion in the hospital's equipment-maintenance program. (In Standard EC.6.10, EP 3, in the *CAMH*, JCAHO indicates that equipment should be included in an equipment-management plan only if a careful assessment — one based on the device's function and risk, the facility's experience, and the manufacturer's recommendations — indicates that it would benefit from being included.)

ECRI suggests that the following equipment be included in the life-support category (note that implantable devices, which are beyond the scope of this standard, are not included):

- Anesthesia units and anesthesia ventilators
- External pacemakers
- Heart-lung bypass units
- Intra-aortic balloon pumps
- Left ventricular assist devices
- Ventilators

Organizations do have the option to include a wider range of devices, though they are not required to do so. In fact, a hospital could elect to include *all* of its high-risk items in the life-support category. However, ECRI sees no safety advantage to the hospital or to patient care in doing so. And there is a potential downside to this approach: By expanding the life-support category, the hospital may create confusion for JCAHO surveyors, who may expect similar types of equipment-management strategies for all equipment in this category. Consequently, the hospital could unnecessarily place itself at greater risk of adverse survey findings if the additional equipment does not meet the expectations for life-support equipment.

We do see one potential benefit to calling all high-risk equipment life-support equipment and applying all relevant policies to this entire group of equipment: It may simplify equipment categorization and possibly allow the hospital to continue to use an existing categorization strategy. Hospitals considering this approach will have to balance this advantage against the possible drawbacks discussed above, however.

2. Identify all of your life-support equipment and make sure it is included on your equipment inventory. In fact, ECRI recommends that a comprehensive inventory of all medical devices be maintained. This is essential for identifying equipment for your hazard and recall management program and may be useful for other purposes. Including a

device on the inventory does not imply that IPM or other specific equipment-management strategies are required.

3. Make sure that your equipment-management program is functional and adequately supported. The primary intent of the life-support EP is to eliminate fundamental flaws in policies or practices that could result in a pattern of devices not being appropriately maintained or being inadvertently omitted from the equipment-maintenance program. Examples of problems that would be serious concerns for patient safety and reasons for a noncompliant score include:

- Grossly inadequate personnel resources resulting in critical maintenance functions not being reliably performed.
- For a facility relying on an outside equipment-maintenance organization, failure to either renew the contract with that organization or to provide an alternative maintenance option.
- Failure to include equipment from a hospital-owned ambulatory surgery center, specialty clinic, or skilled nursing center.
- Failure to have effective mechanisms in place to ensure that the facility addresses relevant inspection and maintenance requirements, where appropriate, of all newly acquired, rented, or leased equipment.

4. Review equipment-management procedures. Verify that equipment in the life-support category is on an IPM program and that completion of maintenance requirements is monitored. JCAHO does not specify the strategy that hospitals must use and, in general, allows hospitals to use different strategies — such as conducting IPM on only a limited sample of devices that are then monitored for excessive failure rates. However, it makes sense for life-support devices to be on a scheduled (or metered) IPM program. Also, measures should be taken to ensure that backups for life-support equipment are available when needed (e.g., if a unit is in need of repair). Such measures might include having spare units in the hospital or having arrangements with a supplier or leasing organization to provide spare units as needed.

ECRI recommends that, to ensure patient safety and avoid raising concerns during a survey, a very clear and well-documented reason be provided for excluding any device in the life-support category from periodic IPM and that the reasons be approved by the facility's safety committee. However, if the facility has chosen to expand the life-support category to include all high-risk devices, then routine scheduled IPM may not be appropriate for all devices in that category. For example, although ECRI

classifies infusion pumps as high-risk devices, we believe that it may be possible to reduce or eliminate routine IPM of these devices under some circumstances. (See the discussion of establishing infusion pump inspection intervals in the Talk to the Specialist article "Focus on Infusion Pumps" in the May 2001 *Health Devices*. Also see "Inspecting General-Purpose Infusion Pumps: How Often Is Enough?" in Guidance Section 4 of the Health Devices Inspection and Preventive Maintenance System, available from ECRI [see page 249].)*

ECRI recommends classifying all equipment into high-, medium-, and low-risk categories (many hospitals already

A very clear and
well-documented reason should
be provided for excluding a
life-support device from IPM.

do this). The high-risk category should, of course, include life-support equipment. We recommend that all equipment in the high-risk category, whether life-support or not, be given an equal amount of thought when developing an equipment-management strategy. (For a definition and list of high-risk devices, see page 249.)

Whichever approach you choose, document your equipment-management decisions, as well as your compliance with the hospital's equipment-management policies and procedures.

5. Make sure fallback policies are in place to ensure reliable adherence to the equipment-management plan. Policies and procedures should exist — and there should be documented evidence that they are followed — to address cases where scheduled IPM cannot be performed by the due date. (ECRI recommends that this be done for all high-risk devices, not just life-support equipment.)

An example might be to have a goal of completing all inspections of life-support equipment on time, but to allow up to one month (for an annual inspection period) for special circumstances such as equipment that is in use when the inspection is due. For instance, if a ventilator is in use on a patient at the time an inspection is scheduled, the hospital

(continued on page 250)

* To find out how other hospitals handle infusion pump inspection frequencies, log onto the members area of our Web site (www.ecri.org), and register your vote in this month's Web poll. Responses will be tabulated through the end of July, and current results are available at any time.

High-Risk Devices Defined

As described in the main article, we believe that all high-risk devices in the hospital — not just life-support equipment — should be considered for high prioritization in maintenance programs. To help hospitals identify high-risk devices, we present the following excerpt from the Health Devices Inspection and Preventive Maintenance (IPM) System, which provides a definition of this class of equipment.*

This category includes all life-support devices, key resuscitation devices, and other devices whose failure or misuse is reasonably likely to result in serious injury to patients or staff. Any device that has been associated with serious injury in the past (either repeatedly or by nature of its design, but not simply because of an isolated incident) should be included unless a modified device design has greatly reduced the risk. Many of the

items in this category are therapeutic equipment capable of delivering substantial energy. Examples include electrosurgical units (ESUs) and lasers, which can cause unintended burns; resuscitators, which, if not functional, could result in death; and heart-lung bypass units and ventilators, which, if they fail, could result in permanent neurologic damage or death.

However, not all therapeutic devices capable of delivering energy to the patient are classified as high risk. For example, we consider ultrasound therapy and physical therapy neuromuscular stimulators to be rated low-risk devices because they have relatively low energy output levels, the related treatments are closely supervised, and they are not associated with a significant history of serious injuries.

Also included in the high-risk group are critical monitoring devices. Equipment such as pulse oximeters, ECG/heart-rate monitors, and apnea monitors have critical alarms; if the alarms fail, a serious condition is reasonably likely to go unnoticed and quickly result in serious patient injury or death. ♦

* The Health Devices IPM System is a CD-ROM providing ready-to-use, customizable IPM procedures and forms, along with guidelines for implementing an effective IPM program. For more information or to place an order, contact our Communications Department at +1 (610) 825-6000, ext. 5888, or at communications@ecri.org.

Examples of High-Risk Devices

Anesthesia units and vaporizers	Left ventricular assist devices
Anesthesia ventilators	Mobile high-efficiency-filter air cleaners
Apnea monitors	Nuclear medicine systems
Argon-enhanced coagulation units	Oximeters (pulse)
Aspirators (emergency and tracheal)	Oxygen monitors and analyzers
Autotransfusion units	Pacemakers (external)
Blood pressure units (invasive)	Peritoneal dialysis units
Capnometers	Phacoemulsification units
Defibrillators (including automated external defibrillators)	Physiologic monitors and monitoring systems
Electrosurgical (surgical diathermy) units	Radiant warmers (infant)
Fetal monitors	Radiographic dye injectors
Heart-lung bypass units	Radiologic imaging systems
Hemodialysis units	Regulators (for tracheal suction)
Humidifiers (heated)	Resuscitators (cardiac)
Hypo/hyperthermia units	Resuscitators (pulmonary)
Incubators (infant, including transport units)	Sterilizers (e.g., steam, ethylene oxide [EtO])
Infusion pumps/controllers	Tourniquets (pneumatic)
Intra-aortic balloon pumps	Transcutaneous oxygen and carbon dioxide monitors
Lasers (surgical)	Ventilators

(continued from page 248)

should ensure that the ventilator is inspected once it is removed from the patient or, for long-term ventilation, should substitute a different unit to allow that one to be inspected. Policies for lower-risk devices might allow greater leeway by permitting longer IPM delays (e.g., allowing “annual” IPM to be performed within 15 months of the last one). Note, however, that there is nothing in the JCAHO standards about on-time completion or about using any specific slippage window. These are examples only and should be adjusted for the specific equipment based on experience and professional judgment.

Also, if you are unable to locate a piece of life-support equipment when its IPM is due, there should be a determined effort to locate the device, and that effort should be documented.

6. Document corrective action plans and actions taken. If the hospital fails to meet the requirements for any equipment, whether life-support or non-life-support, ECRI strongly recommends that a corrective action plan be documented and its success monitored. ECRI also recommends that periodic reports to the safety committee (or equivalent group) include any life-support equipment maintenance not completed within the targeted time, the reason, and a corrective action plan, with follow-up documentation of implementation success.

Note that there is an odd inconsistency in the *CAMH*: EP 4, for non-life-support equipment, is marked with a Measure of Success (MOS) icon — an M in a filled circle — meaning that if the hospital is found *not* to be in compliance with this EP during a survey, it must establish and document a quantifiable means of assessing whether its corrective action is effective. Yet EP 3, which applies to the more critical

life-support equipment, is not marked as requiring an MOS if a hospital is found to be noncompliant. Nevertheless, we believe having a corrective action plan is important for both categories of equipment.

WHAT YOU *DON'T* NEED TO DO

Unless review of your procedures and data indicates otherwise, a separate inventory of life-support devices is *not* required. However, flagging these devices in your inventory and having a separate IPM-completion summary report for life-support equipment could help prevent equipment from falling through the cracks and could simplify demonstration of compliance.

In addition, you do *not* need to change the criteria for selecting equipment for inclusion in your equipment-management inventory.

Also, you do *not* need to increase the frequency or the level (that is, the content) of IPM conducted on life-support devices.

Finally, as noted above, a Measure of Success quantifiable assessment is *not* required for EP 4, unless the hospital is found not to be in compliance with this EP during a survey.

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Using Blood Glucose Meters

Minimizing Errors, Maximizing Accuracy



UMDNS terms. Analyzers, Point-of-Care, Whole Blood, Glucose [16-488]
■ Monitors, Personal, Glucose [20-184] ■ Reagents, Home-Test Kits, Whole Blood, Glucose [19-312] ■ Reagents, Clinical Chemistry, Rapid Test, Whole Blood, Glucose, Strip [17-419]

Summary. Blood glucose meters (BGMs) provide fast and generally accurate measurements of the glucose levels of individuals with diabetes. But they aren't foolproof. A number of problems can affect BGM accuracy, including technical faults, user errors, and variations in patient physiology. An erroneous reading could mean that a hypo- or hyperglycemic patient might receive inappropriate therapy or perhaps no therapy at all, with potentially life-threatening consequences.

In this article, we provide recommendations to individuals and health-care providers on ways to minimize erroneous BGM readings. We also offer some troubleshooting tips and itemize the physiologic factors that can impact readings — a potential source of errors that is often overlooked.

BGMs: Invaluable but Not Foolproof

During the past few decades, the treatment of diabetes has progressed considerably. Research and development, pharmaceutical advances, and patients' increased involvement in their own health and therapy have all contributed to the improvements. And so, of course, have technological advances — one of the most important being blood glucose meters (BGMs).

BGMs allow glucose in a blood sample to react with a glucose-specific enzyme. They then use either reflectance photometry or electrochemical technology to convert a measured change to a blood glucose level, producing a result within seconds. The value of BGMs to both individuals and healthcare facilities is immense. BGMs allow patients to check their blood glucose levels wherever and whenever they wish. And they allow healthcare facilities to provide improved patient care: With BGMs, glucose levels can be checked and treatment can be applied quickly; also, BGMs can reduce patient blood loss due to laboratory testing since they require a smaller blood sample than is needed for lab tests.

Though their results are usually clinically accurate, BGMs are susceptible to a number of problems that can affect that accuracy. Such problems often involve some

The best remedy for BGM problems is usually prevention.

form of technical malfunction, but they may also stem from user errors or from variations in patient physiology. And they can have serious consequences, since routine insulin doses are often adjusted based on BGM readings, and in more acute situations clinicians may use BGM readings as the basis for decisions about whether a patient requires treatment for hypo- or hyperglycemia (e.g., whether insulin or glucose should be administered, whether the patient should go to the hospital). An erroneous reading that leads to a failure to implement therapy or to implementing inappropriate therapy could contribute to a serious or even fatal outcome.

Unfortunately, there is usually no obvious indication at the time of glucose testing that there is a problem or that a result may be inaccurate. Identifying the reasons for inaccuracies after the fact can also prove difficult: Incident reports usually don't provide enough information to determine the specific cause of an inaccuracy, and in many cases it is not

even certain whether an adverse clinical outcome was directly related to an erroneous BGM result. Complicating the investigation process is the fact that glucose levels can change rapidly. Results can therefore vary depending on, for example, the time between the taking of test specimens (if, say, a BGM test is followed by a laboratory glucose result, or a second BGM is used to check the results from the first one), the time between eating and testing, the time between medication administration and testing, and physiologic changes (such as those caused by exercise or dehydration). The case histories described on page 254 illustrate some of the complexities of BGM problems.

Maximizing Accuracy

Given the difficulty of identifying BGM problems as they happen, the best remedy is usually prevention. We recommend that users — both individuals and healthcare facility staff members — take the following steps to help keep BGM readings as accurate as possible.

RECOMMENDATIONS FOR ALL USERS

The following recommendations should be useful for both individual users and caregivers:

Read the manufacturer-supplied instructions for use and follow those directions exactly. Test-strip inserts contain valuable information, including the factors that can affect test results.

Clean reflectance-type BGMs as necessary (at regular intervals and whenever visibly dirty) according to the manufacturer's instructions and your facility's policy. Dirty optics can produce incorrect results.

Check the physical integrity of the meter, especially the display. An incomplete display of a reading could result in an error. For example, an incomplete "9" could read as a "4," meaning that a result of "95" could be read as "45."

Check for correct operation when needed — for example, if the meter has been dropped or exposed to temperature extremes — by using the manufacturer's protocol and running test strips to which control material (solutions with a known amount of glucose in them) has been applied. The use of control material checks the performance of both meter and strip. Some meters also include a "check" strip that can be used to test the meter's electronics. Every manufacturer recommends using control material to check meter and strip performance, and most healthcare facilities do so. But relatively few individuals do: Often they forget — or are unaware of — the importance of running controls; also, they may not have ready

Physiologic Factors Affecting BGM Readings

Since their introduction, blood glucose meters (BGMs) have been subject to performance limitations and inaccuracies due to human physiology. It's easy to overlook these types of factors and to focus on technical problems or human error as the source of incorrect results. But the physiologic effects are real and need to be considered.

One significant source of physiology-based errors is the use of alternate-site testing (AST), a capability available on some BGMs. AST allows the use of blood samples that are obtained from locations other than the fingertip, such as the forearm or thigh. Users need to be aware, however, that blood flow to alternate testing sites has a different perfusion rate and capillary distribution than blood flow to fingertips. This difference generally causes the glucose levels at alternate sites to "lag behind" those of fingertips during periods when glucose levels are changing rapidly. Users need to refrain from AST testing during such periods to avoid inaccurate results.

In addition, the following physiologic factors can cause potential problems in all applications:

- Hematocrit — Very low or very high hematocrit levels can influence meter results, depending on the test methodology being used.
- Oxygen status — Glucose meters typically utilize an oxidation/reduction process as part of the measuring system. An extremely low or high level of oxygen in the blood sample can affect the accuracy of some of these meters.
- Dehydration, hypertension, and hyperosmolar states — These conditions may interfere with glucose measurement on the test strip, causing the meter result to be incorrect.
- Changed perfusion rates — Any condition that changes the rate of perfusion, such as shock or exercise, will influence fingerstick glucose results, since the blood flow to the fingers will differ from normal and may not reflect current blood glucose levels. This factor also impacts AST.

Other physiologic factors that affect glucose results will generally be more of a concern during testing by medical personnel than during self-monitoring of blood glucose (SMBG), since most individuals performing SMBG are relatively healthy.

Also, while not strictly a physiologic factor, drug interferences can occur. Very high levels of some drugs, such as acetaminophen and salicylate, along with reducing substances such as ascorbic acid (vitamin C), may interfere with some BGM determinations. ♦

access to the materials, which are not frequently found in local commercial outlets.

Establish protocols for confirming questionable results (e.g., results that don't match the expected values for the patient or don't match how the patient is feeling). In healthcare facilities, this might include using a different meter, using a different vial of test strips, using control material, or performing laboratory testing. But while repeating a questionable test can be helpful and is generally recommended, it's important to recognize that if the error stems from a problem with a meter or a vial of strips, repeating the test with the same meter or vial could simply produce the same erroneous result again. When using a laboratory specimen to confirm a BGM result, follow your facility's policy for specimen collection, testing, and treatment protocols. Individuals encountering a questionable result should also repeat the test but, when possible,

should do so with assistance from a knowledgeable family member and/or using a test strip from another package.

With the number of meters available in the commercial market, the potential for obtaining the wrong test strips exists; make sure that you have the correct strips for your meter. "Off-brand" test strips — strips made by someone other than the BGM manufacturer — are available. But most BGM manufacturers will be unable to help users troubleshoot problems if off-brand strips are being used.

Check that the BGM is correctly calibrated for the test strips. Individual users need to ensure that the meter is calibrated with each new package of test strips and check for correct calibration daily or with each use. (Unfortunately, some users may not know that calibration is needed, may forget to do it, or may forget how it's done.) In healthcare facilities, there may be multiple users with multiple

packages of test strips in use, so the calibration code for the strips being used should be checked against the BGM calibration code with each use. It's good practice, whenever possible, for a care area to have only one container of test strips in use at any time. The introduction of newer meters with bar-coded calibration features for facility use makes correct strip calibration easier.

Store strips in the original container, kept tightly sealed; store individually wrapped strips in the original sealed wrapper. Exposure of strips to humidity and heat can cause erroneous readings. In a facility, where many people could be performing testing several times an hour, staff members should resist the temptation to merely put the lid on loosely because "it'll just have to be opened again in a few minutes." Also, individual users, especially older people or those with arthritis or other hand problems, might find closing and opening the test strip vials difficult;

nevertheless, they should develop the habit of closing the vial tightly. (This problem is discussed further in the Hazard Report "Improper Use or Storage of Blood Glucose Monitors and Test Strips Can Lead to Inaccurate Results — Possibly with Fatal Consequences" in the February 2004 *Health Devices*.)

Wash hands before testing. Small amounts of food or sugar on your hands can affect test results.

Avoid squeezing the finger to obtain a drop of blood. Fluid from the surrounding tissue can mix with the blood sample and affect test results.

Be sure to apply an adequate volume of blood to the test strip. Too small a sample can produce an inaccurate result. Many of the newer meters will display an error message if the sample is too small. But other meters do not perform this check and will provide a result — even an incorrect one — unless the sample is so small that it

Case Histories

Problems with BGM Use

The following accounts of problems involving blood glucose meters (BGMs) are drawn from the U.S. Food and Drug Administration's (FDA) MAUDE problem reporting database. They illustrate many of the difficulties both in using BGMs and in gathering useful information about BGM-related incidents. The comments following each account, which are based largely on manufacturer-supplied information that appears in the MAUDE reports, generally focus on possible technical issues and do not address, for example, possible physiologic factors that might have contributed to the incidents.

(As a reference to gauge the glucose readings in these reports, the American Diabetes Association considers normal blood glucose readings to be the following: <110 mg/dL when fasting, 90 to 130 mg/dL before eating, and <180 mg/dL one to two hours after eating.)

- After obtaining a high glucose result (248 mg/dL) from a BGM, a patient self-administered insulin, ate dinner, and went out to play ball. The patient started feeling "bad" and went to the hospital, where laboratory glucose results were very low (35 mg/dL). Treatment was initiated, and the patient was later discharged.

Comment. The BGM supplier later stated that the patient had not followed the labeling for test-strip

storage and glucose-control use: The strips had evidently been stored in a high-humidity area, such as a kitchen or bathroom, and no controls were used before or at the time of the incident. Improper storage might have caused strip deterioration, resulting in a falsely high BGM result on which the patient based the decision to self-medicate.

- A patient reported erratic BGM results: first a result of 163 mg/dL, then two hours later a result of 290 mg/dL, and then an hour after that a result of 403 mg/dL. Yet during that time, no food was ingested, and the patient did not experience any hyperglycemic symptoms.
Comment. The patient had been using off-brand test strips that may not have been suitable for use with that model of BGM. The BGM supplier was not able to assist the patient with troubleshooting because an off-brand test strip had been used.
- In two separate incidents, BGM results varied widely from laboratory results: 105 versus 62 mg/dL in one instance, and 169 versus 288 mg/dL in the other.
Comment. These are examples of incidents for which the reports are too sketchy to provide useful

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doesn't register a reading at all. It is the responsibility of the person performing the test to ensure adequate sample; if there is any doubt, the test must be repeated.

Correctly apply the sample to the test strip. Application methods vary with the meter and strip. For example, with some devices, the blood must be applied directly to the test area; with others, the blood must be applied to the side of the strip, where it is drawn into a test area inside the strip. Holding the meter upside down or inserting the test strip upside down may produce erroneous results.

Healthcare workers should consider physiologic conditions that could cause fingerstick glucose levels to be inaccurate, such as severe dehydration, shock, or hypotension. (See the article on page 253 for further discussion of these conditions.) Individuals practicing self-monitoring of blood glucose (SMBG) should discuss with their healthcare provider the actions they should take when they are

feeling ill, as well as any changes they should make in their medication.

When BGM results are being compared with a laboratory result, it is important that both results be reported in the same units. Most new meters can report either plasma equivalents or whole blood results, with most meters in the United States set to report plasma results. Laboratory measurements are also usually given as plasma results, but there are a few instruments that can report a whole blood result. Your facility's policy should clearly indicate which form the results are reported in. In general, whole blood results are 10% to 12% lower than plasma results.

Timing is also important when comparing results — lab specimens should be drawn within five minutes of the BGM specimen and preferably before any treatment is initiated. If the laboratory specimen will not be analyzed immediately, it should be collected with a preservative to

(continued from page 254)

information. In neither case was the BGM supplier able to examine the suspect meter. The divergent results could have had any number of causes.

- After dropping a meter on the floor, the patient reported that it displayed a result of 7 mg/dL. The meter should not have been able to report a result that low — it should simply have displayed "LO."

Comment. The supplier reviewed system operation with the patient. During the review, it was noted that portions of the "hundreds" digit were missing. Possibly the "tens" digits were absent too, so that the reading of "7" might have been the last digit of a larger figure.

- At 5:05 a.m. in a nonhospital care facility, blood was drawn from a patient and sent out to a lab for testing. At 6:00 a.m., a BGM reading on that patient yielded a normal result (80 mg/dL); 20 units of Humulin, along with vitamins and antipsychotic drugs, were administered around 6:30 a.m. No symptoms were noted in the patient's chart. The laboratory glucose result, available between 11:00 a.m. and noon, was very high (775 mg/dL); a BGM reading taken at 11:50 a.m. was also very high (469 mg/dL). At this time, the patient did not feel well, had a temperature of 102°F, and was extremely lethargic. The patient

was sent to the hospital, where a blood glucose reading yielded 877 mg/dL.

Comment. At the time of the first BGM reading (6:00 a.m.), the BGM had displayed a low-battery message. A low battery could have caused a falsely low reading, leading to the inappropriate administration of drugs. The fact that a later reading with the same BGM showed a very high result — nearer to the laboratory result — suggests that the battery might have been changed between readings. Unfortunately, the supplier was unable to examine the BGM or the test strips, so a definite conclusion is impossible.

- A patient was found slumped in a chair at 8:35 p.m. A BGM reading was taken and yielded a glucose level of 122 mg/dL. En route to the hospital, however, a second BGM reading was obtained. The result was "LO," indicating an extremely low glucose level, and the patient was admitted with hypoglycemia.

Comment. Another mystery. Because the specific BGM involved in the incident could not be identified, the hospital returned 10 BGMs to the supplier. No test strips were returned, however, nor could the lot numbers of the test strips or control solutions used be identified. One of the meters failed electronic and calibration testing; the other nine passed. Ultimately, the supplier could not replicate the problem or determine its cause. ♦

prevent glucose utilization by the red blood cells. (Of course, these recommendations should be adjusted as needed to accommodate your facility's policies for BGM use.)

RECOMMENDATIONS FOR HEALTHCARE WORKERS

The following recommendations are intended specifically for healthcare workers providing support and care for individuals with diabetes:

Review with patients and family members the proper use of meters. Include a discussion of frequent sources of error, such as failure to perform maintenance, failure to use the correct test strips for the meter, failure to calibrate the meter with new strips, failure to store the strips or meter properly, and use of inadequate sample sizes.

Provide clear instructions on what to do if there is a questionable reading or other problem. Encourage individuals to have controls on hand to help detect problems.

For individuals having difficulty using their BGMs, consider one of the many new, user-friendly products that are on the market. For example, if a patient has trouble opening strip vials, consider a BGM with individually packaged test strips. A patient who has trouble with calibration may benefit from a meter that calibrates itself when a new supply of test strips is added. If applying sample correctly is a problem, consider a BGM with strips that absorb sample rather than requiring the user to apply it. For users with impaired vision, meters with large displays or audible results are available.

Periodically inspect patients' meters, and review their technique. Have the patient bring the meter and strips along when coming in for an appointment so that you can check that the meter is clean and not damaged, that correct, unexpired strips are being used, and that the meter is correctly calibrated. Have the patient perform a reading to verify that the correct technique is still being used. The frequency with which this is needed will vary with the individual. It is recommended that a meter glucose result be compared to a laboratory glucose result at least once a year.

For patients using meters approved for alternate-site testing (AST) — that is, testing that uses samples drawn from somewhere other than the finger — review with the patient and family members when such testing is appropriate. Review with the patient other physiologic causes of inaccurate or misleading results, such as illness (e.g., dehydration) or exercise. (AST and other physiologic influences on meter accuracy are discussed in the article on page 253.)

Tips for Troubleshooting

If you encounter questionable readings, this checklist may help you identify basic use errors that might have been committed. If these checks don't help and you have to contact the manufacturer or a hospital technician, be sure you have the following information available: meter serial number, test strip lot number and expiration date, control material lot number and expiration date, control values obtained for that testing day, and any error codes displayed by the meter.

STRIPS

- Are you using the correct strips for your meter? For example, some BGM manufacturers offer more than one model, and the test strips must be for the meter in use.
- Are the strips within their expiration date?
- Before the container or wrapping was opened, had it been securely closed?

METER

- Does the meter pass all the start-up electronic checks?
- Does the meter calibration information match the calibration information for the test strips in use?
- Is the CHECK BATTERY or REPLACE BATTERY message lit?
- Are any error messages displayed?
- Is the meter reporting plasma results (most commonly used in the United States) or whole blood results? ♦

Problem Reports

Policy statement. ECRI encourages members, healthcare providers, patients, and suppliers to report all medical-device-related incidents and deficiencies to us so that we can determine whether a report reflects a random failure or one that is likely to recur and cause harm. Reports can be generic or model specific. We add all reports to our internal confidential databases to track trends of device failure or lot-specific defects. Although many reports do not result in a published article, we inform the reporting party of our findings or opinions when appropriate. As soon as we become aware of device hazards and problems, we inform the suppliers and invite them to respond constructively.

If our investigations yield information that should be communicated to the healthcare community, we publish the information in *Health Devices* as either a Hazard Report or a User Experience Network™ (UEN™) article, depending on the level of risk associated with the problem. Member hospitals may reproduce these reports for internal distribution only. This policy does not apply to other articles in *Health Devices*, unless otherwise noted.

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Hazard Report

Medi-Mech Supplies the Wrong Replacement Casters for Video Cart

PROBLEM

A member hospital reports that a replacement caster supplied by Medi-Mech for use on its Olympus 9C video cart snapped off nine months after installation. A nurse suffered minor injuries, and equipment was damaged. The hospital subsequently learned that Medi-Mech had supplied inappropriate replacement casters.

ECRI is concerned that this problem could affect other carts that have replacement casters supplied by Medi-Mech, not just this hospital's Olympus 9C video cart. Medi-Mech manufactured carts for a number of medical device companies but is no longer in business. Since ECRI is unable to ascertain whether other video carts may have been fitted

with an incorrect replacement caster, healthcare facilities must assume that any cart with replacement casters supplied by Medi-Mech could fail at any time, possibly causing injury and equipment damage.

DISCUSSION

The hospital's video cart was supplied by Olympus in 1997 as part of a surgical video system. In June 2003, the original casters were found to be failing, and replacements were sought from Olympus. Olympus informed the hospital that it no longer supplied spare parts for this cart and that the cart had been manufactured by Medi-Mech. Medi-Mech supplied the hospital with replacement casters (Medi-Mech Part No. 702046).

About nine months later, a caster snapped off the cart while the cart was being wheeled into the OR. The hospital attempted to contact Medi-Mech and found that the company was no longer in business. However, a message left by Medi-Mech directed inquires about replacement casters to the supplier, Faultless-Rhombus Casters.

Faultless-Rhombus informed the hospital that the replacement casters supplied by Medi-Mech were the wrong size and cannot be fitted properly to the Medi-Mech carts. The use of these ill-fitting casters caused the cart's weight to be borne by the threaded stem, rather than the caster's mounting plate (see the photo). The correct caster is Faultless-Rhombus Part No. 367H29K150VZLU. If fitted properly, individual casters are specified to hold up to 220 lb (100 kg), which is more than adequate for any video cart. Faultless-Rhombus Casters can advise customers and supply the correct casters.

CONCLUSIONS

A significant amount of expensive medical equipment is mounted on carts that are themselves mounted on casters. And casters are available in a wide variety of sizes and styles. As this incident demonstrates, it is possible to fit an inappropriate caster without immediate effects. But over time, the stresses on the caster could cause it to fail prematurely, possibly leading to equipment damage and personal injury. Thus, a simple clerical error, such as misreading a part number, could eventually have serious consequences.

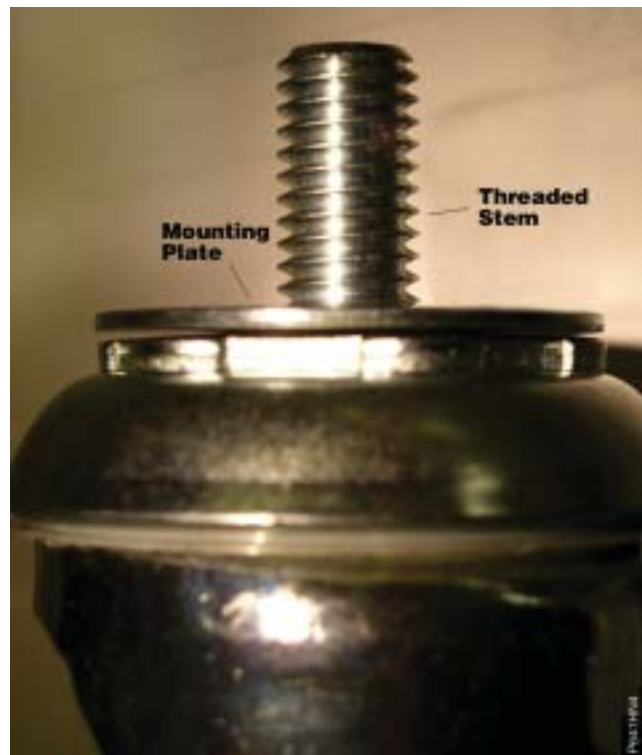
Although it is not possible to ascertain how many other devices could be affected, the fact that Medi-Mech left a

message for customers suggests that the problem could be widespread.

RECOMMENDATIONS

The following recommendations are directed to any hospital that has received replacement casters from Medi-Mech. Tracing such casters may be difficult since carts supplied by Medi-Mech are incorporated into a number of medical systems supplied by other manufacturers. The cart involved in this incident was clearly labeled with the Medi-Mech name. However, ECRI is unable to verify whether this is always the case. Therefore, records of purchase orders should be searched, if possible, to identify casters ordered from Medi-Mech.

1. Alert users of Medi-Mech carts that such carts might include inappropriate replacement casters. Carts with the wrong casters may appear to function normally, but the casters could fail at any time.
2. Check your procurement records to ascertain whether any replacement casters for these carts have been supplied by Medi-Mech.



The type of Medi-Mech caster involved in the reported incident. If an incorrect caster is installed on a cart, the weight of the cart is not properly supported by the mounting plate. This can put stress on the threaded stem, eventually causing it to crack.

ECRI's Hazard Reports

A Hazard Report describes a possible source of peril, danger, or difficulty. We publish reports about those units in which we have identified a fault or design feature that *might*, under certain circumstances, place patients or users at risk. These reports describe the problem and ECRI's recommendations on how to correct or avoid it. Publication of a report on a specific brand name and model of device in no way implies that competitive devices lack hazardous characteristics.

When deciding whether to discontinue using a device that ECRI believes poses a risk, staff should balance the needs of individual patients, the clinical priorities, and the availability of safer or superior products against the information we provide. Clinical judgment is more significant than an administrative, engineering, or liability decision. Users can often take precautions to reduce the possibility of injury while waiting for equipment to be modified or replaced.

3. Examine any cart that has had replacement casters supplied by Medi-Mech. In particular, ensure that the weight of the cart is borne by the caster's mounting plate. If schematics and part lists are available, check that part numbers match.
4. Remove from service any cart that shows signs of improper caster fitting or other evidence suggesting that

the wrong caster is fitted. Until the correct replacement caster is fitted, another cart should be used.

UMDNS term. Carts, Instrument [10-641]

Supplier. Faultless-Rhombus Casters USA, Medford, New Jersey (USA); +1 (609) 654-2223; www.faultlesscaster.com ♦

Talk to the Specialist

Pulse Oximeter Accuracy Specifications

Question. The SpO₂ accuracy specifications for our pulse oximeters are stated as 70% to 100% $\pm 2\%$ for adult patients ($\pm 3\%$ for neonates). Does this mean that our pulse oximeter readings should *always* be within $\pm 2\%$ ($\pm 3\%$ when monitoring neonates) of SaO₂ values obtained by arterial blood gas measurements, provided that the patient's SaO₂ is between 70% and 100%?

Answer. No. A pulse oximeter that is functioning according to its accuracy specifications can provide SpO₂ readings that differ from SaO₂ values by more than the amount specified — in your case, 2% for adults and 3% for neonates. (SpO₂, which is determined by pulse oximetry, provides an estimate of the oxygen saturation of hemoglobin in the patient's blood. SaO₂, on the other hand, is a direct measurement of arterial oxygen saturation obtained through arterial blood gas measurements.)

The reason that your pulse oximeter readings may occasionally differ from SaO₂ measurements by more than the specified 2% or 3% is that pulse oximeter suppliers define accuracy specifications for their devices using a statistical measure of reading accuracy for a population of subjects and observations. In these accuracy specifications, the number that follows the plus/minus (\pm) sign represents one standard deviation (SD) for a statistically normal distribution.

By definition, specifying accuracy with SD means that about two-thirds of the SpO₂ readings you will observe can be expected to agree with SaO₂ measurements within ± 1 SD — that is, within $\pm 2\%$ for adults and $\pm 3\%$ for neonates. The remaining one-third of the SpO₂ data can be outside the range defined by ± 1 SD. However, approximately 95% of all the SpO₂ data should agree with SaO₂ measurements within ± 2 SD — that is, within $\pm 4\%$

for adults and $\pm 6\%$ for neonates in your case. (All of this is provided that SaO₂ values are between 70% and 100% and that situations known to affect the accuracy of pulse oximetry are not present. Some examples of such situations are patient motion, low perfusion, dysfunctional hemoglobins, intravascular dyes, light interference, and improper sensor placement. Some pulse oximeter suppliers provide additional accuracy specifications for when their devices are used under conditions of motion and low perfusion.)

As a highly simplified example, consider a group of 100 healthy, nonsmoking adults who all had pulse oximetry readings taken when their SaO₂ was measured to be 95%. A pulse oximeter that is functioning within the accuracy specifications for your devices would likely yield the following results:

- SpO₂ readings of 93% to 97% (i.e., readings within ± 1 SD) for about 68 or so of the 100 adults
- SpO₂ readings outside this range for about 32 of the adults, although the readings for no more than about 5 of the adults should fall outside the range of 91% to 99% (i.e., ± 2 SD)

Thus, although the pulse oximeter may seem to be producing readings that fall outside the accuracy specification of $\pm 2\%$ for the 32 or so adults, the device is, in fact, still meeting its accuracy specification.

UMDNS terms. Oximeters, Pulse [17-148] ■ Monitoring Systems, Physiologic [12-636]

Supplier. These devices are available from a variety of sources; consult ECRI's *Health Devices Sourcebook* or Health Devices International Sourcebase for suppliers. ♦

Health Devices System

Objectives

To improve the effectiveness, safety, and economy of health services by:

- 1.** Providing independent, objective judgment for selecting, purchasing, managing, and using medical devices, equipment, and systems.
- 2.** Functioning as an information clearing-house for hazards and deficiencies in medical devices.
- 3.** Encouraging the improvement of medical devices through an informed marketplace.

