

DATA MANAGEMENT

Metrics for Equipment-Related Patient Safety

Malcolm Ridgway and Larry Fennigkoh

There is no question that the most effective way to respond to a question is with a set of relevant facts. Facts are generally irrefutable; colloquially we say, “The facts speak for themselves.” A database is nothing more than a convenient vehicle for collecting, organizing, and storing facts.

However, since all tasks involve some level of effort, it is appropriate to ask what is to be gained by committing valuable technical resources to the task of building some particular database. What will we get in exchange for this effort? In other words, what important question, or questions, will this collection of facts allow us to answer? Identifying these important questions is the very first step toward designing a database that will be useful.

An examination of the typical clinical engineering department’s basic mission statement reveals that we need answers to at least the following three questions:

1. Does the department have all of the facility’s medical equipment under “appropriate control”?
2. Is the department’s equipment control and maintenance program producing a level of equipment-related patient safety that is within an acceptable range?
3. Is the net cost of the program (the total cost less any tangible economic benefits) reasonable?

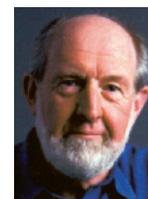
The first question is concerned with the program’s basic operating processes—what

can be called the program’s “housekeeping” parameters. Is the program meeting the quantitative objectives (if any) set out in the program’s policy documents? Are all of the devices in use properly tagged? Are they checked before being used for the first time? Are recalls being handled properly? Is the preventative maintenance (PM) done according to the prescribed schedules? And so on. These are the basic process or “housekeeping” questions that are generally examined during the traditional accreditation surveys.

The second question is much more fundamental, and while it is clearly important to define some kind of clear, easily comprehended patient safety metric, it is something with which clinical engineers have struggled over the years. Surely, though, it is a basic question that the patient safety officer of every healthcare facility, as well as the Centers for Medicare and Medicaid Services (CMS) office, has every right to ask. It could perhaps be considered the ultimate program performance standard.

The survey work that was done to provide initial responses to the questions asked by the CMS more than two years ago revealed that the amount of PM being performed on the different types of medical devices by different facilities is quite variable. Some facilities do all of their PM “by the manufacturer’s book,” while many others do it according to so-called “evidence-based schedules;” schedules that themselves seem

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to cover a quite wide range of variation. Compounding this apparently random diversity is the fact that at this time there are no generally accepted minimum PM schedules for devices that can be defined as potentially critical; there are no minimum requirements as to which potentially-critical nondurable parts should be restored during PM, nor which potentially critical functions should be checked for hidden failures.

And since we have not yet agreed on a minimum acceptable level of equipment-related patient safety, we simply cannot say which of the many PM program variants is optimum. Without some agreement on this key issue, it is impossible to provide administration with an answer to its very important basic question: Is the net cost of the facility's clinical engineering program reasonable? Just as too many nonproductive diagnostic tests push up the cost of defensive medicine, we probably will find that most clinical engineering programs are doing too much nonproductive PM. If we are to develop a true evidence-based approach to PM, we

must have the facts on how the levels of reliability and safety of the critical devices are changed by different PM procedures and different PM schedules.

Possible Solutions

As a first step to breaking this impasse, we need to investigate possible solutions to the primary issue that is blocking our ability to produce a quantitative answer to the patient safety question. Are there any reasonably practical metrics that could be used to provide a measure of the level of equipment-related patient safety prevailing in a particular healthcare facility?

Ideally, the metric, or metrics, should be simple, practical, and easy to comprehend. One solution that has been proposed by an ad-hoc Maintenance Practices Task Force² is to use the demonstrated reliability (expressed as mean time between failures [MTBF]) of devices that are considered to be reliability-critical (i.e. capable of causing a patient injury if they simply stop working) and the demonstrated reliability (again expressed as

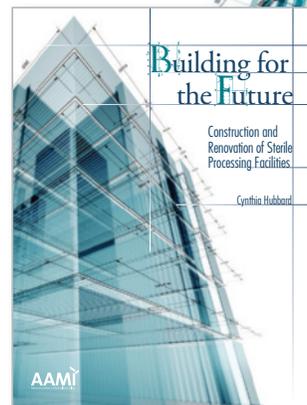
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MTBF) of devices that are considered to be performance/safety-critical (i.e., capable of causing a patient injury if they develop a certain kind of hidden failure).

Hidden failures are the shortcomings in performance or safety that are discovered during the performance and safety testing that is a part of many PM procedures. Examples of devices that are reliability-critical are critical care ventilators, transport ventilators, anesthesia units and intra-aortic balloon pumps. Examples of devices that are performance/safety critical with potential hidden failure modes that could cause a patient injury are apnea monitors, defibrillators, infant incubators, and neonatal monitors.

The task force contends that the format of these metrics (a simple time period, such as three months, one year, or 50 years) is simple and easy for lay people to comprehend. For example, a refrigerator that doesn't need any repairs over its 15-year lifespan is easily understood to be more reliable than an old automobile that has to be repaired every six months or so. And if the device becomes dangerous when it fails, it is easy to understand that this measure of reliability will also serve as a reasonable measure of safety.

With respect to practicability, however, there are some statistical issues that make these two proposed metrics a little problematic. The statistical complication arises from three factors.

First, because they are designed and constructed differently, different manufacturer-model versions of a given device type, such as defibrillators, can be expected to show different levels of reliability. So, each different manufacturer-model combination has to be analyzed and characterized separately.

Second, most individual healthcare facilities probably will have only a few devices that are reliability-critical and not too many more that are performance/safety-critical at the life-threatening level.

The third factor has to do with the likelihood that devices that are potentially critical

with respect to their ability to cause a patient injury (if they fail completely or if they develop a certain type of hidden failure) are likely to be designed and constructed to have a high level of reliability and a low failure rate.

The result of these complicating factors is that individual facilities may not generate enough data to get a good indication of each device's true reliability. To get accurate estimates of the reliability of high-reliability devices it will usually be necessary to pool maintenance statistics for each manufacturer-model version of each device from a number of institutions. This requirement is discussed below.

For example, suppose a facility has only three similar (same manufacturer—same model) heart-lung units and only three years of maintenance history for each unit. Since the facility has a total of only nine device-years of experience, it is unlikely—if the actual MTBF of the units is, say, 50 years or more—that the facility will have experienced even one single failure during the three-year testing period. In this case

they would have to report their finding with respect to the devices' indicated reliability (zero failures over nine device-years) as undetermined. If, however, they did experience one or more failures of one of these devices during this relatively short period, then the indicated MTBF will probably be unacceptably short for a critical device and it would be prudent for the facility to consult the findings on the reliability of these specific types of devices in the national database to see whether or not their particular experience was indeed typical (and this type of device is, in fact, not sufficiently reliable) or if their experience was atypical.

Let's look at how these two proposed metrics would be implemented.

A. Failure rates of the facility's reliability-critical devices (expressed as MBTF).

Using this type of analysis will require the facility to identify which devices on their

Examples of devices that are performance/safety critical with potential hidden failure modes that could cause a patient injury are apnea monitors, defibrillators, infant incubators, and neonatal monitors.

How You Can Help

With respect to ways in which individual members of the healthcare technology management (HTM) community can help with this project, there are three ways.

- **Review and offer comments on any of the documents or any of the other materials provided on the website.** Do they make sense to you? How can they be improved? E-mail us (at htmc.mptf@gmail.com) with either broad, general comments, or offer specific alternate wording.
- **Do the same thing with the tables that make up the heart of the project.** In particular, we are soliciting input from experts on any of the specific device types featured in the tables. Have we missed any critical failure modes? Have we understated or overstated the severity of any of the already-identified failure modes?
- **Provide us with your PM findings for any of the critical device types.** This is the very essence of the project. We do, however, ask that you comply with the process and formatting requirements described in HTM ComDoc 7.² Creating a community database of findings on current levels of equipment reliability and safety.

Thank you in advance for your willingness to support this important project.

inventory they consider to be reliability-critical.

Since only a relatively small fraction of the total number of device failures are preventable by conventional clinical engineering activities, it will be necessary to create a consistent classification method for identifying which of these failures were reasonably preventable.

Then, if X preventable failures were documented during the testing for a particular manufacturer-model of device over an experience base of P device-years, then the MTBF would be P/X years. Although there is no consensus yet on what might be an acceptable value for this parameter, a value greater than 50 years would seem to be reasonable.

However, as noted above, for many facilities, an experience base of more than 50 device-years for their relatively small number of reliability-critical devices may be rare, so it is quite possible that the number of reported preventable failures will be zero. In this case, as noted above, the facility will have to report the reliability as undetermined and, if a relatively short MTBF is found, check the indicated value for consistency with the values documented in the more substantial national database.

B. Hidden failure rates of the facility's performance/safety-critical devices (expressed as MBTF).

Again, as with tallying the number of preventable failures of the facility's reliability-critical devices, using this type of analysis will require the facility to identify which devices on their inventory they consider to be performance/safety-critical. The count of hidden failures discovered during PM testing must be confined to hidden failures that could conceivably cause some kind of patient injury.

If during the testing, Y hidden failures were found over an experience base of Q device-years, then the mean time between failures (MTBF) would be Q/Y years. Again, there is no consensus yet on what might be an acceptable value for this parameter, but a value greater than 50 years would again seem to be reasonable.

Again, for many facilities, an experience base of more than 50 device-years might be quite rare, so it is fairly likely that the number of reported critical hidden failures will be zero. In this case, as noted above, the facility will

have to report the reliability as undetermined and, if a relatively short MTBF is found, check the indicated value for consistency with the values documented in the more substantial national database.

For a more detailed explanation of the terms and concepts mentioned here, we recommend that you look at the material in HTM ComDocs 1-9 on the Maintenance Practices Task Force website.²

Using pooled data from the national database to supplement facility-specific data in the event of undetermined or atypical findings on the failure rates of the facility's critical devices.

In June 2013, the Maintenance Practices Task Force published a post on the *AAMIBlog*, titled "Doing It by the Numbers." It described a suggested approach to reassuring a facility's device users about the level of patient safety associated with its equipment and what the clinical engineering department is doing to ensure that equipment-related patient safety is maintained at an acceptable level. While the statement itself is a hypothetical example, meant only to illustrate the concept, it does make reference to "statistics from our national database to confirm that each specific make and model of the devices that we have classified as reliability-critical (and performance/safety-critical) is demonstrating an average or mean time between failures (MTBF) of at least several hundred years."

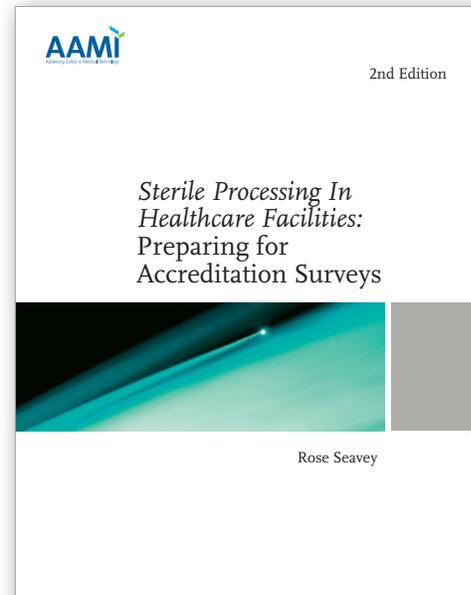
This latter figure of "at least several hundred years" is, for the moment, also completely hypothetical. We will have to see what actual values we find when we analyze real-world data. Building just such a national database to use in this way is the number one goal of the Task Force. ■

References

1. **TechNation.** Up in the Air: The Industry Hopes for a Positive Revision of the CMS Equipment Maintenance Directive." Available at <http://1Technation.com/air-industry-hopes-positive-revision-cms-equipment-maintenance-directive>. Posted Jan. 31, 2013. Accessed April 16, 2014.
2. **HTM Community.** Healthcare Technology Management (HTM) Community's MediaWiki-powered database website. Available at www.HTMCommunitydB.org. Updated April 9, 2014. Accessed April 16, 2014.

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