FEATURE ARTICLE

Fault Tree Analysis of Clinical Alarms

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Clinical alarms have a deceptively simple purpose, which is to notify caregivers when a patient or a device needs their attention. This simple concept has been proven to be challenging as the number of available alarms has grown and been poorly integrated. When an anticipated notification is not received or an actual notification is not acted upon in a timely manner, patient harm can occur. In this regard, false alarms have been proven to be highly detrimental to the effective use of clinical alarms to enhance patient care. Equally problematical is the issue of false reliance in which a clinician's vigilance is degraded by the expectation that if anything bad happens, the system will notify him or her. Similarly, alarms have also been part of staff downsizing and shifting to lower expertise, wherein it is believed that the alarms are an appropriate substitute. Human factor issues associated with setting, observing, and responding to alarms have also been proven to be inadequately addressed. This article presents a fault tree analysis of the patient harm-related clinical alarms failures. This analysis can be used to understand, debate, and educate.

Medical device alarms continue to be a challenging area of clinical engineering and hospital patient care, and the subject continues to receive a great deal of scrutiny.[1-7] Alarms have the clear purpose of improving patient care by calling an attendant's attention to a situation that may require his or her intervention. In many cases, each of the potential alarms must be set by the user with respect to a number of alarm parameters including on/off, upper/lower limit, volume of the alarm sound, and possibly a connection to or activation of a remote alarm notification location or system. This can involve a significant number of settings over a range of parameters and across a number of individual devices. Each of these settings may include default values that might be locally set or set by the manufacturer. When there are default values, it can be important when the device does or does not reset to the defaults.

An alarm may be triggered by a patient parameter (eg, heart rate) or a machine parameter (eg, infusion pump back pressure). Because of the widespread use of alarms, the occurrence of an alarm can have a widely varying degree of urgency ranging from a situation which calls for the need for an immediate response to one in which a response can be delayed until time permits a response. There may also be alarms that are very easily triggered (oversensitive) so that the alarm condition occurs frequently without there being in fact a serious underlying event. Low urgency and false alarms are so common that it is not unusual to hear one or more alarms sounding continuously in a patient care area with no apparent staff response. In fact such alarms can become in effect an ongoing part of the background noise to the point that the staff is not fully aware of the sound. This can be particularly unfortunate when an alarm is misinterpreted as not being important when in fact it is. This situation leads to an Food and Drug Administration (FDA) MedWatch Safety Alert[8] for a hemodialysis system in which it was determined that personnel were not responding quickly enough to an alarm condition.

The abundance of alarms is further confused by the fact that many alarms make identical or nearly identical sounds regardless of their priority. In addition, when multiple devices are in use, there may be more than one alarm that is triggered for the same patient condition either because of direct duplication or they are both related to the underlying event. There have been ongoing discussions of adding another layer of equipment that will receive the alarm signals and perform an integrated analysis before transmitting a response request to the patient care provider.[9-11]

Safety Analysis

These ongoing issues with clinical alarms make this topic a suitable one for formalized proactive safety analysis. There are a number of techniques that could be applied to this issue, including healthcare failure mode and effects

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analysis,[12] hazard analysis and critical control points,[13] and fault tree analysis (FTA).[14,15] Healthcare failure mode and effects analysis differs from the more traditional failure mode and effects analysis by emphasizing the process within which a failure mode might occur rather than isolating failure modes as might be done in a design failure mode and effects analysis. This makes healthcare failure mode and effects analysis similar to hazard analysis and critical control points. Fault tree analysis has similarities to root cause analysis (RCA), although RCA is generally thought of as being applied after an event has occurred for the purpose of finding the specific cause, whereas FTA can be applied more generally.[16] In fact, an RCA could be accomplished using an existing an FTA; that is, the FTA should, if it is thorough and complete, contain the specific situation that led to the incident that is being analyzed by the RCA.

In this article, FTA will be applied to the broad analysis of an adverse event associated with the failure of an alarm to generate the appropriate response. Fault tree analysis is chosen here because of its general applicability to diverse causation of a common event and because the end result is a useful tool for graphical visualization of the issues.

Fault Tree Analysis

The basic ideas of FTA have been previously presented.[14] In this technique, a specific undesirable outcome or hazard is identified. In the analysis presented here, the adverse outcome is alarm related harm to the patient. Contributing factors or events and their interactions are then identified that can lead to the undesirable outcome. This is then presented graphically as a branched structure of successive levels of causation and interaction. There are 2 basic kinds of links that connect causative events to the next higher level. These are the OR and AND connections. An OR connection is used when anyone of the lower level events can by itself lead to the higher level event. An AND connection is used when all of the linked events must occur to cause the event above. The standard logic symbols for OR and AND are often used as part of the FTA graphical presentation. This basic structure is shown in Figure 1. It can be readily seen that in general, AND situations are ''safer'' than OR situations in that neither event alone can cause the higher event. Safety improvement is often achieved or attempted by adding an AND activity. For example, if one person can misset an alarm, subsequently leading to an alarm-related event, then adding a requirement that a second person should routinely confirm the first person's setup would create an AND event since both users would have to make the same mistake for the event to propagate upward. However, it must be noted that the theoretical value of a second observer is offset by the reality that this cross-check may not actually occur or would be perfunctory, or there is a tendency for users and checkers to reconfirm what is seen even when it is wrong.

A fundamental question in the use of FTA is how many levels should be considered. Part of the answer to this question lies with the analyst's judgment. Certainly, there must be enough depth for the analysis to be

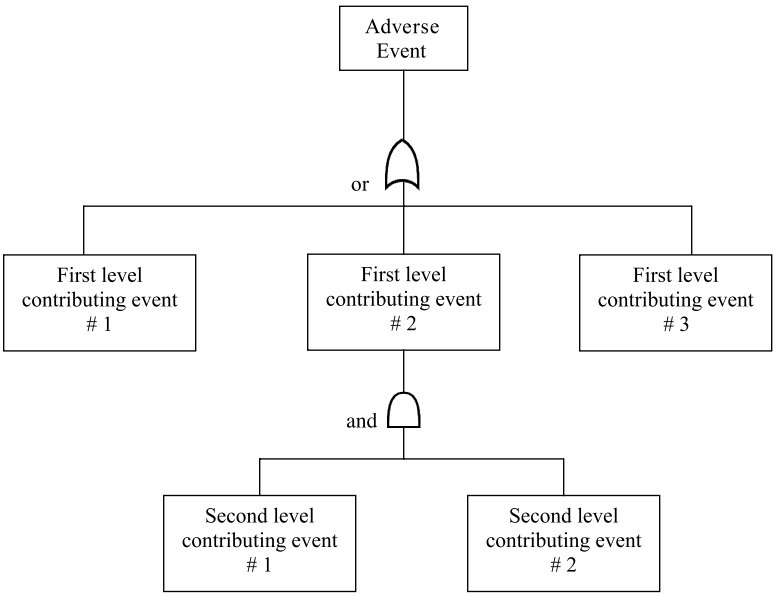

FIGURE 1. *Basic structure of a fault tree analysis.*

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comprehensive and useful. This is similar to The Joint Commission's (TJC) requirement that an RCA should be thorough and credible. The depth issue is also addressed in the RCA context by the ''5 whys'' analysis, that is, ask the causation question at least 5 times.[17] On the other hand, an overly complex FTA can become too difficult to easily understand. It is a mistake to be locked into a specific number of levels rather than letting the analysis itself determine the appropriate stopping points. When an event is the final one that will be considered, there is a practice to indicate this by using either a diamond or circle to enclose that event rather than a rectangle. There are other symbols that are also sometimes used, such as an ellipse to provide restrictive conditions on an event or other notes.[18]

Fault tree analysis can be used in several ways. One is as a predictive model of how the top event can occur and what subevents lead to the top event. A part of this analysis is the identification of easily occurring pathways to the top, in particular, those that can occur without interference by other parts of the system. These are generally OR events or a set of linked OR events. Such an analysis can be used as a basis for discussion in developing a fuller and/or more accurate picture of what can cause the top event or subevents.

In this regard, new viewers are generally required to add perspective and the ''what about this. . .'' aspect of the discussion since a single analyst will become convinced of the thoroughness of his or her own work. If sufficient data were available, the probability of reaching the top through any particularly pathway could be calculated from the probability of each event occurring. This could allow for a particularly rational means of deciding which part of the system deserved priority correction. Unfortunately, such data are rarely available. It is still appropriate however to consider how a proposal to address one particular event or pathway will impact the overall risk rather than just the risk of that one event or set of events. Without adequate consideration of this kind, it is possible to ''fix'' a small part of the problem that actually has little or no impact on the occurrence of the top event. Such fixes should always address the following questions:

1) What exactly is the problem the fix is going to address?
2) Why is that problem important to fix?
3) How will I know if I have fixed it?
4) Can I measure the impact of the fix on the overall problem?

A second use of the analysis is to demonstrate the role of corrective measures as indicated by a modified fault tree in which a previously easy path to the top has been either eliminated or made more complicated, often through the addition of an AND event. An example of elimination relevant to alarms is the risk associated with turning an alarm volume down to an inaudible level. The technical correction would be that the alarm volume cannot be turned below an acceptable level and therefore the ''turned to low'' event is eliminated. As mentioned above, a requirement for cross-checking adds a new AND event. In the design context, the FTA is an evolving document in which initially unacceptable hazards are modified through design choices or changes, with the FTA then indicating the revised configuration. In the hospital setting, an FTA can also be an evolving document as procedures and/or equipment are changed to address the risks illustrated by the original FTA.

Fault tree analysis can also be used after an incident occurs to illustrate the nature of the system as it existed and perhaps to argue how it should have been designed to prevent the occurrence of the top event. This postincident use in effect maps an RCA onto the already existing FTA, with the applicable layers of the FTA being equivalent to the further probing required in an RCA. If the FTA is complete, the RCA for any subsequent event should already exist as a path to the top on the FTA. If the facts of a specific event do not correspond to the FTA, the FTA must be incomplete, and it should be revised.

A potentially important further use of FTA is as a teaching tool. The illustrative nature of the analysis can be used to present the big picture and the interactions between events and subevents. Such a systematic presentation prevents the perception that the problem being addressed is so multifactorial that it is difficult to understand and deal with it or there are numerous unrelated factors that must be individually remembered and mentally integrated. In addition, showing an actual event on the FTA demonstrates that the event was not an inexplicable glitch in the system but instead was one that was predictable and fully understandable.

The FTA presented here is for the broad case of adverse patient situations associated with an alarm event. If successful, this provides an integrated basis for understanding, preventing, and evaluating a broad spectrum of alarm events.

The Alarms FTA

As noted above, the top event being considered here is an alarm related hard to patient. This generally includes the situation in which an alarm did sound but it was not appropriately responded to or an alarm that should have occurred did not or the condition that leads to the harm did not generate an alarm because that condition was not monitored. Because alarms in most cases supplement direct observation at least in theory, harm will occur only if there is not an independent observation of the patient's condition. In reality, alarms may have the effect of reducing vigilance when the staff has the sense that the alarm will notify them when they are needed, and therefore, their own attention can be reduced.

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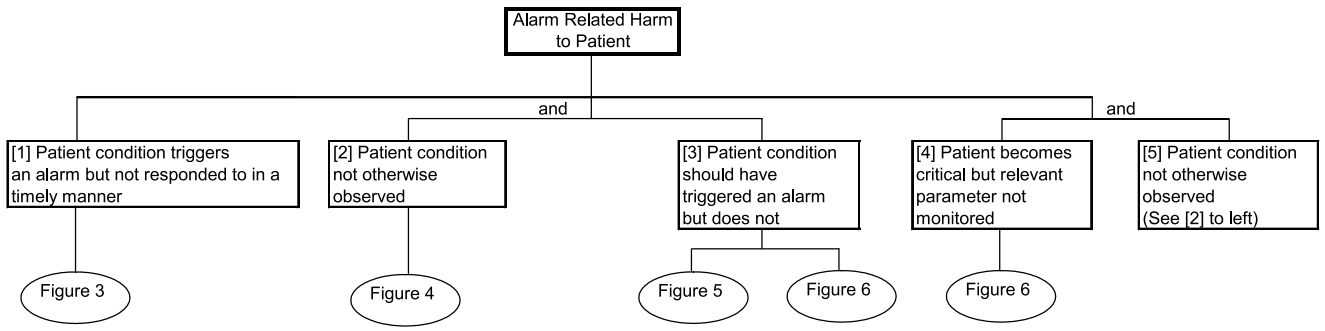

FIGURE 2. *Alarms fault tree analysis: top level*

For the purpose of the subsequent explanation of the FTA, in Figure 2 , each first event box is numbered (1, 2, etc), and then the events leading to that event are subnumbered 1.1, 1.2, and for event 1 and so forth. The sequencing of events from left to right is arbitrary, although there may at times be reason to segregate groups of events together, for example, personnel events as distinguished from device events. All branch points are considered to be OR unless AND is expressly noted. Connectors are used to indicate that the tree branch is extended in another figure.

Alarm Triggered

In [1], the event is that the alarm does occur but is not responded to in a timely manner (Figure 3). There are multiple potential reasons why the staff may not adequately respond. The alarm may not reach the staff [1.1], which could be a result of an alarm sounding in an ineffective location or not being loud enough [1.1.1]. This could be a failure in the design of the alarm system and possibly inadequate staffing (not shown). The alarm may also have been manually set at a too low volume. A similar situation arises when the staff is not where they are expected to be [1.1.6]. Here this is shown with an AND link to inadequate backup staff [1.1.7]. Actually, hearing alarms was one of the focuses of TJC's clinical alarms National Patient Safety Goals.[2] Some of these ideas occur again in [1.2], staff too busy.

The communication failure in [1.1.2] imagines the type of system in which the alarm is monitored remotely and actually received, and then the appropriate caregiver is notified by some form of communication system. When this is the primary means of alarm notification, the reliability of the system is critical to the proper function of this concept. In this regard, it is interesting that at least one major supplier of such a system has a disclaimer that its product should not be the primary means of communication.[19]

Box [1.1.4] includes the situation in which there is a software analysis of alarms with some associated decision making. Here, too, it is assumed that the alarm condition was correctly communicated to this software. Such software could reach an inappropriate conclusion, delaying or suppressing an alarm. In this situation, it could also be considered whether there is a parallel local audible alarm. If there is, then it would also have to be unresponded to by the staff. Including local audible alarms however results in a duplicated system since the staff members are also going to get a call to respond to an alarm that they can hear themselves. It is not clear if this kind of redundancy would be a good thing. One alternative would be for the remote system to only process the call if the primary alarm is not manually cancelled within a set period of time.

Similarly, [1.1.5] considers a human in the loop who is monitoring alarms (and possibly other events) and determining when to call for intervention. Environmental confusion [1.1.3] suggests the situation in which there is so much noise and activity that the alarm event does not rise above the background.

In [1.2], the staff are assumed to be aware of the alarm but they are genuinely too busy to respond. This could be a result of generally inadequate staffing or an excess of simultaneous or near simultaneous events, as shown in Figure 3A in boxes [1.2.1], [1.2.2], and [1.2.3]. This situation can be challenging to explain from a postincident risk management perspective, but it is certainly real in the clinical environment. If the staff were truly busy on tasks of equal or greater importance, how can they be expected to respond to the new alarm? If the task was of lesser importance, could this be easily determined? Is the staff forced to continually jump from one uncompleted task to the next as a result of some kind of ongoing priority scheme? Or are there simply too few people on a chronic basis. If the situation is really one of unanticipated and nonchronic demands, how can the staff call in backup?

Moving to [1.3], the staff may deliberately ignore the alarm. As noted above, it is not uncommon to hear numerous alarms in a clinical area without anyone

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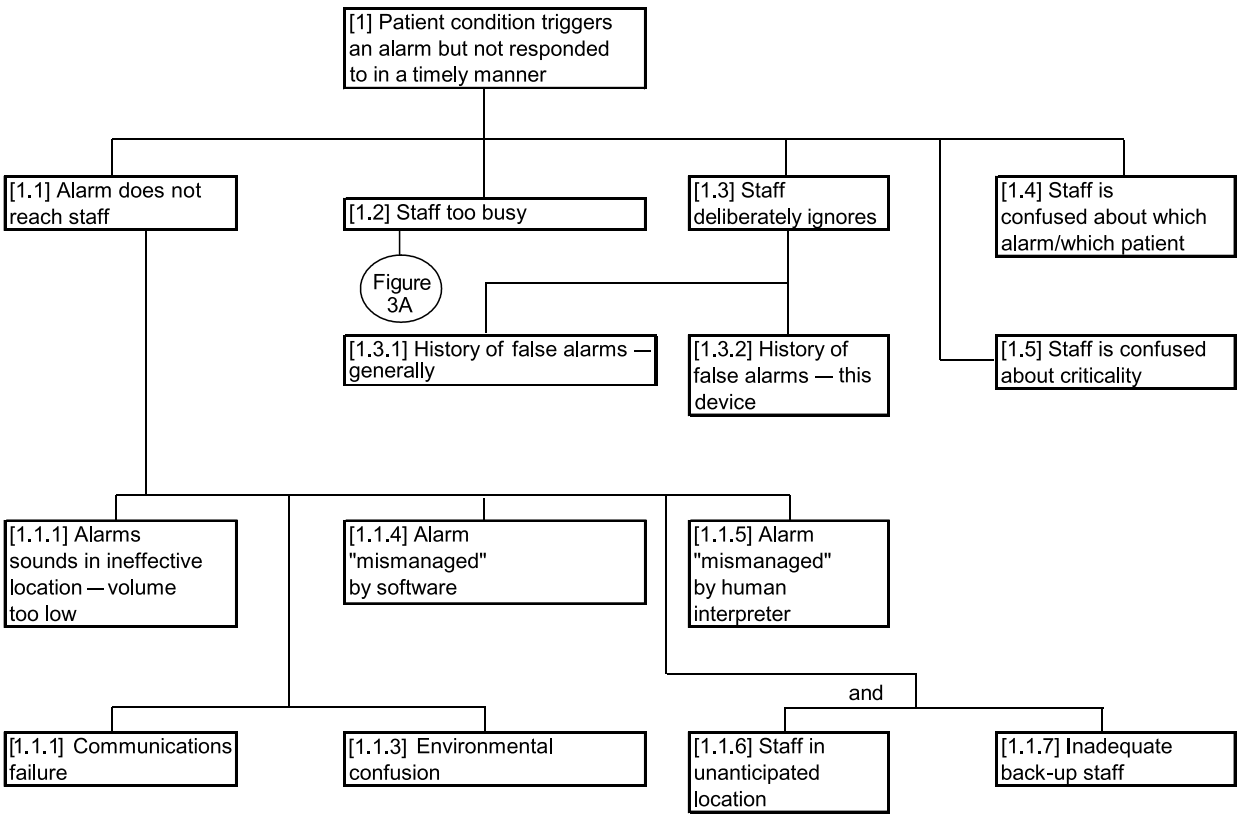

FIGURE 3. *Section [1].*

appearing to be particularly concerned. If the staff are experienced with a history of false alarms from any number of machines in the department [1.3.1] or the staff are familiar with false alarms with a particular device [1.3.2], the alarm may be ignored easily if it went off inappropriately. False alarms are often a result of the high sensitivity of the detection electronics/software or the setting of alarm limits too finely. The first is fundamentally a design issue, whereas the latter is a clinical practice issue. Preliminary results from one study have shown that delaying a secondary alarm by 10 seconds produced a drop in nuisance alarms by more that 30%.[20] The net effect of false alarms is well known from folk law. Frequent false alarms may also result in the silencing of alarms or sabotage of the alarm function.

A staff member may be unaware as to the criticality of the alarm [1.5]. This can be a direct result of the duplication of alarm sounds across a range of criticalities. Criticality can also be a subtle issue. For example, a lead off alarm may present no immediate threat to the patient,

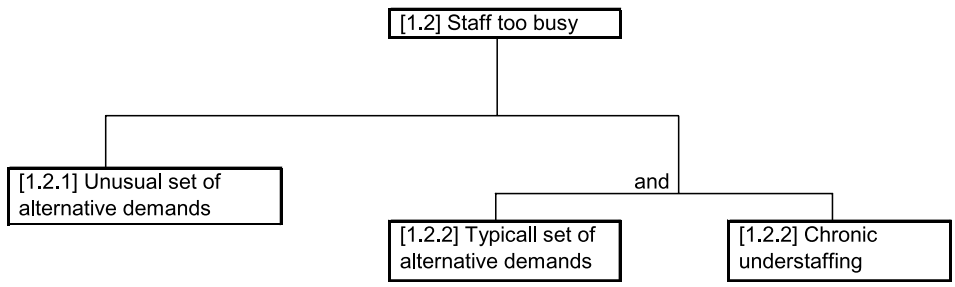

FIGURE 3A. *Section [1.2].*

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but if it is not responded to in a timely manner, the lead off condition may result in a missed event, as will be discussed in [3]. With the redundancy and sheer quantity of alarms, the staff might also be confused about which alarm is sounding or even to which patient the alarm refers [1.4]. This problem may be further complicated with the development of wireless monitoring and telemetry so that even tracing leads could not answer the question. This problem invites a solution in which audible alarms are supported by local and remote visual displays.

Alarm Not Triggered

The next section of the FTA deals with situations in which an alarm event should have been triggered but was not (part [3]). This is coupled through an AND link in which a patient or device condition was also not observed (part [4]).

In today's partially integrated environments, failure of an alarm to trigger can mean one of several things. The first is when the monitoring device itself does produce an alarm output when it should have or was reasonably expected to. The second is when the alarm message is generated but does not reach the remote software or the human being that is supposed to process the alarm information. If the alarm does not also occur locally, then the only failure to trigger can be at the remote device. This was the subject of a notice by the UK Medicines and Healthcare Products Regulatory Agency about an analyzer that had stopped communicating with its monitoring system (because this option had been switched off) but where the local audible alarm was not in use.[21]

The case of an alarm system that does not trigger an alarm when it should have done so is further analyzed in section [3]. Two major potential causes of such an event are considered. The first is a system or technical failure [3.1]. The second arises from usability issue [3.2]. Note that the same usability issues arise from the next section, and so the usability branch occurs twice. Three causes of system failures are considered. Potential causes of system failure include the disconnection of remote alarm [3.1.1], a hardware failure [3.1.2], a software failure [3.1.3], or a communications failure [3.1.3]. One example of hardware failure is a medical device report (MDR) that reported that there was a ''faulty alarm board assembly'' that had to be replaced.[22] Disconnects might include undetected lead disconnects or, for remote alarm monitoring, a disconnected communications line. Hardware failures can easily occur that disable the alarm, without disabling the rest of the device.[23,24] Software failures [3.1.3] that occur either within a device or along the communication path can also result in alarm conditions not resulting in a triggered alarm, as do other communications failures [3.1.4]. In one recall, it was reported that a particular version of the telemetry software could lead to the loss of an audible alarm when the operating system memory reaches a certain value.[25] Another example that may be software related is an MDR in which it was reported that the patient dropped off the central monitors and had to be ''readmitted'' to the monitor system.[26] Some bed exit alarms have been known to not generate an alarm when the detector pad is folded, with the fold causing the same effect as the presence of the patient in bed.

Wireless devices and/or electromagnetic interference can also create opportunities for communication pathways to be disrupted. Allegations of failure to alarm are common, and this is a unique category in the MUADE database product problem search engine. One side issue in these instances is data logging by the instrument that shows that an alarm did occur. When investigating an incident of this kind, it is important to not take on faith that a logged event did in fact occur. The log driver can be separate from the alarm driver such that the message that goes to the log does not correlate with an event that manifested actually manifested itself.

Any failure of an alarm to sound despite the indication that an alarm should sound only provides a critical path of potential harm to a patient if the patient condition is not otherwise observed by the staff [2], and the critical events generate a timely and observable condition. Inadequate attention can be caused by a false reliance on alarms to function as a substitute for caregiver's vigilance [2.1]. This can be especially critical when the parameters being monitored are not those that will be most affected by the patient's condition or when there is an alarm failure. One example here is the use of a heart rate monitor on a patient in respiratory distress. If the alarm limits are set too wide (as they may be to avoid false alarms), the patient may be seriously compromised by a lack of oxygen before this is evident in his or her heart rate. Another example was featured in an FDA Patient Safety News where it was noted that in hemodialysis, alarms may not sound if a catheter separates from the venous blood line because the alarm triggers only when the pressure in the venous blood line falls below the limit set by the user.[27] A patient condition going undetected by staff may also result from inadequate staffing such that the opportunity to make observations is reduced [2.3], or other work-related causes [2.4] (Figure 4).

Usability and Human Factors

Usability/Operator issues are addressed in Figure 5A. This is a major area of interest in medical device safety because it is believed that a high majority of medical device mishaps are due to use-related issues. This does not mean that the user should be directly blamed for the bad outcome since the culture of blame has been largely discredited as both incorrect and ineffective. Instead, user issues should be addressed from the system safety and human factors perspectives.[14] In fact, the term *use error* has

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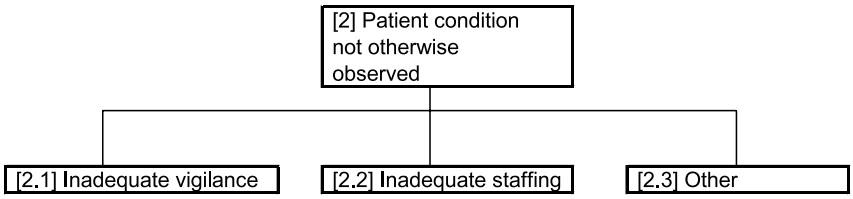

FIGURE 4. *Section [2].*

been recommended over *user error* since the latter implies a conclusion of blame where the former only describes what has occurred.[28]

Two traditional operator issues are alarm parameters being misset [3.2.2] and the alarm sound being misset [3.2.3]. In the modern era, missetting the communications link is also possible [3.1.1]. These 3 possibilities share a common set of causes. The design of the alarm system might be overly complex [3.3.1], continually challenging the user to get the correct result. Excessive complexity can be associated with the classic human factors dilemmas of too many steps to complete the task, the actions not being intuitive and/or the actions being otherwise too time consuming. Each of these can be impacted by the users being too busy to perform the tasks with adequate deliberation, including their being interrupted in their pursuit of the task. These issues can be further related to inadequate staffing, although the emphasis here is meant to be on the design. The user might also be inadequately trained [3.2.4], although training is a poor and often ineffective substitute for what might be fundamentally design or staffing issues. The study by the American College of Clinical Engineering Healthcare Technology Foundation[1] found an interesting result with respect to training. Although use errors are commonly observed in incident investigations and are often cited in FDA MDR reports, users when surveyed did not believe that their alarms systems were difficult to use correctly. This may be another kind of false reliance, that is, reliance on oneself to always perform safely and adequately (Figure 5A).

Failure to Monitor

The next section of the FTA deals with the lack of relevant alarms for a patient injury event in which the adverse event that occurred was not subject to monitoring, but other monitoring was in place (Figure 6). It is probably not possible to monitor every patient for every possible event. In this regard, no amount of monitoring can replace a vigilant staff with sufficient time and training to properly observe patients. However, the issue can be more insidious when a seemingly allied parameter is monitored but where that monitoring will not detect a closely related event. This can include a hear rate monitor when the critical condition is respiratory distress or a line pressure monitor when the critical issue is bleeding away from the line. Similarly, an infusion pump downstream occlusion alarm is not an infiltration detector, unless the infiltration causes an alarm-triggering back pressure.[29] These seemingly allied situations can add to the false reliance issue also discussed in reference to [2]. In all of these cases, there is a simultaneous failure to adequately

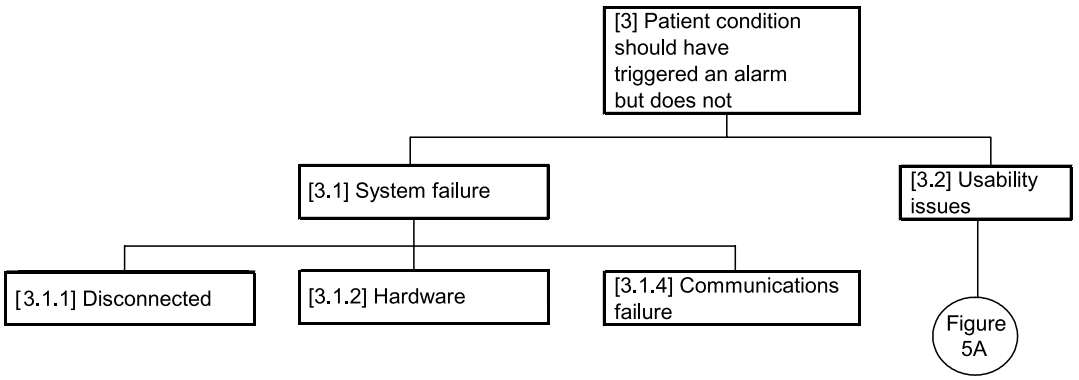

FIGURE 5. *Section [3].*

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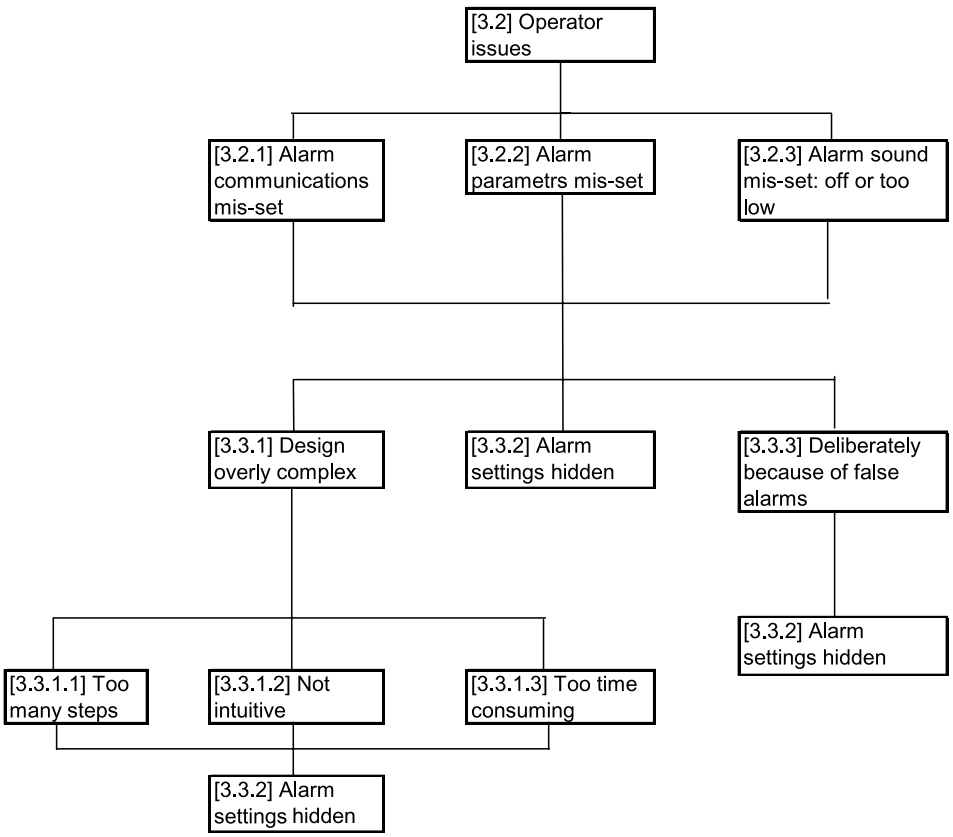

FIGURE 5A. *Section [3.2].*

observe the patient as indicated by the AND connector and as previously discussed in part [2]. In some cases, what can generate an alarm and what does not can be confusing. An FDA adverse event report for a defibrillator notes that the absence of any status or error messages could be due to ''poor patient-to-electrode pad contact, high transthoracic patient impedance or a combination of these factors that prevented the device from analyzing the patient.''[30]

Staffing

Note that there is a purposeful duplication of some event boxes throughout the FTA or the subevents drawn as

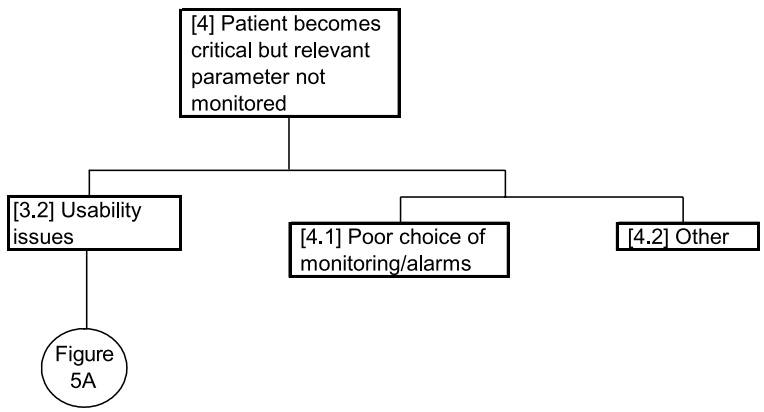

FIGURE 6. *Section [4].*

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common branches. These have potential important implications for improving safety. For example, inadequate staffing influences a number of the issues enumerated above, and therefore, a proper level of staffing can increase patient safety via a number of the existing event pathways. The staffing issue is probably the hardest for clinical engineering to influence. On the other hand, clinical engineering should not be party to the notion that the introduction of technologies will reduce the need for skilled staff or reduce the need for vigilance. In fact the FTA can be and should be used to demonstrate just the opposite.

FTA as a Living Document

Conducting an FTA is meant to actually be useful, as opposed to a pointless exercise. As such it should be the subject of a lively and active discussion as it is developed, modified, and corrected. In the course of developing, the FTA presented a number of items were added, deleted, moved, and otherwise revised. We invite you to critically examine it and comment if you wish. Furthermore, an FTA should not be a one-time analysis that is filed away or, worse, thrown away. As new information and new events occur, the FTA should be reexamined to see if it captures these events or it needs to be revised. As a teaching tool, it should also find ongoing use.

Role of Clinical Engineering

Essentially every aspect of a full service clinical engineering program (Table 1) can impact on the alarm issues. Equipment selection is clearly important, including both purely technical issues and, importantly, human factor issues. Once equipment is obtained, it must be put into use in concert with all of the other medical devices that may be in use in the area. This involves at least physical issues, default settings, and communications. The communications issue may be a bridge to information technology if it is to occur over the computer network which may also include voice communications via the voice over Internet protocol. Training often needs to be a combination of clinical and technical issues. Training can also occur with respect to the broad topic of alarm safety, using the FTA presented here to show that the issue can be systematically identified and evaluated. An alarm focus within equipment risk management could include settings on individual devices as well as integration issues. Potential error prediction can be important here; that is, if it is possible to turn an alarm off with the alarm status being subsequently hidden, appropriate training and policies and procedures must be put into place along with monitoring to ensure that actual user performance is consistent with such policies. Field monitoring can also look for sabotage and other intentional misuses. Field monitoring can also be extended outside the hospital including being responsive to recalls and safety alerts and other forms of communications from organizations, manufacturers, colleagues, and the medical and clinical engineering literature. Preventive maintenance and repair of alarm-generating and associated communications equipment can be important, especially where the alarm could fail while the device remained operational. Alarm testing is an appropriate part of risk-based preventive maintenance, including triggering, local presentation, and remote presentation. Alarm audibility should also be ensured. There may be several kinds of events and incidents that are important here, wherein events mean issues that arise apart from adverse patient outcomes, and incidents mean anytime a patient is impacted by an alarm problem. Near misses are interesting in this regard because of the inconsistent way in which they are logged (if at all) and investigated. Events might include frequent false alarms or observations of alarms being ignored. Incidents would include anytime there is an adverse patient event or a serious malfunction. Incidents may be reportable internally, to the manufacturer, to the FDA, state authorities, TJC, and voluntary report receiving entities (eg, Medical Product Safety Network).

Table 1. *Elements of a full-service clinical engineering program*

CE SERVICES
Equipment selection
Equipment deployment and training
Equipment risk management
System integration
Interface with information technology
Equipment policies and procedures
System risk management
Preventive maintenance and repair
Event and incident investigation
Incident reporting
Design and development
Professional standards development

It would be less common to find clinical engineering engaged in in-house design and development, although this certainly does occur in some institutions. Such work might be relatively fundamental or associated with interfacing and integration or modifications to existing equipment. Finally, clinical engineers might choose to play an active role in standards development so that the next generation of medical devices may present fewer problems.

Summary

Clinical alarms continue to be a challenging area within healthcare for both technologists and end users. The classic dilemma occurs when an alarm that occurs is not adequately responded to or an alarm that is anticipated and at least partially depended on does not occur. As shown in the FTA, this is a multifactorial problem including individual pieces

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of equipment, system integration, administrative issues, and end users. It is only through a systematic evaluation of the issues that rational fixes to the system can be identified, and their true impact evaluated.

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