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COMMENTARY

"Turn It Off!": Diabetes Device Alarm Fatigue Considerations for the Present and the Future

Joseph P. Shivers, B.A.,[1] Linda Mackowiak, M.S., R.N., C.C.R.A., C.D.E.,[2] Henry Anhalt, D.O.,[3] and Howard Zisser, M.D.[1,4]

Abstract

Safe and widespread use of diabetes technology is constrained by alarm fatigue: when someone receives so many alarms that he or she becomes less likely to respond appropriately. Alarm fatigue and related usability issues deserve consideration at every stage of alarm system design, especially as new technologies expand the potential number and complexity of alarms. The guiding principle should be patient wellbeing, while taking into consideration the regulatory and liability issues that sometimes contribute to building excessive alarms. With examples from diabetes devices, we illustrate two complementary frameworks for alarm design: a "patient safety first" perspective and a focus on human factors. We also describe opportunities and challenges that will come with new technologies such as remote monitoring, adaptive alarms, and ever-closer integration of glucose sensing with insulin delivery.

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Introduction

Beeping, buzzing, humming, thrumming, shaking, and flashing are familiar to users of diabetes technology as signals that something—be it glucose control, insulin delivery, or the alarm system itself—is amiss. Many people with diabetes are willing to accept the burden of alarms as part of the tradeoff from multiple daily injections to insulin pumps and/or from exclusive use of blood glucose meters to adjunctive continuous glucose monitoring (CGM). However, many also experience alarm fatigue. We define alarm fatigue to occur when the user of a device is frequently exposed to alarms (in particular, false or unnecessary ones) and, over time, becomes less likely to respond appropriately to true alarms. Alarm fatigue may even discourage someone from using a device at all.

Problems with general health care alarm systems have been noted for decades.[1–4] Despite this attention (or perhaps because of pressure to design excessive alarms), alarm fatigue in hospitals has been linked to over 200 patient deaths since January 2005.[5] The topic has received attention at high levels: in October 2011, the Association for the Advancement of Medical Instrumentation, the U.S. Food and Drug Administration, and other stakeholders convened a Medical Device Alarm Summit to reduce fatigue and make alarm systems safer.

Author Affiliations: [1]Sansum Diabetes Research Institute, Santa Barbara, California; [2]Linda Mackowiak LLC, Cazenovia, New York; [3]Medical Affairs, Animas Corporation, West Chester, Pennsylvania; and [4]Department of Chemical Engineering, University of California, Santa Barbara, Santa Barbara, California

Abbreviation: (CGM) continuous glucose monitoring

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Corresponding Author: Howard Zisser, M.D., Sansum Diabetes Research Institute, 2219 Bath St., Santa Barbara, CA 93105; email address hzisser@sansum.org

Alarm fatigue has been described in diabetes devices, especially in CGM systems, which are designed to alarm when glucose readings fall below or rise above certain user-adjustable thresholds, when they are predicted to go beyond these thresholds, or simply when glucose values are rapidly changing. New CGM device users are often instructed to initialize hypoglycemia and hyperglycemia alarm thresholds at extremely low and high values, respectively, in order to minimize early "nuisance alarms" and thus increase the likelihood of effective long-term use.[6,7] But because CGM sensors can often err, especially in hypoglycemia detection,[8] some clinicians set hypoglycemia thresholds artificially *high*.[7,9] (McGarraugh[10] observes that, "in general, any alarm indicating low, descending glucose in advance of a true hypoglycemic condition is useful to patients.")

For example, adjusting a hypoglycemia alarm to go off at 90 mg/dl rather than at 70 mg/dl will increase sensitivity—the rate of "true positives"—meaning that more hypoglycemic events will be detected and predicted. At the same time, it will decrease specificity—the rate of "true negatives"—meaning that more alarms will occur when glucose levels are safe and stable. Continuous glucose monitoring systems have an inverse relationship between sensitivity and specificity, which is described by that particular sensor's receiver operating characteristics curve.[11,12] A sensor's receiver operating characteristics curve reflects the fact that, as more true events are detected, more false alarms will occur. Unfortunately, psychological research suggests that people respond to relatively fewer alarms if they perceive the false alarm rate to be high,[13,14] and frustration with sensor accuracy may lead some patients to stop using CGM altogether.[15] If alarms are so frequent that a user ignores them or discontinues CGM, then those alarms have failed to meet their purpose—potentially with negative clinical results.

Alarm fatigue is emblematic of many human-factors issues critical to the design and use of alarms for diabetes devices. Fortunately, these issues are already being considered by researchers, manufacturers, regulators, clinicians, and patients. Yet we believe that even greater consideration will be necessary for even more effective alarm systems—especially as technologies become more complex and the potential for alarm fatigue grows.

Alarm Considerations for Diabetes Technologies: Present

At the aforementioned Medical Device Alarm Summit, a central message was how medical alarms must earn and maintain users' trust. Wiklund[16] explained that trustworthy alarms should reliably detect and draw attention to events requiring clinical intervention, and they should clearly explain the cause of the alarm, its potential consequences, and the action(s) required—all with a user-friendly interface (e.g., familiar language, simple graphics). In designing such alarms, two frameworks can be particularly useful: a "patient safety first" mentality and an emphasis on the human factors.[17] We illustrate each with examples from diabetes technology.

People with diabetes, including those who utilize diabetes devices such as insulin pumps and CGM, are at risk for developing severe hypoglycemia or hyperglycemia and subsequent diabetic ketoacidosis. To mitigate possible insulin pump malfunctions, alarms were designed to detect occlusion, active temporary basal rate, low insulin reservoir, low battery, and pump suspension. The most relevant CGM alarms include those for low and high glucose values as well as trending patterns. Such alarms should be distinctive so that recipients can quickly recognize the nature and severity of the problem. They should also persist until the problem is addressed, escalating so that each subsequent alarm is likelier to draw attention to the unaddressed problem. (This escalation might include a failsafe action, such as low glucose suspend or predictive low glucose suspend,[18] designed to mitigate the problem in the absence of user intervention.) Already, people using diabetes devices are exposed to a significant number of alarms. Therefore, when designers are modifying alarm technologies, they would do well to re-evaluate all the existing alarms rather than simply adding new alarms to the mix.

In trying to reserve the most urgent alarms for the riskiest situations, system designers may find it useful to characterize a scenario's risk with multiple inputs. For example, a CGM product could tailor its hypoglycemia alarm based on other information from the sensor itself (e.g., What is the glucose trend?), an integrated diabetes device (e.g., Was insulin recently delivered by the pump?), or the user (e.g., Is treatment with fast-acting carbohydrate underway?). The addition of extra data can change a system's receiver operating characteristics, enabling simultaneous improvements in both

sensitivity and specificity. The system could then become better at judging whether a situation deserves an alarm (a signal requiring time-critical action), an alert (a signal that does not require time-critical action), or no signal at all.

Human factors design involves a more holistic look at who will use a device or device feature, the environments where they will use it, and the other people who might interact with its alarms. Human factors design is typically considered with regard to device usability, but it can also provide useful perspective on safety concerns (including alarm fatigue). A simple example is provided for an increasingly common alarm feature: vibration. Compared with audible alarms, the chief advantages of vibrating alarms are that they work even in loud ambient settings and that they may cause less embarrassment to the user or less disruption to the external environment. The chief drawback is that fewer nonusers are likely to be aware of a vibrating alarm that the user himself/herself does not address. Thus vibrations should not be the only signals sent when the user is potentially in need of assistance, e.g., during a persistent and unacknowledged low glucose value. Technical considerations (e.g., the fact that vibration drains batteries faster than beeping) should certainly inform the design of an alarm system. However, designers must keep in mind that their goal is to design the safest and most user-friendly alarm system that the technology will allow—not to design the most technologically advanced system with human factors as an afterthought.[17] Part of this process should be to consider distractions in the user's environment that could interfere with responses to the diabetes-specific warnings (e.g., vibrating cell phones or the "phantom vibration" experienced by many cell phone users[19]).

One scenario that demands particularly careful human factors design is nocturnal hypoglycemia, which—if prolonged and severe—can be associated with seizures and even "dead-in-bed" syndrome.[20,21] An individual must be woken up in order to take action—a feat that standard alarms might not necessarily achieve.[22,23] (Some clinicians believe that hypoglycemia can actually make arousal harder. Although a small study by Ly and coauthors[24] indicated that hypoglycemia does not impair arousal in adolescents with type 1 diabetes, these findings might not extend to people with longer duration of diabetes and/or impaired counter-regulatory hormone response.) The environment at night tends to be quiet, and the user can move around unwittingly in sleep. Thus audible alarms may be a more appropriate option than vibrating ones (though, obviously, both can be used at once). However, even loud audible alarms may not be sufficient, because people who could respond to the alarm may be in a different room and/or asleep themselves.

A consideration of human factors will not necessarily lead to changes in an alarm system's receiver operating characteristics. Nonetheless, if systems are made more user-friendly, they may become more clinically useful. In this vein, several enhancements to CGM alarms are being used to address nocturnal hypoglycemia. One manufacturer has developed an outpost that can be placed near a sensor-augmented pump to extend the range of CGM signals to 50 ft. or more; this facilitates remote nocturnal monitoring by parents or other on-site caregivers (mySentry™; Medtronic Diabetes Inc., Northridge, CA). An alternative used by some families with diabetes is to place the CGM receiver near an extra-loud, bed-shaking alarm clock and/or baby monitor (or simply inside a glass).[25,26] Regardless of the interface chosen, the potential for alarm fatigue will remain especially high at night, when decisions are governed by a subconscious that hates waking up unnecessarily: in the words of Kafka, "A false alarm on the night bell once answered – it cannot be made good, not ever."[27] Even alarms that are consistently true could contribute to fatigue over time, considering that the prevalence of nocturnal hypoglycemia in type 1 diabetes has been estimated at over 50%.[28,29] No technology will ever provide a perfect solution. Still, these challenges highlight the potential benefits of new, better systems for hypoglycemia detection and mitigation, which we discuss here.

Alarm Considerations for Diabetes Technologies: Future

The success of future alarm systems will depend foremost on accuracy and reliability, and the trends here are encouraging. The newest commercial CGM systems, which are available or soon to be available in the United States, feature better hardware, better software, and, hopefully, better performance than their predecessor devices.[30–32] Additionally, research is underway on CGM data-processing algorithms specifically for closed-loop insulin delivery, enabling increasingly robust predictive monitoring and control.[33] Another important approach, referenced earlier, is to integrate data from several sources. This process could involve a parallel array of identical glucose sensors,[34,35] an orthogonal setup of multiple glucose-sensing modalities[36] and/or non-glucose sensors,[37,38] or cross-referencing of insulin delivery data in order to detect sensor errors.[35] Meanwhile, the time delay required to trigger insulin pump

occlusion has received attention in the literature;[39] hopefully, future pump alarms will take effect sooner after occlusion (i.e., be more sensitive) without sacrificing specificity. In general, better accuracy and reliability should translate to fewer false alarms, less alarm fatigue, and greater safety.

Alarm systems based on more accurate and reliable sensors can become "smarter" in a variety of ways. For example, alarm threshold and intensity could be set to vary based on time of day,[40] risk of imminent severe hypoglycemia as indicated by recent glycemic disturbances,[41] or "announced" by the user (e.g., using an interface to inform the device that exercise is starting or that a manual insulin injection has been administered).[42] Future systems might individualize their settings based on the input of learning algorithms.[43,44] They could also use past data to give patients personalized predictions (e.g., "Based on your glucose pattern for the past 2 h and the times that you have had similar patterns in the past 3 months, your likelihood of hypoglycemia during the next 30 min is 80%").

Whatever the precise nature of future modifications, in order to be translated into greater safety and better quality of life, they must not overwhelm the user with alarms and alerts. People should receive only signals that they need, and these signals should be designed to promote calm, appropriate decision-making rather than a startled, "turn it off!" response.[17] (On that note, alarm fatigue might be reduced if users had more power to choose and customize their alarms. This approach could pose regulatory challenges, but it also has potential to improve the usability of diabetes devices.)

The design of new diabetes alarm systems will involve a variety of special cases, including a host of issues related to remote monitoring. With the potential for around-the-clock messaging to health care professionals and noncertified caregivers, remote-monitoring systems could dramatically improve preventive care but, alternatively, could worsen alarm fatigue among all involved. These systems could also create new concerns about legal liability and regulatory oversight. The Food and Drug Administration has allowed diabetes technologies to send text messages that recommend specific therapeutic interventions in research settings.[45] However, the agency's draft guidance on mobile medical applications indicates that its perspective on remote monitoring remains in flux.[46] Meanwhile, many other alarm-related concerns, already relevant, will need to be considered anew as systems become more complex. These include how to send signals to users with limited vision, how to transmit alarms from multipiece devices (e.g., patch pumps with handheld remotes), how to run call centers with sufficient capacity, and how to prevent programming errors, theft, and security breach (a challenge even for nuclear facilities, as shown by the July 2012 break-in at the weapons stockpile in Oak Ridge, TN).

To conclude, everyone working with new diabetes technologies should seek to make alarms as safe and user-friendly as possible. Manufacturers should continue to communicate with patients, families, and providers about how existing systems can best be used and how new systems can best be built. Regulators should continue to prioritize human factors in their review of new products, they should keep in mind the tradeoffs between comprehensiveness and the risk of alarm fatigue,[10] they should consider the risks of current diabetes management practices when evaluating new technology (including alarm features), and they should encourage alarm-related innovation—especially in "training-wheels" environments such as inpatient studies. More broadly, we believe that regulators should view alarms as tools to help patients manage their disease, not just as a safety net. Researchers and engineers should consider the potential for alarm fatigue in their design and evaluation of experimental technologies. (Of particular interest are systems for closed-loop insulin delivery, which pose a slew of alarm-related issues beyond this article's scope.)

For patients and health care providers, currently the simplest and most effective way to minimize alarm fatigue is to avoid situations likely to generate alarms—in other words, to practice safe and effective diabetes management. Thus the ultimate lessons from alarm fatigue analysis are simple and familiar ones. Patients and providers must be well educated about diabetes and the therapeutic tools at their disposal. They must be invested in continually improving their quality of care. Finally, they must be empowered to manage diabetes based on their personal insights into the disease—information that will always be more important to diabetes care than any theoretical discussion such as this.

Disclosures:

Joseph Shivers does part-time freelance work for Close Concerns, which counts multiple diabetes companies as subscribers. At the time of manuscript preparation, Linda Mackowiak and Henry Anhalt were full-time employees of Animas Corp., a Johnson and Johnson company, and were minor shareholders in Johnson and Johnson Co. Linda Mackowiak is also a minor shareholder in Medtronic and Abbott. Howard Zisser has received honoraria for scientific lectures and travel reimbursement from Animas, Cellnovo, Insulet, MannKind, and Roche and research grant and product support from Animas, Abbott, Dexcom, Eli Lilly, GluMetrics, Insulet, LifeScan, Medtronic, Novo Nordisk, Roche, and Sanofi and is a board member of Artificial Pancreas Technologies.

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