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MEETING PROCEEDINGS

Second Insulin Pump Safety Meeting: Summary Report

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Abstract

Diabetes Technology Society facilitated a second meeting of insulin pump experts at Mills-Peninsula Health Services, San Mateo, California on November 4, 2009, at the request of the Food and Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories. The first such meeting was held in Bethesda, Maryland, on November 12, 2008. The group of physicians, nurses, diabetes educators, and engineers from across the United States discussed safety issues in insulin pump therapy and recommended adjustments to current insulin pump design and use to enhance overall safety. The meeting discussed safety issues in the context of pump operation; software; hardware; physical structure; electrical, biological, and chemical considerations; use; and environment from engineering, medical, nursing, and pump/user perspectives. There was consensus among meeting participants that insulin pump designs have made great progress in improving the quality of life of people with diabetes, but much more remains to be done.

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Introduction

Office of Science and Engineering Laboratories (OSEL) researchers are working on the concept of a generic insulin infusion pump (GIIP) safety model as a means to support advanced research for the development of high confidence medical device software. Insulin pumps were selected as a case study because they represent the desired degree of research complexity, and the results of such research can have a significant benefit to public health.

On November 4, 2009 a group of interested insulin pump clinical experts, users, and physicians met with researchers from the Food and Drug Administration (FDA), Center for Devices and Radiological Health, Office of Science and Engineering Laboratories at Mills-Peninsula Health Services, San Mateo, California to discuss insulin pump design safety issues.

This was the second meeting with FDA researchers hosted by the Diabetes Technology Society. The first such meeting was held in Bethesda, Maryland, on November 12, 2008.[1] Issues raised in this meeting served to lay the foundation for the current GIIP hazard analysis.

The GIIP safety model is an abstract representation of safety features common to insulin pumps. To construct

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Abbreviations: (BG) blood glucose, (FDA) Food and Drug Administration, (GIIP) generic insulin infusion pump, (OSEL) Office of Science and Engineering Laboratories, (PDAs) personal digital assistants

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the safety model, OSEL researchers established a compendium of insulin pump hazards, their causes, and the (safety) requirements to mitigate the causes.

Office of Science and Engineering Laboratories researchers met with this group of experts to identify additional insulin pump hazards and their causes to make the ongoing GIIP hazard analysis more complete. It became clear that there are many subtle opportunities for insulin pumps to contribute to user/patient harm. Further, as new features are added to insulin pumps, design complexity necessarily increases. This complexity provides new ways to contribute to patient harm. The challenge then is to manage and reduce the associated risks to an acceptable level.

The remainder of this report summarizes discussions and consensus on pump design, use, and environmental issues among the meeting attendees.

Design Flaws and Engineering Defects

Attendees agreed that even though insulin pumps can benefit diabetes patients in maintaining desirable blood glucose (BG) levels, they are subject to poor engineering designs, implementation flaws, manufacturing defects, and unfriendly pump/user interfaces that may expose users to harmful situations. Attendees described several engineering defects in devices currently on the market. For example, one diabetes patient was hospitalized because of severe hypoglycemia. Later investigation indicated that her insulin pump did not shut down as commanded, resulting in an unexpected delivery of insulin. Another example described an insulin pump that would continue priming when the drug reservoir was empty rather than terminating the priming process and alarm.

Bolus Issues

Meeting attendees expressed that the combination of usability issues and design defects is a significant source of inappropriate boluses being recommended to the user. Many current insulin pump models implement their bolus recommendation features as complicated procedures that require detailed parameter and configuration information from the users. Consequently, many users experience difficulties working with bolus recommendations or are reluctant to use this feature. The situation is exacerbated by the fact that manufacturers and physicians generally do not offer adequate training to pump users in this regard.

Attendees generally agreed that bolus recommendation procedures and user actions should be improved to reduce over/underdosing risks. The attendees recommended that manufacturers reduce the complexity of using bolus calculator software and provide more thorough training and education to health care practitioners and pump users. The risk associated with bolus recommendations can be reduced further if manufacturers would include the capability to monitor user inputs in their pump designs. Inappropriate/incorrect user inputs can then be detected during a bolus calculation and an alarm issued if unsafe.

Some insulin pumps on the market incorporate food databases to aid the user in estimating meal carbohydrate intake to facilitate the accurate calculation of meal boluses. Integration of food databases does not, however, rule out use errors in carbohydrate estimations, according to Thomas Love from the Ashvin Group, Inc., Miami, Florida, because the information contained in current food databases is not precise, up to date, or accurate enough.

Manufacturers should ensure the correctness, preciseness, and accuracy of information contained in their food databases. One way to improve the accuracy of food databases is to include information about the digestion time of each particular type of food.

User Interface Issues

Insulin pump/user interface (human factor) issues are another major source of safety issues. A few examples of common user/pump interface issues raised during the meeting included: display fonts that are too small to read, inadequate display backlighting, misleading am/pm displays, imprecise time formats, confusing display menus, inaudible alarms, and insensible tactile notifications. Attendees recommended that manufacturers improve the human factors engineering aspects of user/pump interfaces by conducting comprehensive human factors evaluations/validation of use scenarios. This will ensure that the interface is compatible with the intended (often diverse) user population.

Safe user/pump interaction also depends on whether the insulin pump safety architecture can detect hardware abnormalities and other operational hazardous situations and then inform users of the fact. Incorrect annunciation of pump abnormalities jeopardizes user safety by leaving the user unaware of the existence of a problem or by annoying users with nuisance alarms or alerts. Take low battery alerts, for instance. If the threshold to trigger a

low battery alert is set too high, the pump might issue nuisance (and false) alerts even though the batteries still have enough power. If the threshold is too low, batteries might drain so quickly that the pump is shut down right after a low battery alert, leaving the user no time to react to the alert.

One issue that did not have consensus is whether an automatic-off feature, if present, can improve pump safety. An automatic-off feature is the capability of a pump to turn itself off if the user has not interacted with it for a predefined time. This feature was included in several insulin pump designs to protect users from receiving insulin when they fall into coma due to severe hypoglycemia. However, David C. Klonoff, M.D., FACP, from Mills-Peninsula Health Services in San Mateo, California, suggested that this feature might not improve patient safety as much as one might think. Many users do not understand this particular feature, so they incorrectly set a time threshold that triggers this feature unnecessarily. As a result, these users receive less insulin than desired. Gloria Yee, R.N., CDE, from University of California at San Francisco Diabetes Teaching Center, San Francisco, California, confirmed the safety importance of the automatic-off feature and suggested that this feature should be implemented as an option that users can choose to enable. She recommended 12 to 13 hours as a suitable time threshold to trigger the automatic-off feature. A quick survey of pump users in attendance revealed that the automatic-off features of their pumps were *on*.

Another topic that lacked consensus deals with safe recovery measures after a pump fails. Two options, each with its own risks and benefits, were discussed—either set the pump to factory default settings or set the pump to a default insulin delivery profile.

Use Errors

Attendees agreed that use errors contribute to a significant portion of pump adverse events. Insulin pumps are generally considered as *home-use* devices. As such, users might operate their pumps without sufficient guidance or supervision by experts. Attendees identified three major issues in this context: (1) users do not follow pump operation instructions, (2) users do not understand features of their pumps, and (3) users fail to program appropriate delivery profiles.

In the first case, many users disconnect their pumps without terminating ongoing delivery first. This results in insulin leakage and miscalculation of the amount infused. Another example is when, under circumstances not detected by the user, the infusion set becomes disconnected, preventing insulin from reaching the user. Such circumstances include the infusion set needle being caught on the infusion site tape or the needle being pulled out during sleep. These examples show that it is critical that insulin pumps detect and inform users about accidental pump/infusion set disconnections in a timely manner, a feature that, unfortunately, insulin pumps currently on the market do not support.

In the second case, use errors also arise when users do not understand the technical and engineering characteristics of their pumps. For example, siphon effects due to the height difference of the pump and infusion site can cause the actual infusion rate to deviate from the programmed rate.[2] If the user does not know this and locates the pump much higher/lower than the infusion site, a siphon effect will occur, which affects the accuracy of insulin administration.

Finally, a "soft factor" attributed to use error is that some users get lazy or refuse to acknowledge the amount of attention operating a pump requires. For example, a user may not bother to keep track of the carbohydrates in their meals. Further, changes in activity levels, health conditions, and living routines may require adjustments to insulin delivery profiles. A typical use error is failing to provide a special delivery profile for unusual circumstances or failing to activate such profiles when these circumstances occur.

The attendees felt that the safety of insulin pumps can be improved if device designs can perform "sanity" checks to prevent typical use errors or inform users to correct their errors.

Advanced Technologies

The meeting attendees discussed new technologies that have emerged in recent insulin pump products and suggested a set of potential safety issues related to these technologies.

Several insulin pumps allow users to utilize personal electronics devices, such as iPhones and *personal digital assistants* (PDAs), as remote monitoring and control devices.

Such a design increases the complexity of operation in these pumps. Manufacturers need to implement safety measures that guarantee communication robustness, integrity, privacy, security, and availability between the insulin pump and remote control device. The group proposed risk control measures to mitigate communication failures. One such proposal was for the pump to gradually decrease basal rates during communication failure and alarm if communications were not restored within a certain period.

Another remote control issue concerns the difference in battery life between the insulin pump and the remote control device. Users who use a PDA to control their device may have communication problems when they do not realize that the battery life of PDAs is shorter than the battery life of an insulin pump.

Time synchronization between the pump and a remote control device also presents a risk to the user because different times in the pump and remote controller may cause errors in insulin delivery calculations and clinical data statistics.

A second technology discussed is the capability for users to use audio instructions even when there are display failures or screen breakage. Risks are introduced if the audio signals are not discernible. In assessing the risks and benefits of this technology, Dr. Klonoff suggested that audio prompts, audio instructions, and audio responses to user actions and so on are likely to reduce use risks for vision-impaired users.

In addition to new technologies, modern insulin pumps implement sophisticated features to improve their functionality or usability. Meeting attendees argued that these sophisticated features could also introduce safety risks that both manufacturers and pump users might not realize. For example, some pump designs include training procedures in pump computer memory to familiarize users with pump characteristics. This training can take more than half an hour, during which insulin delivery is disabled. Another feature some pumps have either forbid bolus recommendations for a couple of hours during their first use or do not allow boluses when the user's BG level is under a certain threshold (e.g., 70 mg/dl). Even though these sophisticated features have benefits, they also increase the chances of hyperglycemia by denying pump users the capability of commanding insulin delivery for a certain period.

The attendees would like manufacturers to thoroughly understand potential risks behind new technologies and features before integrating them into insulin pumps. Manufacturers should verify and validate that established risk control measures perform as intended in their devices.

Environmental Factors

The doctors, clinicians, and pump users of the group emphasized that environmental factors could significantly affect the correct and safe use of insulin pumps. A number of environmental factors, listed here, were discussed. Each factor either impairs the normal operation of insulin pumps or prevents users from interacting with their pumps correctly.

- Ambient temperature. Exposing an insulin pump to temperature extremes can affect its performance, as well as the potency and activity of insulin loaded in the pump.

- Excessive ambient noise and abnormal ambient light conditions. The ability to attend to pump alarms or alerts can be impaired if the user is in an environment with excessive ambient noise. Similarly, it can be difficult to read pump displays correctly under unusual ambient light conditions.

- Excessive humidity or water ingress. Excessive environmental humidity or fluid ingress may cause erratic operations or a failure in pump electrical circuits. Users without "waterproof" pumps must suspend insulin delivery and detach their pumps when facing the possibility of contacting water or other fluid.

- Environments with enriched allergenic substances, including contaminated glue adhesives and tapes for infusion sets, can cause allergic reactions to pump users.

- Home pets might disconnect infusion sets or kink tubing without the users' awareness. A static electrical discharge from the pet (or the user) to the pump may cause potential problems in the electrical circuitry of the pump.

In addition to the aforementioned factors, atypical use environments such as camping sites may result in limited or no access to pump supplies, such as batteries and insulin, preventing normal operation of the insulin pump.

Conclusions

During the meeting, attendees discussed typical engineering defects, common use errors, and environmental factors pertaining to insulin pumps. The attendees agreed that while new technologies can improve the capability, usability, and performance of insulin pumps and user quality of life, these technologies also introduce complexity and new risks to user safety.

The attendees concluded the meeting by listing future pump features that can improve the usability of insulin pumps and increase user safety.

- Detection of low BG readings. Users should be allowed to configure their minimum/maximum blood glucose thresholds. The pump should alarm when input BG readings exceed these thresholds.

- Time-synchronizing capability. Dr. Klonoff recommended that future insulin pumps synchronize their time bases with accessory devices, such as glucose meters and remote control devices.

- Multiple time systems. Clinicians and pump users may have different uses of time-related information pertaining to insulin pump operation. Future insulin pump designs should incorporate two independent time systems—one for generating and maintaining clinical data and the other for displaying to the users.

- To protect pump users from being injured by pump failures, future insulin pump designs should either implement a default safe state—a state where there is no harm to the user—or perform sufficient self-testing so that impending pump failures can be detected and the user forewarned.

- More informative statistical data for the user. Future insulin pumps should provide more precise and informative statistical data, e.g., the distribution of basal and (food/correction) boluses in previous insulin deliveries, so that the programming of delivery profiles can be done on a more informed basis.

- More complete and comprehensive training for clinicians and pump users. The meeting attendees advocated that the Diabetes Technology Society establish a set of training protocols and programs for both pump users and clinicians so that the trainees obtain a better understanding of insulin pumps and their use.

- Future insulin pump designs should consider data upload/download via the Internet, telecommunication networks, or other data communication networks so that pump users can conveniently manage their clinical data and obtain remote expert and technical support.

- More robust detection of device operation abnormalities. Future insulin pumps should improve their accuracy of detecting pump abnormalities. For example, the detection of low battery levels, as suggested by Dr. Klonoff, should be based not only on the remaining battery capacity, but also on the current time of day. For example, it may be safe not to alert during regular hours if the pump batteries have 4 hours of life remaining. However, at bedtime, the pump should alert when the batteries can only last for 4 hours to avoid the pump running out of power when the user is sleeping.

- Safety tips for pump users. Ideally, future insulin pumps should not only inform users about the occurrences of abnormalities, but also notify users when they are likely to make an operational mistake. For example, it would be helpful if insulin pumps could remind users to double check basal rate settings every time they change infusion sites or query them as to whether or not to compensate for the loss of basal infusion after pump disconnections.

- More robust alert/alarm notification signals. A desirable feature for future insulin pumps is to permit users to configure different volume/tone settings of alarms/alerts for different situations. Also, insulin pumps should support escalating alarms/alerts in case users fail to react to alarms/alerts in a timely manner.

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