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More Focus is Needed to Reduce Adverse Events for Diabetes Devices

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Abstract

Advances in devices for people with diabetes have demonstrated many improvements; yet, the number of adverse events has almost doubled from 2018 to 2019. It is a challenge to examine these events due to a difficult query tool on the FDA website. There are several possible reasons why effort is not devoted to decreasing the number of adverse events including the fact that user error is a common cause. This commentary serves to raise awareness of the adverse event problem.

Keywords

adverse event, continuous glucose meter, glucose meter, insulin pump, MAUDE

Advances in devices for people with diabetes have demonstrated improvements in key metrics such as time in range, lower A1c, and fewer hypo and hyper glycemic events. Yet, a recent study also showed that a new hybrid closed loop system exhibited more adverse events than its control.[1] The adverse events here were attributed to the device being investigational, but one can still ask, are adverse events a significant problem in devices for people with diabetes?

US law requires that manufacturers report any event that has caused or may have caused death or serious injury.[2] Note that "has caused" implies an outcome, whereas "may have caused" implies a probability. Moreover, one of the causes listed that requires an event to be reported is user error. This must be vexing to manufacturers, since if a perfectly functioning medical device produces an erroneous result due to a user mistake, this event must be reported and is associated as a malfunction of the device.

Adverse events in the United States are publicly available in a database (commonly known as MAUDE) on the Food and Drug Administration (FDA) website.[3] Although a query tool is provided on the website, that tool is difficult to use and will only return 500 records for any query.

Using Microsoft Access, I downloaded text files from the FDA website[4] into a database and performed queries to examine the number of adverse events for 2018 and 2019 for three diabetes devices: glucose meters (BGMs), continuous glucose monitors (CGMs), and insulin pumps. The results are displayed in Table 1.

In this table, the three possible event types are listed: malfunction, injury, and death. All events are malfunctions, but if the outcomes are either injury or death, then the events are classified according to the most serious outcome. This information would not be possible to obtain using the query tool on the FDA website since there are multiple terms in the database for each diabetes device but only one term listed in the MAUDE field "product class."

Except for BGM, the number of adverse events increased markedly in 2019. The percent of adverse events due to diabetes devices as a percentage of adverse events from all medical devices increased from 20.4% in 2018 to 30.5% in 2019 and is the largest contributor of any medical device.

One cannot determine the rate of adverse events without knowing how many glucose tests were performed (for BGMs or CGMs) or how many pumps (or pump actuations) were used. One would also need to know whether manufacturers submitted all adverse events. Although I did not have this information, the rate of events must be quite small since the number of glucose tests performed annually is in the billions. But as Table 1 shows, the absolute number of adverse events experienced by people with diabetes is large.

One can ask why more attention is not given to reducing the number of adverse events. Possible reasons for this include:

1. Focusing on new improvements to diabetes devices is more exciting than examining device problems
2. User error is a likely factor in many adverse events[5,6] and reducing user error is challenging
3. Data from MAUDE are rarely published in product evaluations for marketed products, so awareness of adverse events is limited
4. Evaluations of BGMs and CGMs are carefully controlled studies with data that invariably look good. The ISO 15197 standard to evaluate glucose meters states: "If a measurement result is generated during a performance evaluation, it may be excluded from the

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Table 1. Adverse Events for Diabetes Devices by Event Type for 2018 and 2019.

Year		Malfunction	Injury	Death	Total
2018	BGM	17 646	1482	0	19 128
	CGM	82 998	1623	3	84 624
	Pump	84 072	25 551	318	109 941
	Total	184 716	28 656	321	213 693
		Malfunction	Injury	Death	Total
2019	BGM	13 499	1286	0	14 785
	CGM	138 598	5937	10	144 545
	Pump	205 591	40 272	352	246 215
	Total	357 688	47 495	362	405 545

Abbreviations: BGM, blood glucose meters; CGM, continuous glucose monitors.

data only in the following circumstances: — the blood-glucose monitoring system user recognizes that an error was made and documents the details." This is not only a biased approach, it also discounts the importance of user error. And while there is a user evaluation protocol in ISO 15197, the acceptance criteria are relaxed. The need for 99% of the results to be within the A and B zones of a Parkes error grid has been dropped.

5. There is no standard for CGMs and a general technical standard for insulin pumps.[7]
6. A Joint Statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group[5] made a series of recommendations that have not yet been implemented.

Ideally, FDA should analyze adverse event data[5]. This involves considerable effort. There were 405 545 distinct events in 2019. But for each event, there are one or more additional records which describe the manufacturer's actions. Thus, there would be close to a million text records to analyze, each often containing 300-500 words. The MAUDE database requires improvement with standardized user input forms and a website accessible query tool that allows for SQL (structured query language) queries. The Office of the Inspector General of Health and Human Services has issued reports and recommendations regarding FDA's use of adverse event reporting with one report expected in 2020.[8-10]

There are examples of reducing user error such as the reduction in central line infections, or in the reduction of general aviation accidents.[11,12]

It is time to revisit reducing adverse events in diabetes devices.

Abbreviations

BGM, blood glucose meter; CGM, continuous glucose monitor; MAUDE, Manufacturer and User Facility Device Experience.

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