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CLINICAL APPLICATIONS

Are Current Insulin Pumps Accessible to Blind and Visually Impaired People?

Darren M. Burton, B.S., B.A., Mark M. Uslan, M.A., M.S., Morgan V. Blubaugh, B.B.A., and Charles W. Clements III

Abstract

Background:

In 2004, Uslan and colleagues determined that insulin pumps (IPs) on the market were largely inaccessible to blind and visually impaired persons. The objective of this study is to determine if accessibility status changed in the ensuing 4 years.

Methods:

Five IPs on the market in 2008 were acquired and analyzed for key accessibility traits such as speech and other audio output, tactual nature of control buttons, and the quality of visual displays. It was also determined whether or not a blind or visually impaired person could independently complete tasks such as programming the IP for insulin delivery, replacing batteries, and reading manuals and other documentation.

Results:

It was found that IPs have not improved in accessibility since 2004. None have speech output, and with the exception of the Animas IR 2020, no significantly improved visual display characteristics were found. Documentation is still not completely accessible.

Conclusion:

Insulin pumps are relatively complex devices, with serious health consequences resulting from improper use. For IPs to be used safely and independently by blind and visually impaired patients, they must include voice output to communicate all the information presented on their display screens. Enhancing display contrast and the size of the displayed information would also improve accessibility for visually impaired users. The IPs must also come with accessible user documentation in alternate formats.

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Author Affiliation: American Foundation for the Blind (AFB TECH), Huntington, West Virginia

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Corresponding Author: Darren M. Burton, B.A., American Foundation for the Blind (AFB TECH), 949 3rd Ave., Suite 200, Huntington, WV 25701; email address dburton@afb.net

Introduction

Since 2002, the American Foundation for the Blind has been focusing on the interface design of diabetes-related self-management technology such as blood glucose meters, insulin pumps (IPs), blood pressure monitors, and insulin pens.[1] The reason for this is that, of the 17.9 million people diagnosed with diabetes (another 5.7 million are believed to be undiagnosed[2]), 11% (2.6 million) are believed to have some level of visual impairment.[3] It should be noted that visual problems are more prevalent among type 2 diabetes patients who make up a smaller percentage of IP users.[3]

Although it is difficult to find estimates of the number of people with diabetes who are blind or visually impaired and who are candidates for insulin treatment and intensive management, there are reliable projections of IP usage among the entire diabetes population. Insulin pump usage among type 1 diabetes patients is expected to reach 476,000 users (37.8% of type 1 patients) in 2009, a significant increase from only 178,000 (17%) in 2002. This positive trend is expected to continue.[4,5] Insulin pump usage among insulin-treated and intensively managed type 2 diabetes patients has risen from only 600 in 2002 (0.3% of insulin-treated intensively managed type 2 diabetes patients) to an estimated 17,600 (6.0%) in 2009, a rise of nearly 3000% in 7 years. This market is expected to grow rapidly in coming years.[4,5]

Simply stated, an IP is accessible to a blind or visually impaired person if it is designed so that the person can independently operate it without the need for sighted assistance. The product design criteria for IPs to be accessible to and usable by blind and visually impaired persons are of two types. First and foremost are criteria that are related to using the device nonvisually or with a visual limitation:

1. Spoken display data.
2. High-contrast, large-font display and the option for reverse contrast polarity.
3. Control buttons that are tactually identifiable.
4. An accessible operating manual (i.e., large print[6] and in an electronic format that can be read by PC screen-reading or magnifying software).

Second are design criteria related to the overall convenience and ease of use.

Examples of convenience and ease-of-use design criteria are as follows:

1. Highly portable.
2. Tasks must be simple, highly tactile, and not require a high level of manual dexterity. These tasks include
   - battery replacement,
   - reservoir filling and replacement, and
   - infusion insertion, connection, and disconnection.

In 2004, Uslan and associates reported that most IPs on the market featured tactually identifiable control buttons.[7] In most cases, infusion set up and reservoir replacement required considerable manual dexterity but were manageable even for those without useable vision.

However, the 2004 IPs had not been designed to meet accessibility design criteria. To varying degrees, they provided some limited audio output in the form of tones and beeps, but none had spoken output of display information. This audio output was found to be of minimal use to people who are blind or visually impaired other than for providing assistance with setting a bolus injection. None of the 2004 IPs used high-contrast displays with consistently large fonts preferred by people who are visually impaired. They also did not have an option for reverse contrast polarity (white text on a black background), which is preferred by many visually impaired people. User manuals were also found to be less accessible than required.

The purpose of this article is to determine if IPs on the market in 2008 became more accessible than those on the market in 2004.

Methodology

Five of six IPs on the U.S. market in 2008 that had been introduced since 2004 were compared to the eight that were evaluated in 2004 to determine if change in accessibility had taken place and, if so, to what extent. One manufacturer did not agree to participate in the study. The five IPs on the market in 2008 that were evaluated included Animas IR 2020 from Animas Corp. (West Chester, PA), Accu-Chek Spirit from Disetronic

Medical System (Fishers, IN), Paradigm 515 from Medtronic MiniMed (Northridge, CA), Diabecare IIS from SOOIL Development Co. (New Orleans, LA), and Insulet OmniPod from Insulet Corporation (Bedford, MA) (see **Figure 1**). The eight IPs on the market in 2004 that were evaluated included D-TRONplus and H-TRONplus from Disetronic Medical System; 508, Paradigm 511, and Paradigm 512 from Medtronic MiniMed; DANA Diabecare IIS from SOOIL Development Co.; IR 1000 from Animas Corp.; and the Cozmo from Smiths Medical (St. Paul, MN).

Figure 1. Insulin pumps evaluated in 2008. Far left, Insulet OmniPod; upper row (left to right), Animas IR 2020 and Disetronic Accu-Chek Spirit; bottom row (left to right), Medtronic Minimed Paradigm 515 and SOOIL Diabecare IIS.

As was done in 2004, the physical features of the 2008 IPs were characterized and measured. However, since infusion set up was determined to be manageable in 2004 and had not changed in four of the five IPs since then, this feature was not examined. The one 2008 IP that introduced significant change in infusion set up was the OmniPod. Its infusion procedures are described and analyzed in the Discussion section. The same accessibility expert, who is blind, rated the ease of identifying control buttons in 2004 and 2008. The extent of audio output was tabulated for each IP, and product documentation manuals were characterized and rated for accessibility by the same expert who rated the control buttons and manuals in 2004. Displays in 2004 were not characterized through objective measures, but they were in 2008. A computer-controlled Canon EOS 40D camera with an attached Canon EF 200 mm lens, reticle, and integrated light source that that works in conjunction with IMAQ Vision Builder image analysis software was used to measure contrast, resolution, and font size.[8,9]

Results

Table 1 shows that the average size and weight of IPs, which affect portability and ease of use, have not changed significantly. A pump with the ability to be programmed with a PC adds the potential for added accessibility as long as the software used to do this is compatible with screen-reader and magnifier software. **Table 1** shows that, in 2004, two of eight IPs had this capability, and in 2008, two of five had it; however, none of the PC software programs used to control the pumps are compatible with screen-reader and magnifier software used by people with vision loss.

Table 1.
Physical Features/Ease of Use

	2004 IPs	2008 IPs
Size (L x W x H) (in.)	$\overline{m}$ = 3.33 x 2.00 x 0.83	$\overline{m}$ = 3.82 x 2.24 x 1.00
Weight (oz.) with battery, without cartridge	$\overline{m}$ = 3.3	$\overline{m}$ = 3.56
Reservoir capacity (0.1 ml units)	$\overline{m}$ = 271	$\overline{m}$ = 238
Prefilled insulin reservoir	2 of 8	0 of 5
Number of control buttons	$\overline{m}$ = 4.24	$\overline{m}$ = 5.6
Computer programmable via PC	2 of 8	2 of 5
Button attributes	6 of 8 have raised and textured buttons	4 of 5 have raised and textured buttons
Ease of identifying buttons (1–5 scale)[a]	$\overline{m}$ = 3.7	$\overline{m}$ = 4.0
Minimum button spacing (in.)	$\overline{m}$ = 0.155	$\overline{m}$ = 0.113
Battery type	4 of 8 have raised "+"	All have raised "+"
Number of steps to replace battery	$\overline{m}$ = 8.8	$\overline{m}$ = 5.2

[a] Ratings scale for ease of identifying buttons: (1) buttons cannot be identified or used tactilely; (2) buttons are very difficult to identify and use tactilely; (3) buttons can be identified and used, but there is a definite need for improvement; (4) buttons easy to identify and use, but minor improvements would help; and (5) buttons are very easy to identify and use tactilely.

Although the average number of control buttons increased by 2008, the complexity related to using the buttons did not. Raised and textured buttons aid in button identification. **Table 1** showed that six of eight in 2004 had those characteristics, and four of five had them in 2008. Ratings of the overall ease of identifying buttons showed a slight improvement from 2004 to 2008. Battery-replacement procedures improved by 2008. The average number of steps to complete the battery replacement process has lessened (from 8.4 in 2004 to 5.2 in 2008), and ease of use has improved, because all 2008 IPs use batteries with easy-to-identify raised positive terminals. Prefilled insulin reservoirs that significantly increase the ease of use for reservoir replacement were found in two of the 2004 models but none of the 2008 models. Additionally, the average reservoir capacity decreased by 33 units (0.1 ml). A larger capacity allows for less frequent cartridge replacement, reducing the possibility of errors related to associated tasks.

Table 2 demonstrates that some IPs provide audio tones to help a person with vision loss count the number of units when setting up a bolus injection. While seven of eight IPs had this feature in 2004, only three of five had it in 2008. Similarly, the number of IPs with tones to assist with priming the pump has decreased from two to one. All the IPs in both 2004 and 2008 have audio tones to indicate alarms and alerts that are shown on the display screen. However, in both 2004 and 2008, the audio tones do not indicate exactly what has occurred or what to do about it.

Table 2.
Audio Output

	2004 IPs	2008 IPs
Basal rate	0 of 8	0 of 5
Basal history	0 of 8	0 of 5
Bolus history	0 of 8	0 of 5
Bolus	7 of 8	3 of 5
Prime	2 of 8	1 of 5
Alarms and alerts	8 of 8	5 of 5
Time and date	0 of 8	0 of 5

Table 3 shows that accessibility of IP manuals in 2008 has remained about where it was in 2004, with print manuals that do not meet large-print standards and a lack of availability of Braille manuals. Although the accessibility of manuals in electronic format has improved slightly, there are still no manuals that are completely accessible to people with vision loss.

Table 4 presents comparative data regarding display features that affect accessibility for people with low vision. Although display size has increased by over 30% by 2008, font size has remained about where it was in 2004.

Table 3.
Documentation[a] / Manuals

	2004 IPs	2008 IPs
Print manual font size (in.)	$\overline{m}$ = 0.160	$\overline{m}$ = 0.153
Accessibility of electronic format (1–5 scale)	$\overline{m}$ = 2.7	$\overline{m}$ = 2.9
Large print available	1 of 8	0 of 5
Available in Braille	0 of 8	0 of 5

[a] Ratings for documentation: (1) screen access software can access none of the documentation; (2) screen access software can access very little of the documentation; (3) screen access software can access some of the documentation; (4) screen access software can access most of the documentation; and (5) screen access software can access all of the documentation.

Table 4.
Visual Displays

	2004 IPs	2008 IPs
Display screen area (in.^{2})	$\overline{m}$ = 1.08	$\overline{m}$ = 1.43
Maximum font size (in.)	$\overline{m}$ = 0.250	$\overline{m}$ = 0.313
Minimum font size (in.)	$\overline{m}$ = 0.109	$\overline{m}$ = 0.142
Resolution	Data not available	Range: 96 x 32 to 240 x 240
Average contrast ratio	Data not available	Range: 35.99% to 83.93%
Reverse polarity	0 of 8	1 of 5
Backlit screen	7 of 8	5 of 5
Color screen	0 of 8	1 of 5
Adjustable contrast	0 of 8	1 of 5

All the other visual display features remain virtually unchanged between 2004 and 2008, except for one important exception. The Animas IR 2020 evaluated in 2008 has a high level of contrast and resolution, reverse contrast polarity, and a color display, all of which can make it easier to read by people with low vision.

Discussion

The Insulet OmniPod has a unique design that is distinct from the other IPs. Its control interface is on a separate remote control that communicates wirelessly with the insulin-delivery unit. The delivery unit has no control buttons, and it is much smaller than the other IPs. It is a stick-on unit with an adhesive for connecting it directly on your skin. When it is primed and ready, a press of a button on the remote control causes it to automatically insert a cannula into the skin for insulin delivery. The OmniPod's unique design approach has several effects on accessibility and usability. Because its controls are on a separate remote control unit, its insulin delivery unit is smaller and less obtrusive than the other IPs on the market, which increases usability. Its automatic infusion process removes accessibility barriers and possibilities for human error related to the connection and infusion steps required by traditional IPs. There are also no wires that can get tangled in clothes or accidentally ripped loose during physical activity.

Although the wireless communication capabilities of the Insulet OmniPod and MiniMed 515 do not currently provide accessibility solutions, they do provide possible new ways to make IPs more accessible. A remote control has more options for designing in accessibility, because it is not confined to the small footprint desired by an insulin delivery system. There would be more room for a larger, more viewable display, and there would be more room for larger, easier-to-identify, easier-to-use buttons. The authors had previously assumed that the speech output required to make pumps fully accessible would have to be built into the pumps themselves. However, an accessible remote control might be an alternative solution. Manufacturers could focus on building speech access into the remote controls and not worry about reconfiguring the electronics of the pump itself. Because of the portability advantages, a strategy of designing accessibility into a remote control device would also be a much more practical solution than designing accessibility into the PC software that can control some pumps.

One might argue that having to carry an additional remote control device adds to the overall complexity of insulin delivery. However, the IP controls could be built into existing wireless devices that people already carry. There are currently several software programs that make cell phones and hand-held PDAs accessible to people who are blind or have low vision, and perhaps they could be configured to control IPs.

Conclusions and Recommendations

Although there have been some minor improvements, no substantial progress was made between 2004 and 2008 in the accessibility of IPs to persons who function nonvisually. None of the 2008 IPs had added the necessary speech output to convey visual display information, and this lack of speech output is still the main barrier to the accessibility and usability of IPs for people who function nonvisually. On the other hand, the Animus IR 2020's improved visual interface indicates that progress has been made in one IP in regard to accessibility for persons with low vision who function visually. Improvements in resolution, contrast, and color have been observed, but font sizes are no larger than the average font sizes of the other IP displays.

Overall, a slight improvement in the tactile nature of control buttons was noted, but that was not a major problem in 2004. As was the case in 2004, the criteria related to operating manuals were not met in 2008. Regarding convenience and ease-of-use design criteria, it is easier to change the batteries on the 2008 IPs, and one IP, the OmniPod, has significantly enhanced the ease of infusion set-up.

It can therefore be concluded that there is still not an IP on the market designed with enough accessibility features for a person with significant vision loss to independently operate it without the need for sighted assistance. To rectify this situation, IP manufacturers should consider the following design recommendations:

- Include speech output for all menu navigation, programming, and warning/alarm messages. This could be designed into the pump itself or via an accessible remote control.
- Incorporate high-contrast visual display technology and consistent use of large font sizes as well as a reverse contrast polarity option for all displayed information.
- Produce all manuals and other documentation in accessible formats, including large print, audio, and electronic format such as text or HTML. Braille should also be available upon request.
- Use a prefilled insulin cartridge instead of having users inject insulin manually.

Manufacturers might also consider providing a "try before you buy" policy so that blind and visually impaired persons can make a more informed choice of which IP is best for them. This will be especially important once manufacturers begin to design significant accessibility into their pumps.

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