

A Comparison of Dosing Accuracy: Visually Impaired and Sighted People Using Insulin Pens

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Abstract

Background:

In the United States, 18% of people with diagnosed diabetes have visual impairment. Insulin pens are widely used by both blind and sighted people. However, major manufacturers include a disclaimer in the instructions warning against use by visually impaired people, without giving a rationale. Published studies neither support nor refute the disclaimer.

Method:

The purpose of this study was to compare accuracy of dosing with insulin pens between visually impaired and sighted people. Inclusion criteria were self-reported diabetes and inability (visually impaired group) or ability (sighted group) to read regular print. The sole exclusion criterion was inability to pass a brief test of decisional capacity. Each participant received standardized instructions for insulin pen use, either in recorded (visually impaired group) or in printed (sighted group) format, and delivered 10 systematically varied doses into an injection ball, which was weighed on a precision laboratory balance.

Results:

No significant correlation with accuracy of insulin dosing was found for any of the analyzed variables: visual status, age, gender, years of having diabetes mellitus (DM), or treatment of DM with or without insulin.

Conclusions:

This study provided preliminary evidence of the safety of use of insulin pens by visually impaired people and raised questions about the validity of the disclaimer. Further study of the safety of use of insulin pens by blind people is needed. Inclusion of people with disabilities in research on technology intended for patient use would ensure that people with disabilities can benefit from new technology.

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Abbreviations: (DM) diabetes mellitus, (DSM) diabetes self-management, (NFB) National Federation of the Blind, (UD) universal design

Keywords: blindness, disability, dosing accuracy, insulin pen, universal design, visual impairment

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Introduction

Among the 18 million people with diagnosed diabetes in the United States, an estimated 3.3 million, or about 18%, have visual impairment or blindness.¹ These people have all the same diabetes self-management (DSM) needs as people without visual impairment. In addition, they need information, tools, and techniques that are accessible to them. Only a few research studies have been published about accessible DSM tools and techniques used by visually impaired people.²⁻⁸ However, both health professional and lay publications describe numerous DSM tools and techniques that are accessible to and used by this population.⁹⁻¹⁶

The definition of “visual impairment” used in this article is inability to read regular print, which is functionally similar to the definition used by the Centers for Disease Control and Prevention: inability to see well when wearing glasses or contact lenses.¹ The terms “visual impairment” and “blindness” are used interchangeably, following the functional definition of “blindness” used by the National Federation of the Blind (NFB), i.e., needing to “devise alternative techniques to do efficiently those things which he would do if he had normal vision.”¹⁷

Self-administration of insulin is an important DSM task for all people, whether sighted or blind, who use insulin for diabetes self-management. Worldwide, insulin pens are common tools for this task. Numerous publications have reported widespread patient satisfaction with insulin pens.¹⁸⁻²² Benefits include “improved acceptability and compliance, reduced injection pain, increased convenience and lifestyle flexibility, greater reliability and accuracy of dosing, and simplification of insulin administration.”²³ The dose-setting mechanism on insulin pens provides visual, audible, and tactile feedback. This redundancy of information makes insulin pens potentially accessible for people who do not see well. In fact, many blind people do use insulin pens using nonvisual techniques for procedures that are not inherently accessible,^{24,25} as they have done since insulin pens were introduced in the late 1980s.

Major insulin pen manufacturers include a disclaimer in the instructions warning against use by visually impaired or blind people without sighted assistance. The disclaimer implies that blind people cannot measure and deliver doses as accurately as sighted people. No rationale is offered, and no similar warning discourages use by people with

other disabilities that may affect accurate dosing, such as impairment of hearing, manual dexterity, tactile sensation, or short-term memory.

Recent studies of insulin pen accuracy have demonstrated that insulin pens reliably deliver accurate doses of insulin,²⁶⁻³⁰ and earlier studies showed that pens are more accurate than syringes.³¹⁻³³ Most insulin pen studies make no mention of whether visually impaired people were included as participants. A literature search revealed only five relevant articles: two accuracy studies that included visually impaired people, but did not offer them complete nonvisual instruction;^{34,35} a study of nonvisual cues for insulin pen use performed by blindfolded sighted people;³⁶ commentary on that study pointing out that real blind people may use their senses differently than blindfolded sighted people because of their different experiences relying on nonvisual senses;³⁷ and a task analysis of insulin pen use conducted by Burton and Uslan³⁸ of the American Federation for the Blind. This analysis showed that most of the steps needed to use pens can be accomplished by visually impaired people. The authors pointed out that inspecting the insulin level, priming the pen, resetting the dosing mechanism to zero for certain pens, and replacing the cartridge are not inherently accessible to people with visual impairment with the pen designs reviewed. In this discussion, Burton and Uslan³⁸ highlighted the lack of design features that would make safe use of insulin pens easy. However, with proper training, blind insulin pens users can employ “work-arounds” that make safe use of insulin pens possible when they are applied consistently. Readers interested in knowing details of techniques for accomplishing all of these tasks safely and consistently using nonvisual senses are referred to articles elsewhere.^{24,25}

No evidence was found in the literature comparing the accuracy of dosing by sighted people who have received visual instruction to that of blind people who have received equivalent nonvisual instruction.

The disclaimer about insulin pens has received recent attention from the NFB. In July 2008, the NFB passed a resolution calling for the removal of the disclaimer about use of pens by blind people from insulin pen instructions.³⁹ This resolution emphasizes the real-world importance of rigorous investigation of the accuracy of insulin dosing by visually impaired people using nonvisual techniques.

The specific purpose of this study was to compare the accuracy of dosing with insulin pens between two groups that had received equivalent standardized instructions: sighted people who received printed instructions in visual techniques and blind people who received audio instructions in nonvisual techniques.

Methods

Participants

Inclusion criteria were self-report of having been diagnosed with diabetes and either the ability (sighted group) or the inability (blind group) to read regular print. This particular criterion was chosen as a proxy for visual impairment because the inability to read regular print corresponds closely to an inability to see the numeral in the dose window on an insulin pen. Therefore, for purposes of using an insulin pen, all individuals in the visually impaired group functioned nonvisually. The sole exclusion criterion was inability to pass a three-question test of decisional capacity.⁴⁰ Blind participants were recruited at the 2009 annual convention of the NFB in Detroit, Michigan. Sighted participants were recruited at DSM education events held by the Diabetes Association of Greater Cleveland in Cleveland, Ohio.

Forty blind participants and 41 sighted participants were recruited and enrolled in the study. Dosing data from one sighted participant contained four consecutive extreme errors out of 10 doses, with one of those errors so large that dosing was not possible with this insulin pen. These values were assumed to reflect measurement error. Therefore, data from this participant were excluded from further analysis.

Informed Consent and Enrollment

This study was approved by the institutional review board of Case Western Reserve University. Prior to enrollment, all participants received a copy of the informed consent form in a format of their choice—in print, by email (legible to screen reading programs used by blind people), or as an audio recording. Immediately following signing of the informed consent form, all blind participants were offered a copy of what they signed so that they could request verification of the contents of the form from a trusted sighted person.

After signing the informed consent form, all participants were asked about their visual status, age, gender, years of diabetes mellitus (DM) diagnosis, treatment of DM with or without insulin, and, for the blind group, years

living with blindness. This information is summarized in **Table 1**.

Materials and Instruments

The insulin pen used in this study was the HumaPen[®] Luxura[™] (Eli Lilly and Company, Indianapolis, IN), which has somewhat more complex procedures for use than a disposable pen. It requires insertion of a 300-unit insulin cartridge and has ½-unit increments for dosing. The researcher purposefully chose a more complex pen, reasoning that the ability to use a more complex pen accurately may generalize to the ability to use a simpler pen accurately.

An injection ball was used to receive each injection. Prior to the full study, a pilot study to validate methods was conducted with 12 blind staff members of the NFB as participants. For the initial pilot study, doses were delivered into small cups. Researchers noticed that with some of these doses, hanging drops of insulin remaining on the pen needles became a source of measurement error. This error was eliminated in the larger study by using injection balls to receive the doses, more closely simulating injection into subcutaneous tissue.⁴¹

An audio recording of instructions for use of the insulin pen was created for this study. The recording was essentially the same as the printed instructions included in the packaging. Two types of modifications were included in the audio version of the instructions to ensure that equivalent instruction was available to both groups. All pictures in the printed instructions were described

Table 1.
Characteristics of Participants

N	Blind group	Sighted group
	40	40
Age in years (mean ± SD) ^a	54.90 (±10.16)	62.4 (±9.36)
Gender N (%)	Male: 18 (45%) Female: 22 (55%)	Male: 9 (22.5%) Female: 31 (77.5%)
Years diagnosed with DM (mean ± SD)	20.53 (±14.81)	12.3 (±10.96)
Years living with blindness (mean ± SD)	30.05 (±20.76)	NA
DM treatment: Without insulin N (%)	10 (25%)	24 (60%)
DM treatment: With insulin N (%)	30 (75%)	16 (40%)
^a SD, standard deviation.		

verbally in the recorded instructions, including nonvisual (mostly tactile) descriptions of all parts of the pen shown visually in the pictures. In addition, all procedures described or pictured visually in the printed instructions were described nonvisually in the recorded instructions, using the senses of touch, hearing, and smell. For example, instead of describing the visual appearance of a stream of insulin to confirm an effective “air shot,” the recording described how to feel for the spray and smell the distinctive odor of insulin. The nonvisual descriptions and procedures had been tested, modified, and validated by blind staff members of the NFB during the pilot study.

A Mettler–Toledo laboratory balance accurate to 0.0001 mg was used to weigh each dose.

Procedures

All participants received standardized instructions for using the insulin pen. The sighted group used the printed instructions that come in the pen package, a typical way to learn insulin pen use in the United States. The blind group used recorded instructions equivalent to the print instructions. Each participant was given as much time as necessary to handle the pen, pen needles, and cartridges while going over the instructions as long as needed to feel comfortable using the pen.

Following instructions with the insulin pen, each person was asked to deliver 10 doses into an injection ball, a rubber ball used commonly to teach insulin injections. The order of low (≤ 10 units), medium (11–20 units), and high (21–30 units) doses was varied systematically. The tare weight of the injection ball was obtained immediately before injection of each dose, and the dose weight was obtained immediately after dose delivery.

Results

SPSS 17.0 software was used for statistical analysis. Gravimetric measurement was converted to volumetric measurement, and the absolute value of the percent error was calculated as defined in **Table 2**. Mean percent error for all doses was compared between blind and sighted participants using a *t*-test. These calculations are summarized in **Table 2**.

Regression analysis was used to check for the possible unique contribution of each independent variable: age, gender, length of time since vision loss, length of time since diagnosis of diabetes, and type of diabetes treatment to the observed variance in the percent error. These calculations are summarized in **Table 3**.

Finally, assuming that an absolute dose error of $\leq 10\%$ was not clinically significant and $>10\%$ could be clinically significant, the number of clinically significant absolute dose errors ($>10\%$) was calculated for both blind and sighted groups and compared using χ^2 analysis. Results of these calculations are summarized in **Table 4**.

Table 2.
Summary of Absolute Value of Percent Errors and *t*-Test^a

DU = DG/1.005		APE = $ (\text{DU} - \text{IU})/\text{IU} \times 100\%$		
	Minimum	Maximum	Mean (\pm SD)	
Blind group (N = 40)	1.30%	18.62%	5.83% ($\pm 3.34\%$)	
Sighted group (N = 40)	1.23%	89.15%	6.59% ($\pm 13.74\%$)	
$t = -0.34 \quad df = 78 \quad p = 0.136$				

^a DU, delivered dose in units; DG, delivered dose in grams; 1.005, specific gravity of insulin; APE, absolute value of percent error; IU, intended dose in units; SD, standard deviation

Table 3.
Summary of Multiple Regression Analysis for Variables Predicting Absolute Value of Percent Error (N = 80)

	B	β (SE)	T	P
Age	-0.102	-0.106	-0.920	0.361
Gender	2.054	0.098	0.848	0.399
Years diagnosed with DM	0.111	0.152	1.141	0.258
Insulin user	-3.328	-0.167	-1.289	0.201

Table 4.
Summary of Clinically Nonsignificant/Potentially Dose Errors

	Clinically nonsignificant dose error ($\leq 10\%$)	Clinically significant dose error ($>10\%$)
Blind group doses (N = 400)	289	111
Sighted group doses (N = 400)	271	129
$\chi^2 = 0.952 \quad p = 0.329$		

Discussion

Dosing accuracy was not predicted significantly by any of the analyzed variables: visual status, age, gender, years

of having DM diagnosis, or treatment of DM with or without insulin. The sighted group had a larger number of clinically significant dosing errors than the blind group, but the difference was not statistically significant.

Both sighted and blind groups had a high level of errors that were potentially clinically significant (>10%). This is consistent with previous research showing that patients commonly make significant errors in insulin dosing.⁴² Implications of this inaccuracy for insulin use in general are beyond the scope of this article. However, this particular study was designed to compare the accuracy of dosing by blind people to that of sighted people, assuming that if a certain level of errors does not preclude use of insulin pens for sighted people, it should not preclude use for blind people.

Limitations of the study include that this study was conducted with a nonrepresentative sample and on only one of several insulin pens currently available in the United States. It cannot be reasonably concluded that the specific results would generalize to the entire population of visually impaired people or to all insulin pens. However, if visual impairment were a strong predictor of dosing inaccuracy, at least some indication of that should be seen in data, even for this relatively small nonrepresentative sample. It was not.

Another limitation is that a greater percentage of the sample of visually impaired people than of the sample of sighted people was current users of insulin. This introduces the potential alternative explanation for these results that the lack of differences between visually impaired and sighted groups is due to the fact that the visually impaired group was more familiar with insulin than the sighted group. However, in light of the fact that familiarity with insulin did not emerge as a strong predictor of dosing errors, this explanation does not provide a compelling account of data.

These results do not support the assumption that blind people are unable to dose insulin accurately, implicit in the disclaimer warning against insulin pen use by blind people. In fact, there is a suggestion in these results that blind people may make fewer clinically significant errors in dosing overall than sighted people do; however, the difference was small enough to not be statistically significant. Although this relatively small study is, understandably, not likely to be considered adequate evidence to remove the disclaimer, it calls into question the implication that blind people are unable to use insulin pens to deliver accurate insulin doses.

One common argument against removal of the disclaimer is that, in the absence of research evidence, manufacturers are erring on the side of safety. This may seem logical at first. However, manufacturers do not consistently include disclaimers about other conditions for which there is no safety research. For example, there are probably limits to manual dexterity below which use of insulin pens is unsafe. Cognitive impairment can be a safety concern, as can attention deficit hyperactivity disorder, depression, schizophrenia, bipolar disorder, and abuse of intoxicants. Yet these reasonable disclaimers are not included with any insulin pen.

Most health care professionals understand that when there is no disclaimer, medical devices are not automatically considered safe for all people. When a possible safety concern is present for a particular patient, they know that they need to assess the individual situation and collaborate with the patient to decide whether use of the device is safe and appropriate. The same criterion for a disclaimer could be applied to visual impairment as is applied to all other conditions that raise potential safety issues.

Ample anecdotal and research evidence exists that in both the historical and the recent past, sighted people have severely underestimated the abilities of blind people.^{43–46} Research suggests that when combined with feelings of pity, these negative perceptions of the abilities of blind people serve as the primary expression of prejudice toward this population, giving rise to systematic paternalism and discrimination.⁴⁷ Discrimination in the form of paternalism is often carried out by people who do not have malicious intent, but are unaware of the effective tools and techniques used by blind people. Even so, it is damaging. The attempt to protect adult, cognitively intact blind people from potential errors in the use of insulin pens is an example of well-intentioned paternalism that leaves blind people without easy access to a necessary self-management tool.

When insulin pens were first released in the late 1980s, the social context concerning the rights of people with disabilities was in the process of shifting. The disability rights movement was well underway.⁴⁸ Passage of the Americans with Disabilities Act in 1990⁴⁹ resulted from this shift and also provided impetus for further social change.

One major manifestation of that change has been the promotion of universal design (UD) as a way to readily include people with a full range of abilities and disabilities at minimal cost and with minimal disruption.

Universal design is defined as the design of products and environments to be usable by all people, to the greatest extent possible, without the need for adaptation or specialized design. There are seven principles of UD that are widely used: equitable use; flexibility in use; simple and intuitive use; perceptible information (i.e., redundant multisensory information); tolerance for error; low physical effort; and size and space for approach and use.⁵⁰

The design of insulin pens has always incorporated principles of UD, in that information necessary for use has always been available as redundant, multisensory information. Yet apparently the UD elements were not included to intentionally improve the design for people with disabilities. Rather, they improved the design for everyone, incidentally making it accessible for people with vision impairment. In any case, manufacturers did not include blind people in initial or later product safety testing.

When insulin pens were first released in the late 1980s, before passage of the Americans with Disabilities Act, exclusion of people with disabilities from safety testing of products intended for use by diabetes patients was a regrettable, but understandable, omission. Such exclusion can no longer be defended scientifically or ethically. People with varying abilities and disabilities are as much a normal part of any typical population with diabetes, as are other previously excluded groups such as women and racial minorities. Even though there may be no ill will on the part of researchers, exclusion of a normal part of a typical population from diabetes technology research is not a benign omission. Instead of protecting people with disabilities, exclusion of disabled people leaves health care providers and diabetes patients without adequate evidence-based information about the safety and limits of safety for the use of technology for diabetes management.

In contrast, inclusion of people with disabilities in safety research on technology intended for DSM could provide robust real-world data about use of the technology, encourage designs that benefit a larger percentage of both disabled and nondisabled populations through adherence to the principles of UD, and ensure that recommendations about use of diabetes technology are based on factual information about a wide range of human abilities.

Conclusions

The disclaimer recommending against use of insulin pens by visually impaired and blind people is not supported by this study, raising questions about its validity. Further research is needed to determine the safety of the use of insulin pens by people with a variety of disabilities and combinations of disabilities.

Results of this study provoked questions about the common practice of excluding people with visual or other disabilities from research on diabetes technology intended for use by diabetes patients. Significant benefits would follow inclusion of disabled people; in particular, robust data about real-world use of the technology, encouragement of technology designs that can benefit both nondisabled and disabled people through adherence to principles of UD, and expanded reach of the benefits of technology to people with a broad range of abilities.

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Disclosure:

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