Accessibility of Diabetes Therapy Management for Patients with Visual Impairment

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Abstract
Introduction: According to the Centers for Disease Control, 11.8% of adults diagnosed with diabetes have severe vision difficulty or blindness, a complication of uncontrolled diabetes. The study evaluated the accessibility features of the most commonly used injectable products for diabetes and blood glucose monitors and obtained recommendations from manufacturers regarding use of these products in patients with visual disabilities. Additionally, accessibility of the medication guides was assessed using a checklist and screen reader. *Methods*: Selection of the most commonly prescribed insulin products, GLP-1 receptor agonist drugs, and blood glucose monitors were identified from the ClinCalc DrugStats database and ADA list. The accessibility features of these products were determined from the medication guides and verification of the information with the manufacturers were done in August 2022. All medication guides were then assessed using a checklist and tested with a screen reader for accessibility. Descriptive statistics were used to report the data. *Results*: No injectable products or glucose monitoring systems were fully accessible and manufacturers advised to use the product with caution and/or required assistance from a caregiver or family member. In evaluating the 14 medication guides for accessibility using the checklist, the most common issues were lack of structured headings to help with navigation, no descriptions for images, and tables did not have appropriate headers. *Conclusions*: Due to the lack of accessible features on diabetes medical devices and glucose monitoring systems, healthcare professionals can seek alternatives to assist this patient population to effectively manage their therapy.

Keywords: Diabetes, accessibility, disability, insulin, blood glucose monitoring, GLP-1 agonists

Introduction

According to the Centers for Disease Control and Prevention 2021 National Diabetes Statistics report, approximately 11.8% or 38.4 million adults have diabetes. Unfortunately, diabetes is the leading cause of new cases of blindness in adults aged 18 to 64 years and a major contributor to other forms of visual impairment.[1]

It is estimated approximately 11% of adults in the U.S. with diabetes experience some degree of vision loss, a rate higher than the 5.9% in individuals without diabetes.[1,2] Additionally, data from 2016-2017 in the National Health Interview Survey revealed that among adults aged 45 and over diagnosed with diabetes, 32.2% had cataracts, 8.6% had diabetic retinopathy, 7.1% had glaucoma, and 4.3% had macular degeneration.[3] Globally, diabetic retinopathy has been a cause for vision impairment or blindness in 3.9 million people.[4] Consequently, as the prevalence of diabetes increases, so will the number of patients experiencing vision loss.

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Adults with disabilities including visual impairment frequently encounter barriers that prevent access to available healthcare and other services pertaining to wellness leading to poor patient comprehension of their health and current/potential medications, low quality of life, and unfavorable health-related outcomes.[5,6] Given the correlation between self-efficacy and diabetes outcomes, individuals with visual impairment experience disproportionately higher rates of poor quality of care compared to those without visual impairment.[7]

Due to the complexity of diabetes management and utilization of products or devices that rely heavily on visual cues, patients with a visual disability experience difficulties in self-managing their health using these products.[8] A study conducted in 2004 with a follow up study in 2009 evaluated insulin pumps for accessibility features that would enable users to operate the product independently without needing assistance from a sighted individual. The results showed insulin pumps assessed in 2004 were not accessible, and there was no improvement in the products by 2009. Moreover, none of the insulin pumps featured speech output, only one insulin pump had an enhanced visual display, and no large-print or Braille manuals were available for any of the products.[9,10] In another study conducted in 2008, the Prodigy® Voice was the only blood glucose monitoring system assessed to have speech output, enabling people with blindness and other forms of visual impairment to fully access the functions of the product.[11] Another study conducted in 2012 evaluated features of 13 blood glucose monitors, and the results showed that all blood glucose monitoring systems allowed a person with vision loss to

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obtain a blood glucose measurement; however, only 4 blood glucose monitoring systems contained audible output to allow users to fully access all functions of the meters without assistance from a sighted individual.[12]

Despite the advancement in technology over the years, the availability of accessible medical devices and/or products for patients with any form of vision loss is scarce. Additionally, the literature lacks substantial information regarding resources aimed at enhancing the accessibility of medication information for injectable products for patients with diabetes and visual impairment. Without an understanding of these available resources, clinicians face challenges in identifying methods to enhance the self-efficacy of these patients and consequently enhance their quality of care.

Therefore, the study objectives were to evaluate the accessibility features of the most commonly prescribed diabetes injectable products and blood glucose monitors and obtain recommendations from manufacturers regarding use of these products in patients with visual disabilities. Additionally, accessibility of the medication guides and patient information of each of these products was assessed.

Methods

Research Design

This study was a cross sectional analysis of accessibility features of injectable diabetes products using information in the medication guides or patient information sheets (for products without medication guides) and glucose monitoring systems using the accompanying manuals. Determination of the accessibility of the drug information in the medication guides or patient information sheets of the injectable products were based on a checklist developed using the 508 Standards with verification of accessibility issues by a screen reader, VoiceOver. Because of the nature of the study, no human involvement or patient-related data, no IRB approval was required.

Selection of injectable products and blood glucose monitoring systems

Selection of the injectables products was based on a review of the Clincalc Drugstats Database Top 200 Most Commonly Prescribed Drugs of 2021 in which the data were derived from the annual Medical Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality. The additional criteria for selection included injectable products with an indication for diabetes and were categorized as a glucagon-like-peptide-1 (GLP-1) agonist or an insulin product on the Top 200 drugs list.[13] The injectable GLP-1 agonists included in the analysis based on the inclusion criteria were dulaglutide (Trulicity®), liraglutide (Victoza®), semaglutide (Ozempic®, Wegovy®), and exenatide (Bydureon®). Because several of the insulin products had multiple brand names, each manufacturer of an insulin product available on the market was included. The insulin products that met the aforementioned criteria were insulin glargine (Lantus®, Basaglar®, Toujeo®), insulin lispro (Humalog®, Admelog®), insulin aspart (Novolog®, Fiasp®), insulin detemir (Levemir®), insulin degludec (Tresiba®).

Because blood glucose monitoring systems do not require a prescription, no organizations have a list of commonly used systems available in 2022. Therefore, these products were chosen based on the available products provided in the American Diabetes Association Consumer Guide on blood glucose monitoring systems then further refined by the list of the most utilized blood glucose meters reported by Forbes Health.[14,15] Based on these criteria, the five blood glucose monitoring systems included for evaluation were OneTouch® Verio (OneTouch), Contour® Next (Ascensia), Acu-Chek® Guide (Roche), Contour® Next One (Ascensia), and Prodigy Voice® (Prodigy).

Evaluation of accessibility features and medication guides

The investigators reviewed the instructions for use section within the patient information or medication guide of each diabetes medication to determine if each insulin and GLP-1 agonist injectable product consisted of any accessibility features. The same review process was applied to the blood glucose monitoring systems using the accompanying manual to determine presence or absence of accessibility features. Furthermore, accessibility features of blood glucose monitoring systems evaluated in this study were derived from previous studies and included a back light on the screen of the monitor, test strip light, different audible features such as beeps or readback, tactile markings, and Bluetooth capability. If a blood glucose monitoring system contained all of these features, the blood glucose monitoring system was considered to be accessible for patients with visual impairment without assistance from another individual.

After the review, the manufacturer of each respective injectable diabetes product was contacted via phone call to request information about recommendations for use of their product by a patient with visual impairment and availability of accessible medication guides or patient information sheets for use with a screen reader. Additionally, if the medication guides or patient information sheets were not accessible using a screen reader, the companies were asked if any alternative formats (e.g., audio recordings or HTML format of drug information) are offered. All data provided by the pharmaceutical companies were recorded in an Excel Spreadsheet.

When evaluating the accessibility of drug information in medication guides or patient information sheets, a checklist was created based on the updated Section 508 standards from the U.S. General Services Administration. This checklist provides guidance on how electronic documents can be made accessible to people with disabilities. Some of the 508 standards focus on using appropriate headings and labels within a public document to introduce content, including providing alternative text for

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images, and organizing a logical sequence for content.[16,17] The checklist includes items such as structured headings to help users navigate through the document using a screen reader, alternative text or descriptions for images, descriptive wording for hyperlinks, layout and headers for tables, definitions for acronyms and terms, using bold or italic fonts instead of color, ensuring high contrast between text and background, and formatting bulleted or numbered lists in the Word processor. These items on the checklist are essential components that enhance accessibility by enabling screen readers to read the document effectively.

After utilizing the checklist, each medication guide or patient information sheet was tested using a screen reader, VoiceOver, to verify or find additional accessibility issues. This software was chosen as it is one type of screen reader that allows for users who are blind or visually impaired to read the text displayed on the computer screen with a speech synthesizer.[18]

Data Analysis

Descriptive statistics (count) were used to describe data regarding accessibility features and accessibility of medication guides or patient information sheets. Because of the descriptive nature of the study, no formal inferential analysis was conducted.

Results

A total of 19 products, diabetes medications (n=14) and glucose monitoring systems (n=5), were reviewed in the study. None of the 14 insulin and GLP-1 agonists had any accessibility features such as audible options on the device or any tactile options. As for the blood glucose monitoring systems, none of the systems were fully accessible, as they all lacked the four categories that would allow a patient with visual impairment or blindness to use the meter without assistance (see Table 1). The Acu-Chek® Guide meter had the most features that offered assistance for individuals with visual impairment but not for those with blindness. These features included a backlight monitor, test strip light, and Bluetooth capability to allow the values to be read using a smartphone app; however, no audible features were available to allow patients to use all of the functions of the meter. All other monitoring systems either had audible features or Bluetooth capability.

None of the manufacturers of the injectable products provided a Braille medication guide or offered an alternative format compatible with a screen reader. Based on our review, the manufacturers advised those who have blindness or vision impairment to request assistance from a caregiver or family member trained in using the injectable product.

In evaluating the 14 medication guides or patient information sheets for accessibility using the checklist, the most common issues were a lack of structured headings to help with navigation, no descriptions for images, and tables with inappropriate headers (see Table 2). The same medication guides and patient information sheets were then tested using a screen reader for accessibility issues. The most commonly detected errors were mispronunciation of drug names, medical terminology, or reading bullet points as 'dots.' Additionally, the majority of these medication information documents were created in a table format without using universal design; therefore, the screen reader was unable to read any of the content. All of these errors lead to barriers for patients when using a screen reader.

Discussion

Diabetes continues to negatively impact a large number of patients with visual impairment or blindness. Technological advances have introduced a plethora of diabetes treatments to the market, including GLP-1 agonists; however, this study was the first to determine that the commonly prescribed GLP-1 agonists do not have any accessibility features to help patients with vision loss self-administer the products. The results were similar for the insulin injectable products while the glucose monitoring systems do not have sufficient accessibility features to improve self-efficacy among patients who are visually impaired. These findings align with those of previous studies evaluating the accessibility of insulin pumps and glucose monitoring systems. [9,10,11,12] Furthermore, due to the lack of accessibility features, these patients require help from a third party to use these products as prescribed in their diabetes therapy. This incurs personal costs to obtain external assistance and may impact adherence. Patients who cannot find assistance may use the injectable products improperly, increasing their risk for medication errors and misuse, as well as the potential for bodily harm. Some patients may choose not to use these therapies at all or may be limited to other suboptimal options, leading to uncontrolled blood glucose levels and the development of other health concerns.

Healthcare professionals play an important role in supporting the management of diabetes for this patient population by recommending treatments that not only effectively control blood glucose levels but allow for patients to feel empowered to self-manage their therapy while preventing medication errors and misuse. In order to meet the needs of patients who have a visual disability, providers in some situations have recommended insulin pens and hybrid closed loop systems along with continuous monitoring systems and Dexcom G6 with voice activation.[19,20] Additionally, healthcare professionals have the option to explore oral treatments along with recently developed technology such as insulin patch pumps, V-Go, currently available in the U.S.[21] These new systems and medications offer advantages to patients with visual impairment; however, cost may be a barrier in those who are low-income or resource-limited.

The results of this study have other public health implications. A novel finding of this study was the lack of accessible drug

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information available in the medication guides or patient information sheets, and that manufacturers do not offer alternative formats compatible with a screen reader. This aspect prevents patients from having drug information essential for proper usage of the product and understanding of adverse events. Recognizing the negative effects on patient health outcomes, the American Foundation for the Blind (AFB) recommends consumer medication information be available in Braille format. If Braille cannot be provided and the patient can read Braille, the patient can be referred to Braille translation services.[22]

In addition to Braille, this study highlights the importance of pharmaceutical companies in creating accessible medication guides and patient information sheets or providing alternative formats for patients with visual impairment and blindness. Alternative formats may include audio recordings and electronic text of medication information. These options support patients with visual impairment who have low health literacy levels and require additional resources beyond what is typically provided for patients without vision loss at the clinic or by other health professionals to manage their diabetes. The availability of accessible medication guides or patient information sheets on the pharmaceutical company's website give patients the opportunity to obtain reliable drug information and be more informed about their therapy leading to improved self-management of diabetes in a population susceptible to visual complications.

This study had several limitations. Firstly, the evaluation of accessibility focused on the most commonly prescribed injectable products and blood glucose monitoring systems. Including other injectable diabetes products not widely prescribed and glucose monitoring meters available on the market may provide greater insight into accessibility features for individuals with visual impairment or blindness. Additionally, comparing the accessibility of injectable products to oral formulations may offer knowledge on differences and ease of management for patients who use these products. Secondly, the accessibility features of the products were determined based on pictures and information found in the medication guides or patient information sheets provided by the manufacturers rather than the physical products. Currently, no validated approach exists to assess the accessibility features of medical devices or products.

Conclusion

Due to the significant public health impact of the lack of accessible features in blood glucose monitoring devices and injectable products, stakeholders, such as government agencies and pharmaceutical companies, should collaborate to ensure the inclusion of accessibility features for individuals with visual impairments who have diabetes. This action will improve medication self-efficacy while reducing medication misuse or errors. Additionally, making drug information in medication guides or patient information sheets accessible not only addresses a health disparity but has the potential to enhance health outcomes among this population.

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Table 1. Accessibility Features of Blood Glucose Monitoring Systems (N=5)

Blood Glucose Monitors	Back light on monitor	Test Strip Light	Bluetooth capability	Audible Features	Tactile markings
OneTouch® Verio (OneTouch)	---	---	**X**	---	---
Contour® Next (Ascensia)	---	---	**X**	---	---
Prodigy Voice® (Prodigy)	---	---	---	**X**	---
Contour® Next One (Ascensia)	---	---	**X**	---	---
Acu-Chek® Guide (Roche)	**X**	**X**	**X**	---	---

Accessibility features of blood glucose meters evaluated in this study were similar to previous studies; If a blood glucose monitoring system contained all of these features, the system was considered to be accessible for patients with visual impairment without assistance from another individual.

Table 2. Accessibility of Patient Information or Medication Guides of Injectable Insulin Products and GLP-1 Inhibitors (N=14)

Item	No. of Patient Info or Med Guides		
	Yes	No	NA
High contrast between text and background	14	--	--
Lists are bulleted or true numbered	--	14	--
Structured headings present to facilitate navigation through different sections of document	--	14	--
Descriptions (alternative text) present for all images and tables	--	14	--
Descriptive wording for hyperlink text	--	14	--
Tables designed with appropriate layout using headers and repeat header rows	--	1	13
Acronyms spelled out or terms are defined	--	14	--
Bold or italic fonts are used to show emphasis (rather than color) to convey importance or meaning	--	14	--

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