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ORIGINAL ARTICLES

Analysis: Including Visually Impaired Participants in Validation Design Studies of Diabetes Technology

Mark Uslan, M.A., M.S., and Morgan Blubaugh, B.B.A.

Abstract

In an article in this issue of *Journal of Diabetes Science and Technology*, Sherwyn Schwartz, M.D., presents a study to validate the design of the ClikSTAR® insulin pen from sanofi-aventis and demonstrates that the device can be used correctly by participants with diabetes. Concern with this article lies with the selection of participants, which was meant to reflect the intended audience for the insulin pen device but does not address the inclusion of visually impaired individuals, who comprise over 20% of the adult diabetes population. Visually impaired individuals need to be included as part of the intended audience for insulin administration technology, and manufacturers of these devices need to design their products for safe use by all people, including those who are visually impaired. The study demonstrated successful use of the ClikSTAR insulin pen in a population that did not include subjects with severe visual impairment. We believe that future validation studies for insulin administration technology should also include samples of visually impaired users and that visually impaired patients will embrace the use of insulin pens designed with their needs in mind.

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In an article in this issue of *Journal of Diabetes Science and Technology*, Sherwyn Schwartz, M.D.,[1] presents a study to validate the design of the ClikSTAR® insulin pen from sanofi-aventis. In the article, Schwartz documents the rising popularity of insulin pen devices worldwide as well as the advantages, both health and convenience related, that insulin pens offer over the traditional vial-and-syringe option. The author cites the potential for improved long-term outcomes when using insulin delivery devices properly and also warns of the adverse health risks posed by incorrect use, especially in regard to dosing errors.

The study consisted of two groups of diabetes patients tasked with successfully delivering a set dose of insulin. Individuals aged 13–79 years who had been diagnosed with type 1 diabetes or type 2 diabetes for at least 1 year were selected based on criteria designed to exclude individuals who were unlikely to be candidates for insulin pens in clinical practice. These participants were organized into two groups, group A (n = 256), who were provided training by a diabetes specialist in the proper use of the device, and group B (n = 47), who were self-trained. After receiving training or orienting themselves to the device and operating procedures, members of both groups were tasked with delivering three 40 U insulin doses into a receptacle.

The study measured the proportion of participants who delivered a successful dose, defined as 75–115% of the

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

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Corresponding Author: Mark Uslan, M.A., M.S., American Foundation for the Blind (AFB TECH), 1000 5th Ave., Suite 350, Huntington, West Virginia, 25701; email address muslan@afb.net

intended 40 U, on all three dose delivery repetitions. In group A, 99.6% (n = 255) of participants delivered three successful doses of 40 U, with 767 of 768 individual doses being within the predefined target range. In group B, 93.6% (n = 44) of participants delivered three successful doses of 40 U, with 134 of 141 individual doses being within the predefined target range. None of the enrolled participants (n = 345) reported an adverse event during the study. The 99.6% success rate for group A members, with a 95% lower bound of 98.2%, was above the predefined validation limit of 90%.

Through the use of clear objectives for success and failure defined in the study, Schwartz effectively achieved the stated objective of demonstrating the validity of the ClikSTAR in being used correctly among the sample groups. We were impressed by the testing methodology used and the inclusion of, and success with, a self-taught group. People often learn how to use a product on their own, with the help of the operating manual. However, we would have liked for the sample to have captured a wider range of diabetes patients, particularly users who are visually impaired.

When discussing the criteria for participant elimination, Schwartz states that participants were removed if they exhibited "severe visual impairment" but does not provide any further clarification as to what constitutes visual impairment or how the researchers determined whether a participant was visually impaired. In the National Health Interview Survey given by the National Center for Health Statisitics,[2] visual impairment is defined as any person who reports difficulty in seeing while wearing glasses or contact lenses. This is a very broad category that includes millions of Americans, including 20.5% of adults with diabetes in the United States aged 18 years or older.[2] That amounts to a total of over 3.6 million diabetes patients in this country alone who have difficulty seeing, many of whom need to operate insulin administration technology to manage their health.

Visually impaired users of insulin pens encounter problems not typically considered in the design of validation studies that do not include them in the sample.[3] This would include determination of the amount of insulin remaining in the cartridge; delivery of a "safety dose," which Schwartz identifies as being a crucial part of giving accurate measurements; and, most importantly, the task of setting and verifying a dose amount. There is also the issue of the accessibility of the device's operating manual.

The study performed by Dr. Schwartz was effective in validating the design of the ClikSTAR pen for use by non-visually impaired people and populating samples that reflect this market focus. There is a market for diabetes products designed to be used by visually impaired patients. Insulin pens, with their tactile features, are particularly helpful for visually impaired patients. We believe that the insulin pen manufacturers would discover an enthusiastic consumer base for these products if they were to manufacture and design them with the visually impaired population in mind. We recommend that, during the product design phase of the development of new insulin pens, emphasis should be placed on designing these devices for correct and safe use by all people, including those who are visually impaired. Validation studies similar to the one performed by Dr. Schwartz can then be conducted to ensure correct and safe use, employing samples that include participants with varying degrees of vision loss. Development of insulin pens designed for visually impaired patients with diabetes is an example of a win–win situation: better products to meet the needs of a specific group of patients and a new market for the manufacturers.

References:

1. Schwartz S. Correct use of a new reusable insulin injection pen by patients with diabetes: a design validation study. J Diabetes Sci Technol. 2010;4(5):1229-35.
2. Centers for Disease Control and Prevention, National Center for Health Statistics. National health interview survey. http://www.cdc.gov/nchs/nhis.htm. Accessed August 20, 2010.
3. Uslan MM. Analysis: beyond the "clicks" of dose setting in insulin pens. Diabetes Technol Ther. 2005;7(4):627–8.