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Analysis: Linking Laboratory Data to Human Factors and Inclusion of Persons with Disabilities in Diabetes Technology Research

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Abstract

In this issue of *Journal of Diabetes Science and Technology*, Friedrichs and colleagues present a study of the injection force of four reusable insulin pens and another study of the dosing accuracy of three different insulin pens. For the study of injection force, the authors claim that lower injection force has numerous advantages for patients, including making use of pens easier for people with decreased hand strength. For the study of dosing accuracy, the authors state that dose accuracy is critical for glycemic control.

Both study designs have significant strengths, including measurements of the variable of interest using two different methodologies and thorough documentation of methods and materials. However, the careful, precise measurements of injection force and dosing accuracy are not matched by equivalent precision supporting the significance of the studies. The authors do not provide any information about what measured injection force is easy or difficult for individuals with and without manual problems or what level of dosing inaccuracy is clinically significant. Therefore, the implications for practice remain unclear. Data about these and other relevant human factors are needed to provide meaningful context for laboratory measurements of diabetes technologies. Furthermore, researchers conducting studies of diabetes technology that include human subjects should intentionally recruit persons with disabilities so diabetes care professionals can know whether and how technical information about diabetes technology applies to the full range of patients, including those with disabilities.

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In this issue of *Journal of Diabetes Science and Technology*, Friedrichs and colleagues present a study of the injection force of four reusable insulin pens[1] and another study of the dosing accuracy of three different insulin pens.[2] In the introduction to the study of injection force, the authors support the importance of their study with published studies demonstrating that lower injection force reduces injection-site pain and makes pens simpler and more comfortable for patients. In addition, they assert that, because diabetes is associated with a variety of conditions that decrease dexterity and hand strength, lower injection force may be important for diabetes patients who have impaired manual dexterity or strength. The authors support the study of dose accuracy by stating

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Abbreviation: (ISO) International Organization for Standardization

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that dose accuracy is critical for glycemic control and citing the International Organization for Standardization (ISO) standards for insulin pen accuracy.

The design of the injection force study did not involve human subjects. Rather, injection force was measured mechanically in a laboratory setting at six different constant volume flow rates and at two constant button speeds. Each pen was tested using the needle and insulin recommended by the manufacturer at the maximum dose that each pen can deliver. One of the four pens, the ClikSTAR, was tested at two different doses: at 80 U as the maximum dose and also at 60 U as the maximum for the other three pens to allow comparison with the other pens. For each flow rate and each button speed, measurements were taken three times. The injection force was significantly lower ($p < .05$) for ClikSTAR both at constant button speed and at constant flow rates. The authors conclude that this reduced injection force may provide significant benefit to patients, especially those with reduced manual dexterity or hand strength. They also acknowledge that clinical research involving human subjects is necessary to assess the impact on clinical outcomes, compliance, and quality of life. The design of the dose accuracy study similarly involved two ways of measuring the variable of concern: a laboratory study with doses delivered by a trained technician and a simulated clinical setting with doses delivered by individuals who have diabetes.

The designs of these studies have significant strengths. With the inclusion of measurements of both constant flow rates and constant button speeds in the injection force study, and measurements in both laboratory and simulated clinical settings in the dose accuracy study, the authors eliminated potential sources of ambiguity in their results. Furthermore, the careful documentation of methods and materials in both studies should enable interested researchers to verify the results and perform future studies that can be directly compared with these.

However, the careful, precise measurements of injection force and dose accuracy are not matched by equivalent precision in supporting the significance of these studies. Therefore, the implications for clinical practice remain unclear. As suggested by the authors, the significance of laboratory-measured injection force to humans who use insulin is undetermined. In fact, a similar concern appeared in a 2009 analysis of a study reporting injection force for a different insulin pen.[3] For example, measured injection forces of 5.06 ± 0.40 and 6.85 ± 0.28 at a constant flow rate of 6 U/s are reported in the current study as statistically significant, but the reader has no way to judge the significance of these very precise measurements to individual insulin pen users, including persons with weak hands. It seems likely that both upper and lower limits exist for useful injection forces for people with typical hand strength and dexterity and also for people with a variety of types of manual impairments. However, information about the range of useful injection force does not exist in the published literature on insulin pens. Similarly, although ISO standards for insulin pens exist and are useful for providing an assessment of dosing accuracy, it is not known from the background information at what level variations from ISO standards would have clinical significance for people using insulin.

Another limitation of these studies is the omission of persons with disabilities that comprise important groups of insulin pen users. Numerous reports of insulin pen technology state that insulin pens can make insulin administration easier for individuals with visual impairment and dexterity impairment.[1,4–7] Yet very few clinical studies of insulin pens have included persons with either of these disabilities, and those that do commonly exclude individuals with severe impairment. Moreover, no published study was found that included persons who have both dexterity and visual impairments, yet this combination is not uncommon among persons with diabetes.

There has been increased attention to disabilities that can affect use of insulin pens. Several studies have appeared examining hand function and disorders in people with diabetes.[8–11] One published study compares accuracy of dosing with an insulin pen by sighted and blind people.[12] A brief report commented on the importance of examining the validity of measurements in studies involving disabled persons.[13] In addition, publications have specifically called for inclusion of visually impaired participants in research on diabetes technology[12,14] and inclusion of persons with disabilities in translational health research in general.[15]

Studies and reviews of technical qualities of insulin pens commonly claim theoretical usefulness to people with dexterity or visual disabilities.[4,5,7,16–22] Future studies making such claims should clarify the significance by linking laboratory data to information about the relevant human factors. Furthermore, studies of diabetes technology that include human subjects should purposefully include individuals who have a full range

of severity of the impairments for which benefit is claimed. Diabetes care professionals need the information such studies would produce to know whether and how technical information about useful qualities of technology applies to diabetes patients who have disabilities.

Based on the two studies presented by Friedrichs and colleagues, as well as other studies of insulin pens, I believe that future studies of insulin pens and other technologies designed for use by people with diabetes should include

- Measurements that eliminate ambiguity concerning the critical factors under study through use of more than one type of measurement, as these studies do;
- Thorough documentation of methodology to enable other researchers to replicate the results;
- Presentation of background information concerning the human factors related to the study to enable the reader to judge the significance of any differences discovered. If specific measures related to a particular technology are not available, more general human factors information drawn from appropriate disciplines such as occupational therapy or physical therapy, may be presented. Furthermore, when human factors for specific technologies are not documented in the literature, these could be an important focus for research; and
- Intentional recruitment of persons with disabilities commonly represented in the population under study, with documentation of disabilities as demographic factors and analysis of these factors related to the outcome variables (this is particularly important for studies claiming benefit for persons with specific disabilities or limitations).

Future studies including these factors will help diabetes care professionals evaluate the use of diabetes technologies for a full range of their patients, including those with disabilities. Users of diabetes technologies, with the wide variety of personal characteristics represented in real-world populations, will be the ultimate beneficiaries.

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