

## Ensuring Valid Measurements for a Disabled Population: An Insulin Pen Pilot Study

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**H**ealth promotion and self-management for persons with disabilities have been severely underemphasized in health care research. As researchers seek to fill these gaps in knowledge, it is essential that they validate their methods through use of pilot studies. The following pilot study illustrates how such exploration can lead to unexpected and necessary modification of methods.

The study focused on measurement of dosing accuracy by blind people using insulin pens. The National Federation of the Blind provided in-kind support for the study. The original study design used a common method for measuring dose accuracy: weighing insulin delivered into a small cup. For the pilot, 12 blind staff members of the U.S. National Federation of the Blind received instruction on insulin pen use and delivered doses into a small cup. Audible “clicks” for each dose were counted and recorded by the researchers, and the cups were weighed immediately before and after each dose using a precision balance.

All doses (100%) were dialed correctly according to the click count. However, four doses had greater than 20% error by weight. During the last two of these doses, the principal investigator and research assistant independently noticed a large hanging drop of insulin remaining on the end of the needle. The hanging drop was a source of error for these two doses and may have been an unnoticed source of error for the other two doses.

Measurement error produced by hanging drops is much less likely when sighted people deliver a dose, since they could see and shake off the drop. Blind people do not see the drop, and their dosing may seem inaccurate in comparison. This source of error has no clinical significance; anyone using an insulin pen would inject into subcutaneous tissue, which would not leave a hanging drop on the needle. The error is an artifact of the measurement method.

Because this source of error was discovered in the pilot study, the measurement method for a larger follow-up study was changed to weighing insulin delivered into an injection ball (a rubber ball used to teach injections), which simulates injection into subcutaneous tissue more closely. If this source of error had not been noticed in pilot testing, the results of the larger study would have been artificially biased.

The importance of conducting pilot studies to validate methods with disabled populations cannot be overemphasized. As this pilot study illustrates, a method that is valid in a nondisabled population but not pilot tested with a disabled population could reinforce inaccurate and limiting stereotypes about the true abilities of people with disabilities.

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