First-ever diabetes-related tool receives FDA qualification as "Medical Device Development Tool" - June 25, 2020

Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations (INSPIRE) questionnaires provide psychosocial measures for evaluating AID systems

Exciting news is just in from FDA; the agency just qualified an excellent new tool that was created by a powerhouse team, led by Dr. Katharine Barnard-Kelly (Barnard Health) and with support from Helmsley and the Jaeb Center, along with Drs. Korey Hood (Stanford), Lori Laffel (Joslin), Jill Weisberg-Benchell (Northwestern), and Diana Naranjo (Stanford). The tool is a questionnaire called the Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations (INSPIRE) and that has been qualified as a Medical Device Development Tool (MDDT).

The INSPIRE questionnaires are just the sixth *ever* MDDT qualified by the FDA and the first related to diabetes. The FDA's MDDT program is designed to drive medical device innovation by providing FDA-evaluated tools that produce "scientifically-plausible measurements and work as intended within the specified context of use." Also of note, we believe the INSPIRE questionnaires are the third-ever psychosocial measure to be qualified as an MDDT. The nine-page FDA qualification decision summary outlines the intended use for INSPIRE: "The INSPIRE questionnaires may be used as secondary or additional endpoints in a clinical study to evaluate subjects' perceptions of the impact of AID systems on their psychosocial functioning and quality of life."

The INSPIRE questionnaires include relevant factors specific to youth and adults with type 1, as well as parents/caregivers of youth and adults with type 1. The questionnaires were developed and tested "in close partnership" with people with diabetes, and quantitative assessments ensure the measures' internal and external consistency and validity. Examples of questions from INSPIRE include, "What would be some of the tasks that would be involved in using an automated insulin dosing system with type 1 diabetes?," "What are your expectations about what the system might do?," and "What would stop you from wanting to try or use one of these systems or what might get in the way?" It's great to see both researchers and the FDA get ahead of the curve as questions like this have become increasingly important for device manufacturers to think about as AID (automated insulin delivery) not only becomes more common, but also more accessible and as more options and more *different* options become available to people with diabetes.

In its MDDT qualification letter to the researchers, the FDA asserts that "including user perspective information [from INSPIRE questionnaires] may be helpful to understand the benefits and risks of AID systems." It is important to note "this qualification does not constitute clearance or approval of this product as a medical device, and does not affect a previous approval or clearance of a device." Likewise, the use of this MDDT does not change the IDE requirements for a medical device clinical study, nor do the INSPIRE questionnaires change the benefit-risk threshold for regulatory decisions about medical devices. Rather, the FDA argues that the questionnaires should primarily be seen as a "more efficient and predictable means for collecting necessary information to make regulatory assessments." Notably, INSPIRE results can also be included in an AID system's device labeling - this should be terrific inspiration for many systems to use this and we hope to be able to see more standardization on "patient impressions" created by this.

As Dr. Barnard-Kelly reiterated to us, the goal of the INSPIRE questionnaires is to "increase awareness of the hopes, concerns and wishes of those who live with diabetes." We are so excited to see the tool receive MDDT qualification and we look forward to seeing how it is used in future research to share the thoughts and perspectives of people living with diabetes.

--by Hanna Gutow, Katie Mahoney, Albert Cai, and Kelly Close