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PsychDT Working Group: Report Psychosocial Aspects of Artificial Pancreas Systems

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Abstract

Background: Diabetes technology is a cornerstone of diabetes management in the 21st century, with advances in available devices over recent years playing a central role in the way that health care has progressed. Psychosocial interventions have been shown to have a positive impact on glycemic control, reduce psychological distress and reduce costs of health care. Addressing and improving psychosocial outcomes that complement biomedical improvements and looking to the future are crucial to enhance patient acceptance of artificial pancreas (AP) systems.

Methods: To achieve closer collaboration and comparability across different AP research trials, a working group was established.

Results: Existing measures fail to adequately capture the extent to which human and psychological factors play a role in the uptake and efficient use of AP systems. Understanding these factors will ultimately lead to the most benefit for users. Reliable measures of the psychosocial impact of AP systems for users is crucial to ensure that (1) regulatory authorities are able to robustly consider these aspects as part of their approval process, (2) government and private payers are able to factor these aspects into their decisions regarding reimbursement, and (3) persons with diabetes maximize benefits in terms of both glycemic control and quality of life to minimize the burden of diabetes in everyday life.

Conclusions: This working group will serve as a platform to foster exchange, identify research needs, and guide and initiate collaborative research laying the groundwork for optimal utilization of diabetes technology in clinical diabetes care. A close collaboration among all key stakeholders is crucial to ensure that devices are designed, trialed, approved, and provided with minimal user burden and maximum beneficial effect.

Keywords
artificial pancreas, psychosocial, quality of life, diabetes technologies, human factors

Diabetes technology is a cornerstone of diabetes management in the 21st century, with advances in available devices over recent years playing a central role in the way that health care has progressed. Uptake of some technologies in daily practice however has remained poor with continuous glucose monitoring (CGM) systems a key example; that is, the expectations of higher uptake when this technology was introduced have not come to fruition. Major reasons beside costs are psychosocial characteristics and barriers. Psychosocial interventions have been shown to have a positive impact on glycemic control, reduce psychological distress and reduce costs of health care.[1] Addressing and improving psychosocial outcomes complements biomedical improvements, and looking to the future, are crucial to enhance patient acceptance of artificial pancreas (AP) systems.

Recently a regulatory approvals body, the German Institute for Quality and Efficiency in Healthcare (IQWiG), strongly criticized the heterogeneity of patient-reported outcome (PRO) measures used in clinical trials with CGM systems, saying they made comparisons across clinical trials almost impossible.[2] Traditionally, clinical trials are always powered to achieve a certain medical outcome (usually

improvement in metabolic control) rather than PRO outcomes. This often results result in blunt, inappropriate or inadequate PRO assessment with insufficient or poor quality data on PROs. As such IQWiG disregarded all information based on PROs for their benefit assessment, thus rendering all efforts to evaluate PROs in such trials useless when it comes to important aspects of regulatory approval such as reimbursement decisions. Thus it is clear that improved assessment strategies and/or better PRO tools are required to enable government and private payers to fully consider the psychosocial aspects and avoid a repeat of this with any new technology developments like AP systems.

Choosing which PROs to assess can be a challenge, requiring consideration of both the technology itself and the complexity of the treatment regimen. It is important to consider the complexity of the demands of both T1D and its management/treatment on people's experiences and ability to self-manage adequately, especially with respect to use of diabetes technologies. Physical, emotional and psychosocial challenges will all contribute to the success of any future AP system and must be adequately addressed. Workshop discussions highlighted the fact that treatment innovations demand increasing, substantial and focused efforts for people with diabetes and the diabetes team. It should be remembered that the user, their family, friends and working environment are all of relevance when assessing effective use. Attempts to optimize glycemic control often come at the cost of increased diabetes burden, poorer quality of life and impaired psychosocial functioning and this balance must be addressed when assessing AP technology.

February 2015 First Workshop on Psychosocial Aspects of Diabetes Technology With a Focus on Artificial Pancreas Systems

To achieve closer collaboration and comparability across different AP research trials, a working group was established. The first meeting with presentations and an intensive discussion took place at the Advanced Technologies & Advanced Treatment for Diabetes (ATTD) conference in Paris (February 2015). In attendance were over 300 attendees from a range of stakeholders, including clinicians, patients, researchers, industry, and diabetes-focused nonprofit foundations. During the discussion a variety of topics related to psychosocial aspects of AP and, more broadly, the development and utilization of diabetes technology. The key themes from this discussion are listed below.

Theme 1: Lessons Learned From CGM

Some participants pointed to lessons from the past, particularly from CGM (see above). Although enthusiasm for CGM at the time of its clinical introduction was high, its usage today remains fairly limited. Workshop attendees agreed that CGM can provide meaningful benefits for patients when used effectively, but some users do not always perceive the cost-benefit balance (broader than financial cost) in the same way that researchers and clinicians do. The negative short-term psychosocial demands of CGM, such as discomfort during sensor insertion and frequent alarms/alerts, can win out over the longer-term benefits of improved glycemic control. It is not the technology per se, but rather the way technology is used, that improves outcomes. Rather than faulting patients for suboptimal adherence, participants suggested that the onus is on the developers of new technologies to create products that patients will want to use (like with other electronic products). A key challenge and occasional source of frustration for providers is that users are sometimes wary of trying new technology based on preconceptions, unrealistic expectations and/or past experiences that were not positive ones.

Psychological measurement instruments can assist in assessments of diabetes technologies with research showing self-efficacy as a key indicator of adherence, motivation, health behavior change and glycemic outcomes.[3] Subjective clinical experience is mixed; however, with Dr Weinzimer reminding us that self-efficacy may not necessarily be predictive of medical or psychosocial outcomes (ie, people are able and confident to act but may choose not to do so). This was reiterated by Dr Pinsker who noted that many of his patients don't use their CGM often, not because of cost or lack of interest in glycemic control, but because they don't

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see the benefits as outweighing the costs (both financial and personal, presumably). Thus a broader assessment of psychosocial impact of future AP systems may be required.

Theme 2: A Stepwise Path to the AP

An emerging theme during the discussion was that small steps toward AP systems rather than a (quantum) leap to full automation may be the most user-friendly path toward AP systems. While there are already fully automated single or dual hormonal closed loop systems nearing pivotal clinical trials, a stepwise approach could potentially help build trust in the technology by the PWD (persons with diabetes), family members of PWD and the health care community as well. It may be that the term "artificial pancreas" does not represent a single technology but rather a series of systems on the path toward full automation. Enabling users to turn on features selectively to provide for a more gradual initiation process may be helpful.

In addition to building confidence in the technology, having a variety of closed loop systems at varying levels of automation could also help address a wider range of needs for PWD. A younger, more technology-savvy user for example may prefer a different level of automation than an elderly patient with less technology experience. In addition, users' occupation, lifestyle, and level of comfort with giving control to an AP system may also influence the type of device that may best suit them and their individual and current situation.

Preliminary psychosocial assessments of the impact of bionic pancreas and other AP systems have shown mixed results. Teen summer camps have provided an opportunity for interviews with youth using bionic pancreas devices with feedback showing that users like to wake up with "good" control, not having to miss out on activities to treat low blood sugars, not having to think about what or how much to eat so much, and having to spend less time overall thinking about diabetes. The negatives however were frustration with the alarms and the size of the device/discomfort when sleeping. There were too many devices to manage and struggles with calibration. Similar positive and negative opinions were reported in the AP@home trials for children and families in the United Kingdom.[4]

Similarly for adults in the Bionic Pancreas trials, reduced worry about hypoglycemia (particularly whilst sleeping), about high blood sugars and whether the insulin was working were all reported positive aspects of the bionic pancreas. Adult users trusted the AP system; they felt freer with food choices; were able to relax knowing that unwanted changes to blood sugar levels would be addressed automatically and felt they could do more things and that it was easier to do the things they liked. Negatives included having to change the glucagon solution every day, carrying around all the equipment and the discomfort of doing so. Again, these results mirror those reported in AP@home trials. It appears as if the potential benefits do not yet fully outweigh the downsides. These downsides might prevent uptake and continued use and need realistic assessment, especially related to PRO and psychosocial impacts.

Theme 3: Managing Expectations

Despite enormous enthusiasm for the AP in the scientific and medical communities, many attendees underscored the importance of setting realistic expectations for PWD about what the technology can and cannot do. Systems that exist today with features such as predictive low glucose suspension of insulin delivery can only be depended on to reduce hypoglycemia frequency. Even the fully automated AP systems that are in development today require carefully managed expectations. As one attendee put it, PWD using an AP system may not have to be "on duty," but he or she will still need to be "on call" in the event of a malfunction or scenario that exceeds the system's capabilities. Appropriate framing of the technology and its potential will only grow more important as AP systems draw closer to regulatory approval.

Theme 4: The Need for Better Ways to Assess Psychosocial Factors

The discussion touched on the primary goal of the PsychDT working group, which is the development of novel validated tools to assess the psychosocial aspects of diabetes technologies. There was a call for a multicultural approach with new measures ultimately needing to be socially and culturally relevant across a range of settings. The concept of diabetes self-efficacy emerged as one possible tool for assessing the user (and family in the case of pediatric patients) experience with diabetes technology. Assessments that capture perceived burden and diabetes-specific emotional distress were also discussed. Better tools for studying psychosocial aspects of diabetes technology were cited as vital for communicating the value of such technology to payers, regulatory bodies, and other key health care system stakeholders.

Theme 5: Optimism for the Future

Despite the early stage in the development of novel psychosocial assessment, the tone of the workshop was, above all, optimistic. Less than a decade ago, the entire concept of the AP was limited to in silico study and short-term studies under highly controlled experimental conditions. The relatively new focus on human factors is a marker of the technology's rapid maturation over the past few years. Although a lot of the engineering work for the AP has already been accomplished, little is understood regarding the psychosocial aspects of the technology. Therefore much research lies ahead.

Identified Needs

Existing measures fail to adequately capture the extent to which human and psychological factors play a role in the uptake and efficient use of AP systems. Understanding these factors will ultimately lead to the most benefit for users. Reliable measures of the psychosocial impact of AP systems for users is crucial to ensure that (1) regulatory authorities are able to robustly consider these aspects as part of their approval process, (2) government and private payers are able to factor these aspects into their decisions regarding reimbursement, and (3) PWD maximize benefits in terms of both glycemic control and quality of life to minimize the burden of diabetes in everyday life.

The new measures being developed, in consultation with the PsychDT working group are intended to help research teams understand the factors important to users of AP systems. These include living with the devices and their impact on quality of life and psychosocial functioning to facilitate flexibility and minimize burden.

Outlook

The aim of the workshop was to establish a working group of interested researchers, clinicians, and other stakeholders to facilitate collaboration and understanding of the psychosocial aspects of diabetes technologies. This working group will serve as a platform to foster exchange, identify research needs, and guide and initiate collaborative research laying the groundwork for optimal utilization of diabetes technology in clinical diabetes care. Over 120 stakeholders have already signed up to join the working group. A close collaboration among all key stakeholders is crucial to ensure that devices are designed, trialed, approved, and provided with minimal user burden and maximum beneficial effect.

The next meeting of the PsychDT working group will be held on the first day of the American Diabetes Association's 75th Scientific Sessions (Friday, June 5, 2015, Boston, MA) from 9:30 to 11:30 AM.

Abbreviations

ADA, American Diabetes Association; AP, artificial pancreas; ATTD, Advanced Technologies & Treatment of Diabetes Conference; CGM, continuous glucose monitoring; IQWiG, German Institute for Quality and Efficiency in Healthcare; PRO, patient-reported outcome; PsychDT, Psychosocial Aspects of Diabetes Technology; PWD, persons with diabetes; T1D, type 1 diabetes

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