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SYMPOSIUM

Closed-Loop Glucose Control: Psychological and Behavioral Considerations

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Abstract

Since 2000, the diabetes community has witnessed tremendous technological advances that have revolutionized diabetes management. Currently, closed-loop glucose control (CLC) systems, which link continuous subcutaneous insulin infusion and continuous glucose monitoring, are the newest, cutting edge technology aimed at reducing glycemic variability and improving daily management of diabetes. Although advances in knowledge and technology in the treatment of diabetes have improved exponentially, adherence to diabetes regimens remains complex and often difficult to predict. Human factors, such as patient perceptions and behavioral self-regulation, are central to adherence to prescribed regimens, as well as to adoption and utilization of diabetes technology, and they will continue to be crucial as diabetes management evolves. Thus, the aims of this article are three-fold: (1) to review psychological and behavioral factors that have influenced adoption and utilization of past technologies, (2) to examine three theoretical frameworks that may help in conceptualizing relevant patient factors in diabetes management, and (3) to propose patient-selection factors that will likely affect future CLC systems.

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Introduction

Since 2000, technological advances in continuous subcutaneous insulin infusion (CSII) and continuous glucose monitoring (CGM) devices have produced a dramatic paradigm shift for future diabetes management. Development of closed-loop glucose control (CLC) systems, or the artificial pancreas, is now considered a feasible goal. Currently, development of CLC systems is the focus of several research projects around the globe, and several prototypes have undergone successful initial testing.[1-3] As diabetes management moves toward the development and integration of these new technologies, it is important to begin to consider the psychological and behavioral factors likely to play a significant role in the use of CLC systems. With the advent of technological advances, it is often easy to underestimate the central role human factors will continue to play in diabetes management.

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Abbreviations: (AADE) American Association of Diabetes Educators, (BG) blood glucose, (CGM) continuous glucose monitoring, (CLC) closed-loop control, (CSII) continuous subcutaneous insulin infusion, (DIT) diffusion of technology theory, (HbA1c) hemoglobin A1c, (HBM) Health Belief Model, (JDRF) Juvenile Diabetes Research Foundation, (MDI) multiple daily injections, (SAP) sensor-augmented pump, (STAR) Sensor-Augmented Pump Therapy for A1c Reduction, (T1DM) type 1 diabetes mellitus, T2DM) type 2 diabetes mellitus, (TPB) theory of planned behavior

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The purpose of this article is to review and explore some of the psychological and behavioral factors that are likely to significantly influence patient adoption and utilization of future CLC systems.

Most research into CLC systems has been aimed at system development and refinement and demonstration of safety and efficacy. Only a few studies have considered patient reactions, or expected reactions, to the use of these emerging systems. However, there is existing research on patient adoption and use of CSII and CGM, two essential components of any CLC system, which may provide insight into human factors likely to be important for upcoming diabetes technology. There is also a small but growing literature on patient use of the newly-developed sensor-augmented pump (SAP) therapy, the first step toward integrated use of CSII and CGM, which may also provide useful information. The review of studies of these existing technologies will focus on findings that have relevance to patient selection and training for CLC use, predicting barriers likely to interfere with optimal use and therapeutic benefits from this technology, and developing the type of patient support systems needed for long-term success. In addition, this article will review several theoretical frameworks for exploring those psychological and behavioral processes that are likely to influence patient adoption and use of CLC systems. These include the Health Belief Model, theory of planned behavior, and diffusion of innovation theory, each of which can serve as a useful guide to identifying and understanding human and social factors important to diabetes technology dissemination and utilization.

Before this scientific and theoretical review, however, we begin by looking at two recent surveys of patient attitudes about CLC systems.

Patient Interest in and Acceptance of CLC Systems

Two studies investigating interest in and acceptance of CLC have yielded encouraging findings, demonstrating a very high level of enthusiasm on the part of patients and family members. In the first study,[4] parents of children with type 1 diabetes mellitus (T1DM) using CSII were surveyed concerning their attitudes toward overnight CLC systems. The overwhelming majority believed that they could use these systems with confidence, with most parents reporting that they would trust the system to deliver the correct insulin dose and would not be worried about their child's overnight insulin being controlled by a computer. However, only 19 parents participated in this survey and none of the families had used CGM before. The second study[5] surveyed 132 adults with T1DM who used CSII on their attitudes toward the artificial pancreas. Patients completed a questionnaire based on the Technology Acceptance Model that defines acceptance as the individual's perceptions of a new technology in terms of usefulness and ease of use as well as trust. The majority (75%) reported that they intended to use the artificial pancreas and gave high ratings to the artificial pancreas on perceived usefulness, ease of use, and trust (administering correct insulin dose/accurately measuring glucose). However, these patients also had limited exposure to the actual components of an artificial pancreas. Patients based their ratings on a detailed written description of the system rather than the presentation of a prototype, and only ~33% had any experience with CGM, and that was with short-term use.

These studies point out that a key factor when predicting patient adoption of CLC technology may be the extent to which patients' expectations about the device will match their actual experience when using it. These surveys show that patients and family members have very high expectations regarding the positive impact of CLC on diabetes control (usefulness), the low level of effort needed on their part (ease of use), and the accuracy of the system (trust). While this can be viewed as positive, expectations that are unrealistically high are likely to be problematic and contribute to discontinued or reduced use of these systems. Evidence for this type of effect was reported during the Juvenile Diabetes Research Foundation (JDRF) randomized CGM trial.[6] Youth who used CGM less than 6 days per week, which resulted in less improvement in diabetes control, reported that using the device was more difficult than as expected. It may be important to assess patient expectations early in the process of exposure to CLC or other technological innovation in diabetes management in order to identify individuals who have unrealistic expectations and intervene to improve the match between patient expectations and actual experience.

Patient Adoption and Use of CSII Therapy

To put patient adoption and use of CSII into perspective, it is helpful to begin with some statistics. Since 2000, estimates of worldwide CSII use in T1DM patients range from 300,000 to 700,000, with the majority of users living in the United States.[7,8] Approximately 37,000 patients in the United States with type 2 diabetes mellitus (T2DM) also use insulin pump therapy.[7] Given that approximately 3 million people and more than 20 million people in the

United States have T1DM and T2DM, respectively, one obvious challenge to the widespread dissemination of CLC will be in increasing the willingness of patients to use insulin pumps. From the patient's perspective, CSII may have both benefits and barriers. Potential clinical advantages can include tighter glycemic control, more precise insulin dosing, increased therapeutic flexibility,[9] better management of the dawn phenomenon,[10,11] and reductions of exercise-related[12] and other hypoglycemic episodes. In spite of the many possible clinical benefits, studies and meta-analyses[13–15] comparing glycemic control in patients using multiple daily injections (MDI) versus CSII have produced equivocal results. Thus, there is no guarantee that an individual patient will achieve improved diabetes control with CSII. However, these inconsistent results may occur because some patient populations are more likely to experience improvements in glucose parameters than others. For example, a meta-analysis[16] found that improvements in metabolic control with CSII were more likely in patients with the highest hemoglobin A1c (HbA1c) levels when using MDI and the greatest reductions in severe hypoglycemia occurred in those with the most frequent severe hypoglycemia on MDI.

There are also potential psychological and behavioral barriers to insulin pump use. Across studies,[15,17,18] estimates of rates of CSII discontinuation in children and adults range from 0–64%. From a behavioral perspective, CSII is in some ways the most demanding insulin regimen, requiring constant engagement on the part of patients and/or family members. However, research has not found this demand to be a major factor when CSII is discontinued. Some patients report discontinuing because of failure to achieve improved glycemic control with CSII, but the majority cite skin discomfort, irritation, or infection at the infusion site as the primary reason.[19, 20] This finding points out the critical role played by characteristics of the technology itself, which can reduce likelihood of adoption.

A psychological issue of special importance for adolescents is body image concern, assumed to be the reason females aged 10 years and older are repeatedly found to be at high risk for discontinuing CSII.[17,18] Long-term pump use may also be associated with the undesired side-effect of weight gain.[15,21] Older pump users can face other age–related psychosocial and behavioral barriers, including cognitive and visual impairment, impaired dexterity, lack of caregiver assistance, and anxiety about technology.[22] Feelings of vulnerability and fear of device failure may also preclude optimal pump use and lead to eventual discontinuation.[23]

Because of the wide range of potential clinical outcomes and possible barriers to long-term use, appropriate patient selection for CSII is critical. Although there are standards for patient selection, albeit difficult to define objectively, and there are no standardized clinical, psychological or behavioral guidelines for the process of patient selection. The American Diabetes Association's standards[24] state that candidates should demonstrate (1) strong motivation for improved glucose control, (2) willingness to work with their health care provider in assuming substantial responsibility for diabetes management, (3) an ability to understand and demonstrate the use of CSII, and (4) adherence to self-monitoring of blood glucose (BG) and the ability to translate BG data into pump use. The American Association of Diabetes Educators[25] (AADE) further recommend that a number of psychological and behavioral factors be considered in the assessment of patients for pump therapy, including effective coping patterns, adequate social support, and ability to solve diabetes management issues. Unfortunately, systematic implementation of these recommendations is greatly limited by the lack of consensus and concrete criteria for measuring these characteristics.

Surprisingly little research has tested patient characteristics that are associated with long-term maintenance of CSII therapy and positive clinical outcomes. One easily identified behavioral variable, found to be highly predictive of CSII success, is a history of vigilant BG self-monitoring, which likely serves as a proxy measure of behavioral engagement in diabetes management.[26,27] Other patient characteristics have been recommended as important to patient success, including maturity, acceptance of diabetes, realistic expectations about pump therapy,[27,28] and adequate knowledge about numerous aspects of diabetes management.[22,29] Good candidates for CSII have also been described as those who have the ability to problem-solve, troubleshoot, engage in sophisticated self-care behaviors, and master the technology.[27,29] However, most of these recommendations are based on clinical experience, not empirical evidence. In fact, there is evidence that the relationship between these positive patient characteristics and likelihood of success using intensive therapies may be more complex. A study[30] investigated the impact of self-management competence in pediatric patients and their families on their response to intensified insulin therapy with MDI or CSII. Contrary to predictions, families with the lowest levels of self-management competence benefited just as much from intensified treatment, in terms of HbA1c improvements, as those with moderate and high levels. These results challenge some of the most common assumptions about patient-selection factors for more complex regimens, and suggest that it may be beneficial to implement such treatments in individuals and families who struggle with diabetes management and control.

Continuous subcutaneous insulin infusion use requires comprehensive training for the patient and members of the family/support system involved in diabetes care, and this will also certainly be the case for CLC systems. There are existing programs that serve as models, such as the one at Children's National Medical Center in Washington D.C., that require pediatric candidates and their families to follow a complex CSII regimen with intensive record keeping for 3–6 months in preparation for pump initiation.[31] The diabetes clinic at the Royal Children's Hospital in Melbourne, Australia, employs regular progress review and practical integrative workshops to help maintain optimal management behaviors in their pediatric pump program.[27] The AADE has recommended education and training that includes comprehensive instruction in numerous aspects of diabetes management. Despite these models and recommendations, there are no standardized requirements for CSII training or methods for measuring patient competence to begin pump use. More research will be needed to establish the requirements of training and support programs for patients using CLC.

Continuous Glucose Monitoring

Because CGM technology has only recently been made available to the larger public, there is limited data on its adoption and use in diabetes management. Use of CGM has rapidly expanded, increasing from 7,000 users in 2006 to 15,000 users in 2007.[32,33] Reports from 2007 projected more than 140,000 users in 2009, but user data for 2011 is unclear.[33] Unlike CSII, reimbursement for the cost of CGM devices and supplies varies greatly across insurance providers, so finances can also pose a significant barrier for many patients who might otherwise want to use this technology.

It has been demonstrated that real-time CGM has the ability to improve metabolic control, including lowering HbA1c without increasing the time spent in hypoglycemia, for some individuals with T1DM.[34–37] A recent meta-analysis[38] of six randomized, controlled trials of two or more months' duration yielded positive results, with significant reductions in HbA1c with CGM use, especially in those patients with the highest baseline HbA1c levels, as well as those who used the device more. This same study also found some evidence, although weaker, for a reduction in time spent in hypoglycemia. Despite the expected advantages of CGM, more research is needed to determine which patients will reap the most benefits from this technology. In addition, few studies to date have examined the psychological impact of CGM use, including issues related to quality of life and reductions in fear of hypoglycemia. Early results[39] indicate that CGM use has neither adverse nor beneficial effects on psychological functioning in youth, but clearly more research is needed. Actual data on level of interest in CGM in the T1DM community is scarce. In one survey[40], 90% of parents endorsed a high level of interest in having their children with T1DM use CGM but only if the cost was covered by insurance. Without insurance coverage, only 50% of parents believed they would use CGM.

It is important for potential users and their families to have realistic expectations about CGM, such as understanding that this technology is not a cure for diabetes, nor is it the artificial pancreas.[41,42] Additionally, users should understand that with novelty comes imperfection, including discrepancies between interstitial glucose and BG meter readings, frequent false alarms, and a potentially overwhelming amount of glucose data.[41,42] A common unrealistic expectation is that CGM will prevent all episodes of hypoglycemia and hyperglycemia, which, unfortunately, is not accurate. Ideally, a structured assessment of patient knowledge of intensive diabetes self-management, as well as patient expectations, would be conducted prior to CGM initiation, to identify those individuals who can most successfully use this technology, as well as those who might need more preparation. As research into patient acceptance and long-term use of CGM continues, it can serve as an essential guide for the development of patient selection, training, and support needed for CLC systems.

Research is just beginning to investigate potential psychological and behavioral barriers to CGM use, and initial findings indicate that patients will need to have the motivation, willingness, and ability to use CGM extremely consistently in terms of the number of hours/days per week that the device is worn. As noted above, a meta-analysis[38] of CGM studies indicates that improvements in glycemic control most likely occur in patients who use the device more consistently. In the JDRF CGM trial[43], which was included in that study, use of CGM was more consistent among adults age 25 years or older than in the younger age groups, with 83% of adults averaging at least 6 days of usage per week. Adults 25 years and older also demonstrated a significant reduction in HbA1c levels compared to the younger age groups. Those aged 15–24 years showed the least HbA1c improvement, and only 30% of these participants used the device at least six days per week. The fact that CGM may be beneficial in improving metabolic control only for those individuals who will use the technology almost all of the time has important implications for patient selection and education. One factor has been identified that appears to predict greater CGM use, which is pre-CGM frequency of BG monitoring.[34] Because this behavioral variable also predicts success with CSII, it should be considered as an important patient selection characteristic for CLC trials.

Psychological factors, such as coping skills and perceived support, have also been identified as predictors of CGM success.[44] A recent study comparing adult responders to CGM (improved HbA1c) to non-responders (no improvement) demonstrated the importance of type of coping strategy and perceived social support in reaping glycemic benefits from the device. Although participants in both groups experienced frustrations related to CGM use, responders tended to engage in self-controlled coping strategies (i.e., taking a neutral problem-solving approach), and they reported receiving more support from their significant others. Given the hassle factor that comes with CGM use, which can include frequent false alarms, physical discomfort of the sensor, sensor calibration failures, and discrepancies between CGM interstitial glucose and BG meter readings,[45] patients' ability to cope with these stressors, as well as their willingness to use CGM consistently and make changes in diabetes management behaviors, appear to be predictors of individuals who will fare best with this technology.[46]

The abundance of glucose data that CGM provides may also render feelings of anxiety.[41] It is critical that patients know how to interpret and apply the data that they receive from the system, but there are no published guidelines for outpatient use at this time.[47] In response to this problem, the DirectNet Study Group developed the DirecNet Applied Treatment Algorithm, which utilizes algorithms to help patients make diabetes management decisions (i.e., insulin dosing) based on real-time glucose values and downloaded sensor data.[47] Promising results of a pilot pediatric study found that, after 13 weeks, all participants and their parents believed the algorithms provided clear instructions and improved postprandial BG excursions.

Not surprisingly, adoption and utilization of CGM requires ample patient education not only on the specific features and functions of the device, but also on how to utilize glucose feedback to improve diabetes self-management.[48] Graded, gradual, systematic training is recommended, similar to the education protocols currently in place for initiating CSII.[49] An education and training model has been proposed for health care professionals to enhance their efficiency with CGM technology and better train patients in its use.[48] Such comprehensive education and close follow-up are likely to be necessary for many patients to achieve optimal glycemic control from CGM.[49,50]

Sensor-Augmented Insulin Pump Therapy

Sensor-augmented pump therapy, which integrates CSII and CGM, is considered the first step toward development of a CLC system. An increasing number of studies, including two prominent randomized controlled trials (Sensor-Augmented Pump Therapy for A1c Reduction [STAR] 3; Sensing with Insulin Pump Therapy to Control HbA1c), are evaluating clinical efficacy.[51–54] In both adults and children, SAP therapy has been shown to have beneficial effects on metabolic control[51,55,56] and decreased hypoglycemia,[51,56] though results are inconsistent regarding whether these improvements are significantly greater than when CGM is paired with MDI.[57-59] Similar to findings in CGM trials, consistent SAP therapy use (at least 60% of the time) appears to be necessary for improvements in HbA1c,[34,59] again highlighting the importance of patient motivation and behavior. In terms of patient training and support for use of SAP, the STAR 3 study group has proposed a model utilizing a stepwise, systematic protocol to introduce CSII and CGM sequentially, along with web-based diabetes management modules and therapy-management software for patient support.[60]

Theoretical Frameworks

Successful implementation of CLC systems will depend on a number of complex processes that determine patient willingness to adopt, utilize, and continue using this type of technology. As one author has noted,[61] even the efficacy of technological devices themselves often depends on patient adherence, and this certainly appears to be the case with CGM. Past studies have revealed a few of the important psychological and behavioral variables that may influence adequate utilization of CSII and CGM. However, clearly much more effort is needed in order to prepare for patient transition to CLC systems. To advance research in this area, we need to begin to consider theoretical frameworks that can explain the critical processes involved in patient adoption, utilization, and continued use of technology in diabetes self-management. There are a number of health care-related theories that can serve as guides in understanding these processes and identifying those psychological and behavioral variables most likely to be relevant to CLC technology. Here we will focus on three of these theories: Health Belief Model (HBM), theory of planned behavior (TPB), and diffusion of innovation theory (DIT). There is strong empirical evidence that each of these theories predicts health and diabetes management behaviors.[62–64] However, it should also be noted that there are other theories of health care behavior, not included in this review, which may also provide valuable insight and deserve consideration.[65]

The HBM is the oldest of the theories discussed here, and it emphasizes the role of patient perceptions, attitudes, and beliefs in health care decision-making and behaviors.[62,66] Critical patient constructs include perceptions of personal vulnerability and seriousness of a health problem, perceived cost versus benefit ratios, perceived locus of internal or external personal control, and self-efficacy. Other important constructs in the HBM include coping styles, environmental cues to action, and perceived barriers to goal achievement. Diabetes-specific constructs such as fear of hypoglycemia and hyperglycemia, as well as tendency to have negative emotional reactions to glucose readings, will also likely influence use of diabetes technology.[67,68] Numerous studies support the relationship between the HBM and a wide range of diabetes self-care behaviors in both adolescents and adults, including foot care[69] and adherence to insulin, diet, and exercise.[70–73]

The TPB is another behavior change model that predicts diabetes management behaviors, including a healthy diet and engaging in physical activity.[63,74] In TPB, the process of behavior change is a product of patient attitudes, subjective norms, and perceived behavioral control, which determine intention to engage in a new behavior. Patient attitudes relevant to successful adoption and use of CLC systems might include patient perceptions and beliefs about the positive versus negative effects of using the system, perceived social pressure and network support for use, perceived control over the behaviors involved in use of the technology, and personal confidence in the ability to use it effectively. The TPB places a unique emphasis on the importance of existing social support systems to facilitate not only changes in behavior, but also maintenance of new behaviors. These systems include family members and friends, but also education, training, and other support programs to optimize patient success.

Finally, the DIT provides a model of how innovations (i.e., new ideas, products, or practices) are adopted by groups, and what factors inhibit or facilitate the speed at which innovations are accepted and implemented.[64,75] Diffusion is conceptualized as a five-step process moving from an individual's or group's knowledge (first information and exposure to the innovation) → persuasion (formation of favorable or unfavorable attitudes) → decision (to adopt or reject) → implementation (procurement, training and use) → confirmation (evaluation of reinforcement). This process is not necessarily sequential and linear, but rather contains feedback loops; for example, evaluation can trigger a new decision to continue or discontinue innovation use. As with the HBM and TPB, this theoretical perspective recognizes that more than just objective evidence and benefits are necessary for rapid diffusion of innovations. In all of these theoretical models, adoption, successful implementation, and maintenance of new health care behaviors are highly dependent on the subjective perceptions of the potential user. For this reason, it is critical to keep in mind that achieving widespread adoption and utilization of CLC systems will require more than studies showing evidence for its objective benefits on glucose control.

Summary

Research into patient use of CSII and CGM has focused primarily on the objective clinical benefits of these technologies, with much less emphasis on systematically studying and understanding patients' subjective reactions to these technologies. This empirical approach ignores the evidence that patient decisions about adopting and using new technologies are rarely based solely on objective benefits, and, therefore, has led to a limited understanding of important psychological and behavioral factors. For example, the CSII literature has relatively little to offer on questions of patient selection and those patient characteristics that are positive (or negative) prognostic indicators for pump therapy. However, there are encouraging signs that future investigations into diabetes technology will be more inclusive of psychological and behavioral processes, with recent CGM studies addressing the impact of constructs such as patient satisfaction[6] and coping styles.[44] More studies such as these are critical for a more comprehensive understanding of the human factors likely to play a pivotal role in the successful adoption and use of CLC systems, and to begin to build an empirical foundation for the development of patient selection, training, and support tools.

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