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Psychosocial aspects of diabetes technology

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Abstract

Aim To identify key psychosocial research in the domain of diabetes technology.

Results Four trajectories of psychosocial diabetes technology research are identified that characterize research over the past 25 years. Key evidence is reviewed on psychosocial outcomes of technology use as well as psychosocial barriers and facilitating conditions of diabetes technology uptake. Psychosocial interventions that address modifiable barriers and psychosocial factors have proven to be effective in improving glycaemic and self-reported outcomes in diabetes technology users.

Conclusions Psychosocial diabetes technology research is essential for designing interventions and education programmes targeting the person with diabetes to facilitate optimized outcomes associated with technology uptake. Psychosocial aspects of diabetes technology use and related research will be even more important in the future given the advent of systems for automated insulin delivery and the increasingly widespread digitalization of diabetes care.

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Introduction

Diabetes technology is a term that incorporates a range of technologies, including devices, online resources, mobile apps and telemedicine. For the purposes of this article, we focus on devices. Diabetes technology has experienced an ever-increasing role in diabetes care over the past years, offering novel opportunities to facilitate diabetes self-management and insulin therapy [1]. This development is linked to and driven by the rapid advances in technology over the past 25 years. From the perspective of care, three milestones stand out in terms of their impact on diabetes care: the broader use of continuous subcutaneous insulin infusion (CSII) systems beginning in the 1990s; systems for continuous glucose monitoring by the person with diabetes (real-time continuous glucose monitoring, CGM) in 2006; and the recent advent of systems for automated insulin delivery as key technologies.

In recent years, reimbursement bodies around the globe have frequently assessed the value of pump therapy and other diabetes technologies, including CGM and sensor-augmented pump therapy. These assessments, known as Health

Technology Assessments (HTAs), incorporate quality of life and psychosocial assessment and impact access to pump therapy and reimbursement. Psychosocial factors, including the attitudes and beliefs of the person with diabetes that may impact diabetes self-management are a key factor when it comes to diabetes technology uptake and successful use. In this review, key psychosocial research in the domains of CSII, CGM and automated insulin delivery use are summarized, highlighting challenges and implications for diabetes care and future research.

What we knew in 1995

Twenty-five years ago, we had recently seen publication of the landmark DCCT trial [2]. Within this was included a secondary outcome of quality of life, systematically assessed using the Diabetes Quality of Life self-report questionnaire. Despite this inclusion, it would take another 20 years before robust psychosocial outcomes were routinely included alongside safety and biomedical outcomes in clinical trials.

Advances in diabetes technology shape not only diabetes care, but also research questions and themes in the psychosocial domain. The 1990s saw the advent of increasingly sophisticated CSII devices with the capability for multiple and flexibly adaptable basal rates and insulin dosage adjustments, emerging as a tool with novel options for effective diabetes self-management. CGM has provided both

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What's new?

- Although advances in diabetes technologies have developed apace over the past 25 years, routine psychosocial assessment has failed to keep up with those advances.
- We highlight four key areas of psychosocial research and explore these different factors to highlight the importance of psychosocial research and its implementation into routine care.
- The clinical implications indicate that addressing modifiable barriers and the individual strengths and resources of people with diabetes is paramount when it comes to devising interventions and counselling approaches to facilitate diabetes technology uptake and to build related self-management skills.

healthcare professionals and the individual with diabetes with novel insights into glucose dynamics and trajectories. Simultaneously, demands in diabetes self-management skills have expanded. Novel research questions and their impact on diabetes care address contemporary issues. These include diabetes self-management becoming increasingly more demanding, the acquisition of novel skills, as well as better glycaemic control while also increasing safety with CGM alarm features. With the introduction of CGM, user-set alarms for hypoglycaemia increased users' feelings of safety, but the rich, detailed and dynamic CGM data also confront individuals with the task of meaningful integration of that CGM information into appropriate treatment decisions.

What has the past 25 years of research told us?

Four major trajectories characterize psychosocial diabetes technology research across the past decades:

1. Recognition of the importance of psychosocial themes in diabetes technology use is increasingly acknowledged as is the need for more research into psychosocial factors that goes beyond self-reported outcomes [3]. This is echoed by the establishment of dedicated platforms for fostering research and exchange such as PsychDT, a working group open to all interested stakeholders, to explore and inform the development of INSPIRE measures, which are self-report brief questionnaires specific to automated insulin delivery systems. These novel measures are a validated, reliable assessment of expectations, hopes, anxieties and behaviours associated with automated insulin delivery systems [4].
2. The focus of research in diabetes technology specifically and its impact on users' everyday lives has broadened considerably. Early on, the main focus of psychosocial

research was on the impact of technology in the psychosocial domain, as reflected by related self-reported outcomes in clinical trials. That research addresses psychosocial predictors of diabetes technology uptake and treatment success to a greater extent, identifying barriers and facilitating conditions in the psychosocial domain [3]. Here, psychosocial research adopts a dedicated human factors perspective on diabetes technology, exploring comprehensively the interactions of psychosocial and behavioural characteristics with technology. Elaborate models of technology acceptance, uptake and sustained use, such as the technology acceptance model, are used to guide predictor-focused research and intervention development.

3. The course of psychosocial diabetes technology research also reflects major developments in the behavioural health sciences. These include, but are not limited to, the development of well-validated psychosocial measures, such as the CGM Satisfaction Scale [5]. Related research guidance [6] addresses the call for domain-specific measures that are designed to pick up specific effects of CGM [7]. Again, models from human factors research and technology acceptance are used increasingly to guide diabetes technology research [8,9].
4. Focusing not only on self-reported outcomes, but also on psychosocial concomitants of diabetes technology uptake and its successful use paves the way for dedicated self-management interventions that explicitly address psychosocial barriers and facilitating conditions.

We explore these factors in this overview, referencing relevant literature including reviews, meta-analyses and recent studies in the field that report on insulin pumps, continuous glucose monitors and automated insulin delivery systems use.

Key evidence

Diabetes technology generally yields favourable results in terms of self-reported outcomes such as reduced diabetes distress, improved treatment satisfaction or reduced depression. This holds true for CSII and CGM, as well as for automated insulin delivery systems, albeit evidence for the latter is still limited.

With regard to CSII, there are several meta-analyses that show generally favourable outcomes in terms of HbA_{1c} and hypoglycaemia, as well as psychosocial outcomes [10,11]. Thabit and Hovorka [12] highlight the beneficial impact of CSII on the quality of life in people with diabetes. Similarly, beneficial effects of CGM have been demonstrated in the domains of quality of life and treatment satisfaction [13,14]. In terms of psychosocial outcomes, two studies offer some in-depth insights. In the JDRF trial, the randomized controlled trial (RCT) was complemented by qualitative research that

enabled the authors to identify psychosocial key themes of CGM such as problem-oriented coping skills and therapy involvement of significant others [15,16]. The PRECISE trial studied the effects of CGM in CGM-naive and CGM-non-naive individuals with type 1 diabetes and found beneficial effects across a range of psychosocial domains, with 80% of study participants reporting feeling better about their diabetes control. Further effects concerned an increase in feelings of safety and confidence in diabetes management associated with the use of technology [17]. Smaller scale studies complement the picture: Vloemans *et al.* [18] investigated the effects of CGM in people with diabetes and impaired hypoglycaemia awareness, and found CGM use enhanced a sense of control and safety for most participants, but not all. Specific benefits included perceived helpfulness in gaining more insight into glucose variability, temporarily improved sense of control, reduced distress and reduced dependency on others. However, some participants experienced confrontation with CGM output as intrusive, whereas others reported frustration due to technical failures and difficulty trusting the device. Active and passive self-management behaviours were reported by participants, mirroring individual differences in attitudes and coping styles.

Automated insulin delivery studies remain low in number and sample sizes; however, Naranjo *et al.* [19] published a detailed report of what end users and stakeholders want from automated insulin delivery systems. Data from 284 participant interviews or focus groups across four sites in the USA and the UK explored expectations, desired features, potential benefits and perceived burdens to such systems. Twelve thematic data clusters revealed burden associated with use, trust and personal control over the system, challenges with the technical aspects of device use and financial aspects as potential barriers to use. Facilitators included expectation of improved quality of life, sleep and nocturnal glycaemic control and reduced burden for family members. Overall, participants were hoping for reduced burden of diabetes management. The data show that multiple psychosocial factors influence initial and persistent use of automated insulin delivery systems. These factors include, but are not limited to, trust and control of the system, night-time benefits of improved sleep and reduced anxiety surrounding hypoglycaemia, reduced mental burden, and relief from perceived intensity of diabetes management. Technological solutions are sought to improve blood glucose stability and reduce the risk of long-term complications, at the same time without increasing management-related burden. Balancing these factors is crucial to effective use over the long term.

In a 2017 review, Farrington [20] identified 13 studies including qualitative and quantitative research in children, adolescents and adults, with only one study having a sample size larger than 100. However, findings to date point towards favourable effects, particular in terms of reduced anxiety and an increase in feelings of security. Research into the expectations, hopes and fears associated with potential automated

insulin delivery use has reflected many of the concerns reported previously with CSII and CGM. Hopes were expressed for reduced burden, greater flexibility and spontaneity as well as improved glycaemic control. However, over-reliance on the device, accuracy, ability to trust and control the device, and visibility of disease state were frequently reported as key themes to be addressed. These similarities reflect the failure of clinical research to date to adequately address the concerns of those who ultimately must live with the technology [19]. There remains uncertainty regarding the management burden of automated insulin delivery systems which will only be more fully understood as more systems are introduced to the market.

The increasing availability of data and data presentation options could be argued to widen the burden of diabetes. Data are now 'shared' literally with family members and others, which for some (e.g. teenagers) is associated with unwanted interference and attention to their diabetes. This reduction to being nothing more than a glycaemic control number and a signal of brokenness or disability, rather than the recognition of the person's self, can have detrimental impacts on self-identity, personality and self-confidence. These psychosocial hurdles are far from understood and may again exclude significant segments of people with diabetes from living the lives they want rather than the lives they are boxed into.

Irrespective of the type of technology, a most intriguing and clinically relevant finding pertains to interindividual variability in diabetes technology uptake. Not all individuals use CSII or CGM consequentially (in terms of time the devices are used) and, therefore, cannot benefit from CSII or CGM to the full extent [16,21]. It remains to be fully clarified as to why some individuals do not engage with diabetes technologies or even discontinue their use altogether. Furthermore, healthcare professionals need to be able to provide education about diabetes technologies; however, not all are capable of giving appropriate technology education or are able to discuss CGM-/pump-/automated insulin delivery system data. Unregulated do-it-yourself automated insulin delivery system devices receive even less support due to the lack of legislation covering this type of treatment. Many users choose not to disclose use of such do-it-yourself systems to their healthcare provider.

It could be argued that continually developing technologies will have incremental benefits for people with diabetes, as latest generation devices and additional features become available. For example, Weiss and colleagues [22] demonstrate further benefit of sensor-augmented pump therapy that connects insulin delivery to sensor information with threshold suspend (as compared with sensor-augmented pump therapy without threshold suspend) in reducing nocturnal hypoglycaemia, in terms of both rate and severity for participants. Weiss *et al.* concluded that use of the threshold suspend feature could help protect against hypoglycaemia in those individuals wishing to intensify diabetes management

to achieve target glucose levels. Automated insulin delivery systems may well proffer additional benefits beyond these in time.

Qualitative research methodology, alongside quantitative assessment, provides key insights, steeped in rich and deep understanding of the personal interaction and acceptance or otherwise of technology uptake. Such research identifies psychosocial factors that are missed in the 'blunt' questionnaire data and signals key candidates that may play a decisive role in technology uptake [23,24].

Psychosocial barriers

A recent large-scale survey in people with type 1 diabetes examined barriers in diabetes technology uptake covering CSII and CGM [24]. Two barriers that were identified stood out. Almost half of the respondents referred to the hassle of wearing the device as a significant barrier, and disliking devices on one's body was mentioned by approximately one-third of the respondents. Constantly wearing a diabetes device on one's body may negatively impact body image in select individuals [3]. Body image concerns seem to substantially impact the user's attitude towards visibly worn diabetes technologies [16,25].

Self-reported stigma associated with diabetes is common, with 76% of people with type 1 diabetes and 52% of people with type 2 diabetes reporting feeling stigmatized [26]. In the same survey, 72% of participants felt that others saw their diabetes as a 'failure of personal responsibility', 65% as a 'burden on the healthcare system' and 52% as 'having a character flaw or fault'. It is perhaps unsurprising that diabetes related distress, burden and psychological morbidity such as depression and anxiety disorders remain prevalent.

CGM leads to vast amounts of glucose data, including information on glucose dynamics, that the user with diabetes is confronted with. This can easily result in feelings of being overwhelmed with the sheer amount of information in the sense of 'information overload' [3], preventing people with diabetes from appropriately using this valuable novel source of information or even discontinuing CGM. Vloemans and colleagues [18] also highlight that some CGM users experience feelings of frustration due to frequent alarms, information overload and technical defects that may dampen their trust in the technology. Borges Jr and Kubiak [9] also showed that fears (such as being dependent on a technical device) or unrealistic expectations (such as being 100% safe when it comes to hypoglycaemia) may hamper diabetes technology uptake.

Facilitating conditions

Less is known about specific factors that facilitate technology uptake. However, it is clear that the attitudes of both healthcare professionals and the person with diabetes play a significant role in access. Potentially inappropriate 'gate-keeping' by healthcare professions, restricting technology

access, may impair optimal technology use, as graphically demonstrated in the REPOSE trial [27]. In this study, staff described how, 'alongside clinical criteria, they had tended to select individuals for insulin pump use in routine clinical practice based on their perceptions about whether they possessed the personal and psychological attributes needed to make optimal use of pump technology'. They also noted, however, how those assumptions about personal and psychological suitability had been challenged by 'observing individuals make effective use of CSII who they would not have recommended for this type of therapy in routine clinical practice'. Such gatekeeping is a hidden barrier in routine clinical care reflecting outdated paternal attitudes to healthcare that are inconsistent with national guidelines for access to diabetes technologies.

Research that was guided by the technology acceptance model suggests that factors such as openness towards technology use or 'tech savviness' (level of engagement with the device) may facilitate technology uptake [8,9]. Similarly, the T1D Exchange Survey identified positive technology attitudes in people with diabetes who initiated CGM [24]. In addition, perceived benefits from device use – particularly if experienced early on after uptake – may have a sustaining positive impact on use and may bolster feelings of control and empowerment in individuals. In a small-scale qualitative study in adolescents with type 1 diabetes and their parents, respondents highlighted these empowering effects of CGM use and an increased sense of safety (related to hypoglycaemia) [28]. These beneficial effects were also observed in the study by Vloemans and colleagues [18], who found similar beneficial effects in people with type 1 diabetes and impaired hypoglycaemia awareness where the increase in feelings of safety was most important. In particular, research that includes the perspective of the partner, family or caregivers points towards the importance of social support as a factor that may facilitate technology uptake [29].

Finally, appropriate skills relevant for successful diabetes technology use, such as skills to appropriately integrate CGM data within one's diabetes self-management on a daily basis or to effectively adjust CSII basal rate, are a prerequisite not only for successful technology uptake [3], but also for favourable outcomes on HbA_{1c}, hypoglycaemia and the psychosocial domain.

It is noteworthy that barriers and facilitating conditions are not disjunct and stable sets of psychosocial factors, but interrelated and prone to change within individuals. For instance, a CGM's alarm features and the constant glucose readings it yields may have both empowering effects and contribute to additional burden, discouragement and distress, depending on the degree to which users are successful in managing their glucose and their sense of control over their diabetes [28].

It is well-known that there is considerable variation in the delivery of diabetes care processes, diabetes structured education, uptake of diabetes technologies and achievement

of diabetes-related targets [30]. This variability extends beyond geographic areas, with inequalities also reflected across age, gender and level of social deprivation. Inequalities in diabetes outcomes were reported in a systematic review by Lindner *et al.* in 2018 [31] who examined the associations of individual-level as well as area-level socio-economic status and area-level deprivation with glycaemic control, hypoglycaemia and diabetic ketoacidosis in people with type 1 diabetes. Twenty studies were included; however, most were of average quality. Results showed contradictory results on associations of socio-economic status and area-level deprivation with glycaemic control and hypoglycaemia. They also showed that lower socio-economic status and higher area-level deprivation were associated with a higher risk of experiencing ketoacidosis. The authors recommended that access to care for socially deprived people needs to be expanded to overcome impairing effects on the course of the condition and to reduce healthcare disparities. Greater efforts are required to consider health inequalities when prescribing diabetes technologies to ensure all people with diabetes have equal opportunities to benefit, both biomedically and psychosocially.

Translation/implementation into clinical practice

Addressing modifiable barriers and the individual strengths and resources of people with diabetes is paramount when it comes to devising interventions and counselling approaches to facilitate diabetes technology uptake and to build related self-management skills [1].

In 2019, Choudhary *et al.* [32] published a type 1 diabetes technology pathway: a consensus statement for the use of technology in type 1 diabetes. This consensus of expert views, in collaboration with NHS England and Diabetes UK, recognized that whereas the National Institute for Health and Care Excellence (NICE) recommended some diabetes technologies, others have not been appraised, and new technologies are emerging all the time. The different guidelines for adults and children further add to the confusion, particularly complicating access to technologies in the transition from paediatric to adult care. The pathway supports the incremental addition of technology as monotherapy and then dual therapy in the same way that therapeutic agents are added to support people with type 2 diabetes to achieve their personalized glycaemic targets. It emphasizes the importance of structured education, specialist support and appropriate access to psychological therapies, as essential pillars for optimized use of diabetes-related technology. The pathway was based on the existing model of the American Diabetes Association/European Association for the Study of Diabetes guidelines for type 2 diabetes that set out a road map for incremental escalation of treatment to try and support people with diabetes to achieve their individualized glycaemic goal.

Given the importance of diabetes education to facilitate diabetes technology uptake and use, respective education programmes targeting the person with diabetes have been recently developed and evaluated: the structured multi-lesson education programme INPUT for individuals with CSII explicitly addresses key psychosocial topics and potential barriers of CSII uptake (e.g. individual motivation for CSII, learning from mistakes, perceived impairments of one's body image if wearing the CSII device). INPUT has been evaluated in a larger-scale multicentre RCT and had favourable outcomes in terms of HbA_{1c}, CSII uptake and diabetes distress, compared with the control condition [33]. Following a similar rationale of self-management education intervention, the structured programme FLASH has been devised for people with diabetes using intermittently scanned CGM systems and has also been found to have favourable effects in terms of glycaemic outcomes and psychosocial variables [34]. Recently, a manufacturer-independent self-management programme for CGM has been introduced that also addresses key psychosocial themes [35].

In addition to structured multi-lesson education programmes, brief materials have been developed that may serve as complementary tools to facilitate technology uptake. For example, Barnard-Kelly and Polonsky [36] showcase leaflet materials to support the engagement with CGM and to optimize outcomes, Ritholz *et al.* [23] report beneficial effects of a CGM 'companion app' that incorporates functions aimed at providing social support.

Current gaps

Little is known about the performance of CGM systems outside the clinical research setting, and the experience and skill of the individual and clinical team are crucial in this regard. Russell-Jones and colleagues [37] state that clinical inertia is a major barrier to implementation of insulin therapy, with introduction of any new modality of therapy requiring time, energy, effort, judgement and initiative on the part of the physician. Coupled with lack of reasonable reimbursement of physician time, ancillary resources required to support CGM, potential medical–legal liability and uncertainties associated with the new intervention, Russell-Jones *et al.* argue that it is unsurprising that there has been clinical inertia for CGM implementation in clinical care. It is concluded that there is a need for considerable education regarding the use of CGM for the physician and the entire 'healthcare provider' community to redress the current situation in which CGM has been left primarily in the hands of the person with diabetes, while several usability issues remain unaddressed. It would be useful if studies could be powered sufficiently to ensure that psychosocial outcomes, such as fear of hypoglycaemia (meaningful difference therein) are more closely linked to biomedical outcomes to

ensure that the impact of psychosocially driven behaviours associated with diabetes self-management are prioritized.

Conclusions

Diabetes technology continues to have an increasing impact on diabetes self-management and care. Consequentially, psychosocial outcomes and concomitants of diabetes technologies are a key area of psychosocial research for the years to come. Although there is solid evidence in favour of CSII, CGM and to a more limited extent, automated insulin delivery in terms of psychosocial outcomes, less is known when it comes to barriers and facilitating conditions of diabetes technology uptake. Research in the latter domain is very much needed as it will expand our knowledge for designing effective interventions to facilitate diabetes technology uptake and success. Future psychosocial diabetes technology research should draw from research and models from the field of human factors and technology acceptance that may serve as a framework guiding research. This may include approaches from technology development such as the use of ‘personas’ (grouping of potential users) to identify subgroups of users with specific characteristics and needs [38]. Exploring relationships between diabetes technology engagement with social determinants of health may also prove useful in expanding its availability and uptake to a broader population of people with diabetes where diabetes technology use is less common.

Almost all psychosocial diabetes technology research investigated children, adolescent or adults with diabetes, leaving a significant gap with regard to use in older adults which may come with specific barriers [39]. Given increasing life expectancy in people with diabetes and an ageing population, diabetes technology use in older adults with diabetes is an important topic to address for the future.

In terms of future psychosocial diabetes technology research, increasing activities are very much needed given the sheer pace of technological advances. In addition to dedicated diabetes technological devices and the advent of automated insulin delivery systems, digitalization in health care, wearables and smart home solutions are likely to further reshape diabetes self-management and to affect the psychosocial impact of technology. Ubiquitous computing and mobile sensing will connect domains data, offering up novel avenues of self-management options, but also posing challenges to the individual with diabetes. For example, smart mobile devices may integrate CGM, activity tracking, sleep tracking and detailed dietary records. Although this will provide rich and dense information from several domains, putting this information to use for diabetes self-management, distinguishing relevant from irrelevant data and covariates, requires skills-building in people with diabetes and dedicated education programmes targeting the person with diabetes.

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Competing interests

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