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Title: Optimising the use of technology to support people with diabetes: research recommendations from Diabetes UK's 2019 diabetes and technology workshop

Short Running Title: Research recommendations for diabetes and technology

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HRM sits on the Medtronic European Scientific Advisory Board and reports personal fees from Novo Nordisk, Roche, Abbott Diabetes Care, Dexcom and Medtronic, outside the submitted work.

RH reports having received speaker honoraria from Eli Lilly and Novo Nordisk, serving on advisory panel for Eli Lilly and Novo Nordisk; receiving personal fees from BBraun, Medtronic and Abbott Diabetes Care; patents related to closed-loop insulin delivery, shareholder and director at CamDiab Ltd.

SRH is a CI of an NIHR programme grant which is using technological and other approaches to develop and evaluate the DAFNE educational programme.

Novelty statement:

- Technology has become increasingly important in how diabetes is treated and cared for.
- Research prioritisation exercises have identified technology as an area of need of further research.
- Diabetes UK convened a workshop that identified areas for future research, and develop specific recommendations for research in five of these.

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Abbreviations

CGM Continuous Glucose Monitoring

DRSGs Diabetes Research Steering Groups
DKA Diabetic Ketoacidosis
NHS National Health Service
PROMs Patient Reported Outcome Measures
QoL Quality of Life
SMBG Self-Monitoring of Blood Glucose
TIR Time in Range

Abstract

Aims

To identify key gaps in the research evidence base that could help improve how technology supports people with diabetes, and provide recommendations to researchers and research funders on how best to address them.

Methods

A research workshop was conducted, bringing together research experts in diabetes, research experts in technology, people living with diabetes and healthcare professionals.

Results

The following key areas within this field were identified, and research recommendations for each were developed:

- Matching the pace of research with that of technology development
- Time in range as a measure
- Health inequalities and high risk groups
- How to train people to use technology most effectively
- Impact of technology usage on mental health

Conclusions

This position statement outlines recommendations through which research could improve how technology is employed to care for and support people living with diabetes, and calls on the research community and funders to address them in future research programmes and strategies.

Keywords:

Technology, diabetes mellitus Type 2, diabetes mellitus Type 1, Blood Glucose Self-Monitoring, Health Status Disparities, mental health

Introduction

The need to optimise the use of, access to and effectiveness of technology to help improve the lives of people with diabetes and make managing the condition easier is a key issue for diabetes care and for people with diabetes [1]. Whilst a significant volume of research focuses on the issues around technology in diabetes, the speed at which new technologies have been emerging and developing can ensure that best practice is based on solid evidence and maximises patient benefit challenging [2].

In 2019 a Diabetes UK position statement on the type 1 diabetes technology pathway was published [3], to clarify best practice on the basis of current evidence. However, major gaps in our understanding of how to maximise benefit from technology through targeting provision at those who will gain most benefit and who they are. Research also always needs to continue to drive innovation in these forms of technology. Evidence of the effectiveness of various forms of technology in type 2 diabetes is even less clear, with mixed results from studies designed to establish how various forms of glucose monitoring technology could best be used and how beneficial each is [4,5,6,7], and a clear need for further research.

Huge potential also exists for innovations in new technologies beyond glucose monitoring to either help people to manage their diabetes or prevent the development of type 2 diabetes and gestational diabetes. There is, for example, potential for interventions to use telehealth to connect healthcare professionals and individuals and increase how many people can be reached and supported in their diabetes management [8], particularly important in a time of increased remote consultation due to COVID-19. Equally, new forms of wearable technology beyond glucose monitoring and insulin infusion devices could help self-management [9]. In addition, the growing capacity to collect and analyse large data sets using technology could also increase our ability to identify trends, improve decision making in healthcare [10, 11], improve clinical trial outcomes, assist with risk stratification and advance our understanding of the progression of the condition. These are all growing areas which will be key to the future use of technology in diabetes prevention, treatment and care, and research is needed to make sure existing and future technologies are used in the most effective way possible.

The Diabetes Research Steering Groups (DRSGs), established by Diabetes UK in 2017 and formerly known as Clinical Studies Groups, bring together people with diabetes, healthcare professionals and researchers to examine the research landscape, amplify the voice of people

living with diabetes, and identify research priorities and practical actions to move forward research in areas of unmet need. They have discussed the area of technology and diabetes and identified several research gaps and priority areas. However, concerns around how academic research could best help to improve understanding in a field driven primarily by companies made turning these gaps and priorities into research projects challenging. In order to develop their initial discussions into a more detailed set of recommendations for research, Diabetes UK convened a workshop in December 2019 to pool expertise in the field of diabetes technology and identify how to move the field forward.

Methodology

In December 2019, Diabetes UK brought together DRSG members and experts from a variety of backgrounds, including people living with type 1 and type 2 diabetes, for a 1-day workshop to identify the key gaps in evidence and priority research questions in the area of diabetes technology. In total, there were 55 attendees, including 8 experts by experience of living with diabetes, 39 researchers and healthcare professionals, and 8 members of staff from Diabetes UK who facilitated the workshop. Attendees are listed in Appendix I.

The workshop format began with four presentations from experts in the field. These presentations provided an overview of current evidence related to the use of technology in acute care by Professor Gerry Rayman, Technology in the context of complications and multi-morbidity by Professor Simon Heller, Closed loop technology & Continuous Glucose Monitoring (CGM) by Professor Helen Murphy and the use of technology in paediatrics by Professor Roman Hovorka.

After each presentation, attendees were organized into the same group of six or seven, with representation from different specialities and two people with type 1 or type 2 diabetes, and were asked to discuss and answer three questions: (i) where are the current areas of strength in existing research evidence; (ii) how can this evidence be built on; and (iii) where is further evidence needed?

Each group was asked to identify one or two priority topics for further discussion. In total, around 20 clear research priorities were identified. The Diabetes UK facilitation team then clustered these priorities into themes and in order to focus discussions further, the attendees selected 5 for further in-depth discussion and the development of research recommendations:

- Matching the pace of research with that of technology development
- Time in range as a measure

- Health inequalities and high risk groups
- How to train people to use technology most effectively
- Impact of technology usage on mental health

Attendees joined groups to discuss three questions in each area: (i) what are the research questions; (ii) what approaches could be taken to answer these questions; and (iii) what are the barriers to this research and how could they be overcome?

Each group was asked to feedback on their discussions, and other attendees had the opportunity to input thoughts and ideas. All discussions were captured to inform this paper.

This paper provides a summary of these discussions and the key research recommendations captured to optimise future research in the field of diabetes technology, and ensure it is addressing the needs of people living with diabetes. Unless otherwise specified, these themes and the recommendations for research within them apply in all three specific contexts for diabetes care presented to prompt discussion: acute care, care in the context of multiple long term conditions and paediatrics.

We note that some of the priorities outlined move into policy recommendations related to research, however, they do represent the output of these discussions.

Research recommendations in focus areas selected

1. Matching the pace of research with that of technology development

Context

Technology development continues to advance at a very rapid pace [12], faster than research is able to collect comprehensive evidence of each device's clinical and cost effectiveness. This was identified as a barrier to its wider implementation within care, particularly in the case of glucose monitoring devices [13].

The need to better understand the evidence needed to change practice and policy, and the research needed to generate it, is key in ensuring the right kind of technology is made available to those who will benefit from it. The workshop highlighted the need to explore with trial methodology experts the potential for interrupted time series trials, adaptive trials or the routine

collection of real world data for assessment to improve the speed at which currently available technology can be rigorously and robustly assessed.

Research recommendations

- Real world use of technology can provide a source of glycemic data [14] which could be better utilised both as an evidence base to examine effectiveness on glycemic control and reducing risk of severe hypoglycaemia or Diabetic Ketoacidosis (DKA). This data could also allow for health economic assessment.
- Trials should be designed with methodologies which can be adapted to new developments in technology: for example trials with multiple arms run in parallel to which new arms can be added as new technologies emerge [15], or an interrupted time series design [16].
- Work is needed to develop a pathway for new technologies to be assessed and implemented into care as they are developed, potentially learning from how other fields have handled incorporating new devices into care rapidly.
- Involvement of policy makers is required to ascertain the level of evidence required to implement changes in care, before starting studies to generate evidence.

2. Time in range as a measure

Context

Workshop attendees highlighted the growing relevance of the Time in Range (TIR) measurement. This represents the percentage of the time a person with diabetes spends with blood glucose levels between 3.9 mmol/l and 10.0 mmol/l and international guidelines on the use of this measure were published in 2019 [17]. Research is needed to establish the potential benefit for TIR as a significant marker of health outcomes alongside or in place of HbA1c, as this could eventually inform updates of NICE criteria.

There have been positive reports on how much more meaningful a measure TIR can be for people with diabetes [18] and consensus agreements on how it should be used have been written [19]. However, the exact relationship between this measurement and health outcomes has yet to be clearly determined, both in terms of quality of life and the development of complications. To achieve an effective measurement of TIR also usually requires access to a CGM device which are not always available, particularly those with type 2 diabetes. The need to improve the

awareness and understanding of many health care professionals of TIR as a measurement and how to use it to inform care was also highlighted [20].

Research recommendations

- The relationship between TIR and health outcomes, both in terms of complications risks and quality of life, should be elucidated via large and long-term cross-sectional and prospective studies.
- Questions around the standardisation of TIR across different devices capable of assessing it also exist. Measurements can be obtained from a seven point profile using self-monitoring of blood glucose (SMBG) [21] from the use of CGM and from Flash glucose monitoring but how comparable these are needs to be better understood, particularly in light of the difficulties around accessing some of these technologies.
- If research does demonstrate that TIR is intrinsically linked to health outcomes, then research into the best way to train health care professionals in using it rather than current measurements will also be needed. Online training platforms or events could help with this.
- The importance of research which uses CGM devices reporting TIR was highlighted.

3. Health inequalities and high risk groups

Context

Technology has the potential to assist people in high risk groups with their diabetes management - particularly those who have consistently higher HbA1cs, who miss appointments, experience recurrent DKAs [22] or have reduced hypo awareness [23]. Technology could also, combined with proper implementation, help encourage more technically literate people with type 2 diabetes to improve the management of their condition [4].

However, as technology rapidly advances there are growing concerns surrounding the lack of an evidence base demonstrating the impact of technology on the lives of people with diabetes. This includes identifying specific groups who technology could most benefit or the best practice on how to provide it [24]. There are several barriers to the adoption of advanced user technology in diabetes management rooted in cost and education that could particularly exclude vulnerable people with diabetes from accessing these tools. For example, devices such as CGM sometimes require expensive technology such as smartphones to get the full benefit, may need to be self-funded rather than made available through the NHS and rely on access to the internet [25]: all of

which risk excluding users from certain socioeconomic groups who could be at higher risk of complications [26]. Moreover, optimal use of such technology requires a high level of health, numerical and technical literacy that could be barriers to their adoption by people with diabetes, such as those with poor numeracy [27] or for whom English is not a first language [28].

Research recommendations

- Assess how to effectively provide glucose monitoring technology to people with higher HbA1c and assess whether it improves their health.
- Establish what percentage of people with diabetes do not have access to technology or cannot afford the hidden costs required to use novel diabetes management devices, such as smartphones or internet access, and establish methods to enable these populations to access devices.
- Identify which groups respond most to the provision of technology, to better understand who to target for uptake of technology.
- Increase understanding of the clinical support, people with diabetes need to get the greatest benefit from technology- both in terms of glycaemic and quality of life outcomes.
- Identify the barriers and enablers to technology use to support increased effective adoption of technology by people with diabetes.
- Explore known literacy and engagement barriers and establish best practice protocols to reduce the barriers to people with diabetes using technology to improve their management.
- Researchers and developers of technology should be mindful of the diversity of the population with diabetes when recruiting to trials, to ensure that they are conducted in cohorts representative of the general diabetes population. This should include, but not be limited to, socioeconomic group, geography, ethnicity, gender, disability, marginalised populations and forms of diabetes when recruiting, and bear in mind any additional barriers to technology these groups may face.
- Effective patient and public involvement in research design, and co-design if possible, is beneficial to ensuring the recruitment and retention of a representative population. It also improves the likelihood that technological innovation will be fit for purpose.

Attendees also recommended that a diverse range of researchers, charities and policymakers should be involved in tackling these research questions.

4. How to train people to use technology most effectively

Context

Access to new forms of technology often come with a need to develop new skills to obtain most benefit from them [29, 30). Much information around how people with diabetes can manage their condition can be learned from glucose monitoring devices, but learning how to best interpret this information and put it to good use may also require additional training and support. Research needs to test and identify the best ways to provide additional skills to support the use of these devices, or other new forms of technology which may emerge, to people with diabetes as their usage becomes increasingly common.

Research recommendations

- Research to create training programmes which support people with diabetes and healthcare professionals to develop skills related to the use of technology should involve people with lived experience of using technology to manage diabetes in both design and delivery.
- Training courses should aim to include a group of core competencies required in all situations during development, with additional modules for specific technologies and skills. They should also be designed so that the training needs relating to new forms of technology can be integrated.
- This modular design should also tailor education to the learning styles of the individuals taking part. Qualitative research could increase our understanding of the barriers to learning in diabetes education.
- The initial focus for the creation of programmes like this should be upon those who have had access to devices such as CGM, but have experienced challenges in getting the maximum benefit from technology.
- Whilst there is a need to innovate and examine novel ways to deliver education through non-traditional means, such as online videos, the effectiveness of such programmes will also require rigorous evaluation in comparison to existing methods.

5. Impact of technology usage on mental health

Context

Ways in technologies to assist in the management of diabetes could negatively impact on mental well-being and how to prevent this were highlighted as a priority area for further research at a previous workshop focussed on diabetes and mental wellbeing [31]. A number of recommendations are common themes between discussions at the two workshops, including the importance of appropriate education programmes for glucose monitoring devices, identifying people who could most benefit from specific technologies and matching the pace of research to that of technology development [31].

Additional concerns were expressed around how a reliance on technology could impact on mental well-being, especially if it were to stop working, and whether this could increase the risk of anxiety or diabetes burn out. This is also a risk that people may struggle to reach the level of self-management they are happy with, even with access to technology. Past research has shown that the effect of CGM on mental wellbeing can vary significantly [32], and there is a need to identify factors responsible for this variability.

The potential for web or app based interventions to address issues of mental well-being in people with diabetes was also raised as a way in which technology could play an important role in diabetes care in future. Research is required to understand how this could best be achieved is needed, as current studies have not shown much impact [33].

More understanding of how and why technology affects the mental well-being of people with diabetes will enable us to maximize the benefit these tools can provide to their users.

Research recommendations

- Include suitable psychological outcomes, for example quality of life and other related PROs such as treatment satisfaction questionnaires, in trials assessing the impact and effectiveness of new technologies.
- Involve people living with diabetes in the co-design of technology-driven interventions and involve mental health research expertise in a multidisciplinary approach.
- A clear and agreed international framework on a set of standardised questions to assess the psychological impact technology is having on the mental health of a person with diabetes is needed, as no consensus on the methods to do this exists at present.
- Technology-based interventions to address mental health conditions in people with diabetes should be designed to be modular, where possible. This will ensure that they are

sufficiently flexible enough to adapt to people's needs with additional modules addressing new technology as it emerges.

6. Future Areas for Focus

As outlined in the methodology, in addition to the work to develop research recommendations in these key areas, a number of additional issues were highlighted from the initial discussions:

Lack of Research into or Evidence of the Benefit of Glucose Monitoring and Pump Technology for People with Type 2 diabetes

Whilst new technology for glucose monitoring is growing in use in people with type 1 diabetes, obtaining access to these devices is not routinely provided to people with type 2 diabetes [34] despite the value which some studies suggest could be gained [4,5,6,7, 35]. Many questions were asked around how glucose variability relates to HbA1c in people with Type 2 diabetes and the benefits in both self-management and quality of life which greater access to devices such as CGM or Libre could provide to people with the condition.

The consensus in this area was that an evidence gap exists around the benefits which could be gained from provision of glucose monitoring technology to people with Type 2 diabetes, and that research was needed in this area.

Using Technology to Help Young People with type 2 diabetes

In addition to concerns around the lack of access to technology for people with type 2 diabetes, the need to identify how technology could support children and young adults with type 2 diabetes was highlighted.

This is a growing group of individuals who have been found to be at increased risk of complications [36], and whilst the root cause of this increased risk still needs to be understood, trialling newer forms of glucose monitoring technology to establish whether this risk can be reduced was highlighted as a crucial unmet need. The potential for closed loop technology to significantly reduce the rates of complications in this group was particularly highlighted.

How Best to Support Children and Families with Diabetes Technology

Several additional issues around technology which are faced specifically by children with diabetes and their families were highlighted.

Children with diabetes can find it challenging when transitioning from paediatric to adult care and using technology as they take sole responsibility for diabetes self-management [36]. Research will help to identify ways to overcome these challenges.

A lack of understanding around how puberty can affect diabetes management [37] was an area where additional information could be obtained through data, and this is already being collected through the use of new technology such as CGM as young people with diabetes transition through puberty.

The ways in which stigma impacts on children with diabetes, and how technology could affect this, was also highlighted. The importance of designing devices with an attractive external appearance was thought to be potentially more important to adolescents than other groups. This highlights the need for co-design when developing new technology.

Patient Reported Outcome Measures (PROMs) and the importance of measuring Quality of Life (QoL)

The importance of considering more than HbA1c in the effectiveness of devices designed to assist with diabetes management is key. While research recommendations around TIR were developed in more detail, the importance of PROMs was also highlighted in areas beyond their use in tracking the impact of technology on mental health. Both clinicians and people with diabetes described their experience of the benefit that can be obtained from these devices, and potentially other technology which may be developed in future, which will not be captured with typical outcome measures [38].

The importance of effectively measuring how such devices affect people living with diabetes, both in research and a clinical setting, and the need to establish best practice for collecting and using this information is essential.

Data Sharing and Access

A wealth of glucose monitoring data, as well as other forms of data relevant to diabetes, is generated through the use of wearable devices but not captured or used for research. There is the potential to better use this in research, for example to provide a larger dataset for machine learning or to better understand risk factors [39], as recent work to identify the risk people with diabetes face from COVID-19 have demonstrated [40]. A national register of this information was

suggested, potentially connecting to existing databases such as the UK Biobank or the National Diabetes Audit to compare this data with additional measurements. Diabetes UK has, since the meeting, also started an initiative to set up a UK diabetes research data hub which is looking at ways of improving access to and connection of data for these purposes, in line with HDRUK's data hubs.

Reaching out to people with diabetes who use these devices to encourage them to share their personal measurements on an open data platform was also proposed as an alternative solution for widening access to this information.

Health Economics and Social Impact

The importance of analysing the health economic and social impacts of the use of technology in diabetes management and prevention was highlighted, particularly in light of the need to demonstrate clear benefit to change NHS policy. Aspects of diabetes technology in need of this type of assessment include the potential for glucose monitoring technology or closed loop systems to prevent poor health outcomes with a major health economic cost through reducing HbA1c [41, 42] and the reduction in interrupted sleep for parents of young children with diabetes which glucose monitoring technology can provide [43].

What Users want in the Design of Technology

The need to improve on elements of currently available technology which are identified as sub-optimal, which can be achieved through innovation in research, was highlighted. Examples mentioned by users and HCPs at the meeting included aspects of the user interface, adhesive materials and alarm frequency [44]. The importance of addressing different needs when developing technology, particularly in relation to health inequalities and high risk groups, was emphasised. Innovative approaches to design are required to address many of these issues.

Using Technology to Understand People's Environments and make them Healthier

The potential for technology to assess how the environment in which people live affects their risk of developing diabetes and how they manage it, and thus improve both these factors, was underlined.

Three areas with were considered to have particular untapped potential:

- Technology facilitating healthy and supportive social networks to provide peer support should be further developed [45]

- Monitoring of dietary intake could be improved by technology, for example by analysing supermarket purchasing data [46].
- The use of activity sensors and similar devices in the home [47] may identify patterns of behaviour which could increase the risk of Type 2 diabetes or impair self-management. This information could be incorporated to design more effective environments or ways to help.

Conclusions

This meeting has developed a clear set of recommendations to maximise the benefit and effectiveness of research into diabetes technology. We now need to ensure that these questions are addressed. Diabetes UK calls on the research community, partner organisations, funders and, critically, designers and innovators of diabetes technology to establish how we can work together to achieve this.

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Appendix I

Workshop attendees

The authors are grateful to the following for joining us and providing their expertise to the workshop: Dr Georgios Baskozos (Nuffield Department of Clinical Neurosciences, University of Oxford), Olivia Burr (Diabetes UK), Rachel Connor (JDRF), Anna Cundall (Expert by Experience), Said Dajani (Diabetes UK), Dr Clare England (University of Bristol, NIHR Bristol Biomedical Research Centre, Nutrition Theme), Dr Mark Evans (University of Cambridge), Professor Laura Gray (Department of Health Sciences, University of Leicester), Sarah Gibbs (Expert by Experience), Professor Jorg Huber (University of Brighton), Lalantha Leelarathna (University of Manchester), Dr Kezhi Li (UCL Institute of Health Informatics), Carol Mathias (Expert by Experience), Nathaniel Mills (NIHR Devices for Dignity MedTech Co-operative), Professor Nick Oliver (Imperial College London), Liz Perraudin (Diabetes UK), Dr Daniel Pollard (University of Sheffield), Professor Frans Pouwer (University of Southern Denmark), Dr Tabitha Randall (Nottingham Children's Hospital), Professor Gerry Rayman (Ipswich Hospital), Professor Rebecca Reynolds (University of Edinburgh), Brenda Riley (Expert by Experience), Dr Faye Riley (Diabetes UK), Lise Sproson (Diabetes Theme Manager and PPI Lead, NIHR Devices for Dignity MedTech Cooperative), Tim Street (Diabetech), Dr Emma Wilmot (University Hospitals of Derby and Burton NHS FT, University of Nottingham and Diabetes Technology Network UK)