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Delivering evidence-based interventions for type 1 diabetes in the virtual world – A review of UK practice during the SARS-CoV-2 pandemic

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ABSTRACT

Aims: This review considers the impact of the SARS-CoV-2 pandemic on access to interventions for those living with type 1 diabetes and discusses the solutions which have been considered and actioned to ensure ongoing access care.
Methods: We performed a focussed review of the published literature, and the guidelines for changes that have been effected during the pandemic. We also drew from expert recommendations and information about local practice changes for areas where formal data have not been published.
Results: Evidence based interventions which support the achievement of improved glucose levels and/or reduction in hypoglycaemia include group structured education to support self-management, insulin pump therapy and continuous glucose monitoring. The SARS-CoV-2 pandemic had impacted the ability of diabetes services to deliver these intervention. Multiple adaptations have been put in place – transition to online delivery of education and care, and usage of diabetes technology.
Conclusions: Although various adaptations have been made during the pandemic that have positively influenced uptake of services, there are many areas of delivery that need immediate improvement in the UK. We recommend a proactive approach in recognising the digital divide and inequity in distribution of these changes and we recommend introducing measures to reduce them.

1. Introduction

The incidence of type 1 diabetes has been increasing at the rate of 2–4% annually over the past three decades. This rapid increase in incidence has been attributed to multiple environmental factors. [1] The cost of type 1 diabetes and its complications to the National Health Service (NHS) is around £1 billion a year and around 10% of the total NHS budget is spent on management of diabetes in the UK. [2].

People with type 1 diabetes have been shown to have worse outcomes from SARS-CoV-2 infection. In a large population wide study in the UK, individuals with type 1 diabetes had increased odds (OR 3.51, 95% CI 3.16–3.90) of death with SARS-CoV-2 when compared to those without diabetes. [3] Higher glucose levels, as indicated by HbA1c, are associated with increased mortality risk; the hazard ratio for SARS-CoV-2 related mortality in people with type 1 diabetes with an HbA1c $\geq$ 10% ($\geq$86 mmol/mol) was 2.23 (95% CI 1.50–3.30) compared to those with HbA1c (6.5% – 7% (48 – 53 mmol/mol). There is also a linear association between Body Mass Index (BMI) of over 25 kg/m^2 and increasing risk of death from SARS-CoV-2 infection. [4] Thus, the achievement of optimal glucose levels is central to reducing these adverse outcomes.

This article aims to review the ongoing challenges of achieving optimal glucose levels for people living with type 1 diabetes during the SARS-CoV-2 pandemic and the various ways in which services have adapted to these challenges.

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2. Evidence based interventions in type 1 diabetes.

Many interventions exist that can improve the outcomes of people with type 1 diabetes, ranging from education to technology. All of these aim to improve HbA1c, reduce the risk of acute and chronic complications, improve quality of life, and empower people with type 1 diabetes to be experts in their own diabetes management.

2.1. High quality structured education

High quality, evidence based, structured education is the first line intervention, and it has been shown to improve outcomes in people with type 1 diabetes. Recommended by National Institute of Health and Care Excellence (NICE), randomised controlled trial data show that Dose Adjustment For Normal Eating (DAFNE) structured education can deliver sustained improvements in HbA1c, hypoglycaemia awareness and treatment satisfaction in addition to a reduction in severe hypoglycaemia and episodes of diabetic ketoacidosis. [5–9] DAFNE is designed to provide structured training to promote diabetes self-management whilst simultaneously enabling increased dietary freedom. In the past 2 decades, 7,916 DAFNE courses have been delivered to over 58,264 graduates and at the time of writing, in the UK there are 1091 DAFNE trained educators and 700 doctors.

Another type 1 diabetes structured education course is Bournemouth Type 1 Intensive Education (BERTIE), an educational programme associated with improvements in HbA1c levels in observational data. [10] This course also offers an online option which pre-dates the pandemic. The My Diabetes My Way (MDMW) is an online diabetes self-management platform which also includes a separate section dedicated to people with type 1 diabetes. Data on people with type 2 diabetes using this online system have shown significant improvements in knowledge, motivation, and reduction in HbA1c levels. This programme is also supported by funding from the NHS. [11].

2.2. Intermittently scanned continuous glucose monitoring

In recent years intermittently scanned continuous glucose monitoring (isCGM) ('flash glucose monitoring') has become a standard method of measuring glucose levels. Randomised controlled trial data demonstrated a reduction in hypoglycaemia in people living with well controlled type 1 diabetes but with no significant change in HbA1c. [12] In contrast, observational data have reported that use is associated with a significant improvement in HbA1c levels, reduction in hypoglycaemia in both adults and children with type 1 diabetes, improvements in quality of life, and hospital admissions due to hypoglycaemia and hyperglycaemia. [13,14].

2.3. Real-time continuous glucose monitoring

Real time continuous glucose monitoring (rtCGM) systems that measure interstitial glucose values with additional alarms to alert the users to rising or falling glucose levels have significantly improved HbA1c levels and hypoglycaemia in multiple randomised controlled trials. [15,16] NICE recommends rtCGM for those with problematic hypoglycaemia and hyperglycaemia. However, in England, access to funding for this technology is variable with only 1 in 5 areas having access in line with NICE recommendations. [17] This is due to the differences in availability of a prespecified cost reimbursement framework to the CGM providers (i.e., local hospital trusts) between various regions in England, and due to many regions needing approval on a case-by-case basis through individual funding requests. These additional processes add another layer of complexity to the delivery of CGM. [17]

2.4. Continuous subcutaneous insulin infusion (CSII) therapy

Continuous subcutaneous insulin infusion (CSII) therapy or 'insulin pumps' for the delivery of insulin are associated with significant reductions in the HbA1c levels, lower risk of severe hypoglycaemia, decrease in all-cause and cardiac-specific mortality, increase in quality of life, and reduction in the progression of diabetic retinopathy compared with MDI . [18,19] CSII therapy is recommended for the treatment of type 1 diabetes in adults if the HbA1c levels remain $\geq$ 8.5% ($\geq$69 mmol/mol) on MDI therapy, or if disabling hypoglycaemia is caused by attempts to reach target HbA1c . [20].

3. Changes to diabetes services from 2020

In March 2020, the UK entered lockdown in response to the SARS-CoV-2 pandemic. From the outset, those living with diabetes were identified as clinically vulnerable to SARS-CoV-2 and advised to undertake 'extreme social distancing' and 'shielding'. Most diabetes services stopped offering face to face appointments in all but the most clinically urgent cases. Within days to weeks, services were able to make huge changes to their workflow and adapt to a new way of working by delivering ongoing support for people with diabetes through virtual offerings, whether via telephone, email, or video conferencing . [21] Connectivity of isCGM and real time glucose sensors and insulin pumps has allowed clinical teams to view data remotely to support virtual consultations. Group face to face sessions for education and technology starts were suspended while new pathways could be developed. Below, we explore the extraordinary transformation which occurred in the delivery of evidence-based interventions for type 1 diabetes care.

3.1. Delivering diabetes education in the virtual world

Previously conducted in-person, group educational programmes were adversely affected by the social distancing measures. A cross-sectional survey conducted among diabetes nurses in the UK and Europe showed that around 60% of the respondents thought that diabetes education was 'quite severely or extremely' disrupted during the pandemic. [21].

The DAFNE structured education programme was historically delivered face to face over 5 days or 1 day a week over 5 weeks. This was no longer a viable option and the central DAFNE team worked to produce a virtual offering; Remote DAFNE. This new method of delivery involves both self- directed online learning and remote group work facilitated by a DAFNE educator. Following a successful pilot, Remote DAFNE launched and existing DAFNE educators were provided with support and training to be able to deliver the virtual course. By March 2021, 131 Remote DAFNE courses have been delivered with 90% of DAFNE centres now offering Remote DAFNE. The initial feedback has been 'very positive', with participants highly rating group discussions, feeling very well supported by their DAFNE educators, and feeling much less isolated due to peer support from the other participants. Further analysis of the impact of this course on medical outcomes is ongoing. [22] In addition, despite significant staffing issues within diabetes services during the pandemic, 87 new DAFNE educators have been trained entirely remotely, and 41 doctors have completed their virtual DAFNE training, all at no extra cost to DAFNE centres.

Some people with diabetes would have continued to use other educational programmes for type 1 diabetes for example, 'BERTIE online' although figures for the traffic over pandemic period are not currently available to demonstrate increased usage. NHS England have also secured funding to facilitate access for people with type 1 diabetes to 'my diabetes my way' online e-learning programme. [11].

The current pandemic has accelerated the shift from face-to-face delivery to virtually delivered programmes. Initial outcomes and anecdotes from within service suggests these are preferred by some, but not all, people with type 1 diabetes. [23] More data about the impact of these methods on outcomes is needed, and a mixed offering of face-to-face and/ or remote delivery will likely need to be implemented.

3.2. Continuous subcutaneous insulin infusion (CSII) therapy

Prior to the pandemic, there were significant challenges in commencing CSII in people with type 1 diabetes. The UK National Diabetes Audit (2018) showed that 23.5% of CSII services audited had to suspend CSII starts in the 2 years prior to the audit, citing staffing as the

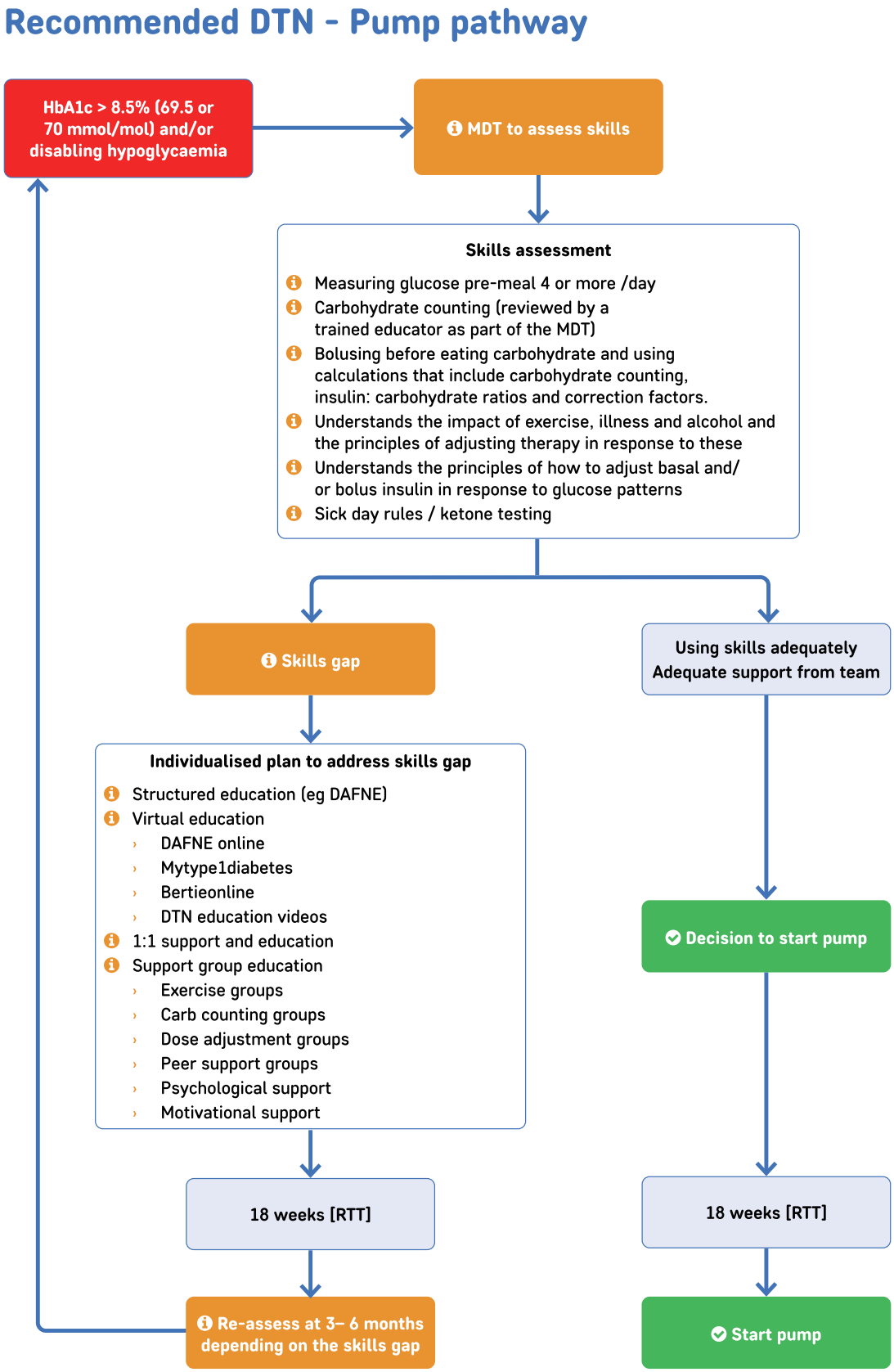

Fig. 1. Recommended DTN pump pathway.

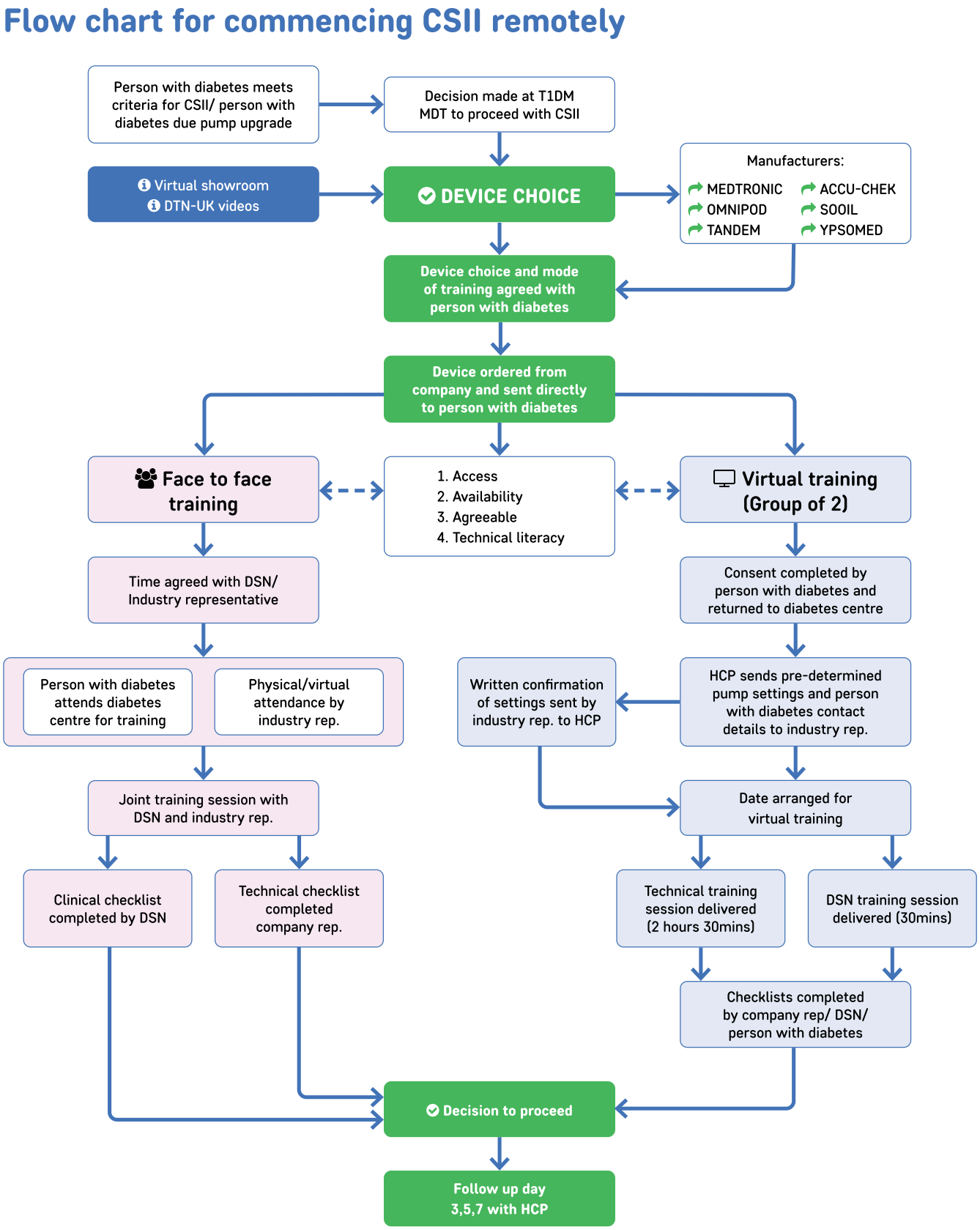

Fig. 1. (*continued*).

main cause. [24] The Getting It Right First Time (GIRFT) NHS quality improvement initiative addresses the challenges in commencing and managing CSII in people with diabetes. There is regional variation between NHS trusts in the distribution of CSII services. The main reason cited for the inadequate uptake is the lack of staff members to provide the service, and the inadequate time to train them. The GIRFT team is

currently working with the Diabetes Technology Network UK (DTN-UK) and the NHS to increase the availability of these services to more people with diabetes and providers. [25] The SARS-CoV-2 pandemic has increased pressures on these services due to its detrimental effects on staffing levels and changes to the way they are organised, with most diabetes services moving towards virtual appointments. The need to minimise face to face contact has impacted on insulin pump services which previously delivered CSII starts in a group setting.

To help ease some of the pressure on pump services, DTN-UK worked with device manufacturers to extend CSII device warranties reducing the immediate need for replacement of out of warranty CSII devices. [26] To support teams in initiating CSII or renewing them onto a new pump remotely, DTN-UK has produced helpful guidance. [27] This includes a practical implementation flow chart process that can be adopted by services - which includes guidance on arranging virtual training sessions for patient education, checklist templates to ensure adequate coverage of the essential aspects of CSII, and standardised 'sign off' procedures to guide appropriate initiation of the therapy. It also provides a standard operating procedure to help clinical teams under pressure by showing how they can take advantage of appropriate clinical skills held within the industry and how to utilise these skills in a safe manner to improve access to CSII. [28] Further, a DTN-UK virtual showroom has been developed in collaboration with industry partners. This showcases the different CSII devices and CGM options currently available and enables people with diabetes to identify the device that best suits their personalised needs. [29] CSII device manufacturers have provided support to services by offering new virtual training material and widening remote support to patients. A retrospective study comparing face-to-face training with virtual training for the initiation of a CSII device during the SARS-CoV-2 pandemic has shown high patient satisfaction rates, less follow up calls to the educational support team, and similar short term glycaemic control. [30].

3.3. Intermittently scanned continuous glucose monitoring

The pandemic had some initial impact on the ability to start people with type 1 diabetes on isCGM. Prior, these were often done in group settings face-to-face. The move to virtual sessions was soon established. The DTN-UK Remote Pathway (show in Fig. 1**)** for CGM starts emphasises the need for partnership between industry and clinicians, but also allows flexibility in situations where remote starts would not be appropriate. [28] Additionally, it directs clinicians and staff to online resources for further support which might include the DTN-UK isCGM webinars and educational resources for people living with diabetes. We have a limited understanding of whether users prefer this style of set-up. However, despite this, during the pandemic the uptake of isCGM has continued to climb.

3.4. Real-time continuous glucose monitoring

Real-time continuous glucose monitoring delivers clinical benefits similar to insulin pumps which includes a reduction in HbA1c across all age groups. [15] Therefore, in situations where pump starts might be more difficult to arrange in the virtual world, the option of a "CGM first" as outlined in the DTN technology pathway [44] could be considered. This approach is supported by leading experts, and in addition, rtCGM systems allow usage of multiple alarms/alert systems that reduce the incidence of hypoglycemic episodes and increase the time in range. [31].

One group who do now have confirmed access to rtCGM funding are women with type 1 diabetes during pregnancy, to be implemented in all regions of the UK prior to April 2021. [32] This technology is available as a result of the landmark CONCEPTT trial [33], which demonstrated that the use of rtCGM in pregnancy improved outcomes for both mother and baby and was shown to be cost effective. [34].

3.5. Closed-loop insulin delivery systems.

The era of commercially available closed-loop insulin delivery was about to dawn when the SARS-CoV-2 pandemic began, compounded by the difficulties already faced with pump starts due to staffing shortages. These systems are likely to be the future of type 1 diabetes care, with multiple clinical trials showing their safety and effectiveness in reducing HbA1c, improving time-in-range and improving quality of life. [35–37].

Uptake of closed-loop therapy has been steady but limited in many areas to the few with a compatible pump and meeting local criteria for NHS funding for rtCGM unless they choose to self-fund the technology. Much work is needed to support the provision of closed-loop systems to those who may benefit and meet the necessary NICE criteria for both CSII and CGM [38]; with the hopes of fully realising the Diabetes UK technology pathway consensus guideline in the future. [39].

4. Improving access to technology

SARS-CoV-2 has put current health inequalities under the magnifying glass and has emphasised that we need to do more to ensure that access to and provision of diabetes technologies is equitable across the country. The annual National Paediatric Diabetes Audit in England and Wales has reported marked disparities in access to diabetes technology between ethnic groups and socioeconomic status in children and young adults. Alarmingly, the disparity has widened over the last 6 years. [40] If we hope to achieve equity, then there are barriers we must remove, as identified in the Juvenile Diabetes Research Foundation's (JDRF) "Pathway to choice" report, published a month before SARS-CoV-2 took hold. [41].

Firstly, we need to ensure that people with diabetes are aware of which technologies are available. The JDRF reports that a third of people with diabetes only receive updates on diabetes technology from their diabetes clinicians. [41] Many learn more from online forums, but we should openly be discussing these treatments, not just to people with diabetes but to the wider public. If knowledge of CGM, CSII and closed-loop becomes mainstream, then it is likely that people who may benefit may prompt their clinicians to consider it when they otherwise may not have.

Secondly, and hand-in-hand with the above, we need to ensure that clinicians are educated on the use of these technologies. We need trained staff to support the setup of these systems and provide ongoing care to the users. This must include more trained nurses, dieticians, and doctors to ensure that users are supported. Outside the immediate pump multidisciplinary team, all diabetes clinicians should understand these systems and education is being freely available. Webinars are available to access at DTN-UK [42] and recently DTN-UK in collaboration with Glooko launched an online educational platform for health care professionals that provides CPD approved education on diabetes technology. This was endorsed by NHS England and is a response to the GIRFT report that recommended better access to education on diabetes technologies for clinicians. Within four months of the launch, over 500 health care practitioners have registered and started their courses [43] (Fig. 2).

The DTN-UK best practice guidelines [44] are also available to support health care professionals to upskill in diabetes technology. In addition, DAFNE are due to pilot a new remote pump course this summer (Fig. 3).

We must all endeavour to ensure access to technology is fair and in accordance with guidelines. The diabetes technology pathway was developed with this approach in mind. [45] Clinicians should support individuals to achieve their goals. If the individual continues to experience a high HbA1c or problematic hypoglycaemia clinicians must support them by considering addition of the next available technology until goals are met. [46].

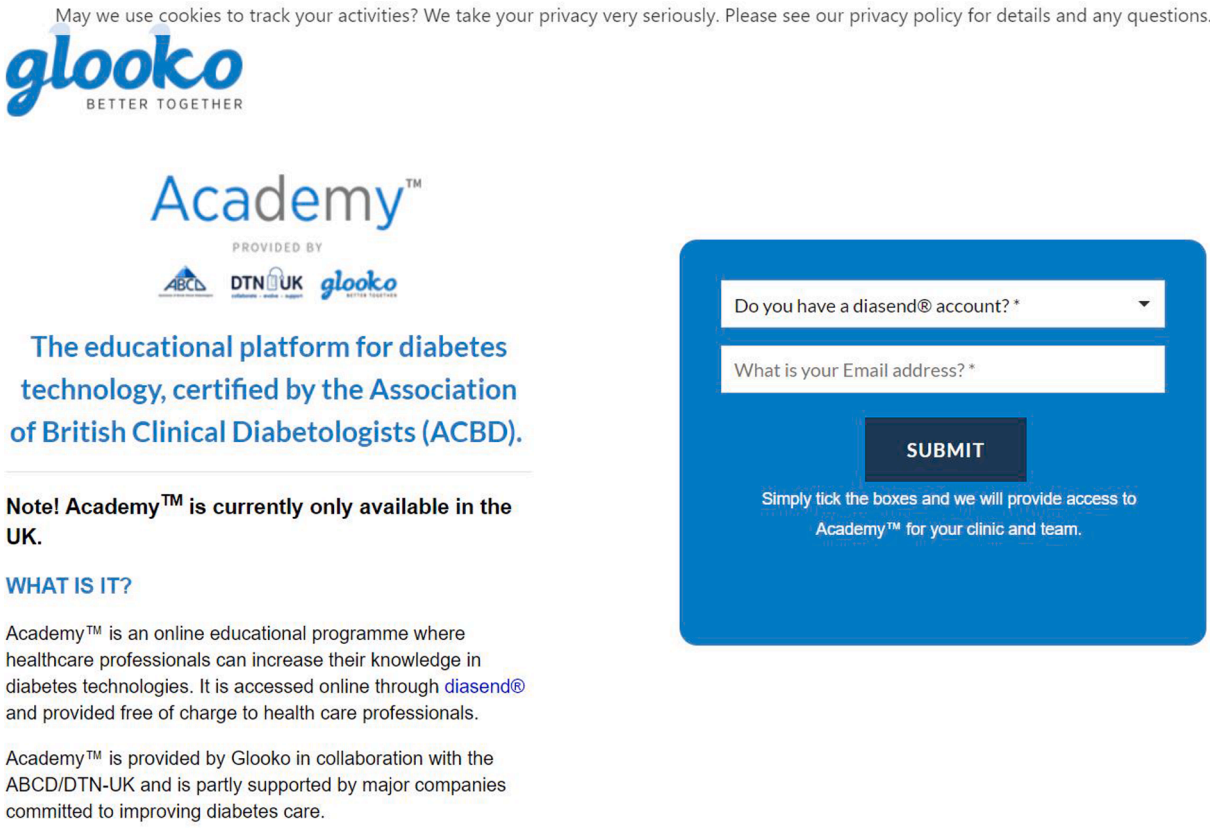

Fig. 2. Front page of the Academy.

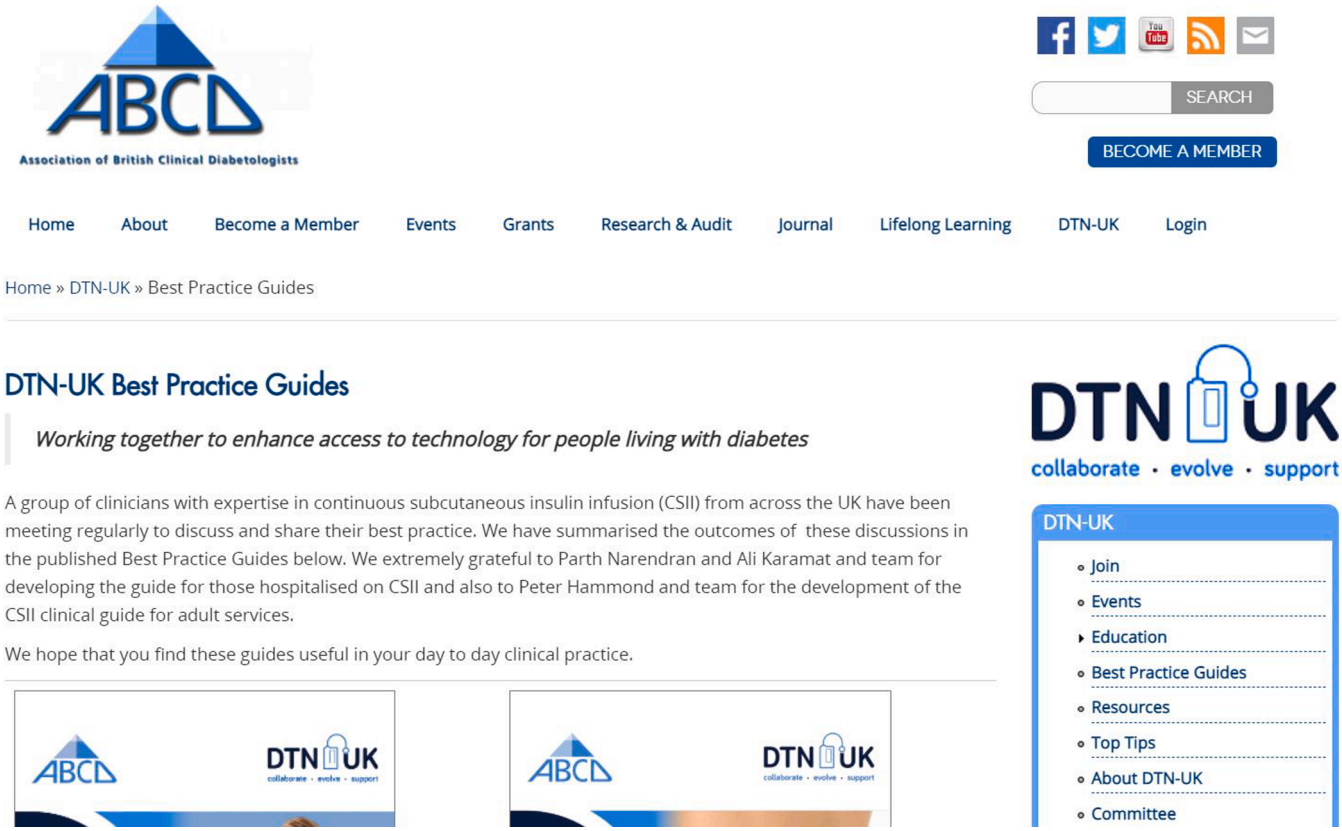

Fig. 3. Webpage of the DTN-UK best practice guides.

4.1. Virtual consultations

Access to technology has been an important facilitator of virtual consultations. Both isCGM glucose monitoring and rtCGM allow access to ambulatory glucose profiles and glucose metrics in the cloud. Those people using insulin pumps can also share their data. This has the potential to support more thorough and effective consultations. Data stored in the cloud allow for mutual discussions about time-in-range and ambulatory glucose profiles, with the potential to improve the identification of nocturnal hypoglycaemia, delayed insulin dosing and other problems that might be difficult to elicit in a tele-consultation. However, even using video vs telephone, concerns have been raised about the ability to detect and support psychological distress using virtual platforms. [47] Nonetheless, virtual clinics held in the form of video consultations have multiple advantages including increased safety to shielding patients, improved accessibility, reduction in the time commitment for people with diabetes and health care professionals, and the ability to reduce overall treatment related burden for people with diabetes. Telephone consultations can also provide many of the above benefits. However, using video consultations can be more beneficial by facilitating a conversation with multiple members of the MDT at the same time, providing benefits of non-verbal visual cues during the consultation, and helping conduct a video examination to guide decision making. [48].

There are a few excellent examples of how some services have used these systems to provide targeted support to those at highest risk of hypoglycaemia or ketoacidosis, with promising results. [49] The need for blood tests for 3 monthly HbA1c could be obviated entirely by use of the glucose management indicator (GMI) or switching our targets from HbA1c to those formed by Batellino et al. in the time-in-range consensus. [50].

4.2. Digital divide and improving access.

Even prior to the SARS-CoV-2 pandemic, in 2018, about 10% of the adult population of UK was categorised as internet ''non-users''. It has long been recorded that a move towards telehealth can have adverse effects on the delivery of healthcare to individuals who have barriers to access these new technologies. The speed at which the SARS-CoV-2 pandemic has catalysed a move towards digital technologies can potentially exacerbate this technological inequity. [51].

Therefore, when adopting these new digital strategies, it is vital to introduce balancing measures and proactively tailor our approach to reach this group of people. One approach may involve providing telephone appointments if video consultations are not feasible for the individual. [52] Based on expert experience of delivering type 1 diabetes care in the UK, the measures that we have found to be effective include - reaching out to this group of people with diabetes via ad-hoc face-to-face consultations selectively, involving carers and family in monitoring progress, and offering more intensive support when adopting new technologies. The authors have also found that adopting a virtual consultation model for clinics can decrease the did-not-attend (DNA) rates for people with diabetes. This improvement in DNA rates has been previously demonstrated in specific centres that have adopted this practice prior to the pandemic. [53].

5. Conclusion

All of the above, education and diabetes technologies have been highlighted as key areas in the Getting It Right First Time (GIRFT) report for Diabetes services. [25] Technology is pivotal to the future of diabetes care. It has the ability to improve the outcomes and quality of life of people with type 1 diabetes and has further implications in facilitating a shift to remote consultations which may be here for the long-term. The Association of British Clinical Diabetologists (ABCD) have produced a 'road to recovery' document to help risk stratify and guide decision making for handling the backlog of routine clinical care for diabetes. This document encourages a paradigm shift from 'routine appointments' to a more intuitive and responsive system in which resources are directed to people who need it the most. [54].

The uptake of diabetes technology in the UK has been lower than the expectations of the national guidance and lower when compared to other high income countries. [55].

More needs to be done now and as we rebuild and recover from SARS-CoV-2, we must grasp this once in a lifetime opportunity to reshape our services to provide better outcomes and quality of life for people with diabetes.

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The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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