

White Paper:

Current Challenges in Diabetes Care and How to Address Them

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The IDEAL Group is a multidisciplinary panel of diabetes specialists with a visionary outlook to improve diabetes care outcomes across the UK. The primary objective of IDEAL is to review current practice across the NHS to assess and recommend better ways to approach education, access and learning for people with diabetes. The IDEAL Group has expertise that spans across diabetes management, medicine, pharmacy, technology, nursing, health professional and patient education, psychology, commissioning and the perspective of living with diabetes. Their programme of action is focused on harnessing this professional expertise to build consensus, network, research, share knowledge and collectively seek to make things better; both for practitioners working in partnership with and for people living with diabetes.

Key Messages:

There are clear and unacceptable variations in the quality and processes of diabetes care delivered on a local and regional level across the UK.

Deficiencies in four key areas must be addressed to improve outcomes:

- Lack of relevant key performance indicators
- Accountability and benchmarking
- Value and quality in blood glucose monitoring
- Education and the digital age

This White Paper and the associated Recommendations Matrix present a systematic evaluation of the challenges in diabetes care. It introduces recommendations for how collaboratively, as key stakeholders in diabetes care and support, improvements in biomedical and psychological outcomes can be achieved with associated cost savings and reduced burden to the NHS, people with diabetes, and public health more broadly.

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1. INTRODUCTION – THE STATE OF DIABETES

Healthcare services are commissioned by Clinical Commissioning Groups (CCGs), Sustainability and Transformation Partnerships (STPs) and NHS England on a local, regional, and national basis. In October 2014, NHS England published its Five Year Forward View (which was updated in 2017) in which it stated that 'Managing the growing incidence of diabetes in England is set to be one of the major clinical challenges of the 21st century. Estimates suggest that the number of people with diabetes is expected to rise to 4.2 million people by 2030, affecting almost 9% of the population [NHS England, 2018].

Type 2 diabetes (T2D) accounts for 90% of all cases of diabetes in the UK (3,402,945 people) [Diabetes UK, 2017]. Lifestyle is a primary risk factor for the development of T2D, however genetic factors are also relevant and there are populations that are at increased risk (for example African-Caribbean and South Asian populations) [Diabetes UK, 2017]. The UK spends an estimated 10% of the annual NHS budget (£10 billion annually) on diabetes care, 80% of which is spent on diabetes-related complications [Baxter et al, 2016], most of which are preventable and could be reduced by early detection of pre-diabetes and improved management of blood glucose levels [NHS England, 2016]. The total impact on the UK economy, including indirect costs, was estimated to be £24bn [Hex et al, 2012].

Despite this huge investment and relevant NICE guidelines, the public health, medical and psychological burden of diabetes is intolerable and, if unaddressed, will continue to deteriorate exponentially.

2. THE PROBLEM(S)

The considerable financial, public health and personal costs of diabetes cannot be under-stated. All of these costs are modifiable, however, with targeted improvements in one area impacting positively the outcomes in another.

Taking the cost of hypoglycaemic episodes as an example, for the Maidstone & Tunbridge Wells NHS Trust, serving a population of 560,000, in the year 2016-2017 there were 91 episodes of hypoglycaemia as a primary diagnosis, with a cost of £149,325. In addition, there were a further 295 admissions where hypoglycaemia was a recorded secondary diagnosis (i.e. it was felt to be clinically relevant to the admission). The total cost for these episodes was £1,307,786. This gives an annual total of 386 admissions and a cost of £1,457,111 for the hospital in question.

For the same year, data from the Patient Cost Benchmarking group of IMS Quintiles (representing approximately 90 Trusts across England and Wales) reported a total of 8,744 primary diagnosis admissions for hypoglycaemia at a cost of £13,495,117. Hypoglycaemia as a secondary diagnosis caused a further 27,926 admissions at a cost of £114,335,149, giving a total of 36,670 admissions at a cost of £127,830,266 (data kindly provided by Patrick McGinley, Head of Costing and SLR, Maidstone & Tunbridge Wells NHS Trust).

Reducing the number of hypoglycaemic episodes, using effective blood glucose monitoring and management strategies, would not only reduce financial costs significantly, it would also reduce fear

of hypoglycaemia which is pervasive, widespread and debilitating, and improve psychosocial functioning and quality of life for people with diabetes (PWDs).

In addition, 80% of the cost of Type 2 diabetes goes on treating complications [House of Commons Public Health Report 2012-13], whilst consultation rates for people with diabetes rose from 5.4 to 11.5 visits per person per year from 1997 to 2007, with an increased adjusted cost of 216% (£98 to £313 per year) [Currie et al, 2010].

2.1 Lack of Relevant Measurable KPIs

The Best Practice Paediatric Tariff for diabetes, introduced in 2012, demonstrates clear criteria for diabetes care provision in England and Wales. This has seen a wholesale improvement in outcomes for children with diabetes over the past six years [NPDA, 2018]. No such tariff exists for adult diabetes services.

Eight care processes are recommended by NICE 'to support holistic and comprehensive care for people with diabetes' [NICE, 2014; NICE, 2016], however audit data shows there are significant variations between CCGs across England in terms of the provision of these processes. There is limited evidence available to show that the indices are always collected, and even less evidence to demonstrate whether they are acted upon.

As an example, Driskell et al. (2012) in an investigation of inappropriate requesting of HbA1c found that "...only 49% of requests conformed to guidance". Perhaps of more concern was the finding that under-requesting was more prevalent than over-requesting [Driskell et al 2012]. In a systematic review of 19 studies (not limited to diabetes) Callen et al. (2012) found that the number of laboratory tests not followed up for patients attending ambulatory settings (including outpatient clinics, academic medical or community health centres, or primary care practices) varied between 6.8% and 62%. Interestingly, in the context of the development of apps, the authors found that access was better in the case where electronic communication was employed [Callen et al 2012].

2.2 Accountability and Benchmarking

In 2016, Public Health England published a detailed analysis of the prevalence of type 1 and type 2 diabetes in England, which highlighted the variation in clinical care and outcomes across CCGs. The prevalence of diabetes ranged from 6.5% to 11.5%, with the highest prevalence in CCGs that had high proportions of African-Caribbean and South Asian populations and the highest levels of social deprivation [PHE, 2016]. Furthermore, the review states that the prevalence increase ranged from 6.3% to 24.6% by CCG, with those having high estimated increases in diabetes having projected significant increases in population age.

Considerable gaps exist in optimal care pathways across England, which have arisen for several reasons, including clinical factors, socio-demographic factors, local administrative and financial factors, and regional or demographic factors.

In 2016 Dietetic Services had on average 2.0 whole time equivalent (WTE) diabetes dietitians [BDA Diabetes Specialist Group, 2016]. This figure has barely changed since 2010 [Diabetes UK, 2010] despite the number of PWDs increasing from 2.6 million to 3.6 million in the same period. Inequity is reported in terms of the commissioning of dietetic services and the level of specialism across the Trusts and CCGs. Dietitians report the inability to impact diabetes outcomes and only seeing 'the tip of the iceberg', further due to low staffing numbers and an emphasis on structured patient education at the cost of reducing availability of individual care.

Pharmacists inherently play a huge part in long-term conditions (LTCs), including diabetes care delivery. Through the stages of drug formulary management/ commissioning, pharmacists often work as an integral part of CCGs medicines optimisation teams, by prescribing medicines in GP practices and MDT integrated care specialist centres, and dispensing medicines daily to PWD as Community pharmacists. Despite this, colossal challenges exist in getting commissioned training courses, and/or community pharmacy services to encourage the development and transfer of good practices that impact and improve patient outcomes significantly.

Pharmacy, as a whole, is often excluded in local diabetes care service delivery pathways, with community pharmacies often not acknowledge as an integral part of the primary care services delivery and referral pathway. Ensuring local service commissioners and NHS England invest in commissioning diabetes specific pharmacy services, to enhance SMBG follow-on care for PWDs is crucial.

2.3 Value and Quality in Blood Glucose Monitoring (BGM)

2.3.1 Quality of Data Interpretation and Action Related to BGM

There appears to be a lack of understanding of the value that measuring glucose readings can provide to people living with T2 diabetes, specifically in relation to understanding how diet, stress, sleep and exercise can impact their condition. Kempf et al. (2008) suggested that 'appropriate use of SMBG data by the patient may be improved by practical lessons that allow the patient to recognise the impact of high versus low glycaemic meals and of moderate physical activity such as 30 minutes of brisk walking'.

Many PWDs report measuring their blood glucose (BG) to inform the Health Care Professional (HCP) who would then provide instruction, however HCPs in contrast report prescribing SMBG as a tool for PWD to use to inform their self-management practices. What is clear is that this gulf in understanding and lack of appropriate support or guidance is untenable and in contradiction to the evidence that structured SMBG results in improved clinical outcomes. Furthermore, budget limitations often mean that some people with Type 2 diabetes are not given access to SMBG and so are unable to benefit from it.

2.3.2 Quality of device

Despite there being a published standard for the measurement of blood glucose (for self-monitoring of blood glucose) there is evidence to show from evaluation studies that there are measurement systems (blood glucose meters) available (being

recommended) that do not meet these standards [Freckmann 2012, Baumstark 2017, Klonoff 2018]. This situation also led to concern expressed in a statement by the European Association for the Study of Diabetes [EASD].

The accuracy standards of blood glucose meter systems encapsulated in ISO: 15197:2003, summarised by Diabetes UK stated that:

95% of blood glucose results should be:

- Within ± 0.83 mmol/L of laboratory results at concentrations of under 4.2 mmol/L
- Within $\pm 20\%$ of laboratory results at concentrations of 4.2 mmol/L or more

In 2013 new, tighter accuracy standards (released as ISO 15197:2013 and implemented in 2015 as EN ISO: 15197:2015) were drawn up, requiring that:

95% of blood glucose results should be:

- Within ± 0.83 mmol/L of laboratory results at concentrations of under 5.6 mmol/L
- Within $\pm 15\%$ of laboratory results at concentrations of 5.6 mmol/L or more

In addition, the guidelines also stipulate that:

- Three different lots of blood glucose strips should be evaluated and reported individually and combined,
- 99% of readings must fall within zones A and B of the Consensus Error Grid for Type 1 diabetes.
- That there should be a user performance study conducted with lay persons, i.e. to demonstrate that the system would work in the hands of the intended user using the same criteria as the laboratory study.

The current certification process for medical devices is performed by a Notified Body but there is no independent agency to verify device performance. Independent research has shown that several devices currently used in the UK do not meet the standards laid out by the ISO, and these findings are supported by the Blood Glucose Monitoring System Surveillance Program by the Diabetes Technology Society (DTS) [Ekhlaspour et al., 2017; Klonoff et al., 2018].

In terms of continuous glucose monitoring (CGM) systems, Danne et al (2017) state that continuous glucose monitoring should be considered in conjunction with HbA1c for the assessment of glycaemic status and for the adjustment of treatment in all people with type 1 diabetes and in people with type 2 diabetes who are treated with intensive insulin therapy and who are not achieving blood glucose targets, and is recommended for patients with episodes of hypoglycaemia. Some CGM systems require calibration with a finger-prick using an SMBG device. Crucially, that calibration must be done with a good quality, accurate BG monitoring system.

Currently, no internationally accepted standards exist for standardizing the accuracy of continuous and flash glucose monitoring systems that are comparable with the International

Organization for Standardization (ISO) 15197 standard for self-monitoring of blood glucose, ISO/IEEE FDIS 11073-10425 provides a definition of the communication between CGM devices and managers (such as cell phones, personal computers) (Garber et al, 2016).

Critically, recent evidence derived from real-world blood glucose results from over 150,000 people with type 1 diabetes showed that “use of more variable/less accurate blood glucose monitoring systems (BGMS) is associated both theoretically and in practice with a larger variability in measured HbA1c” [Heald et al. 2018]. There have also been a number of simulation studies that have drawn similar conclusions [Breton and Kovatchev 2010, Budiman et al 2013, Campos-Náñez et al. 2017] in relation to the increased risk of adverse outcomes, e.g. increased hypoglycaemic episodes. Furthermore, economic evaluations of the impact of inaccurate and imprecise glucose monitoring systems have concluded that poor analytical performance are associated with increased healthcare costs. [Budiman et al. 2013, Schnell and Erback 2014, Fortwaengler et al. 2018, McQueen et al. 2018].

2.4 Education

NHS Right Care identifies the need to improve uptake to structured education for PWDs within 12 months of diagnosis as a ‘national opportunity’ to better manage diabetes. However, the National Diabetes Audit (NDA) of 2016-17 found that in 2015, only 41.3% of people who were newly-diagnosed with type 1 diabetes were offered structured education within 12 months of diagnosis, while only 3.3% attended [NHS NDA, 2017]. Similarly, while 77.3% of people newly diagnosed with type 2 diabetes were offered structured education, only 7.4% attended, which means that out of more than 200,000 newly diagnosed people with diabetes, fewer than 15,000 attended health education programmes. The reasons for non-attendance are multi-factorial and complex. In view of the massive gulf between referral and attendance, there are unanswered questions about the ability of currently offered face to face programmes to meet the needs of those they are seeking to address.

The availability of health education, in the form of material and programmes, to encourage prevention of diabetes and control of diabetes, such as X-PERT, DESMOND and DAFNE, have been shown to improve glycaemic control, self-monitoring, clinical outcomes, as well as benefits for patient psychosocial adjustment to their diabetes [Deakin et al., 2006; Hopkins et al. 2012]. Furthermore, despite the challenges in identifying evidence-based, theory-driven and clinically relevant digital technologies and apps in App stores, a number have passed NHS Digital and QISMET accreditation and are now appearing on the NHS England app library. There are a host of apps becoming available, but few have been properly tested and validated in relation to their clinical effectiveness, so a quality assurance system is necessary to signpost high quality apps for PWDs. NHS England’s initial response to this challenge is welcome.

Ensuring inclusion for those with additional needs is demonstrated in current research work via the ‘Diabetes Attitudes Wishes and Needs (DAWN2) Severe Mental Illness’ trial, which is seeking

to design educational resources appropriate for people living with mental ill health and diabetes to address this unmet need [Taylor et al., 2017]. Those with learning difficulties and those with difficulty speaking or understanding English adequately to participate in group education are often excluded. It is also vital to provide culturally competent educational approaches in diabetes care to support engagement and outreach to potentially isolated communities [Zeh et al., 2018]. Structured cultural competence training for health practitioners can help support delivery of meaningful services to minority populations, to potentially maximise diabetes related outcomes in these populations. Rigidity in delivery also creates barriers to attendance for many.

Practitioners now have greater demands placed upon them because they are responding to increased demands due to the global crisis of diabetes [WHO, 2016]. Informed practice and an effective educated workforce are most effective as key drivers for potential change [Bos-Touwen et al, 2015]. Recognition by practitioners of the need for promotion of self-management skills is fundamental for delivery of effective person-centred care (NICE NG28, 2015; NICE NG17, 2015; NICE NG18, 2015; The Richmond Group, 2016). This is the core and consistent theme which runs throughout all recent NICE, and American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) guidance [Inzucchi et al., 2015, Davis et al, 2018].

However, the difficulties of diabetes care need to be considered alongside the needs of health practitioners to embrace evidence-based practice and delivery of effective person-centred care approaches. Sidani et al. (2016) suggested that there are some barriers in practice which can hinder practitioners from delivering evidence-based recommendations in practice, due to a lack of time, knowledge and limited access to funded professional educational opportunities. Lugtenberg et al. (2011) also demonstrated that practitioners are often still unaware of, and lack familiarity with, the latest evidence-based guidance to facilitate effective change in diabetes care. This need can be met by facilitating HCP access to regular structured diabetes educational opportunities which can then translate into more effective care delivery for people living with diabetes. This call to action needs NHS England and Health Education England to recognise that diabetes education, delivered through diverse mechanisms and pathways to meet the diverse needs of both HCPs and PWD is a fundamental need for effective, efficient and efficacious person-centred care within clinical practice.

2.5 Digital Opportunities

Chavez et al. (2017) evaluated a number of apps using a mobile app rating scale and concluded that the scores the apps received [did] not necessarily reflect their impact in terms of behaviour change and health outcomes. Brzan et al. (2016) in their review noted the variation in the number of features available in the apps they reviewed. A review by Izahar et al, (2017) of 35 mobile apps for diabetes showed that the design of diabetes mobile apps focused more “on reporting and setting reminders, rather than providing personalized education or therapeutic support”. They concluded that “in the future, the design of apps could be improved to integrate patients’ needs, usability for disease management,

and lifestyle modifications” [Izahar et al. 2017]. Whereas Hou et al (2016) undertook a systematic review and meta-analysis of 10 eligible randomised trials to assess the impact of the use of mobile apps on glycaemic control in the self-management of type 2 diabetes. There was inadequate data to describe an effect in type 1 diabetes [Hou et al. 2016]. All of the studies (with a total of 1360 participants) reported a reduction in the HbA1c, with a mean reduction of 0.49% (95%CI 0.30, 0.68). The authors pointed out the variation in the functionality of the apps and highlighted the need for standardisation in the functionality of apps. Kao et al. (2017) in a broader review of the current state and barriers to adoption of consumer mobile health apps reiterated several of the points made. They highlighted limited evidence available on clinical effectiveness and the lack of regulatory oversight.

3. SOLUTIONS

In 2016, a collaboration with the York Health Economic Consortium (YHEC), calculated the potential reduction in health costs through improvements in glycaemic control in adults with type 1 or type 2 diabetes in the NHS [Baxter et al., 2016]. The model estimated the potential accrued cost saving to the NHS of approximately £340 million in the first 5 years, increasing to approximately £5.5 billion after 25 years of sustained improvement in glycaemic control [Baxter et al., 2016].

The cost reduction was mainly due to the reduction in microvascular complications of diabetes [Baxter et al., 2016]. In people with type 1 diabetes, the main cost savings were from a reduction in renal disease (74%); in people with type 2 diabetes, the main cost savings were from a reduction in neuropathy, foot ulcers, and lower limb amputations (57%) [Baxter et al., 2016].

Some of the economic simulation models reported earlier, in relation to the use of poor analytical quality blood glucose monitoring systems, focussed more on the short-term consequences, e.g., hospital admissions associated with hypoglycaemic episodes [McQueen et al. 2018]. This is certainly borne out in the financial and resource burden identified for the real-life data from Maidstone and Tunbridge Wells NHS Trust and the benchmarking group referred to earlier.

In addition, it has been reported that there is an increasing incidence of diabetes-related amputations with costs in 2016 amounting to £46 million. It is also recognised that there is considerable variation across the country [Public Health England, 2016].

3.1 Lack of Relevant Measurable KPIs

The **Best Practice Tariff (BPT) for Diabetes** was introduced in 2012-2013 (and updated in 2017) as a mandated payment system applied to paediatric diabetes services in England. It sets the standard of care required for every child or young person with diabetes under the age of 19 years of age attending a paediatric diabetes clinic. The tariff payment was set at a level intended to enable access by children with diabetes to ‘consistent, high quality management of their diabetes, regardless of where it is delivered’ [NPDA 2011-12]. The criteria underpinning the BPT include the Department of Health guidance ‘Making every young person with diabetes matter’ [DH, 2007], NICE Clinical Guidance CG15 ‘Diagnosis and management of type 1 diabetes in children, young people and adults’ [2004], TA151 ‘Diabetes – insulin pump therapy’ [2008] and NHS Diabetes Guidance ‘Commissioning services for children and young people with diabetes’ [2010].

The National Paediatric Diabetes Audit (NPDA) national reports reflect the positive impact that the BPT appears to have had on diabetes management and outcomes for children. In the 2011-12 NPDA report, only 6.7% of children and young people with diabetes aged 12 years and over had all care processes recorded (HbA1c, Body Mass Index, Blood Pressure, Urinary Albumin, Cholesterol, Eye Screening and Foot Examination). In the 2016-17 report [NPDA 2016-17], this figure had increased to 43.5% (up from 35.5% in 2015-16). Furthermore, almost three quarters of children and young people with type 1 diabetes were recorded as receiving structured patient education in 2017-18, which was in addition to the four clinic visits and up to eight additional contacts with specialist services required in the BPT.

The 2016-17 report shows that diabetes management has improved for the seventh consecutive year, with increasing numbers of children and young people with type 1 diabetes regarded as achieving ‘excellent’ control. In 2011-12, only 17.4% of children and young people with diabetes had an HbA1c of <58 mmol/mol (<7.5%) as compared with 28.9% in 2016-17. Whilst there remains a way to go in terms of percentages of children reaching the optimal target, consistent improvements year on year are promising, particularly when considered alongside the reducing numbers of children with HbA1c results of >80 mmol/mol (>9.5%) from 25.1% in 2011-12 down to 16.4% in 2016-17. A similar approach could be adopted in adult services.

	All patients		Patients without long-term diabetic complications		Patients with long-term diabetic complications	
HbA1c category (%)	Unadjusted	Adjusted*	Unadjusted	Adjusted	Unadjusted	Adjusted
< 8	7.3	8.5	2.5	3.1	19.3	21.2
8 – 10	11.0	10.7	3.5	3.5	27.1	25.5
> 10	16.7	17.8	7.9	8.3	35.0	38.3

Proportion of patients with one or more inpatient stay for short-term complications over a three year period [Menzin et al., 2001]

The **International Consensus for Health Outcome Measures (ICHOM) Standard Set for Diabetes in Adults: Type 1 diabetes and Type 2 diabetes** includes all treatment approaches i.e. non-pharmacological therapy, non-insulin based pharmacological therapy and insulin-based pharmacological therapy for adults aged 18 years and above. The standard set focuses on patient-centred results and provides an internationally agreed upon method for measuring each of these outcomes. This facilitates a comparison of performance globally, enabling clinicians to learn from each other and rapidly improve the care PWDs receive. The sets are implemented by sites downloading the reference guide from the ICHOM website free of charge and incorporating it into their systems, or by using the ICHOM implementation team to support sites in adopting the measures, enabling benchmarking of the outcomes [ICHOM, 2018]. However, the range of KPIs needs to be broadened to embrace accountability of all stakeholders, e.g. including commissioners, service procurers and service provider organisations – as well as PWDs, clinicians and carers - in order to fulfil the commitments to the diabetes population at large - and to take action when poor performance is highlighted.

3.2 Accountability and Benchmarking

Models of excellence have been developed in several CCGs utilising effective education, accurate SMBG and increased engagement. These improvements in outcomes do not appear to have come at higher financial cost. Thus, sharing of best practice could result in widespread improvements in clinical, psychosocial and financial outcomes. Involvement of, and collaboration with, all key stakeholders is essential, with the Diabetes UK 'Taking Control' campaign one example of initiatives aimed at increasing the provision and uptake of diabetes self-management education, so that everyone with diabetes has the skills and confidence to take control of their condition.

Pharmacy has a wide reach with hospital and community pharmacies having a role in improving outcomes for PWDs. Pharmacists are the most frequently seen healthcare professional (3-8 times more frequently than other individuals) [Ali et al. 2012]. Emphasis on the importance of treatment maintenance is demonstrated by Brunton et al. (2017) in an analysis of 11,272 veterans with T2D with a mean follow-up of 5 years. For each 10% increase in the medication possession ratio, the mean HbA1c decreased by 0.24% [Brunton et al., 2017]. The Pharmacist-led type 2 diabetes service in Slough UK led to the improvement of PWD care processes outcomes [Langran et al., 2017]. Several further examples of good practice can be found on the Pharmaceutical Services Negotiating Committee (PSNC) website.

In London UK, AT Medics utilised a Pharmacist-led data driven approach to proactively improving healthcare at scale, improving delivery of care processes (86% compared to previous 40%) and reducing the variation between the highest and lowest performers from 82% to 30% for 8 care processes [Shivani et al., 2018]. Lloyds Community pharmacy has invested in developing readily available diabetes and Ramadan toolkits intended to be used by all clinicians to improve diabetes care during fasting seasons, raising awareness and providing support campaigns for the general public via their diabetes roadshows events, which has led to a 29% uplift

in type 2 diabetes screening instore month on month [Deep et al. 2018].

Overall the evidence suggests that investment in pharmacy diabetes interventions offers a positive return in terms of economic sustainability, enhanced PWDs self-management and improved diabetes therapeutic outcomes, [Wang et al., 2016; Fazel et al., 2017; van Eikenhorst et al., 2017]. Improved access to training and better IT access to medical records to ensure continuity of care across sectors of diabetes care delivery is the cornerstone of reproducing such good practice.

Dietitians are degree-educated registered health professionals with the qualification to translate the science of nutrition into understandable, practical information about food, enabling people to make appropriate lifestyle and food choices. Dietetic intervention in newly-diagnosed type 1 diabetes can offer an additional 8 mmol/mol (0.7%) improvement in HbA1c (Kulkarni et al., 1998). Reductions of up to 21mmol/mol reported in type 2 diabetes (Franz et al., 2008), with intensive dietary interventions in T2D being associated with improved glycaemic control (Coppell et al., 2010; Deakin et al., 2006). Furthermore, dietetic intervention has shown to be cost effective and result in fewer visits to both physicians and health services, as well as reducing the need for diabetes medication [Pastors et al., 2002].

There is clear international guidance from the International Society for Paediatric and Adolescent Diabetes (ISPAD) that there should be a dietitian involved in an interdisciplinary diabetes paediatric diabetes team, as a minimum (ISPAD, 2011). Diabetes UK have made recommendations [Twenefour & Dyson, 2018], which would provide the capacity to increase the time for enhanced provision of individual advice to PWD, increase the role of dietitians by expanding the numbers trained in prescribing, perform more audit of the impact of dietetic-led services and provide more education time and mentoring for MDT members.

Patient-Reported Outcomes (PROs) should be routinely assessed in as part of diabetes best practice. The clinical management of people with diabetes requires a holistic approach that includes the clinical, lifestyle, and psychosocial aspects of the individual people with diabetes. Increasingly, the perspective of the individual regarding their illness and their treatments has become acknowledged when making decisions regarding diabetes health care. Knowledge of the patient's response to medical advice and treatment are of value, and it has been shown that PROs for changes in lifestyle, blood glucose monitoring, and treatment are associated with improved self-management and create an increased sense of involvement in the care pathways by PWDs [Inzucchi et al., 2012; Reaney et al., 2014]. PROs have particular value in the assessment of new treatments, including the use of medical devices, and in clinical trials [Inzucchi et al., 2012; Reaney et al., 2014].

3.3 Quality of Blood Glucose Measurement

It is clear from the evidence obtained from real-life data on the impact of poor analytical performance of blood glucose strips on HbA1c, that steps need to be taken to better understand the impact on resource utilisation across the whole care pathway.

It has been suggested that the poorer performing blood glucose strips have been procured in order to save money. This may, in fact be a false economy as the long-term effects may lead to poorer patient outcomes and an increase in resource requirement.

It is imperative to:

- Make purchasers aware of the adverse impacts of choosing poorer quality blood glucose monitoring systems.
- Advocate the re-establishment of regulation of blood glucose strips through a UK-based technology evaluation unit. This would align to the EASD's statement on medical devices [EASD 2013] which urges other countries to use the same model of excellence as the Scandinavian evaluation of laboratory equipment for primary health care, SKUP, (<http://www.skup.nu>), irrespective of the blood glucose meter having a CE mark through a notified body.
- Consider the introduction of a regular audit process based on Heald et al.'s approach.
- Ensure HCPs are aware of their regulatory obligation to reporting quality issues and adverse events associated with blood glucose meters via the MHRA Yellow Card Scheme (<https://yellowcard.mhra.gov.uk/>)

3.4 Education and the Digital Age

The Structured Education Programme for Adults with type 1 and type 2 Diabetes, Recommended by the National Institute for Health and Care Excellence (NICE) (NICE, 2016)

The following programme recommendations include:

- The components should be evidence-based and suit the needs of the individual person.
- The programme should have specific aims and learning objectives and support the individual, their family members, and their carers to develop attitudes, beliefs, knowledge, and skills to lead to the self-management of diabetes.
- The programme should have a structured curriculum that is theory-driven, evidence-based, resource-effective and has supporting materials, including written instructions.
- Information and instructions should be delivered by trained educators who have an understanding of educational theory appropriate to the age and needs of the patient and who are trained to deliver the programme.
- The educational programme should be quality assured, and reviewed by trained, competent, and independent assessors to ensure consistency.
- The programme's educational outcomes should regularly be audited.

Whilst structured education is considered the gold standard, it must be remembered that education can be carried out in routine clinic appointments every day. Formalising this education into a measurable, actionable checklist would enhance the skills of PWDs and address some of the barriers to uptake of traditional structured

education approaches. Having HCPs educated in diabetes care can enable this to happen more effectively.

In view of the substantial unmet need of education and support for PWDs, as well as the pervasive use by many of digital technologies in everyday life, it is perhaps unsurprising to see a burgeoning number of apps seeking to address the needs of PWDs. The urgency to find effective, evidenced-base solutions is recognised, not least by NHS England with their recent change in stance to encourage recipients of Transformation Funding to use up to 20% on digital solutions. Likewise, the new Diabetes Prevention Programme currently being commissioned by Public Health England asks for 20% of the volume to be provided by evidenced digital solutions. In a fast changing environment where access to education is clearly inadequate, we welcome NHS England and PHEs attention to improve access to evidenced based tools.

It is crucial to support cultural competence education for HCPs in diabetes care delivery to promote engagement of socially excluded communities who are at increased risk and need. Furthermore, we live in an environment whereby many people access a huge amount of information via digital channels. Many PWDs do likewise. There is an urgent need for commissioners and providers of care to make information accessible in a manner fitting to the way they live their lives.

4. CONCLUSIONS

The current and projected prevalence of diabetes pose an unprecedented challenge for healthcare delivery and the NHS. There is a pressing need for all key stakeholders to collaborate effectively and progressively to address the current shortcomings in diabetes care quality and outcomes. Considerable variation exists across the country which presents opportunities for benchmarking for delivery of diabetes care and the sharing of best practice. Evidence of regular education updates for HCPs working with PWDs is essential to ensure provision of high-quality healthcare, alongside novel and innovative mechanisms to deliver structured education to PWDs.

The development and implementation of a KPI system that embraces the contribution of all stakeholders across the diabetes management pathway is necessary to ensure best-practice and delivery of devices, such as blood glucose monitoring, to optimise outcomes for PWDs and reduce NHS burden through wastage or preventable diabetes-related complications due to inferior quality devices.

Primary Action Required

Action is required to ensure provision of best-practice diabetes healthcare and accountability through adherence to NICE guidelines and compliance through key performance indicators (KPIs) as evidenced in clinical outcomes.

A strong collaborative effort across all key stakeholders must be sought to ensure collective action on a grand scale, to reduce costs and public health burden, but most importantly, to reduce the unacceptable personal cost to every individual with diabetes and those that support them. Therefore the recommendations advocated within this white paper focus key areas for improvement with manageable timescales to make the changes required.

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