iDEAL Position Statement

# Safety and accuracy in self-blood glucose monitoring with accompanying individualised education

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This position statement lays the case for improvement and aims to build consensus in response to NHS England's consultation statement on self-monitoring of blood glucose (SMBG) by people with type 2 diabetes (NHS England, 2018). The consultation advises *'The proposed recommendations on glucose testing strips and needles are focussed on substitution for cheaper, but equally effective products…the aim is to ensure consistency across the country and encourage commissioners and prescribers to consider the more cost-effective options to release savings, while not affecting patient care.'*

This position statement gives iDEAL's response to this consultation and emphasises the need to focus on the performance, quality, safety, accuracy and choice of blood glucose monitoring systems, together with education and support to meet each individual's needs when introducing or using SMBG in people with type 2 diabetes (T2D).

The iDEAL Group is a multidisciplinary panel of diabetes experts tasked with identifying novel ways to improve diabetes care outcomes across the UK. On World Diabetes Day 2018 we set out the key recommendations from the published White Paper 'Current Challenges in Diabetes Care and How to Address Them' (https://idealdiabetes.com/) one of which focusses on SMBG.

| Outstanding needs to be addressed |
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| • Lack of relevant key performance indicators |
| • Accountability and benchmarking |
| • Value and quality in blood glucose monitoring |
| • Improving access to education and support in the digital age |

**KEY POSITION STATEMENT RECOMMENDATIONS:**

- **Endorsement of the requirement for the NHS when considering people with type 2 diabetes who need to use SMBG, to ensure that only good quality safe, accurate SMBG systems meeting internationally recognised performance ISO standards are available, in conjunction with individualised education and support for the individuals needs in order to live with their diabetes.**

- **The independent evaluation of all SMBG strips and meters available in the UK based on internationally recognised performance, accuracy and safety standards, prior to procurement by the NHS and recommendation to people with diabetes.**

- **The standardisation and benchmarking of good quality, accurate blood glucose systems so CCGs can use valid clinical data not simply a costing tool to arrive at prescribing policies that favour people with diabetes.**

- **The introduction and piloting of a Key Performance Indicator (KPI) for primary care practitioners relating to the provision of diabetes related education, using a variety of different approaches depending on each individual's needs. Also adoption of culturally appropriate approaches in primary care such as the 'Stepping Up' approach for effective and planned diabetes care (Furler et al. 2017, Zeh et al. 2018).**

The key recommendations in this position statement should harness professional expertise and patient experience to generate consensus in networking, sharing of excellence in practice, research, clinical effectiveness and knowledge outreach to improve care. When implemented, they shall reduce clear and unacceptable variations in quality and processes of care for people with diabetes, while improving knowledge, effective education, care abilities and engagement of practitioners and empowerment of people living with diabetes.

Outstanding deficits have been identified in four key areas relating to people living with type 2 diabetes. It is essential to identify and distinguish which type of diabetes is being referred to in all documentation, as well as governmental and media reporting, to avoid misrepresentation and misunderstanding.

# THIS POSITION STATEMENT CALLS FOR:

## EVIDENCE

SMBG is an unequivocal essential requirement of care for people with type 1 diabetes across the age span (NICE NG17, 2016, NICE NG18, 2015).

Evidence has been widely published regarding the lack of consensus and evidence about the effective and efficaciousness of SMBG routinely in people with non-insulin treated type 2 diabetes without supporting individualisation and education (Farmer et al, 2010, Farmer et al, 2012, Clar et al, 2010, Simon et al, 2018, Klatman et al, 2018). SMBG can be useful for people with type 2 diabetes treated with insulin and at risk of hypoglycaemia (NICE NG28, 2017), and is required when individuals using insulin or a hypoglycaemia risk treatment are driving in accordance with the DVLA Standards (Gov.UK, 2018). A Cochrane review by Malanda et al, (2012) and a RCT by Young et al, (2017) both reported that routine SMBG does not significantly improve HbA1c or quality of life related behaviours for most people with non-insulin treated type 2 diabetes. However, what was identified from this evidence was a lack of a structured educative approach and support to enable people to gain knowledge about the purpose and interpretation of their SMBG. This was advocated by Polonsky and Fisher, (2013) who advised that introduction and use of SMBG in an unstructured way has little clinical benefit without providing the knowledge and upskilling the user. Clar et al (2010) also demonstrated a variation between expectations of many practitioners and people with diabetes in terms of the use of SMBG.

People with diabetes who need, or are advised to use SMBG, should have some choice in the SMBG systems available to them. Also, the SMBG systems made available should be based on internationally recognised ISO performance, accuracy and safety. The type of device also needs consideration of the needs of the user, for example, more complex or sophisticated devices with Bluetooth technology may be appropriate for people with type 1 diabetes using insulin pumps or MDI. For people with type 2 diabetes who need to use SMBG, having a range of systems with less complicated features available, may be entirely appropriate when SMBG is being used for trend data purposes. What is imperative is the performance, accuracy and safety of each SMBG system offered is able to meet the needs of the users and also NHS procurement. This will avoid less accurate and less safe SMBG systems currently used, which do not meet the ISO quality standard requirements (2015) in place (Klatmann et al, 2018, Heald et al, 2018).

> This position statement endorses this requirement for the NHS when considering people with type 2 diabetes who need to use SMBG, to ensure that only good quality safe, accurate SMBG systems meeting internationally recognised performance standards, are available, in conjunction with individualised education and support for the individual needs in order to live with their diabetes.

## ACCURACY OF DEVICES

As identified in the 2018 iDEAL The White Paper (**https://idealdiabetes.com/**) there is concern at the absence of an independent system to verify blood glucose testing device performance and evidence (Freckmann et al, 2012, Baumstark et al, 2017 and Klonoff et al 2018, endorsed by the European Association for the Study of Diabetes (EASD), 2018). This highlights the concern about SMBG system accuracy and variability which accords to several lower quality and SMBG systems currently available in the UK, which do not meet the ISO standards (2015) for blood glucose systems. Currently, each manufacturer self-reports their CE marking for their product. However, several devices are currently being utilised which have been shown not to meet the performance standard required in an independent laboratory. Critically, recent evidence Heald et al (2018) and McQueen et al, (2018) derived from real-world blood glucose results from over 150,000 people with showed that "use of more variable/less accurate SMBG is associated both theoretically and in practice with a larger variability in measured….HbA1c".

This position paper advocates for not choosing the lowest cost alternatives which are less accurate and can cause patient harm. Budiman et al, (2013) and McQueen et al, (2018) identified that inaccurate blood glucose devices are associated with increased rates of severe hypoglycaemia and avoidable hospital admission due to their system variability. Therefore, Klatman et al (2018) publishing in The Lancet calls for SMBG supplies to be subjected to mandated verification and standards with a unified assessment by independent authorities to ensure accuracy and reduce bias (Freckmann et al, 2014). At the same time, recognition of the different needs of people with diabetes and the types of internationally recognised ISO standard SMBG systems available in terms of their use and user appropriateness need to be available.

> This position statement calls for the independent evaluation of all SMBG systems available in the UK based on internationally recognised performance, accuracy and safety standards, prior to procurement by the NHS and recommendation to people with diabetes.

This position statement calls for standardisation and benchmarking of good quality, accurate blood glucose systems so CCGs can use valid clinical data not simply a costing tool to arrive at prescribing policies that favour people with diabetes.

This position statement endorses this requirement for the NHS and for people with type 2 diabetes who need to use SMBG, to have access to good quality individualised education and safe, accurate SMBG systems suitable for their needs in order to live well with their diabetes.

## SMBG EDUCATION

Introduction and use of SMBG in people with type 2 diabetes offers little or no clinical or health-related benefit if unaccompanied by individualised appropriate education to increase knowledge gain (Polonsky et al, 2001, Polonsky and Fisher, 2013, Farmer et al, 2012, Farmer et al, 2007).

Evidence has identified the fundamentals to effective SMBG must include person-centred, culturally appropriate diabetes education with regular updates and reviews of knowledge and SMBG technique (Clar et al, 2010, TREND, 2017, Furler et al, 2017, Zeh et al, 2018). Additionally, accessible diabetes education for people living with severe mental health and diabetes (Taylor et al, 2016) or with a learning disability and diabetes requires effective reasonable adjustment to meet each individual's needs (DoH, 2016, Smith and Phillips, 2018). Evidence from RCTs such as the STeP Trial (Fisher et al, 2012) reported that structured SMBG with education can increase individuals' self-confidence and their understanding and abilities in effective self-management. Polonsky et al (2011) also reported structured SMBG with accompanying education resulted in timely treatment changes which improved glycaemic control and also general wellbeing. Using SMBG in people with type 2 diabetes can establish trend data in relation to nutrition, physical activity and medications (Schnell et al, 2015, TREND, 2017), however unless accompanied with accessible and individualised education, this can be an uneconomic approach in relation to health or knowledge gain (Farmer et al, 2012).

Education can be accessed in a variety of ways, including face to face structured education. However NHS Right Care (2018) and the NHS Diabetes Audit (2017) have both identified uptake of this format across the country is poor. There is considerable scope to dramatically improve access by making available evidenced based and accredited digital channels. Opportunities to provide access to material and support during reviews and consultations should also be exploited. Each method of delivery needs to accord to the needs of the user in terms of acceptability, health literacy, numeracy and culture (Zeh et al, 2018). This approach encompasses each member of the diabetes team in sharing diabetes education including increased use of diabetes educated pharmacists.

Education, as identified in the iDEAL White Paper 2018 (https://idealdiabetes.com/), needs to encompass both practitioners and people with diabetes. Upskilling knowledge and enabling effective self-management in decision making and treatment adjustment as a result of SMBG is the desired outcome (Davis et al, 2018). Having engaged practitioners with current evidence and upskilled in their knowledge about diabetes care can act as the catalyst to make a real difference to people living well with diabetes (Phillips, 2017). Therefore 'making every contact count' (NHS Health Education England, 2018) should ensure each person's knowledge and support needs are met.

## RECOMMENDATION

Introduction of key performance indicators (KPI) to measure and record individualised education having been provided and acted upon by both each person with diabetes and their practitioner, with the aim of upskilling the interpretation and understanding of SMBG results. This KPI will be part of a regular quality measurement in the diabetes care pathway which relates to both the SMBG measurements and the action taken by individuals with type 2 diabetes and practitioners. This maintains accountability and is an important part of NICE (2015) guidance on performance and quality in practice, this also accords with the Health Quality Improvement Partnership (2016) Guidance. The outcome measures of this KPI are the recorded actions of the outcomes of SMBG and knowledge gain in each individual. This can be measured in terms of self-confidence, HbA1c, knowledge gain and quality of life. A pilot site introduction in general practice of the KPI will occur initially before a national roll out by iDEAL.

This position statement calls for the introduction and continued evaluation of KPIs for primary care practitioners relating to the provision and outcome of diabetes related education, using a variety of different approaches depending on the individual's needs. In addition, the adoption of educational methods in primary care such as 'Stepping Up' for effective and planned diabetes care (Furler et al, 2017, Zeh et al, 2018) are called for.

**Further development of the iDEAL Group proposals will be regularly reported back via the iDEAL Website (https://idealdiabetes.com/) and social media via Twitter (@iDEALdiabetes) and we will continue to reach out at every opportunity at all levels of engagement to achieve these goals.**

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## NOTES

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