**DIABETIC**Medicine

DOI: 10.1111/dme.12977

### **Research: Health Economics**

# Promoting health and reducing costs: a role for reform of self-monitoring of blood glucose provision within the National Health Service

S. Leigh<sup>1,2</sup>, I. Idris<sup>3</sup>, B. Collins<sup>2,4</sup>, P. Granby<sup>1,2</sup>, M. Noble<sup>1</sup> and M. Parker<sup>1</sup>

<sup>1</sup>Lifecode<sup>®</sup> Solutions, Liverpool, <sup>2</sup>Liverpool Health Economics, University of Liverpool, Liverpool, <sup>3</sup>Division of Medical Sciences and Graduate Entry Medicine, University of Nottingham, Nottingham and <sup>4</sup>Public Health, Wirral Council, Wirral, UK

Accepted 29 September 2015

#### **Abstract**

**Aim** To determine the cost-effectiveness of all options for the self-monitoring of blood glucose funded by the National Health Service, providing guidance for disinvestment and testing the hypothesis that advanced meter features may justify higher prices.

**Methods** Using data from the Health and Social Care Information Centre concerning all 8 340 700 self-monitoring of blood glucose-related prescriptions during 2013/2014, we conducted a cost-minimization analysis, considering both strip and lancet costs, including all clinically equivalent technologies for self-monitoring of blood glucose, as determined by the ability to meet ISO-15197:2013 guidelines for meter accuracy.

Results A total of 56 glucose monitor, test strip and lancet combinations were identified, of which 38 met the required accuracy standards. Of these, the mean (range) net ingredient costs for test strips and lancets were £0.27 (£0.14–£0.32) and £0.04 (£0.02–£0.05), respectively, resulting in a weighted average of £0.28 (£0.18–£0.37) per test. Systems providing four or more advanced features were priced equal to those providing just one feature. A total of £12 m was invested in providing 42 million self-monitoring of blood glucose tests with systems that fail to meet acceptable accuracy standards, and efficiency savings of £23.2 m per annum are achievable if the National Health Service were to disinvest from technologies providing lesser functionality than available alternatives, but at a much higher price.

**Conclusion** The study uncovered considerable variation in the price paid by the National Health Service for self-monitoring of blood glucose, which could not be explained by the availability of advanced meter features. A standardized approach to self-monitoring of blood glucose prescribing could achieve significant efficiency savings for the National Health Service, whilst increasing overall utilisation and improving safety for those currently using systems that fail to meet acceptable standards for measurement accuracy.

Diabet. Med. 33, 681-690 (2016)

#### Introduction

Self-monitoring of blood glucose (SMBG) is a fundamental component of ongoing diabetes self-management, enabling improved glycaemic control [1], the identification and confirmed resolution of hypoglycaemia [2] and significant improvements in health, well-being and all-cause mortality [3] among those achieving the maintenance of near-normal blood glucose levels [4]. Yet, whilst the benefits associated with SMBG are considerable, reaching £150 m in 2010 [5] and increasing year-on-year [6], so too are the costs. With the rising prevalence and incidence of diabetes [7], SMBG is now

a major contributor to National Health Service (NHS) prescribing spending [5,6].

In spite of increased spending on SMBC, as many as 47% of

In spite of increased spending on SMBG, as many as 47% of individuals with Type 1 diabetes mellitus are currently not having their needs met as a result of SMBG prescribing quotas that restrict access to strips, with 34% of all quotas resulting from cost-cutting measures by clinical commissioning groups [8]. Two-thirds of individuals with SMBG prescribing shortfalls cite a subsequent reduction in their ability to adequately control their diabetes [8], including reductions in hypo- and hyperglycaemia detection and adequate checks before driving, and the ability to monitor glucose levels during periods of illness. This increases the likelihood of hospitalization, the principal driver of diabetes-related costs [9].

Correspondence to: Simon Leigh. E-mail: sleigh@liv.ac.uk

#### What's new?

- This study is the first of its kind to combine information concerning costs of self-monitoring of blood glucose, meter accuracy (ISO-15197:2013) and advanced meter feature availability, for every self-monitoring of blood glucose system funded by the National Health Service.
- The study uses data detailing exactly how all 581 million self-monitoring of blood glucose test strips and 150 million lancets prescribed were distributed between brands.
- During the study period, one in 14 (42 million) selfmonitoring of blood glucose tests were performed with systems that fail to meet ISO-15197:2013 accuracy standards, at a cost of £12 m.
- Self-monitoring of blood glucose prescribing costs varied by up to 19 pence per test, depending on brand.
- Annual self-monitoring of blood glucose efficiency savings of £23.2 m are achievable without compromising care.

Given the numerous attempts by clinical commissioning groups to regulate escalating SMBG costs [10-12], and the 'postcode lottery' that currently exists with respect to SMBG prescribing, in terms of both the volume of testing and the systems recommended for use [8,13], it would seem unlikely that each of the many technologies currently subject to reimbursement by the NHS are of equal clinical and cost-effectiveness. As such, a coordinated and standardized approach to SMBG prescribing, informed by costeffectiveness, has the potential to achieve significant efficiency savings for the NHS, without compromising care. These savings may then be re-allocated to improve diabetes management, either through increasing access to cost-effective options for SMBG, or as previously suggested, by increasing access to publically funded insulin pumps [14].

The present health economic assessment, the first of its kind, aims to provide decision-makers with a framework to assess the multitude of SMBG technologies currently available and in use within the NHS, based entirely on their respective costs, accuracy and clinical benefits, in order to achieve the greatest benefit per NHS pound spent, reduce escalating SMBG prescribing costs, and improve the overall standard of care for those with diabetes mellitus.

#### **Materials and methods**

#### Choice of economic model

A cost-minimization analysis was conducted from an NHS perspective in order to assess the costs and clinical charac-

teristics of the numerous SMBG technologies currently funded by the NHS. This methodology is a form of cost-effectiveness analysis, whereby a predetermined objective, in this case the measurement of blood glucose concentrations, is achieved via the adoption of the least costly of one or more 'clinically equivalent technologies'.

As every blood glucose meter is slightly different, no two tests of the same droplet of blood are likely to produce the same result. This is partly attributable to the large array of interfering factors which may influence the results, including blood oxygen concentrations and humidity [15], haematocrit [16], temperature [15] and altitude [17], but also the fact that no technology is 100% accurate, with measurement biases of between (-) 14.1% and (+) 12.4%, common within the glucose monitors currently in use within the NHS [18]. For this reason, we defined 'clinical equivalence' as the ability to conform to the recently updated international standard for meter accuracy currently adopted by the NHS, the Conformité Européene ISO-15197:2013 guidelines for blood glucose measurement. Specifically, monitors must show that 95% of their results are within  $\pm 0.83$  mmol/l of the results of the manufacturer's measurement procedure at glucose concentrations of <4.2 mmol/l, and within  $\pm 15\%$  for glucose concentrations ≥5.5 mmol/l. Any SMBG systems identified that fell short of these accuracy criteria, as determined by the recent evaluations of 56 blood glucose monitors by Khan et al. [19] and Freckman et al. [18,20] were excluded from our primary analysis, because of the increased likelihood of significant morbidity resulting from incorrect insulin dosing [21] and hypoglycaemia detection [22].

#### Data collection and model development

Data were obtained from the Health and Social Care Information Centre (HSCIC) [23], concerning all 8 340 700 prescriptions dispensed in England between April 2013 and March 2014, relating solely to the measurement of blood glucose. From the HSCIC database we identified every brand of blood glucose test strips and lancets dispensed over this period, the number of prescriptions for each, and their associated net ingredient costs, equal to the purchase price before the deduction of confidential discounts, negotiated with manufacturers.

The British National Formulary was used to identify which blood glucose monitors dispensed during the study period were still subject to NHS reimbursement and also to determine which monitors were compatible with each brand of available test strips, as strips may often be compatible with more than one brand of glucose monitor. We subsequently referred to the user manuals for every glucose monitor identified in order to determine the brand of disposable lancets compatible with the 'stock' lancing device provided with each glucose monitor.

Combining the net ingredient costs of each lancet and SMBG test strip product, we estimated the 'cost per test'

associated with each available test strip, lancet and monitor combination funded by the NHS during the study period. Unlike previous analyses [15], the expected costs of training individuals to use glucose monitors were excluded, as training will be necessary for all glucose monitoring systems, resulting in no incremental difference in costs between one system and another.

#### Taking account of advanced meter features

Because diabetes mellitus has a heterogeneous patient profile, affecting people of all ages and levels of comorbidity, it is reasonable to assume that those practising SMBG will exhibit widely varying underlying health states. As such, the clinical needs of these individuals are also likely to be very diverse, requiring varying levels of care, support and assistance in order to achieve the greatest effect.

After a comprehensive review of the SMBG literature, we identified seven advanced features of glucose monitors, currently available in varying degrees, which were deemed likely to be of clinical importance, albeit in varying degrees, to SMBG users: (1) notifications and alarms to remind to test blood sugar; (2) alternate site testing; (3) ability to measure ketones; (4) bolus insulin adjustment guidance; (5) audible output for those registered as blind; (6) 7- and 14-day + glucose level average; and (7) option to download and analyse blood glucose data via USB data transfer.

We subsequently determined which SMBG systems provided access to each of these features, identifying any 'withingroup' variations in the price of such systems, in order to determine the most cost-effective options available within each subgroup. For any systems that were strictly dominated, that is, they were not only more expensive but also provided fewer advanced features than similar alternative options, we provided recommendations for disinvestment and for switching usage to such lower-priced options. In doing so, we estimated the overall budget impact of switching, along with any additional benefits that may be accrued as a result of improved access to a greater number of advanced meter features that were previously unavailable.

Because our analysis is based on net ingredient costs and not the confidentially negotiated 'true price' paid by NHS purchasers, we additionally provide a summary table listing the discounts that must be achieved when purchasing SMBG strips, and deducted from the listed net ingredient cost, such that clinically equivalent yet initially more expensive technologies, become as cost-effective as lower-priced alternatives.

#### Results

#### Systems for SMBG currently in use within the NHS

Forty-four brands of SMBG test strips were reimbursed through the NHS during the analysis period, compatible with

51 blood glucose monitors and representing 22 manufacturers. This resulted in a total of 56 glucose monitor, test strip and lancet combinations. Of these, we omitted five brands of SMBG strips no longer available as part of the NHS standard of care (Accucheck Active, Accucheck Advantage, Accucheck Compact, Onetouch Ultra and Sensocard) and a further eight glucose monitors (Gluco RX Original, IME-DC, One touch Verio Pro, Contour XT, Microdot +, Element, GlucoRX Nexus Voice (TD-4280) and the Omnitest 3) because of failure to comply with ISO-15197:2013 meter accuracy standards, leaving a total of 38 suitable test strip and glucose monitor combinations.

The mean (range) cost of test strips and lancets for the 38 applicable glucose monitor and test strip combinations were £0.27 (£0.14–£0.32) and £0.04 (£0.02–£0.05) per test, respectively. This resulted in a sample average of £0.31 per SMBG test, but after taking account of the 4:1 prescribing ratio of SMBG strips to lancets, as demonstrated by the HSCIC, this reduced to ~£0.28 per test. The variation in costs was also substantial, with a range of £0.19 per test (£0.18–£0.37), as shown in Table 1, suggesting that some SMBG systems have a list price more than double that of available alternatives.

## Does the availability of advanced meter features result in a higher price per test?

As shown in Fig. 1, the distribution of 'cost per test' for the 38 applicable SMBG systems listed in Table 1 was subject to considerable positive skew. As such, the vast majority of blood glucose tests performed over the study period (84.%) were carried out at a cost of £0.34–£0.36 per test, whilst SMBG systems offering a total of four advanced meter features were, on average, priced equivalent to those providing just one, at £0.30 per test. After adjusting for the capability of SMBG systems to provide specific advanced features, a significant degree of 'within-group' variation in price remained, as shown in Fig. 2, nullifying our prior hypothesis of a positive correlation between market price and the availability of advanced meter features.

## Usage of SMBG systems failing to meet ISO-15197:2013 safety standards

Since initially being awarded Conformité Européene marketing approval, a total of eight NHS-funded SMBG systems failed to conform to internationally accepted standards for blood glucose measurement accuracy, when independently re-tested under laboratory conditions (Table 2). These systems accounted for ~41.6 m of the 581.2 m blood glucose tests funded during the study period, suggesting that almost one in 14 tests (7.2%) were performed with technologies known to frequently produce erroneous results, at a cost of ~£12 m.

Table 1 Self-monitoring of blood glucose system price and product characteristics

reatures	NIC per 7- and 14-day Alternate Site Ketone Audible Bolus insulin test Memory USB average Alarm Testing testing output guidance	(£0.04) £0.18 500 \(\mu\) ts (£0.02) £0.19 500 \(\mu\)	£0.22 500 <b>7</b> £0.22 450	2003	£0.23	£0.23 1000 <b>7</b>	£0.24	hin lancets £0.24 1865 / /	(£0.04) £0.25 250 🖊	(£0.03) £0.28 500 <b>/ / /</b> Inneres (£0.03) £0.30 450 <b>/ /</b>	(£0.03) £0.33 500 <b>7 7 7 7 7 7 7 7 7 7</b>	791 23 23 24 25 25 25 25 25 25 25 25 25 25 25 25 25	£0.33	£0.33 365 <b>7 7</b>	£0.33 420 <b>7</b>	(£0.04) £0.34 50 <b>/</b>	£0.34 N/A	(£0.04) £0.34 250 <b>/</b>	s (£0.04) £0.34 N/A 🗸	t or ultrasoft f0.34 500 /		t or ultrasoft £0.34 750 🖊 🖊	£0.34 480 <b>7</b>	£0.34	0000	£0.33 250 <b>7</b>
NIC per test Memory USB £0.18 500	£0.18 500 <b>£</b> 0.19 500 <b>f f 7 7 7 7 7 7 7 7 7 7</b>	£0.22 500 <b>7</b>	ts (£0.03) £0.22 450	60.32	£0.23 500 <b>/</b>	£0.23 1000 <b>\</b>	£0.24 1865 <b>\rdrace</b>	£0.24 1865 🖊	£0.25 250	£0.28 500 <b>7</b> (£0.03) £0.30 450	£0.33 500 <b>7 7 7 7</b>	00 04) £0 33 1865	£0.33 400 <b>7</b>	£0.33 365 \	£0.33 420 🖊	£0.34 50 <b>/</b>	£0.34 N/A	£0.34 250 🗸	£0.34 N/A	£0.34 500 <b>7</b>		£0.34 750 <b>7</b>	£0.34 480 <b>7</b>	£0.34	lancets (£0.04) £0.35 250 🗸 🗸	I (£0.04) £0.35 250 7 7
Lancets (NIC)			Mylife lancets (£0.03) iCARE advanced lance	TDIE Just Jones (£0.02)	Greenlan lancets (£0.03)	GlucoRx lancets	Agamatrix Ultrathin lancets (£0.04)	Agamatrix Ultrathin lancets (£0.04)	Glucoject no dol (£0.04)	Caresens Lancets (£0.03) iCARE advanced lancets	TRUEplus lancets (£0.03) TRUEplus lancets (£0.03)	B.C.Cean Illenathin		Trueplus (£0.03)	Freestyle lancets (£0.04)	Freestyle lancets (£0.04)	Meditouch lancets (£0.04)	Mendor discreet (£0.04)	Glucodock lancets (£0.04)	Onetolich comfort or ultrasoft	lancets (£0.04)	Onetouch comfort or ultrasoft lancets (£0.04)	Microlet lancets (£0.04)	Onetouch ultrasoft (±0.04)	Mygluco health	Glucoject no do
	SMBG strips (NIC)	SD Codefree (£0.14) Supercheck 2 (£0.17)	Mylife Pura (£0.19) iCARE Advanced	(£0.19)	Glucolab (£0.20)	GlucoRx Nexus (£0.20)	Wavesense JAZZ Duo (£0.20)	Wavesense Jazz (£0.20)	Glucomen GM (£0.21)	CareSens N (£0.25) iCARE Advanced	solo (£0.27) TRUEresult (£0.30) TRUEresult (£0.30)	BCS+2# (£0.29)	Glucomen LX Sensor	TRUEtrack (£0.30)	Breeze 2 (£0.29)	TRUEone (£0.30)	Medisense Softsense	Mendor Discreet	Glucodock Glucose	(£0.30) Onetouch Verio	(£0.30)	Onetouch Verio	Contour (£0.30)	Unetouch Vita (£0.30)	Mygluco health	Glucomen Visio
	Glucose Monitor	SD Codefree Supercheck 2	Mylife Pura X iCARE	Advanced	Glucolab	Gluco RX Nexus	Wavesense Jazz	Wavesense Jazz	Glucomen GM	CareSens N iCARE	Advanced TRUEresult TRUEresult	twist	Glucomen LX	Truetrack	Breeze 2	TRUEone Meditonch	Medisense	Mendor discreet	Glucodock	module Onefolich Verio		Onetouch Verio IO	Contour	Onetouch Vita	Mygluco health	Glucomen Visio

Bolus insulin guidance Audible testing Ketone 1 1 Alternate Site Testing 11 111 7- and 14-day 1 777 11 USB 11 777 11 Memory 000 450 500 1000 500 NIC per test £0.35 £0.36 £0.36 £0.36 £0.35 Freestyle Lancets (£0.04) Freestyle Lancets (£0.04) Freestyle Lancets (£0.04) (£0.04)Freestyle lancets (£0.04) Freestyle lancets Fastclix (£0.05) Fastclix (£0.05) Fastclix (£0.05) Fastclix (£0.05) Lancets (NIC) Freestyle Lite (£0.31) Freestyle Lite (£0.31) Freestyle Lite (£0.31) SMBG strips (NIC) Accucheck Mobile Freestyle (£0.31) Aviva (£0.31) Aviva (£0.31) Freestyle Optium Aviva (£0.31) £0.31) (£0.32) NIC, net ingredient costs. Glucose Monitor Accucheck Aviva Accucheck Aviva Table 1 (Continued) Optium Xceed Freedom Lite Optium Neo Freestyle Lite Aviva Nano Accucheck Insulinx Freestyle

## Can the NHS achieve efficiency savings without compromising care?

We identified 12 opportunities whereby disinvesting in one SMBG system and switching users to a cheaper alternative, at the very least providing the same functionality, would not only reduce NHS prescribing costs, but in doing so, potentially improve the level of glucose monitor functionality experienced by users. If the NHS were to implement these disinvestments, as proposed in Table 3, efficiency savings of ~£23.2 m per year are achievable, whilst four out of 12 of these will also result in improved access to advanced meter features. In the event that these switches are not made, we calculated the absolute minimum discounts that must be achieved and deducted from the list price when purchasing SMBG strips, such that those that are currently more expensive can become as cost-effective as lower priced alternatives (Table 4).

#### **Discussion**

To the best of our best knowledge, this cost-minimization analysis is the first-of-its-kind to combine information regarding the complete costs of SMBG, including both test strips and lancets, meter accuracy and the functional capabilities of systems, providing a nationally representative review of SMBG cost-effectiveness. Our results clearly show that improvements are possible with respect to the current provision of SMBG services, with the potential for both reduced prescribing costs and advances in the standard of care delivered. Of the 581 million blood glucose tests undertaken during the study period, variations in procurement costs were considerable, with a mean (range) cost of £0.19 per test (£0.18 to £0.37). Furthermore, significant within-group variations in costs remained even after adjusting for the presence of advanced meter features, with those providing a total of four advanced features priced equal to those providing just one.

Our results highlight numerous opportunities whereby switching from cost-ineffective technologies to cheaper more-effective alternatives would not only increase access to advanced meter features, but also reduce SMBG prescribing expenditure by ~£23.2 m per year. These savings may then be dedicated to improving other areas of diabetes management, including the provision of >14 500 additional insulin pumps per year [24], moving the NHS closer to the standards set by the rest of Europe [25]. Given that 34% of SMBG prescribing restrictions were reported by Diabetes UK to be the direct result of cost-cutting measures by providers, any savings generated may also then be used to reduce the unmet need that the one-in-two (47%), or ~116 000 [25] individuals with Type 1 diabetes, currently face. Previous research has shown that a restriction in the volume of blood glucose testing is likely to affect an individual's ability to adequately control blood sugar levels [8], including detection

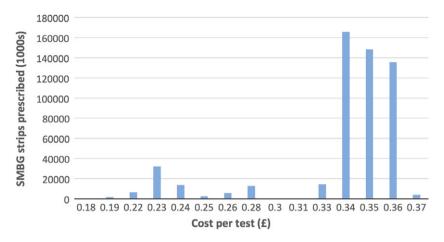


FIGURE 1 National Health Service utilisation of self-monitoring of blood glucose (SMBG) systems at varying cost per test.

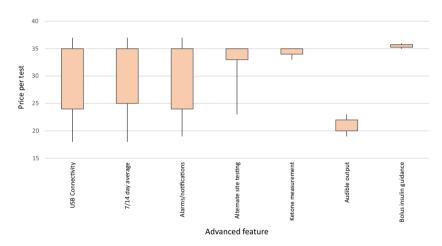


FIGURE 2 Within-group variations in price per test for self-monitoring of blood glucose systems providing advanced features.

Table 2 Self-monitoring of blood glucose systems that fail to meet ISO standards for blood glucose testing accuracy

Current SMBG system	Current utilisation	Current annual cost
Contour XT	20 008 500	£6.8 m
GlucoRX Nexus Voice	12 326 450	£2.84 m
Microdot +	3 505 800	£806,300
Omnitest 3	3 194 300	£766,600
One touch Verio Pro	1 776 900	£604,100
Gluco RX Original	610 700	£134,400
Element	123 600	£29,700
IME-DC	13 100	£3,700
Total	41.6 m	£12 m

of hypo- and hyperglycaemia, management of sick days, and the ability to make adjustments with respect to exercise, food and illness [8]. Through increasing access to more cost-effective strips at the expense of reducing the current reliance on cost-ineffective systems, we propose that this will improve disease management, and as such, reduce hospitalization, the primary driver of diabetes-related costs [9].

Our findings are consistent with observations in other publicly funded healthcare systems, with prescribing costs in New Zealand falling by >40% after the implementation of a more market-led competitive-bidding, winner-takes-all approach to SMBG cost-minimization in 2013 [26]. In Italy, experimental findings have confirmed a greater overall utilization of test strips, a significantly reduced number of hospitalizations and a reduced overall duration of hospitalization after a coordinated approach to SMBG prescribing [27]. Recent NHS activity has also shown, albeit disparately, that a number of clinical commissioning groups throughout England have also been implementing similar approaches to SMBG cost-cutting and prioritization. The West Hampshire [10], Berkshire West [11] and Wirral [12] clinical commissioning groups are just some of those publishing local recommendations for SMBG prescribing, suggesting that, although limited at present,

Table 3 Opportunities for disinvestment: implications to users and budget impact

Current SMBG system	Current utilisation	Current annual cost	Recommended SMBG system	Cost difference from switching	Patient impact from switching
Accucheck mobile	37 373 000	£13.83 m	Wavesense Jazz	(-) £5.23 m	No difference
BG Star	6 891 000	£2.27 m	Wavesense Jazz	(-) £685,100	No difference
Onetouch Verio	1 776 923	£604,100	Wavesense Jazz	(-) £195,400	No difference
Onetouch Verio IQ	1 776 923	£604,100	Wavesense Jazz	(-) £195,400	No difference
Myglucohealth	5400	£1,900	Wavesense Jazz	(-) £700	No difference
Contour	65 343 400	£22.2 m	Wavesense Jazz	(-)£6.53 m	No difference
Accucheck Aviva	42 926 633	£15.5 m	Wavesense Jazz	(-)£5.15 m	No difference
Accucheck Aviva Nano	42 926 633	£15.5 m	Wavesense Jazz	(-)£5.15 m	No difference
Mendor discreet	221 000	£75,140	Wavesense Jazz	(-)£22,100	(+) Alarms and Notifications
Glucodock Module	10 300	£3,502	Wavesense Jazz	(-)£1,030	(+) 7 and 14 day averages
iCARE Advanced Solo	34 300	£10,290	Wavesense Jazz	(-)£3,430	(+) USB connectivity, alarms and notification
Medisense Softsense	33 800	£11,492	Wavesense Jazz	(-)£3,380	(+) USB connectivity, alarms and notifications 7- and 14-day averages.
Total	199 319 312			£23.2 m	

awareness and support of the need for a coordinated approach is growing. Results from the West Hampshire clinical commissioning group [10] estimated yearly savings of ~£35,500 through replacing expensive single-use lancets (Fastclix, Multiclix and Softclix), with lower-cost alternatives, including Apollo twist or Gluco RX lancets. In the case of the Wirral clinical commissioning group, savings of up to £125,000 per year were predicted after the switching of just 50% of SMBG users to either the Supercheck 2 or GlucoRX Nexus [12], with the authors also emphasizing using meter switching as an opportunity to review the use of blood glucose testing and to identify those with the greatest need for educational messages and support to further improve cost-effectiveness.

The finding that £12 m was dedicated to providing almost 42 million SMBG tests with systems that fail to comply with ISO-15197:2013 accuracy standards is not only important with respect to health service efficiency, but also, even more importantly, with regard to user safety and disease management. Although it is generally accepted that off-the-shelf strips fail to replicate the performance of pre-market approval registration data, and that after regulatory approval the quality and reliability of 'off brand' SMBG strips deteriorates, some brands clearly deteriorate faster than others. If left unchanged, the one in 14 individuals currently informing their diabetes management with use of these most inaccurate SMBG systems, will probably continue to face a significantly increased risk of adverse events, including incorrect insulin dosing, hypoglycaemia and long-term increases in HbA<sub>1c</sub> [21,22].

Given the increasing prevalence and costs of diabetes management [7] and growing pressures to increase the volume of blood glucose testing, the prevailing question, as expressed previously [26], is whether the objective of publicly funded diabetes care is to improve survival and health-related quality of life, or to encourage user choice. Subject to a finite budget, this necessitates a trade-off between the two, with the desires of some currently effectively pricing out the clinical needs of others. In the absence of a 'standard reimbursement offer' from the NHS where users may contribute towards the costs of procuring more expensive technologies, and given the imminent availability of increasingly novel SMBG devices, including the bloodless Abbott Freestyle Libre Flash, this question becomes of increasing relevance, as the availability of such SMBG systems will almost certainly reset the benchmark of expectations for those with diabetes mellitus.

The present study has a number of limitations, largely concerning the *a priori* assumptions on which the analysis was based. Firstly, we assumed that lancets would be used as recommended by clinical guidelines, that is, as single-use items. In reality, and as referenced by the observed 4:1 prescribing ratio of strips to lancets, it is possible that lancets may be used numerous times before discarding, therefore marginally reducing the real-world cost per test for all SMBG systems.

Furthermore, some features of SMBG systems, including 7and 14-day averages and ketone testing were considered clinically relevant, whereas others, including slimline and ergonomic design were not. In doing so, we recognize the variable value of these features to the average SMBG user.

Table 4 Discounts required on list price to result in equivalent clinical and cost-effectiveness

Glucose Monitor	NIC per test	USB	7- and 14-day average	Alarm	Alternate site testing	Ketone testing	Audible output	Bolus insulin guidance	Discount required	Otherwise use
Glucomen LX sensor	£0.33	7	7	7	7	7				
Freestyle Optium	£0.35	7	7	7	7	7			5.7%	Glucomen LX sensor
Optium Xceed	£0.35	7	7	7	7	7			5.7%	Glucomen LX sensor
Freestyle Insulinx	£0.35	7	7	7				7		
Accucheck Aviva	£0.36	7	7	7				7	2.8%	Freestyle Insulinx
Expert Supercheck 2	£0.19	7	7	7			7			
Glucolab	£0.23	. 1	. 1	. 1	7					
Gluco RX Nexus	£0.23	7	7	7	7					
CareSens N	£0.28	7	7	7	7				17.9%	Glucolab or GlucoRX
TRUEresult	£0.33	7	7	7	7				30.3%	Glucolab or GlucoRX
	;								;	Nexus
TRUEresult twist	£0.33	7	7	7	7				30.3%	Glucolab or GlucoRX
Truetrack	£0.33	7	7	7	7				30.3%	Glucolab or GlucoRX
										Nexus
Freestyle Freedom	£0.35	7	7	7	7				34.3%	Glucolab or GlucoRX
Freestyle Lite	£0.35	7	7	7	7				34.3%	Glucolab or GlucoRX
,	6	,	,		,				i d	Nexus
Breeze 2	£0.33	7	7		7				30.3%	Glucolab or GlucoKX
Onetouch Vita	£0.34	7	7		7				32.4%	Glucolab or GlucoRX
4. 11	2000	`	,		`				23 40/	Nexus
Meditoucn	£0.34	7	4		7				32.470	Giucolab of Giucora
Glucomen Visio	£0.35	7	7		7				34.3%	Glucolab or GlucoRX
,		,	,	,					0	Nexus
Wavesense Jazz	£0.24	7	7 ,	7 ,					20.8%	Supercheck 2
Wavesense Jazz Duo	£0.24	7 ;	<b>.</b> '	7 ;					20.8%	Supercheck 2
Dustar Orgenich Verio	£0.33	7 7	\ <u>'</u>	7 7					42.4%	Supercheck 2
Onetouch Verio	£0.34	. !	, <u>'</u>	. !					44.1%	Superches 2
Contour	£0.34	7	\ \ \	7					44 1%	Supercheck 2
Myoluco health	£0.35	. 1	. \	. 1					45.7%	Supercheck 2
Accucheck Aviva	£0.36	. 1	. 1	. \					47.2%	Supercheck 2
Aviva Nano	£0.36	7	7	7					47.2%	Supercheck 2
Accucheck Mobile	£0.37	7	7	7					48.6%	Supercheck 2
Mylife Pura X	£0.22	7	7						13.6%	Supercheck 2
TRUEyou Mini	£0.23	,	7	7	7					-
Mendor discreet	£0.34	7	7 ,		,				44.1%	Supercheck 2
CARE Advanced	(.(. U.+		•		•					

le 4 (Continued)

		Features							
Glucose Monitor	NIC per test	7- and 14-day USB average	Alarm	Alternate site Alarm testing	Ketone testing	Audible output	Bolus insulin guidance	Discount required	Otherwise use
Glucomen GM	£0.25	7		7				%8	Glucolab or GlucoRX
TRUEone	£0.34	7		7				32.4%	Glucolab or GlucoRX
Glucodock module iCARE Advanced Medisense Softsense	£0.34 £0.30 £0.34	7	7					44.1% 36.6% 44.1%	Nexus Supercheck 2 Supercheck 2 Supercheck 2
NIC, net ingredient cost.	cost.								

Bolus insulin adjustment, for example, is a feature likely to be used by many, and given the well-documented problems with incorrect insulin dosing attributable to common numeracy issues in patients with diabetes [28], such a feature is likely to be extremely valuable. Other features, such as alternate-site testing, which only has a favourable evidence base with respect to reducing pain and increasing compliance in teens and adolescents [29], are likely to be of less value to the average SMBG user. We further appreciate that other more specific features, not included in the scope of the present analysis, may be equally important when deciding on the appropriate SMBG device, including having sufficient monitor memory to satisfy Driver and Vehicle Licensing Agency requirements [30].

It is also unclear whether manufacturers will be able to meet increased production demands following the proposed standardization of SMBG services as these may, to some extent, prevent the significant savings associated with the bulk purchase of such a small number of SMBG systems. Moreover, the limited availability of published post-market approval surveillance data regarding SMBG monitor accuracy mean that, whilst it is possible to confirm that some SMBG systems do not meet acceptable meter accuracy standards [18-20], questions remain with respect to the accuracy of those that are currently being or yet to be assessed. Because of the small number of SMBG systems used by the NHS which are yet to be assessed future research, in the form of independent reviews of meter accuracy, would almost certainly reduce this uncertainty surrounding the provision of such technologies. Uncertainty around the 'true' price of NHS SMBG testing may also be minimized if the NHS were to disclose the levels of discount achieved on the list price. This would not only increase transparency but also allow wide-scale gains in health service efficiency, enabling a more accurate assessment of the true costs and benefits of SMBG technologies, and a more reliable estimation of the opportunity for cost saving.

The strengths of the present study include the quality and size of the data used. The HSCIC recorded data on 6.4 million test strip and 2 million lancet prescriptions, detailing exactly how each of the 581 million SMBG test strips and ~150 million lancets dispensed during the study period were distributed, leaving little room for uncertainty. The study was also conducted with strict reference to Consolidated Health Economic Evaluation Reporting Standards (CHEERS) reporting standards for health economic outcomes, and as such, is transparent and completely reproducible in the event that new information comes to light which may affect the conclusions reached.

In conclusion, the study uncovered considerable variation in the price paid by the NHS for SMBG, which could not be explained by the availability of advanced meter features. A standardized approach to SMBG prescribing could achieve significant efficiency savings for the NHS, whilst increasing overall utilisation and improving safety for those currently using SMBG systems that fail to meet acceptable standards of measurement accuracy.

#### **Funding sources**

This project was funded by Lifecode<sup>®</sup> solutions in conjunction with the University of Liverpool Management School.

#### Competing interests

None declared.

#### References

- 1 Pollock RF, Valentine WJ, Goodall G, Brändle M. Evaluating the cost-effectiveness of self-monitoring of blood glucose in type 2 diabetes patients on oral anti-diabetic agents. Swiss Med Wkly 2010: 140: w13103.
- 2 American Diabetes Association. Standards of medical care in diabetes—2010. *Diabetes Care* 2010; 33(Suppl. 1): S11–S61.
- 3 Hoffmann F, Andersohn F. Immortal time bias and survival in patients who self-monitor blood glucose in the Retrolective Study: self-monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes (ROSSO). *Diabetologia* 2011; 54: 308–311.
- 4 Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. [No authors listed] *Lancet* 1998; 352: 837–853.
- 5 NHS Information Centre. Prescribing support and Primary Care Services: Prescribing for Diabetes in England: 2005/6 to 2010/11. 2011.
- 6 Diabetes UK. Position statement: Self monitoring of blood glucose (SMBG) for adults with Type 2 diabetes. London: Diabetes UK, 2013.
- 7 Diabetes UK. State of the nation 2012: England. London: Diabetes UK, 2012.
- 8 Diabetes UK. Access to test strips, a post code lottery: Self-monitoring of blood glucose by people with Type 1 and Type 2 diabetes. London: Diabetes UK, 2013.
- 9 Wagner EH, Sandhu N, Newton KM, McCulloch DK, Ramsey SD, Grothaus LC. Effect of improved glycemic control on health care costs and utilization. *JAMA* 2001; 285: 182–189.
- 10 West Hampshire Clinical Commissioning Group. 2013/14 Medicines Optimisation LES Intervention 2.3. Use of Lower-acquisition cost sterile single-use lancets. Available at www.westhampshireccg.nhs.uk/documents/doc\_view/339-23-use-of-lower-acquisition-cost-sterile-single-use-lancets-detail-aid Last accessed 11 September 2014.
- 11 Berkshire West Clinical Commissioning Group. Blood Glucose Test Strip Guidelines (2013-14). Available at www.berkshirewestdiabetes.org.uk/professionals/prescribing/glucose-test-strip-guidelines Last accessed 11 September 2014.
- 12 NHS Wirral. Cost saving switch: Cost effective blood glucose meters. 2013. Available at http://mm.wirral.nhs.uk/document\_ uploads/newsletters/DRUGOFTHEMONTHBloodglucosemetersvo. pdf Last accessed 10 September 2014.
- 13 Your Local Care. *Diabetes Services in England*. Research by Diabetes UK and Dr Foster. London: Diabetes UK, 2005
- 14 Diabetes UK. Availability of blood glucose test strips. Available at http://www.diabetes.co.uk/nhs/availability-of-test-strips.htm Last accessed 26 January, 2014.
- 15 NHS Purchasing and Supply agency. Buyers Guide: Blood Glucose Systems. Centre for evidence-based purchasing. 2008. Available at

- www.healthcheck.nhs.uk/document.php?o=232. Last accessed 23 January 2015.
- 16 Pfützner A, Schipper C, Ramljak S, Flacke F, Sieber J, Forst T et al. Evaluation of the effects of insufficient blood volume samples on the performance of blood glucose self-test meters. J Diabetes Sci Technol 2013; 7: 1522–1529.
- 17 US Department of health and human services food and drug administration. Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use: Draft Guidance for Industry and Food and Drug Administration Staff. 2014
- 18 Freckmann G, Schmid C, Baumstark A, Pleus S, Link M, Haug C. System accuracy evaluation of 43 blood glucose monitoring systems for self-monitoring of blood glucose according to DIN EN ISO 15197. J Diabetes Sci Technol 2012; 6: 1060–1075.
- 19 Khan M, Broadbent K, Morris M, Ewins D, Joseph F. System accuracy evaluation of the GlucoRx nexus voice TD-4280 blood glucose monitoring system. *Dis Markers* 2014; 2014: 602 586.
- 20 Freckmann G, Baumstark A, Schmid C, Pleus S, Link M, Haug C. Evaluation of 12 blood glucose monitoring systems for self-testing: system accuracy and measurement reproducibility. *Diabetes Technol Ther* 2014; 16: 113–122.
- 21 Breton MD, Kovatchev BP. Impact of blood glucose self-monitoring errors on glucose variability, risk for hypoglycemia, and average glucose control in type 1 diabetes: an in silico study. *J Diabetes Sci Technol* 2010; 4: 562–570.
- 22 Baum JM, Monhaut NM, Parker DR, Price CP. Improving the quality of self-monitoring blood glucose measurement: a study in reducing calibration errors. *Diabetes Technol Ther* 2006; 8: 347–357.
- 23 Health and Social Care Information Centre. Prescription Cost Analysis England 2013: Prescription items dispensed in the community in England, listed alphabetically within chemical entity by therapeutic class. 2014. Available at www.hscic.gov.uk/catalogue/ PUB13887/pres-cost-anal-eng-2013-rep.pdf. Last accessed 22 January 2014.
- 24 The National Institute for Health and Care Excellence (NICE). Technology appraisal guidance 57: The clinical effectiveness and cost effectiveness of insulin pump therapy. 2003
- 25 Diabetes UK. UK lagging behind Europe for use of insulin pumps. May 2013. Available at http://www.diabetes.org.uk/About\_us/ News\_Landing\_Page/UK-lagging-behind-Europe-for-use-of-insulinpumps/ Last accessed 15 March 2015.
- 26 Lunt H, Florkowski CM. Transitioning to a National (New Zealand) Sole Supply Scheme for Glucose Meters: Lessons Learned, Problems Yet to Be Solved. J Diabetes Sci Technol 2014; 8: 615–618.
- 27 Giaccari A, Grassi G, Ozzello A. Self-monitoring of blood glucose: guideline application rather than utilization restrictions on testing strips has potential to reduce diabetes healthcare costs in Italy. *Diabetes Technol Ther* 2012; 14: 862–867.
- 28 Sussman A, Taylor EJ, Patel M, Ward J, Alva S, Lawrence A et al. Performance of a glucose meter with a built-in automated bolus calculator versus manual bolus calculation in insulin-using subjects. J Diabetes Sci Technol 2012; 6: 339–344.
- 29 Lucidarme N, Alberti C, Zaccaria I, Claude E, Tubiana-Rufi N. Alternate-site testing is reliable in children and adolescents with type 1 diabetes, except at the forearm for hypoglycemia detection. *Diabetes Care* 2005; 28: 710–711.
- 30 Driver and Vehicle Licensing Agency (DVLA). DVLA's current medical guidelines for professionals –Diabetes: A Guide to Insulin Treated Diabetes and Driving. Available at www.gov.uk/govern ment/uploads/system/uploads/attachment\_data/file/313214/DIABI NF.pdf Last accessed 14 October 2014.