**Institution:** University of Oxford

**Unit of Assessment:** 2 - Public Health, Health Services and Primary Care

**Title of case study:** Saving healthcare resources through avoiding ineffective use of blood glucose self-monitoring for type 2 diabetes

**Period when the underpinning research was undertaken:** 2002 - 2012

**Details of staff conducting the underpinning research from the submitting unit:**

| Name(s): | Role(s) (e.g. job title): | Period(s) employed by submitting HEI: |
|---|---|---|
| Andrew Farmer | Prof of General Practice | 2001 - present |
| Andrew Neil | Professor | 1998-2010 |
| Judit Simon | Research Associate | 2002-2013 |
| Pat Yudkin | Senior Statistician | 2000-2009 |

**Period when the claimed impact occurred:** August 2013 – July 2020

**Is this case study continued from a case study submitted in 2014?** N

## 1. Summary of the impact

Studies led by Professor Andrew Farmer and colleagues at the University of Oxford have shown that routine use of blood glucose self-monitoring adds little benefit to the care of patients with non-insulin treated type 2 diabetes. This work led to changes in the recommendations made in the 2008 National Institute for Health and Care Excellence (NICE) guidelines, from "*self-monitoring of plasma glucose should be available…*" to a clear recommendation in the 2015 NICE guidelines of "*Do not offer routine self-monitoring of blood glucose for adults with type 2 diabetes…*" These changes have been implemented by healthcare professionals and are estimated to have saved the NHS up to GBP100,000,000 since the guidelines were published. The research has also influenced recommendations for clinical practice worldwide regarding the use of blood glucose self-monitoring for non-insulin treated patients with type 2 diabetes.

## 2. Underpinning research

Diabetes is a serious, rapidly growing and expensive disease. Approximately 3,900,000 people in the UK have diabetes, with type 2 diabetes making up about 90% of all adult cases. Blood glucose self-monitoring systems are used for people with non-insulin treated type 2 diabetes and, until the early 2000s, had been commonly recommended. However, evidence supporting monitoring in large numbers of these patients was lacking.

Setting out to investigate the importance of self-monitoring in improving glycaemic control in non-insulin treated patients with type 2 diabetes and in response to an articulated need for evidence to guide the NHS, Professor Farmer and colleagues at the University of Oxford undertook a series of studies from 2005 onwards based on a randomised controlled trial, the DiGEM trial [1], to analyse the benefits of self-monitoring in comparison to traditional clinical care. The trial was sponsored, managed and analysed from the University of Oxford and was carried out with collaborators from the University of Cambridge (who contributed to design of the study and manualising the training programme for nurses) and University of Sheffield (where some participants were recruited). The results, published in 2007, showed that the benefit of blood glucose self-monitoring used in clinical care and targeted at improving lifestyle and other health behaviours (including medication adherence) had been overestimated in comparison to the benefit of good clinical care [2]. It found that there was no significant improvement in glycaemic control after 12 months in patients using self-monitoring when compared to those not self-monitoring.

An economic analysis of the data from the DiGEM trial, published in 2008, investigated the cost-effectiveness of patient education and training in the use of blood glucose self-monitoring

compared to care not using self-monitoring and also looked at quality of life [3]. It showed an initial negative impact on quality of life for patients using self-monitoring, in part associated with increased reported anxiety. In combination with higher costs observed for those using self-monitoring, the study indicated that self-monitoring of blood glucose is unlikely to be cost-effective in addition to standardised usual care ([3] and as reported in the Health Technology Assessment programme report [4]).

A further University of Oxford-led study in 2012 used pooled data from the major studies of self-monitoring of blood glucose at the time, analysed to a common statistical plan [5]. The analysis confirmed that potential improvements in blood glucose control with the technology were small and found no evidence of benefit in sub-groups of patients either, particularly those with poor initial blood glucose control.

Overall, these studies therefore demonstrated that for a large proportion of non-insulin treated patients with type 2 diabetes, routine use of blood glucose self-monitoring added little if any benefit beyond that provided by good clinical care, that there could be an adverse impact on quality of life from self-testing, and that costs of using self-monitoring were substantial in comparison to the likely benefits.

**3. References to the research** (University of Oxford researchers in bold)


1. **Farmer A.,** Wade A., French D.P., Goyder E., Kinmonth A.L., **Neil A**. (2005). The DiGEM trial protocol - a randomised controlled trial to determine the effect on glycaemic control of different strategies of blood glucose self-monitoring in people with Type 2 diabetes. *BMC Family Practice* 6(25): 6–25. DOI: 10.1186/1471-2296-6-25
2. **Farmer A**., Wade A., Goyder E., **Yudkin P**., French D., Craven A., **Holman R**., Kinmonth A.L. and **Neil A**. (2007) Impact of self-monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. *BMJ* 07/21;335:132. DOI: 10.1136/bmj.39247.447431.BE
3. **Simon J**., **Gray A**., Clarke P., Wade A., **Neil A**., **Farmer A**., on behalf of the DiGEM Trial Group (2008). Cost effectiveness of self-monitoring of blood glucose in patients with non-insulin treated type 2 diabetes: economic evaluation of data from the DiGEM trial. *BMJ* 336:1177-80. DOI: 10.1136/bmj.39526.674873.BE
4. **Farmer A**., Wade A., French D., **Simon J**., **Yudkin P**., Gray A, Craven A,. Goyder L., Holman R., Mant D., Kinmonth A.L, **Neil HAW**, DiGEM Trial Group (2009). Blood glucose self-monitoring in type 2 diabetes: a randomised controlled trial. *Health Technology Assessment* 13(15):1-72. DOI: 10.3310/hta13150
5. **Farmer A.J., Perera R**., **Ward A**., **Heneghan C**., **Oke J**., Barnett A.H., Davidson M.B., Guerci B., Coates V., Schwedes U., O'Malley S (2012). Meta-analysis of individual patient data in randomised trials of self-monitoring of blood glucose in people with non-insulin treated type 2 diabetes. *BMJ* 344:e486. DOI: 10.1136/bmj.e486.


**Funding** to the University of Oxford included a Health Technology Assessment award from the National Institute for Health Research (NIHR) for the DiGEM trial, led by Farmer, GBP619,204 (reference 01/38/05, 2002-2007).

**4. Details of the impact**

The DiGEM trial [1,2] and subsequent studies carried out between 2008 and 2012 [3,4,5] shifted national healthcare policy in 2015 regarding use of blood glucose monitoring systems, leading to long-term and sustained impacts from changes in clinical practice. Blood glucose self-monitoring systems are used for type 1 and type 2 diabetes and in 2010 the cost to the NHS of providing blood glucose testing strips was approximately GBP150,000,000. Farmer and colleagues' work was instrumental in challenging the assumption that glycaemic control and quality of life in type 2 diabetes patients not taking insulin (around 88% of the total type 2

population) would be improved with self-monitoring of blood glucose and has led to significant economic savings to the NHS.

**Pathway to impact**

At the time the DiGEM trial was carried out, self-monitoring of blood glucose was widely seen as standard of care for routine management of type 2 diabetes. This view gradually changed in the UK and internationally over time with the publication of the trial [1,2], the cost-effectiveness study [3,4] and the meta-analysis [5], culminating in the recommendation made in the NICE guidelines published in December 2015 [A] (described below). However, national and international awareness of the importance of the findings of the trial in advance of the 2015 NICE recommendations was apparent and some examples of this are provided to illustrate the pathway to impact. For example, the 2010 Scottish SIGN guidelines on management of diabetes [Bi] were updated from previous guidelines to take account of new clinical evidence, including that from the DiGEM trial in recommending that routine self-monitoring of blood glucose was not needed for people with type 2 diabetes not taking insulin or drugs that might lead to hypoglycaemia. Initial results from the trial were also cited in 2008 by the National Prescribing Centre (NPC) [Bii] and used by prescribing support teams across the country to provide up-to-date information about the place of self-monitoring blood glucose in type 2 diabetes [Biii].

An observational study in East London implemented a policy of not routinely using self-monitoring of blood glucose for people with non-insulin treated type 2 diabetes between 2010 and 2013, citing the evidence from DiGEM for lack of a meaningful clinical effect from self-monitoring [C]. In this study, local 'do not use' guidelines were introduced across two Clinical Commissioning Groups with a total population of 425,000. Unnecessary prescribing of self-testing strips for these patients (approximately 18,000) fell from 42.8% in 2010 to 16.5% in 2013. The authors demonstrated that, if extrapolated to a UK-wide population, this policy would have avoided unnecessary testing in 340,000 people and reduced diabetes prescribing costs in 2013 by GBP21,800,000. Removing the need to test blood glucose several times a day could also lead to an improvement in quality of life and reduced anxiety, as reported by the DiGEM trial group [3] and other studies.

**Change in national healthcare policy**

Reinforcing the importance of the DiGEM trial findings, the 2015 RAND evaluation of the NIHR Health Technology Assessment programme [D] selected the trial as one which '*had high potential to impact on policy, practice, and ultimately health outcomes and economic benefits'.* It highlighted the actions of the research team to widen impact: "*the project team went on to synthesise evidence across multiple trials, [and] strengthened their case that self-monitoring of blood glucose offered no significant benefit, and also allowed them to demonstrate this for specific patient groups as well as across the population in general.*"

The RAND evaluation went on to note: "*From an implementation point of view, these findings are easy to adopt…However, in practice, there were some challenges associated with putting these findings into practice. A strong industry lobby continued to push back on these findings and worked to try and convince GPs that monitoring was a necessary part of treatment practice."*

Despite this, the findings from the research were incorporated into the updated NICE guidelines on management of type 2 diabetes in adults in 2015 [A]. The guidelines cite the DiGEM trial over thirty times in summarising and discussing evidence for self-monitoring of blood glucose, stating that it provides the most useful evidence with fewest limitations. Overall, a strong '*do not do*' recommendation was made concerning self-monitoring of blood glucose for the majority of people with type 2 diabetes, because the guideline development group agreed that self-monitoring would not be of sufficient benefit for most people.

**Impact on clinical practice as a result of the NICE guidelines**

The NICE guidelines have had a significant impact on clinical practice throughout the UK, encouraging more effective use of resources for self-monitoring blood glucose. Following their publication, Training, Research and Education for Nurses in Diabetes (TREND-UK) issued consensus guidelines in January 2017 for the healthcare community [E]. This brought together

guidelines from NICE and other national and international bodies with evidence for and against self-monitoring blood glucose in type 2 diabetes and was sponsored by eight of the blood glucose meter companies. DiGEM was one of the six studies selected to provide evidence. Drawing from these sources to suggest who may benefit from self-monitoring, the document states that "*self-monitoring of blood glucose is not recommended as part of routine care if HbA1c is within target"*. The NICE recommendations, including citation of the contribution of the DiGEM study, have also been widely disseminated in professional journals with an emphasis on implementation in day-to-day clinical practice (for example in Nursing in Practice [F]). From 2016-2018, most Clinical Commissioning Groups issued guidance to healthcare professionals on the use of self-monitoring of blood glucose testing in line with the NICE guidance and citing these and TREND guidelines [G].

A wide range of local clinical guidance now recommends that, for many people, routine use of blood glucose testing adds little, if anything, to usual care and should not be carried out unless there is a well-established system for training and support.

**Economic impact**

Since publication of the NICE guidelines in 2015, prescribing blood glucose monitoring has remained static despite an increase in numbers of people with diabetes and an increasing number of prescriptions for continuous glucose monitoring related to the management of type 1 diabetes, consistent with the background of guidance for much wider use of test strips for people with that condition. In 2011, self-monitoring prescriptions cost the NHS GBP158,000,000 in England (National Prescribing Centre) out of a total diabetes prescribing cost of GBP725,000,000 (NHS Digital); in 2018, the figure was GBP157,000,000 (National Prescribing Dataset) out of a total of GBP1,012,000,000. During that period, the number of patients with type 2 diabetes increased from 2,300,000 to 3,800,000 (Public Health England). The East London study, estimated a reduction in diabetes prescribing costs in 2013 by GBP21,800,000 for a UK-wide population [C]. A similar estimate of potential saving was made in a review by Clar et. al. (2010), which reported that GBP17,000,000 per year spent on self-monitoring blood glucose in patients with type 2 diabetes in the UK would be saved by applying the findings of DiGEM to clinical practice [H]. Scaled to the period from the date of publication of the NICE guidelines in 2015 to the end of the REF2021 period, these estimates suggest that savings equivalent to between GBP85,000,000 to GBP100,000,000 may have arisen from implementation of the NICE guidance.

**Change in international guidelines and impact**

The American Diabetes Association cite the DiGEM trial in their 2018 standards of care for diabetes, which was updated in 2019 with new wording of the recommendations, again citing DiGEM, to recognise the strength of accumulated evidence: "*In people with type 2 diabetes not using insulin, routine glucose monitoring may be of limited additional clinical benefit*" [I].
Continuing education programs in the United States are incorporating this advice with explicit reference to the 2007 and 2008 DiGEM publications [2,3] and suggesting that pharmacists should "*challenge prescriptions … for frequent … SMBG testing in patients with prediabetes or diabetes on monotherapy with agents that have minimal hypoglycemic risks*" [J].
Similarly, in Canada, local clinical practice recommendations issued by RxFiles, a well-established Saskatoon academic detailing programme providing objective data on drug use, has issued explicit guidance advising against using self-monitoring of blood glucose in non-insulin treated type 2 diabetes [K], citing the 2008 and 2009 DiGEM papers [3,4] and the 2012 meta-analysis [5].
The Royal Australian College of General Practitioners and Diabetes Australia issued guidance in 2016 including the advice that "*routine self-monitoring of blood glucose for people with type 2 diabetes who are considered low risk and using oral glucose lowering drugs (with the exception of sulphonylureas) is not recommended*" [Li], referencing the 2012 meta-analysis [5].
The Ministry of Health in Singapore issued guidelines in 2014 advising that it did not support considering self-monitoring of blood glucose for people with non-insulin treated type 2 diabetes. The DiGEM study was cited in the included evidence statement [Lii].

## 5. Sources to corroborate the impact


A. National Institute for Health and Care Excellence (NICE) Guideline NG28, December 2015. Type 2 Diabetes in Adults Clinical Guideline Update. https://www.nice.org.uk/guidance/ng28

B. i) Scottish SIGN Guidelines 116, March 2010. Management of diabetes. A national clinical guideline. https://www.sign.ac.uk/our-guidelines/management-of-diabetes/;
ii) National Prescribing Centre MeReC Extra 34, July 2008, archived at https://web.archive.org/web/20081120124543/http://www.npc.co.uk/MeReC_Extra/2008/no34_2008.html
(iii) 'Prescribing advice for GPs' blog, 24 July 2008. https://www.prescriber.org.uk/2008/07/merec-extra-34/

C. Journal article: Robson J et al (2015). 'Reduction in self-monitoring of blood glucose in type 2 diabetes: an observational controlled study in east London'. *Br J Gen Pract* 65 (633): e256-e263. DOI: 10.3399/bjgp15X684421

D. RAND evaluation of the NIHR HTA programme: 'Returns on research funded under the NIHR Health Technology Assessment (HTA) Programme. Economic analysis and case studies'. Guthrie G. et al 2015. https://www.rand.org/pubs/research_reports/RR666.html

E. Guidelines from Training, Research and Education for Nurses in Diabetes (TREND UK) January 2017. Blood Glucose Monitoring Guidelines Consensus Document https://trenddiabetes.online/wp-content/uploads/2017/02/170106-TREND_BG_FINAL.pdf

F. Farid,T. Self-monitoring of blood glucose. *Nursing in Practice*, 9 December 2016. https://www.nursinginpractice.com/cpd/self-monitoring-of-blood-glucose/

G. Local clinical practice guidelines issued by CCGs: Examples of guidelines including:
i) Brighton and Hove et al CCGs June 2015;ii) Calderdale CCG September 2016;
iii) East Kent prescribing Group March 2016; iv) Derbyshire Joint Area Prescribing Committee July 2018; v) Greater Manchester Medicines Management Group December 2015

H. Journal article: Clar et. al. (2010) Self-monitoring of blood glucose in type 2 diabetes: systematic review. *Health Technol. Assess.* 14(12):1-140 DOI: 10.3310/hta14120

I. American Diabetes Association. i) Glycemic Targets: Standards of Medical Care in Diabetes - 2018. *Diabetes Care* 2018 Jan; 41(Supplement 1): S55-S64. DOI: 10.2337/dc18-S006*;* and ii) Diabetes technology: Standards of Medical Care in Diabetes – 2019. *Diabetes Care*. 2019;42(Suppl. 1):S71-S80 DOI: 10.2337/dc19-S007

J. Diabetes Medication Therapy Management Certificate Programme for Pharmacy Technicians. Module 4: Blood Glucose Monitoring. (Published 12th June 2019) https://www.powerpak.com/course/print/118197.

K. Local clinical practice recommendations issued by a Canadian academic detailing programme: Self-monitoring of blood glucose (SMBG) in type 2 diabetes (T2DM) (November 2019) RxFiles, Saskatoon, Canada. https://www.rxfiles.ca/rxfiles/uploads/documents/CHT-Diabetes-SMBG.pdf

L. Examples of international guidelines: i) Royal Australian College of General Practitioners and Diabetes Australia. General practice management of type 2 diabetes. 2016 –18; and
ii) Ministry of Health Singapore, 2014. Diabetes Mellitus: MOH Clinical Practice Guidelines, https://www.moh.gov.sg/hpp/doctors/guidelines/GuidelineDetails/cpgmed_diabetes_mellitus.