

# Blood Glucose Test Strips

## Review of Products

By MKCCG Medicines Management Team &  
Diabetes Specialist Nurses



*October 2015*

## 1 Background

The aim of this document is to provide a description of the process, methodology and scoring mechanism to select a preferred Blood Glucose Testing Strip or strips (BGTS) for Milton Keynes. This project intends to rationalise and reduce the variations in the type of strips used locally, and thus ensure that recommended strips offer comprehensive and high level accuracy monitoring whilst being cost effective to the health economy. Currently, MK has a significantly higher spend on BGTS compared to the national average spend.

The Medicines Management Team has worked closely with the local Diabetes Specialist Nurses (DSNs) throughout this project. We have also liaised with the MKUHFT Biochemist, Phil McCue and involved a Patient Panel.

The Project is based on work done by The Greater Manchester Medicines Management Group (GMMM) which consists of General Practitioners (GP), pharmacists and other key healthcare professionals and is formally accountable to the Greater Manchester collaboration of 12 clinical commissioning groups (CCG), local area team (LAT) and local NHS providers. The GMMM work plan was facilitated and supported by the Regional Drug & Therapeutics Centre in Newcastle and the Greater Manchester Commissioning Support Unit (GMCSU).

## 2 Introduction

- 2.1 It is recognised that self-monitoring of blood glucose (SMBG) is an integral part of the management of diabetes for some individuals – especially those individuals with type 1 diabetes and those with type 2 diabetes treated with insulin and other individuals as indicated below. It can allow individuals to see what impact particular behaviours, such as dietary habits or exercise, can have on their glycaemic control, thus allowing them to understand results and adjust their behaviour in a beneficial way. There is also evidence that excessive testing can make patients unnecessarily anxious about their diabetes control and have a negative impact on their quality of life.
- 2.2 The current NICE guideline on type 2 diabetes (Clinical Guideline 87)<sup>1</sup> and draft 2015 revised guideline, both recommend the following for blood glucose testing:
- a) Offer SMBG to a person newly diagnosed with type 2 diabetes only as an integral part of his or her self-management education. Discuss its purpose and agree how it should be interpreted and acted upon.
  - b) SMBG should be available:
    - to those on insulin treatment
    - to those on oral glucose-lowering medications to provide information on hypoglycaemia
    - to assess changes in glucose control resulting from medications and lifestyle changes
    - to monitor changes during intercurrent illness
    - to ensure safety during activities, including driving.
  - c) Assess at least annually and in a structured way:
    - self-monitoring skills
    - the quality and appropriate frequency of testing
    - the use made of the results obtained
    - the impact on quality of life
    - the continued benefit
    - the equipment used.
  - d) If self-monitoring is appropriate but blood glucose monitoring is unacceptable to the individual, discuss the use of urine glucose monitoring.

2.3 In 2013 there were over 12,000 patients aged over 17 years with diabetes in Milton Keynes according to the latest QOF figures<sup>2</sup> and this number has been increasing every year. Individuals with diabetes monitor their blood glucose to educate themselves, maintain better blood glucose control and to minimise the risks of hypoglycaemia.

2.4 In 2014-15, the total spend across Milton Keynes on BGTS was in excess of £888k, an increase of over £120k from 2012-13<sup>3</sup>. To put this into context, the CCG spent £586k on first line oral hypoglycaemic agents in 2014-15.

The total cost per 1000 QOF registered patients with diabetes aged over 17yrs is £13,507 per year in Milton Keynes compared to £9,661 per year nationally. This represents a 7% increase in cost locally compared to a 2% increase nationally.

As of January 2015 there are 58 varieties of BGTS funded within the NHS<sup>4</sup> with prices ranging from £6.99 - £16.30 for 50 strips. The wide range of BGTS and meters enables individuals with diabetes to select a system that best meets their individual needs, albeit whilst adding complexity for healthcare professionals.

2.5 BGTS and meters are medical devices, not medicines. As such the process to market is different and less robust. For a medicine, randomised controlled trials (RCT) and a product licence are required. To obtain a drug tariff listing in England for a BGTS the process is to complete a DT1 form<sup>5</sup>. This form requires information regarding the manufacturer, the product and the supporting material regarding accuracy and the Conformité Européenne (CE) mark (as opposed to RCT data for a medicine).

2.6 The European Association for the Study of Diabetes (EASD) issued a position statement in March 2013<sup>6</sup> questioning the robustness of the procedure by which medical devices in diabetes, including BGTS and meters get to market and are evaluated post marketing. As these devices are potentially used to alter the dose of an administered medication i.e. insulin, it is vital that blood glucose meters and strips give accurate results when used to avoid any serious consequences.

2.7 BGTS and meters have an international standard that they should be manufactured to - ISO 15197. The standard from 2003 was recently updated in 2013<sup>7</sup>. The new standard has implications not only for the manufacturers of currently available and future devices but also for the end-users. The manufacturers have 3 years from the date of the new standard update to meet the new requirements before compliance becomes mandatory from June 2016.

The ISO 15197 standard requires a complex series of tests and requirements to be completed internally with the results assessed by a regulatory notifying body. It is clear that there has been concern at the lack of consistent performance of many BGTS after regulatory clearance and as a result the new standard and tighter accuracy will be an important criterion for consideration<sup>7</sup>.

The ISO 15197: 2013 requirements for BGTS and meters differ from the previous 2003 version on the following points in terms of accuracy requirements<sup>7</sup>.

	<i>ISO 15197: 2003</i>	<i>ISO 15197:2013</i>
<i>Higher level accuracy</i>	<i>&gt;4.2mmol/l +/- 20%</i>	<i>&gt;5.5mmol/l +/- 15%</i>
<i>Lower level accuracy</i>	<i>&lt;4.2mmol/l +/- 0.83mmol/l</i>	<i>&lt;5.5mmol/l +/- 0.83mmol/l</i>
<i>Number of lots</i>	<i>1</i>	<i>3</i>
<i>Results in zone A/B of Clarke Error Grid</i>	<i>n/a</i>	<i>99%</i>

*Note: There are many other differences published by the international standard but these are the key accuracy differences.*

For a BGTS and meter to surpass the accuracy requirements for ISO 15197:2013 it is required to have the above high and low level accuracy across 3 lots (or batches) of test strips, with all results in Zone A/B of a Clarke Error Grid<sup>7</sup>.

### 3 Aims of the review

#### 3.1 The aims are:

- ✓ To provide better support for patients in the effective utilisation of BGTS
- ✓ To improve the cost effective use of BGTS in Milton Keynes
- ✓ To support the CCG and NHS providers in the delivery of an evidence based rationale on selection of a preferred brand of BGTS from the large variety available

#### 3.2 Out of scope:

There are widely available reports of individuals with diabetes being denied access to BGTS<sup>8</sup>. It is therefore important to state that this guidance is not intended to deny access to BGTS nor is cost cutting the top priority.

This guidance will enable clear and transparent assessment of available data in relation to BGTS provisions to Milton Keynes CCG looking to optimise expenditure and support for individual patients requiring SMBG. It is not a tender process, as no contract award will be made as a consequence of this protocol. However, some elements of the tendering process have been incorporated into the evaluation of products.

### 4 Method

#### 4.1 The work completed by Manchester (referred to in section 1) was reviewed and used as our starting point<sup>10</sup>.

Manchester used a scoring process to evaluate the preferred BGTS and meters. Some elements of the process were pass or fail and some required scoring by a project group to evaluate BGTS use. If any BGTS received a fail then it was excluded from any further scoring within the process (ref 10, section 4).

All BGTS currently included within the drug tariff (January 2015) were assessed and scored according the review process.

#### 4.2 Although we intended to only include products with independent and published evidence demonstrating ISO 15197:2013 accuracy standards ie Group 1 (ref 10, Figure 3), we decided to also consider products in Group 2 (ref 10, figure 4) – where manufacturers were able to provide independently assessed but non-published evidence of conformity to ISO15197:2013 accuracy standards, as we recognised that it is not mandatory for manufacturers to provide independent published data demonstrating conformity currently.

#### 4.3 A pragmatic approach was taken in the selection of meters chosen for the Patient Panel. Eight products from Groups 1 and 2 were selected from the shortlist. Four patients were then asked to review the eight meters.

### 5 Results

#### 5.1 When the CCG procures services, tenders are scored with a weighting of 60% quality and 40% cost, therefore this model was used to analyse the Patient Panel results. The Quality score was subdivided to give weight to the systematic review undertaken by Manchester as well as the Patient Panel evaluation. The impact of the Patient scoring was lower as only four patients were involved in the review and some of their scoring was inconsistent with the written comments they made.

## 5.2 Results Analysis

The patient scores are the sum of scores allocating 5 points to score of 1, 4 for score 2 etc and then dividing by 160 max score to get a percentage.

Cost scores calculated as  $100 \times 7.75$  (lowest cost) / individual costs.

		Accu- chek Active	Care Sens N	WaveSense Jazz	GlucoMen Areo	Contour Next	TEE2	Accu- chek Aviva	Accu- chek Mobile
Patient score		75.6	70.6	77.5	73.1	99.3	80.6	90.6	96.8
20%		15.12	14.12	15.5	14.62	19.86	16.12	18.12	19.36
Evaluation score		87.5	93.7	81.25	93.7	93.7	93.7	81.25	87.5
40%		35.00	37.48	32.50	37.48	37.48	37.48	32.50	35
Total Quality		50.12	51.6	48.00	52.1	57.34	53.6	50.62	54.36
Cost scores		77.9	60.8	78.5	77.9	51.5	100	49.3	48.6
40%		31.16	24.32	31.4	31.16	20.6	40	19.72	19.44
Total Score		81.28	75.92	79.40	83.26	77.94	93.6	70.34	73.80

## 6 Final Recommendations

Based on the analysis above, the locally preferred BGTS choices are:

### **First Tier – For general use**

Blood Glucose Test Strip	Manufacturer	Cost per 50 strips
Accu-chek Active	Roche	£9.95
GlucoMen Areo	Menarini Diagnostics	£9.95
WaveSense Jazz & Jazz Duo	Agamatrix	£9.87 & £9.95
TEE2 (for non-insulin users)*	Spirit Healthcare	£7.75

\*If indicated, for those not using insulin & generally have stable control

### **Second Tier – For those patients who have found First Tier choices unacceptable**

Blood Glucose Test Strip	Manufacturer	Cost per 50 strips
Contour Next	Bayer	£15.04
CareSens N	Spirit Healthcare	£12.75
Accu-chek Aviva	Roche	£15.79

### **Third Tier – For use in special circumstances eg HGV Drivers or other occupational risk grps**

Blood Glucose Test Strip	Manufacturer	Cost per 50 strips
Accu-chek Mobile	Roche	£16.09

## 7 Reviewing and Changing Blood Glucose Meters and strips

7.1 Patients who are currently monitoring their blood glucose who do not fall into the exclusion groups defined below should be identified for review and considered for a switch to preferred First Tier product choices<sup>9</sup>.

Such a review should take into account whether the patient should continue to test at all. Blood glucose testing is unlikely to be necessary in patients controlled on diet and exercise alone. If diagnosed with type 2 diabetes, blood glucose testing is particularly advocated if the patient is on insulin, sulfonylureas or glinides (i.e. glucose lowering therapy) or is experiencing hypoglycaemia, hyperglycaemia or other symptoms of poor diabetic control; it can also be a useful addition to education on diet and lifestyle and for patients with inter-current illness. Blood glucose testing is strongly recommended in all patients with type 1 diabetes mellitus<sup>9</sup>.

Any switching should be done as part of a face to face consultation with provision made for further follow-ups if required<sup>9</sup>.

Where there is shared care between primary care and hospital based specialist teams, it is important that the decision to change meter in primary care is communicated to the specialist service to avoid any potential confusion or misunderstanding<sup>9</sup>.

Patients should be advised that if their test results with a new meter are radically different from those recorded previously, particularly if they are not experiencing any signs or symptoms that indicate a change in their condition, they should seek urgent medical advice<sup>9</sup>.

7.2 Exclusions: When a switch is not recommended<sup>9</sup>

**The following patient groups should be excluded from any switch:**

- Children / adolescents aged less than 18 years of age
- Those with existing or gestational diabetes during pregnancy
- Those using insulin pumps
- Patients with Type1 Diabetes (- two meters currently measure ketones: *Glucomen LX Plus (Menarini)* and *Freestyle Optium (Abbott)*)
- Those who use their meters that support insulin dose calculations
- Those who are registered blind or partially sighted. Will use meters with large displays or with voice guidance. Meters with voice guidance: *Caresens N Voice, GlucoRx Nexus Voice*
- Those who are being remotely managed by systems such as “Telehealth” or those who are reliant on healthcare professionals to download and retain a log of their results
- Any patient for whom the GP considers it appropriate that they remain on a specific meter

## 8 References

1. NICE Clinical Guideline 87 – Type 2 Diabetes - <http://www.nice.org.uk/nicemedia/pdf/CG87NICEGuideline.pdf>
2. <http://www.gpcontract.co.uk/browse/UK/Diabetes%20mellitus/13> Accessed 31st January 2015.
3. Electronic Prescribing Analysis and Cost data (ePACT). Accessed 31st January 2015.
4. [http://www.ppa.org.uk/edt/January\\_2015/mindex.htm](http://www.ppa.org.uk/edt/January_2015/mindex.htm) Accessed 2nd January 2015.
5. <http://www.nhsbsa.nhs.uk/PrescriptionServices/3399.aspx> Accessed 31st January 2014.
6. EASD Report on medical device accuracy. Accessed 19th January 2014. <http://www.easd.org/images/easdwebfiles/press/EASD%20Press%20Release%20on%20medical%20devices.pdf>
7. ISO website: [http://www.iso.org/iso/home/news\\_index/news\\_archive/news.htm?refid=Ref1749](http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref1749).
8. [http://www.diabetes.org.uk/About\\_us/News\\_Landing\\_Page/People-with-diabetes-denied-vital-test-strips/](http://www.diabetes.org.uk/About_us/News_Landing_Page/People-with-diabetes-denied-vital-test-strips/)
9. Prescribing & Clinical Effectiveness Bulletin, Vol 8, No 2, Feb 14. By Greater East Midlands Commissioning Support Unit
10. Manchester Guidance – Blood Glucose Test strip (BGTS) evaluation protocol and results May 2015, version 2.0 <http://gmmmq.nhs.uk/docs/guidance/150508%20NWCSU%20Blood%20Glucose%20Testing%20Strip%20Evaluation%20May%202015%20v2-0.pdf>