

Testing strips in diabetes

Self-monitoring of blood glucose (SMBG) is essential for people with diabetes on insulin therapy and can be beneficial for some people on other hypoglycaemic agents. Where SMBG is not serving a specific purpose in the management of the condition however, it is likely to be a waste of resources and can cause unnecessary pain to the patient. Some studies have even shown anxiety and depression associated with self-monitoring of blood glucose.

The National Institute for Health and Care Excellence (NICE) outlines the specific circumstances when SMBG should be offered to patients with type 2 diabetes to ensure that optimal use is guided by robust evidence and does not result in unnecessary NHS expense or inconvenience for patients and their carers.¹ The continued benefit of self-monitoring should be assessed in a structured way each year.¹

In recent years the cost of prescribing blood glucose test strips (BGTS) has grown rapidly. From August 2017 to July 2018, 17% of the spend on diabetes was for BGTS at a cost of £168 million in England and Wales.²

Recommendations

- Review current prescribing of BGTS and evaluate the need for self-monitoring on an individual patient basis; where there is no need for SMBG, discontinue prescribing.
- Determine appropriate frequency for testing and make necessary adjustments to quantity of test strips prescribed.
- Remove BGTS from repeat prescriptions for patients who only need to test intermittently.
- Use the guidance provided in the attachments 1-3 (audit, product comparison table, patient meter form) to help produce a preferred list of blood glucose testing strips and meters to be used locally. www.prescqipp.info/our-resources/bulletins/bulletin-212-diabetes-testing-strips/
- Ensure a wide stakeholder engagement including GPs, practice nurses, practice pharmacists, specialist community diabetes teams, community pharmacists, hospital diabetes teams and patient representatives.
- Implement a switch program to the formulary blood glucose meters and test strips.

Background

There are an estimated 4.5 million people living with diabetes in the UK.³ Figures from 2014 state that 3.5 million of these are diagnosed and it is estimated that 10% of cases are type 1 diabetes and 90% are type 2 diabetes.³

A report published by NHS Digital states that in the financial year 2016/17 'drugs for diabetes' accounted for 11% of the total net ingredient costs of prescribing in primary care. There were 52 million items prescribed for diabetes at a total net ingredient cost of £983.7 million. In recent years there has also been a steady increase in the number of prescription items of 'diagnostic and monitoring services for diabetes' in primary care (i.e. blood glucose testing reagents, ketone blood testing reagents and urine testing reagents listed in section 6.1.6 of the British National Formulary or BNF).⁴

SMBG is an essential component in managing patients treated with insulin to help them to achieve tight blood glucose control and to prevent severe hypoglycaemia. The purpose of this is to allow a patient

to make necessary adjustments to their insulin dose (applicable in type 1 diabetes) and also to make informed lifestyle changes. In non-insulin treated type 2 diabetes the benefits of regular SMBG are unclear for most people with diabetes.¹

The usual method for monitoring blood glucose control in type 2 diabetes is by measuring glycated haemoglobin (HbA1c) every three months via a blood test. This gives an average of the blood plasma glucose concentration over the previous three months in mmol/mol or as a percentage. Self-monitoring of blood glucose can be carried out in addition, to routinely provide a snapshot measure of capillary blood glucose levels using a finger prick blood test; this can be used to build trends for adults with type 2 diabetes and allows corrective action to be taken more regularly.

However, NICE states that there is limited evidence to guide clinical practice in prescribing self-monitoring regimens, in terms of frequency of testing and optimal blood glucose targets in adults with type 2 diabetes for whom self-monitoring is appropriate.

A Cochrane review found the overall beneficial effect of SMBG on glycaemic control in patients with type 2 diabetes (who were not using insulin) was small up to six months after initiation, and subsided after 12 months.⁵

A previous Health Technology Assessment (HTA) report found SMBG reduced HbA1c by a statistically significant 0.2% (about 2 mmol/mol), however, this was not considered clinically significant as it was less than 0.5% (5.5 mmol/mol).⁶

SMBG reduced HbA1c by a statistically significant 0.3% (about 3mmol/mol) at up to six months follow-up but the reduction was not statistically significant at 12 months.

There was no evidence that SMBG affected patient satisfaction, general well-being or general health-related quality of life. Some studies have shown an association with anxiety and depression due to unnecessary SMBG.⁷

NICE Guideline NG28 on the management of type 2 diabetes in adults recommends that the continued benefit of SMBG should be assessed in a structured way each year and clinicians should check the person's self-monitoring skills, the quality and frequency of testing, that the person knows how to interpret the results and is aware of what action to take, the impact on the person's quality of life, the continued benefit of testing and the equipment.¹

NICE recommends that SMBG should NOT be offered to adults with type 2 diabetes unless:¹

- The person is on insulin or
- There is evidence of hypoglycaemic episodes or
- The person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery (including driving) or
- The person is pregnant or planning to become pregnant (see NICE guideline on diabetes in pregnancy)

NICE also recommends that short-term SMBG is considered:¹

- For those starting treatment with oral or intravenous corticosteroids
- To confirm suspected hypoglycaemia

The Driver and Vehicle Licensing Agency (DVLA) current medical standards of fitness to drive should also be taken into account when offering self-monitoring of blood glucose levels for adults with type 2 diabetes (see table 1, page 5).¹

Flash glucose monitoring (FGM)

FreeStyle Libre® is a flash glucose monitoring (FGM) system which monitors blood glucose levels using interstitial fluid levels rather than capillary blood glucose from finger prick testing. Freestyle Libre was added to the Department of Health Drug Tariff on 1st November 2017.

The Regional Medicines Optimisation Committee (RMOC) position statement on flash glucose monitoring systems does not support its use in type 2 diabetes. The RMOC recommends that “Freestyle Libre® should only be used for people with type 1 diabetes, aged four and above, attending specialist type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by a specialist clinician and deemed to meet one or more specific criteria, in addition to undertaking training and committing to regular follow-up and monitoring”.⁸ The criteria are:

1. Patients who undertake intensive monitoring >8 times daily.
2. Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycemia as described in NICE TA151) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy.
3. Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre® does currently not have that function.
4. Frequent admissions (>2 per year) with DKA or hypoglycaemia.
5. Those who require third parties to carry out monitoring and where conventional blood testing is not possible.

There is currently limited evidence to support the use of FreeStyle Libre® and consequently, it is not considered to be cost-effective in all patients. NHS England announced on 14th November 2018 that from April 2019, type 1 diabetes patients will be able to receive FreeStyle Libre® on prescription if they qualify for it in line with NHS clinical guidelines. The NHS Clinical guidelines are yet to be specified.

<https://www.england.nhs.uk/2018/11/nhs-to-provide-life-changing-glucose-monitors-for-type-1-diabetes-patients/>

Monitoring of blood glucose for patients in care homes⁹

Residents with type 2 diabetes do not necessarily require regular capillary glucose monitoring (i.e. via finger prick testing). It should only be undertaken where there is a documented clinical need.

Residents with diabetes should have a detailed care plan covering when to monitor capillary blood glucose levels, their normal range and action to be taken if values are outside this range. The frequency of monitoring and glycaemic goals need to be established on an individual basis, requiring a consensus decision between the GP, resident, any community nursing support and the appropriately qualified care home staff. Blood glucose monitoring is an invasive procedure and consent should be obtained.

Registered care home managers are responsible for ensuring that staff undertaking blood glucose monitoring for residents are trained in the correct procedure when testing blood glucose. All carers should be aware of what to do in the event of high or low readings. Staff should also be aware of the symptoms of hypoglycaemia.

Some care home residents may be more prone to hypoglycaemia due to variable dietary intake, dementia, poor hypoglycaemic awareness and mental health conditions.

Blood glucose testing for patients counting carbohydrates

Adults and children with type 1 diabetes, who have been taught how to carbohydrate count may require more expensive blood glucose testing strips (and devices) with an additional range of functions. Selection and supply of these meters to patients should be made by the specialist services such as hospital care or community diabetic nurses.

Ketone testing strips

Ketone (blood or urine) testing is occasionally indicated for some patients with type 2 (and type 1) diabetes if they are at high risk of diabetic ketoacidosis. With the exception of insulin pump patients and complex patients under secondary care, the use must be carefully monitored.

Patients required to self-test for ketones should be identified by the diabetes specialist service and are usually provided with the initial supply by the specialist service. Ensure that quantities are rationalised to reflect intended frequency of testing.

Ketone testing strips should not be prescribed on the NHS for testing associated with ketogenic diets intended for weight loss.

Urine glucose testing strips

Testing of glucose present in the urine is not routinely recommended as it is less accurate than blood glucose testing. This method is unsuitable for detecting hypoglycaemia because glucose is only present in the urine when the blood glucose level is relatively high (>10mmol/litre).

Guidance for reviewing the need to test for blood glucose

Key points to note:

- SMBG should NOT be provided routinely to people with type 2 diabetes unless they are on insulin OR there is evidence of hypoglycaemic episodes OR the person is on oral medication that may increase their risk of hypoglycaemia whilst driving or operating machinery OR they are pregnant or planning to become pregnant.¹
- People who drive and are prescribed insulin or other diabetes agents that carry a risk of hypoglycaemia (sulfonylureas, glinides), must be prescribed blood glucose testing strips to allow them to satisfy the level of testing stipulated by the Driver and Vehicle Licensing Agency (DVLA). See table 1, page 5.
- SMBG should be used to optimise blood glucose control prior to conception and during pregnancy, including gestational diabetes.
- SMBG should be used only within a care package, accompanied by structured education with regular review. The education should include clear instructions as to the place of monitoring and how results can be used to reinforce lifestyle change, adjust therapy or alert healthcare professionals.
- The quantity of test strips on prescription should reflect the frequency of testing required by the individual patient. Where testing is only required intermittently, prescriptions should be generated only when needed and not as a repeat prescription.

Patient assessments should include the following:

- 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

Frequency of testing blood glucose should be agreed by local specialist diabetes team and guidelines should be clearly communicated to all healthcare professionals involved in diabetes care. A decision to amend the quantity of blood glucose testing strips (BGTS) or to stop prescribing altogether should be clearly communicated to patients.

Organisations should audit prescribing of BGTS to ensure that it is in line with recommendations in NICE guidance and by the DVLA. Prescriptions should be discontinued, or quantities adjusted as appropriate. Attachment 1 provides an audit to support you with this activity.

A 10% reduction in BGTS items over 12 months would avoid costs of £17 million across England and Wales (April to June 18 ePACT2 data).

Table 1: Summary of DVLA requirements with regards to self-monitoring of blood glucose¹⁰

	Group 1 Entitlement - Car and Motorcycle	Group 2 Entitlement - Bus and Lorry
Insulin treated patients	<p>There must be appropriate blood glucose monitoring. This is defined as two hours before the start of the first journey and every two hours while driving.</p> <p>More frequent testing may be necessary if there is a greater risk of hypoglycaemia such as physical activity or altered meal routine.</p>	<p>Regular monitoring of blood glucose should take place at least twice daily, including on days when not driving and two hours before the start of the first journey and every two hours while driving.</p> <p>More frequent testing may be necessary if there is a greater risk of hypoglycaemia such as physical activity or altered meal routine. In which case, the bus or lorry driver must use a glucose meter with a memory function that stores three months of readings available for assessment.</p>
Patients managed by tablets which carry a risk of inducing hypoglycaemia (includes sulfonylureas and glinides)	<p>It is appropriate to offer self-monitoring of blood glucose at times relevant to driving to enable the detection of hypoglycaemia.</p>	<p>Regular monitoring of blood glucose should take place at least twice daily and at times relevant to driving, i.e. no more than two hours before the start of the first journey and every two hours while driving.</p>

Continuous Glucose Monitoring does not fulfil the DVLA requirements for self-monitoring of blood glucose as this only measures interstitial glucose.

Patients receiving insulin as a temporary treatment (including gestational diabetes and post-myocardial infarction) must notify the DVLA if disabling hypoglycaemia occurs or if treatment continues for more than three months (or for gestational diabetes, continues for 3 months after delivery).

Review of blood glucose testing meters/strips

Approximately £168 million was spent on BGTS in the England and Wales (ePACT2 data August 2017 - July 2018). Table 2 represents a summary of cost of prescribing for diabetes care which highlights the significant spend on BGTS alone.

Table 2: Total cost over 12 months (August 2017-July 2018)

	Insulin	Antidiabetic drugs	Glucose blood testing reagents	Grand total
England and Wales total	£328,143,726	£467,607,780	£167,748,243	£963,499,749

There is a wide variety of blood glucose meters and testing strips to choose from and the October 2018 Drug Tariff lists 55 different blood glucose testing strips ranging in price from £5.45 to £16.65 per 50 strips. BGTS with an acquisition price \leq £9.00 per 50 strips (this does not take into consideration locally agreed rebates) are deemed to be cost-effective and are highlighted on chart 1 (page 7).

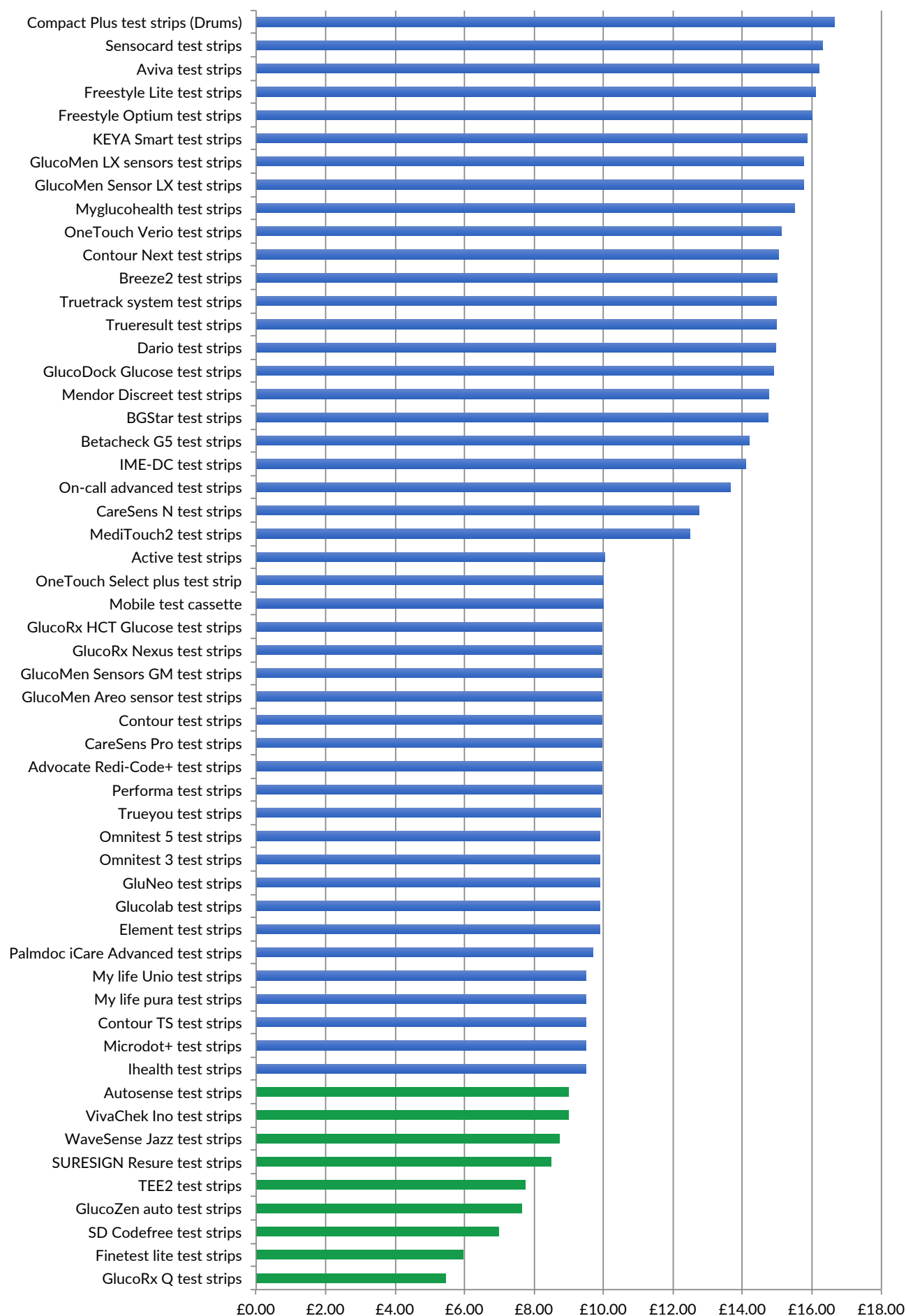
There is little variation between the different meters in their ability to provide an accurate reading of blood glucose so it is appropriate that prescribing should be streamlined to include only cost-effective testing strips.

In England and Wales, 87.4% of prescription items were for BGTS costing more than £9 per 50 strips. By switching patients to cost-effective blood glucose meters and testing strips the cost of prescribing can be reduced by 31% assuming a 100% switch or 25% assuming an 80% switch. This saving has been calculated using £9 as the cost limit for 50 testing strips. **This will generate a saving of £52.9 million across England and Wales.**

Some manufacturers of blood glucose meters may offer rebate schemes to CCGs to bring the price of testing strips in line with the recommended £9.00 or less/50 strips. This bulletin does not consider the rebates offered and CCGs will need to make individual decisions on formulary choices based on rebates. Further information on rebates is available from PrescQIPP at <https://www.prescqipp.info/our-resources/webkits/primary-care-rebates/>

Chart 1: Cost* of blood glucose testing strips per 50 strips

*List prices from Drug Tariff October 2018.



Blood glucose meter selection: Implementation guide

There is a wide variation in prescribing for the different brands of BGTS and costs are very high. It is worthwhile considering implementing a project to choose a preferred meter (or meters) for the following reasons:

Patients are often offered free meters by the companies through diabetes groups and magazines. These are more often the newer meters with high cost strips and inevitably the patients will then request a prescription for these strips from their GP practice. Having a preferred formulary meter and a clear policy to review each patient for clinical appropriateness before initiating prescribing of testing strips will ensure that this does not occur and will minimise spend on testing strips.

There is no evidence to suggest greater clinical benefits are achieved by using the more expensive BGTS over the less costly ones and therefore the products with the lowest acquisition cost that meet requirements outlined in the meter selection process below should be chosen. Clearly identify patient groups that may not be suitable for the formulary meter such as those with visual impairment, patients with type 1 diabetes using an insulin pump or testing for ketones, children, people on dialysis etc. These patients should be given meters that meet their individual needs.

Secondary care clinicians often lead on meter choice as they work with companies and may get certain added benefits by using a particular meter (i.e. nurse support, patient information etc.). It is therefore important that this project is implemented with a wide group of stakeholders and includes secondary care clinicians. The group may need to have discussions about the current perceived benefits of choosing a particular more costly meter over the actual benefits of being able to re-invest savings into diabetes care locally.

A project process for reviewing BGTS and choosing a formulary choice product or products is outlined below. Organisations may adapt this process to suit local requirements. Meters should be systematically reviewed for accuracy, ease of use for meter, strip and lancet device, company customer services and the cost of strips.

Step 1 - Why undertake the project

There is some evidence to suggest that actively implementing a change in the preferred blood glucose testing system is up to 700% more effective in terms of financial savings, compared with a formulary change alone.¹¹

Determine the benefit to patients and your local health economy for undertaking the meter switch. A SWOT analysis would help you to identify the benefits and anticipate the potential difficulties for the project. An example SWOT analysis may look like:

<p>STRENGTHS</p> <ul style="list-style-type: none"> • Significant savings which can be re-invested in other diabetes programs • Supports use of cost-effective products by the NHS 	<p>OPPORTUNITIES</p> <ul style="list-style-type: none"> • Patient review – consider if SMBG is needed, appropriate frequency, monthly quantities required. Stop SMBG where this adds no benefit to patient care • Ensure care package and structured review available to patient • Review patient's technique and use of results • Change old meters which may no longer be accurate • Educate all healthcare professionals involved in the care of diabetes
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<p>WEAKNESSES</p> <ul style="list-style-type: none"> • Time consuming exercise 	<p>THREATS</p> <ul style="list-style-type: none"> • Some patients, e.g. the elderly may be confused with new product • Pharmaceutical company antagonism towards change
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Step 2 – Working group

- Identify a working group to carry out a review of blood glucose testing strips and meters, including representatives of key stakeholders.
- Establish a list of stakeholders and keep them informed throughout the project.
- Stakeholders would include: diabetes consultants, medicines optimisation pharmacists, specialist diabetes nurses (community and secondary care), GPwSI diabetes, practice pharmacists, practice nurses, community nurses, Local Pharmaceutical Committee, patient representatives, pharmaceutical companies.

Step 3 – Selection of meters for initial evaluation for technical requirements

- Select meters with cost-effective testing strips - ≤ £9.00/50 strips (if CCGs have rebate agreements in place around particular test strips, this may be taken into consideration).

Review these meters using the data or template provided by the Centre for Evidence-based Purchasing - Market review of blood glucose monitoring systems.¹² Relevant information on primary care and self-testing meters which were available from October 2018 can be found in attachment 2: www.prescqipp.info/our-resources/bulletins/bulletin-212-diabetes-testing-strips/

You can use this template to review meters introduced to the market after this date using information available from the manufacturers.

Eliminate any meters that do not meet the International Organisation for Standardisation (ISO) requirements for blood glucose monitoring systems.¹³ This is a detailed set of standards that all blood glucose meters must meet.

Produce a shortlist of six meters (or more if capacity available locally) following this evaluation for further analysis and patient evaluation.

Step 4 – Product comparison

Develop a scoring matrix to compare the meters to assess the more practical aspects of these meters. A sample is provided in attachment 3 - patient meter evaluation form, available via: www.prescqipp.info/our-resources/bulletins/bulletin-212-diabetes-testing-strips/

Product comparison should include - cost of testing strips, display features, memory capacity, ease of use, ability to download data and share, customer service facilities.

- Select the two (or more) highest scoring meters for further evaluation (step 5).
- Views of expert patients are key at this stage of the decision-making process.

Step 5 – Final meter selection

- Select a group of patient representatives to use the short-listed meters for a short period (e.g. two weeks) and collate feedback. This will provide a more realistic picture of the expected level of uptake when rolled out to the wider population.
- The working group should then agree a choice of preferred meter(s) for your CCG medicines formulary. Consider having more than one meter to accommodate patient choice.

Step 6 – Formulary change

Obtain agreement from appropriate prescribing committees (Hospital Drugs and Therapeutics Committee, STP/ICS/Area Prescribing Committees) on the choice of preferred blood glucose testing strips and meters.

Update CCG formulary (and acute trust formulary where a joint approach has been agreed) for blood glucose testing meters/strips.

Note that the decision by an organisation to select a preferred blood glucose meter should be a formulary choice rather than a procurement process. This distinction should be clearly documented.

Clearly identify patient groups that may not be suitable for the formulary meter such as those with visual impairment, patients with type 1 diabetes using an insulin pump or testing for ketones, children, people on dialysis, etc. These patients should be given meters that meet their individual needs.

Step 7 - Implementation

- Determine a time scale for carrying out the switches.
- Outline an implementation plan for meter switching and determine resource required to undertake this change. Such resources may include:
 - » Patient information leaflets and FAQ documentation.
 - » Clinic or appointment times for demonstrating use of new meters. This can be particularly time consuming especially where patients need to make a choice. Consider alternative resources such as healthcare assistant led clinics and commissioning community pharmacy staff*.
 - » Active use of formulary meters by specialist nurses initiating new patients including use for gestational diabetes.
 - » Change of repeat medication list for BGTS on GP computer system.
 - » PALs engagement in handling queries and complaints.

*An example of a community pharmacy service to implement the meter switching is available in the Best Practice section of the PrescQIPP website: <http://www.prescqipp.info/resources/viewcategory/117-best-practice>

Once the project is implemented, prescribing data can be monitored to assess the uptake of formulary choice blood glucose testing strips. Consider including all cost-effective meters as part of the monitoring indicator to ensure practices are not penalised for using alternative cost-effective testing strips.

Summary

- The cost of prescribing blood glucose testing strips is still growing rapidly and there are significant savings to be made by rationalising prescribing.
- Self-monitoring of blood glucose in type 2 diabetes is only beneficial for a selective group of patients and this practice should be undertaken in line with NICE guidelines.
- Prescribing should be rationalised by ensuring that self-monitoring is appropriate (including quantities issued on prescription) and that a selection of cost-effective meters and testing strips are used where appropriate.
- The cost of blood glucose testing strips can be reduced by 25% if 80% of prescribing represents cost-effective (\leq £9.00/50 strips) testing strips.
- Cost savings realised from identifying a formulary choice of blood glucose meter and testing strips and implementing a switch can be re-invested into local diabetes care.

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Acknowledgements

Bedfordshire Clinical Commissioning Group - Integrated Community Diabetes Service: Introduction of formulary Blood Glucose Meters

Additional PrescQIPP resources



Audit, product comparison guide, patient meter evaluation form

Available here: www.prescqipp.info/our-resources/bulletins/bulletin-212-diabetes-testing-strips/



Data pack

Available here: https://pdata.uk/#/views/B212_Testingstripsindiabetes/FrontPage?:iid=1

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