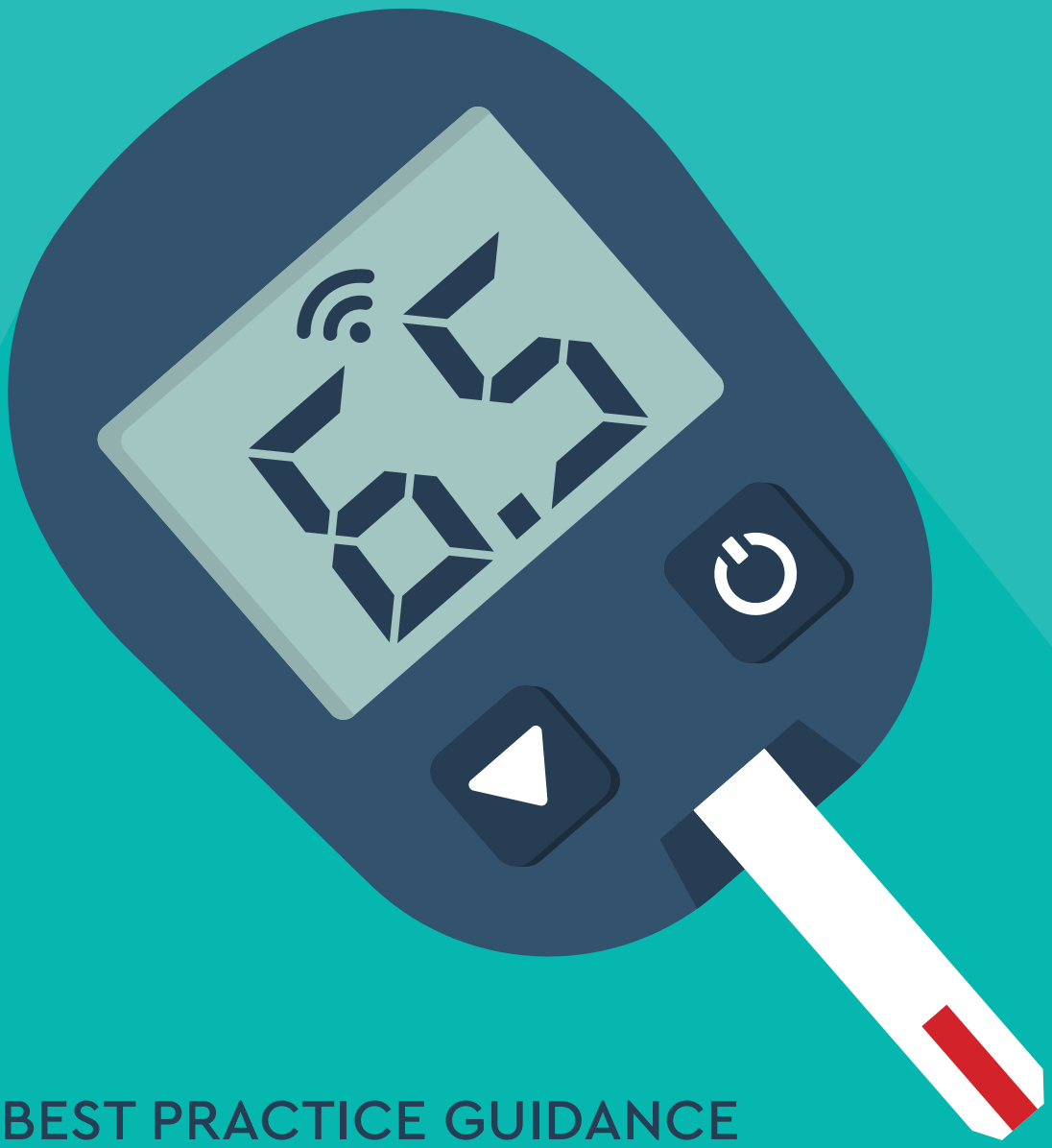

BEST PRACTICE GUIDANCE

# Developing and updating a formulary for self-monitoring blood glucose testing devices

FEBRUARY 2019

# Overview

Self-monitoring of blood glucose, supported by ongoing patient education, offers the potential to improve patient outcomes and experiences and deliver efficiencies and savings to local health systems.

Local formularies can offer support to clinicians in making choices between the different healthcare technologies available, to deliver the best tailored outcomes for patients and the most effective use of available resources to address regional variations. To do so, formularies need to be developed through a stringent process based on the expertise of qualified healthcare professionals and commissioners, with input from people with diabetes and their caregivers.

This guide has been prepared to update the first edition produced in 2014.[1] It is intended to help local health economies draw up and revise formularies for blood glucose testing devices for patient self-monitoring. The aim of the guide is to enable local health economies to take account of local needs and the views of clinicians and patients. It is based on the findings of a Consensus Group (see back outer cover for full list of participants), and does not represent official UK policy, but rather guidance on good practice.

A formulary should be a living document (reviewed every 6 months and formally updated at least every 2 years) to ensure it meets the needs of patients and keeps track of innovation in the industry. This document sets out:

- Background information
- The purpose of a formulary
- Recommended stakeholder involvement
- Practical templates, examples and processes for the development of formularies
- Recommended approaches for implementing, reviewing and updating formularies

By using this document, blood glucose testing formularies can be developed and updated to help to reduce unwarranted regional variation in outcomes and the uptake of technology.

The Consensus Group was chaired by Clair Huckerby (Consultant Pharmacist Primary Care Medicines Optimisation, Dudley CCG) and brought together by Roche Diabetes Care to produce this guidance. Roche Diabetes Care does not have ownership or editorial control over this guidance.

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# Background

## Diabetes in the UK[2]

Diabetes affects more than 4.7 million people in the UK – more than any other long term health condition. Every week, diabetes leads to:

- more than 500 early deaths
- more than 160 amputations
- more than 530 heart attacks
- more than 2,000 cases of heart failure
- more than 680 strokes

At least 10,300 people in the UK have end stage kidney failure because of their diabetes.

## The value of blood glucose testing

For many people self-monitoring of blood glucose is an essential part of day-to-day diabetes management and it can help with necessary lifestyle and treatment choices as well as detect hypo- and hyperglycaemia. The frequency of blood glucose monitoring may relate to diabetes type and therapy, for example people with type 1 diabetes or type 2 diabetes using insulin, or gestational diabetes have to test at different intervals. However, in all cases, the value of blood glucose monitoring is closely linked with patient understanding and it is important that any patient expected to routinely check their blood glucose is provided with relevant educational support. Structured approaches to blood glucose monitoring can also help both the patients and their healthcare team to adjust treatment to achieve better clinical outcomes.

## Importance of a formulary for blood glucose testing devices

The benefits of using a local formulary for medicines management are already well established and their use is routine. Given the prevalence of diabetes, a well-developed local formulary for blood glucose testing is particularly important to reduce complications and realise financial savings from achieving optimal glucose control. The use of formularies is also vital in addressing regional variations in service delivery and health outcomes.

A robust local formulary in blood glucose testing could improve:

- Quality of care
- Patient engagement through shared-decision making
- Patient outcomes
- Equality of access to technology

**1** Best Practice Consensus Group, Best Practice Guidance - Development of a formulary for blood glucose testing devices, 2014
**2** Diabetes UK, Statistics 2019; **https://www.diabetes.org.uk/professionals/position-statements-reports/statistics/diabetes-prevalence-2017**

# Purpose of a formulary

## Why have a formulary?

Before starting the process, it is important to determine who should discuss and decide what the final outcome of the formulary process will be. There is a wide variety of blood glucose monitoring equipment on the market and many systems have been developed with diverse functions to align with specific clinical and patient needs. Not all patients should or could use the same device.

At a minimum, the needs of the following populations with diabetes should be considered when developing a formulary:

- Patients using non-insulin therapies, where intermittent glucose monitoring may be indicated to assess treatment effectiveness
- Patients using fixed daily doses of insulin
- Patients using flexible multiple daily insulin injections (where the blood glucose result, food intake and/or activity level affect the rapid-acting insulin dose)
- Patients who drive frequently or in the course of their employment, recognising DVLA testing guidelines
- Patients with limited dexterity, those with needle phobia and those with visual impairment
- Patients with type 1 diabetes and people with type 2 diabetes at risk of diabetic ketoacidosis (DKA) who require access to blood ketone testing
- Special consideration should be given to patients who need to test ketones and those needing connectivity, as well as to those carb counting

Additionally, a formulary should facilitate:

- Educational support for all patients, including those who use an insulin pump with a linked blood glucose monitoring device
- Access to blood glucose devices offering automatic data transfer to the cloud via the patient's smartphone where appropriate



# Stakeholder involvement

Engaging with a mix of healthcare professionals and patients can provide a wide range of different perspectives that will result in a higher quality formulary, which commands the confidence of all parties and is therefore more likely to be successfully implemented. This mix would have to be determined locally and may be affected by those willing to engage.

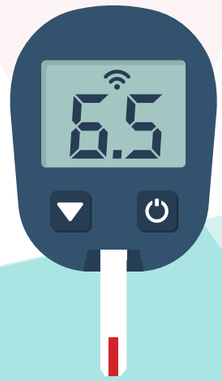
The following stakeholders should be encouraged to attend:

- Patient representatives and diabetes patient advocacy service users (providing representation across the breadth of diabetes therapies)
- Diabetology team members, adults and paediatrics (consultant or diabetes specialist nurse)
- Immediate diabetes service providers
- Nurses representing primary care, secondary care and community care
- Medicines management / optimisation leads
- Healthcare industry / manufacturers

Input from the following health professionals would be vaulable:

- Community pharmacists
- Biochemists / point of care testing managers
- Dieticians
- GPs and practice nurses
- Leaders of local diabetes education programmes

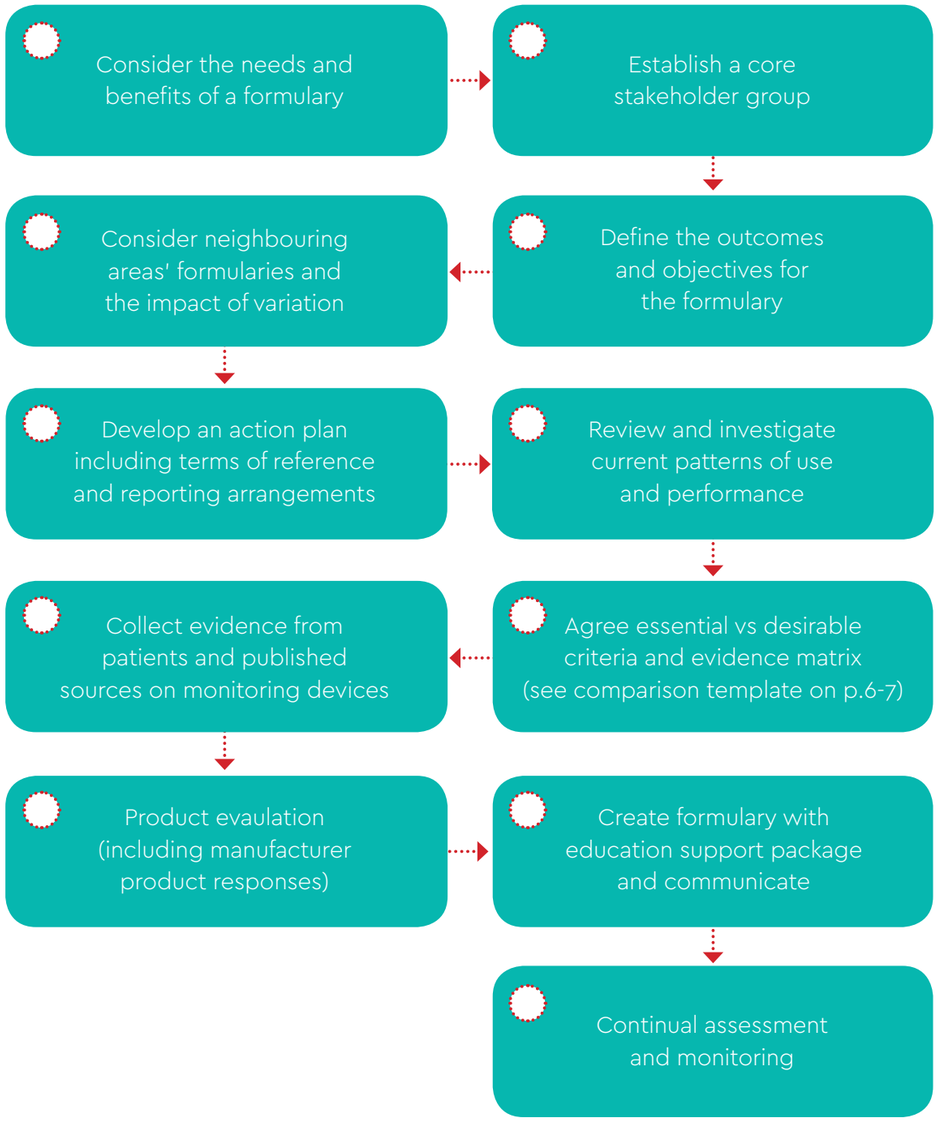
Within a wider implementation programme, a broader stakeholder group should be involved.



# How to develop a formulary for blood glucose devices

To support the development of formularies, we have included below a suggested process, an example product comparison template and a patient feedback form. By utilising these supporting documents and learning from the above examples the Consensus Group believe regional variations in access to appropriate diabetes technology can be reduced.

## Suggested formulary development process






## Example patient feedback form

Thank you for trialling the test glucose monitoring device. We would be grateful if you could take a few minutes to complete and return the following form.

**Which type of diabetes do you have?** .....

**What therapy regime are you on?** .....

○ **Flexible insulin / pump** ○ **Fixed insulin** ○ **Oral drugs (pills)** ○ **Other**

**If other, please specify** .....

**What was the name of your previous device?** .....

**How many packs of test strips do you use a month?** .....

**What is the size of the blood sample required?** .....

**Please could you rate the device just trialled on a scale of 1 to 10 (please tick)**

| | Bad | | | | | | | | | Good |
|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| How helpful is the support line / website? | | | | | | | | | | |
| How easy is the device to use? | | | | | | | | | | |
| How do you like the lancet device? | | | | | | | | | | |
| How easy are the results to read? | | | | | | | | | | |
| How easy is it to view past results? | | | | | | | | | | |
| How quickly do results appear? | | | | | | | | | | |
| How portable is the meter? | | | | | | | | | | |

**Do you prefer your previous device or your new one, and if so why?**

**Can you suggest anything about the device that you would like to change?**

**We would welcome any additional comments, suggestions or feedback.**

*Adapted from the form used by Bedfordshire CCG*

## Example product comparison template (1 of 2)

| | Product 1 | Product 2 | Product 3 |
|---|---|---|---|
| Name of device (image) | | | |
| Name of consumable product | | | |
| Consumable product price | | | |
| Lancet device (comfort and ease of use) | | | |
| Lancing price | | | |
| Manufacturer | | | |
| Enzyme system | | | |
| ISO Compliance | | | |
| Weight of blood glucose meter | | | |
| Size of blood glucose meter | | | |
| Bluetooth function | | | |
| Connected app | | | |
| Back light (Y/N) | | | |
| Display size | | | |
| Memory capacity | | | |
| Clinical data | | | |
| Measurement range | | | |
| Device storage conditions | | | |



## Example product comparison template (2 of 2)

| | Product 1 | Product 2 | Product 3 |
|---|---|---|---|
| Operating temperature (cassette/strips) | | | |
| Measures only in mmol/L units (Y/N) | | | |
| Set up required (Y/N) | | | |
| Coding required (Y/N) | | | |
| Sample size | | | |
| Under-fill detection | | | |
| Measurement time | | | |
| Haematocrit range | | | |
| Ability to flag pre and post meal results (Y/N) | | | |
| Bolus advice (Y/N) | | | |
| Alarm reminders (Y/N) | | | |
| Ketone warning if glucose is high (Y/N) | | | |
| Talking meter (Y/N) | | | |
| Meter free to patient (Y/N) | | | |
| Free replacement batteries, log books, finger pricker (Y/N) | | | |
| Control solution free to patients (Y/N) | | | |
| Data sharing capabilities (hardware, software and apps) (Y/N) | | | |
| Self-eject strip (Y/N) | | | |
| Expiry date of test strips | | | |

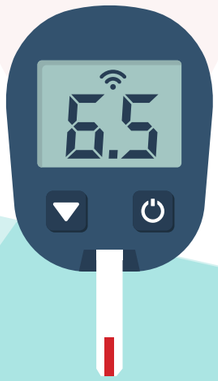
# Implementation

Once the formulary has been created, it is vital that it is supplemented by a local communication strategy through GP champions, practice nurses, diabetes leads and intermediate and specialist clinicians, so that all are aware of the new products that are available.

The creation and communication of a formulary provides an opportunity to support further education around appropriate blood glucose testing to achieve better outcomes.

To implement your formulary, consider:

- How to best communicate formulary decisions across your local area
- How to develop effective plans for sufficient HCP and patient training
- How to keep product wastage to a minimum
- How to ensure appropriate disposal of clinical waste (strips and sharps)

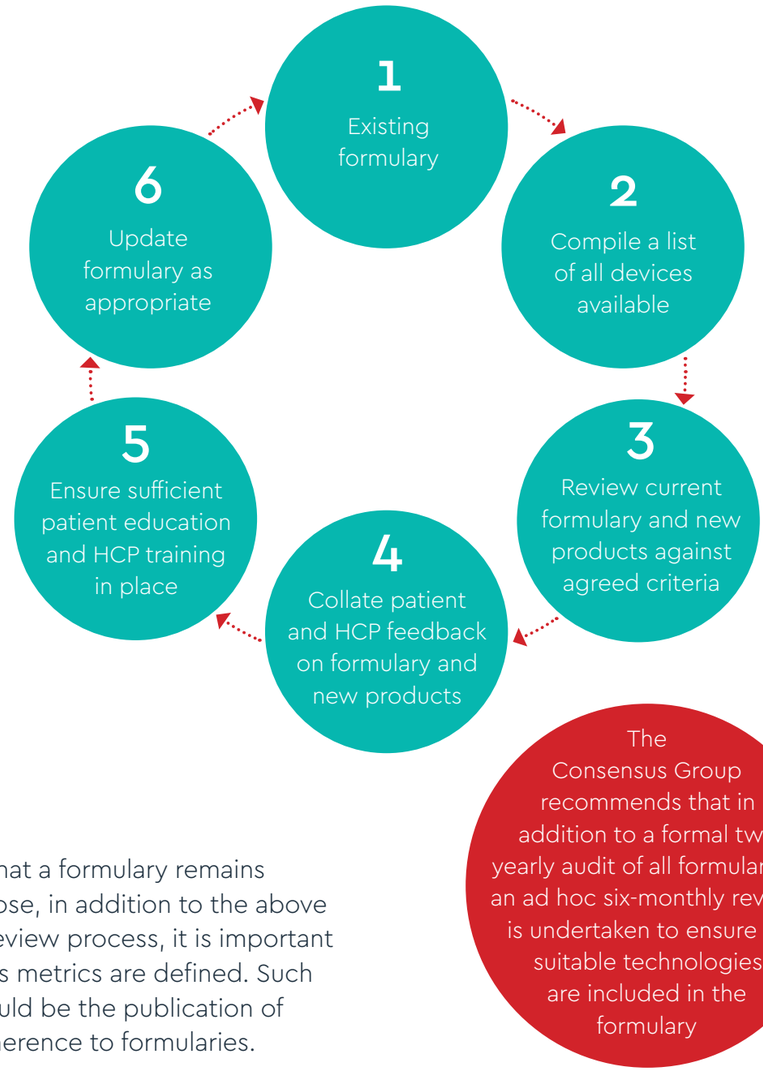





# Review process

The formulary process should be dynamic and adaptable. By following these timelines, patients across an area will continue to be able to get access to the latest technology of most benefit to them.

## Suggested two-yearly formulary review process




To ensure that a formulary remains fit-for-purpose, in addition to the above audit and review process, it is important that success metrics are defined. Such a metric could be the publication of rates of adherence to formularies.

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