Bringing glucose monitoring up to date: Data collection and utilisation in clinical practice

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Article points

1. Glucose monitoring data is an under-used tool in diabetes management that can be used to inform changes in therapy, behaviour or both.
2. Implementing data-led consultation requires a foundation of a clinical desire to change the glycaemic experience of the person with diabetes, which is supported by clinician training.
3. Data collection and analysis is, after more than 40 years, fit for purpose as a mainstay of intervention and should thus be considered a routine part of the specialist delivery of diabetes care.

Key words

- Ambulatory glucose profiling
- Glucose monitoring

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The benefits of structured analysis of glucose monitoring data to glycaemic outcomes in diabetes care have been well documented in research studies. However, despite the availability of the technology for over 40 years, and people with diabetes being encouraged to regularly undertake glucose monitoring, it can be daunting to use data collected constructively and routinely in the real world setting of a busy clinic without a framework. This article aims to provide a framework in which to gather and interpret data, with examples derived from both self-monitoring and continuous glucose monitoring datasets.

The benefits of structured analysis of glucose monitoring data with respect to glycaemic outcomes in diabetes are well documented in research studies. However, despite the availability of the technology for over 40 years, and people with diabetes being encouraged to regularly undertake glucose monitoring, it can be daunting to use data constructively and routinely in the real-world setting of a busy clinic without a framework. Thus, in most clinics, this practice remains the exception rather than the rule. This article aims to provide a framework by which to gather and interpret data, with examples derived from both self-monitoring of blood glucose (SMBG) and continuous glucose monitoring (CGM) datasets. Using Simon Sinek's (2009) approach to reasoning, we will answer "why" use downloaded data, "how" data are best used and "what" needs to be done to change consultation practice to allow routine analysis in the diabetes clinic.

There are two ways in which glucose data can be used to change therapy, behaviour or both. Most commonly, a glucose result is used to decide an immediate course of action – a ***reactive*** process – generally undertaken by the person with diabetes (PWD), but for which the healthcare professional (HCP) may offer education (e.g. how to manage a hypo, or how to make insulin correction strategies for hyperglycaemia). The second is where the pattern of previously collected glucose data is used to adjust future diabetes therapy, in order to prevent repetition of previous outcomes. This is a ***proactive*** profiling process, involving active and objective data observation and interpretation on the part of the HCP in order to offer advice that will change the future experience. Of the two processes, it is clear that a proactive approach has the potential to change the long-term outcomes generally perceived by HCPs to be the focus of a consultation. However, glucose profiling is rarely taught to HCPs involved in diabetes and, thus, rarely employed in routine consultation.

Why: Why use downloaded data?

So why should we *all* make the effort to use downloaded data in a consultation? Although HbA_{1c} may offer a 3-month averaged "overview" of excess glycaemic exposure, HbA_{1c} forms only part of overall glycaemic control and cannot describe the risks associated with the extremes of high and low glucose. To fully understand glucose control and to be able to advise how to improve a PWD's

experience requires glucose change, or flux, to be assessed. There is a triad of variables that comprise the "glucose profile":

- **Glycaemic exposure**: average glucose levels, most commonly represented by HbA_{1c}.
- **Glycaemic variability**: day-to-day glucose changes; for example, between a weekday and the weekend.
- **Glycaemic instability**: within-day glucose change; for example, between breakfast and the evening meal.

All three elements need to be assessed and understood by the HCP if proactive advice is to be given effectively in order to avoid short-term extremes (which are mostly a result of glycaemic flux) and improve long-term outcomes. An appropriate glycaemic profile-related goal would be to minimise glycaemic variability and instability, thereby safely allowing decreased overall exposure without increasing associated hypoglycaemic risk as a result of glycaemic flux (*Figure 1*). The steps to achieve such an outcome need to be carefully structured into the consultation process and methodically made.

At their most basic level, the interventions available to the HCP can be defined into two categories – lifestyle or behavioural interventions and medication or physical therapy-based interventions. The glycaemic data should guide the HCP as to which of these is more appropriate for individualised care. When setting goals for the PWD, the goals should be individualised and agreed (using the SMART[ER] goal-setting process; *Box 1*). Such goals are usually non-numeric in nature (e.g. "I'd like to be able to go running without risking a hypo"), so may need to be "quantitatively translated" to frame into an objective question, such as "during my usual exercise, how fast and how far does my glucose level fall on average?". Once the question is defined, it is then possible to identify the glycaemic data required to answer it, and to determine how the data should be collected. Assessment following an appropriate goal-setting and data collection period allows the data to be organised, analysed, interpreted and explained, with a subsequent intervention plan (and re-assessment process) mutually agreed. This process can be repeated cyclically as needed.

In order to allow such data analysis to be routinely feasible in a clinical setting, it should be conducted with speed and accuracy, and simplicity and reproducibility. Over time, the collection of glycaemic data has become faster and less invasive, making it routine to collect great volumes of data. The more complex the data become, the more suited analysis through image visualisation rather than individual point assessments becomes. In order for a visualised assessment to be made, it is important that the data are first validated (e.g. appropriate time and date stamp in the case of SMBG) and then organised and presented in a structured format, which is universally recognisable and independent of the collection equipment. A good example of a visualised assessment process of data in routine clinical practice is the electrocardiogram (ECG; *Figure 2*). Different ECG machines exist, but all ECG visualisations are structured in the same format, making them diagnostically interpretable by any clinician anywhere in the world. Another key element of this comparison is that effective interpretation requires a full dataset.

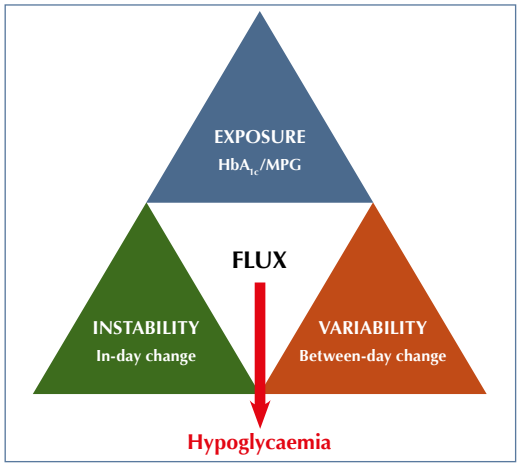

Figure 1. The triad of variables that comprise the "glucose profile" and their relationship to hypoglycaemia. MPG=mean plasma glucose.

How: How to use downloaded data

When considering how to interpret the most common form of glucose data collection, SMBG, it is important to understand why a PWD might check their glucose at a particular point in time, as this will greatly impact on the data's utility. Broadly, there are three reasons, which all have an inherent bias that the HCP must be aware of in order to make the most effective interpretation:

Page points

1. There is a triad of variables that comprise the "glucose profile" of a person with diabetes: glycaemic exposure, variability and instability.
2. All three variables need to be assessed and understood by the healthcare professional if proactive advice is to be given effectively in order to avoid short-term extremes and improve long-term outcomes.
3. In order to allow glucose monitoring data analysis to be feasible in a routine clinical setting, it should be conducted with speed and accuracy, and with simplicity and reproducibility.

Box 1. The SMART(ER) goal-setting process.

The SMART mnemonic proposes that goals should have the following criteria:

Specific
Meaningful
Achievable
Relevant
Time-bound

In addition, the SMARTER mnemonic proposes two further steps to reappraise the goals over the long term:

Evaluate
Readjust

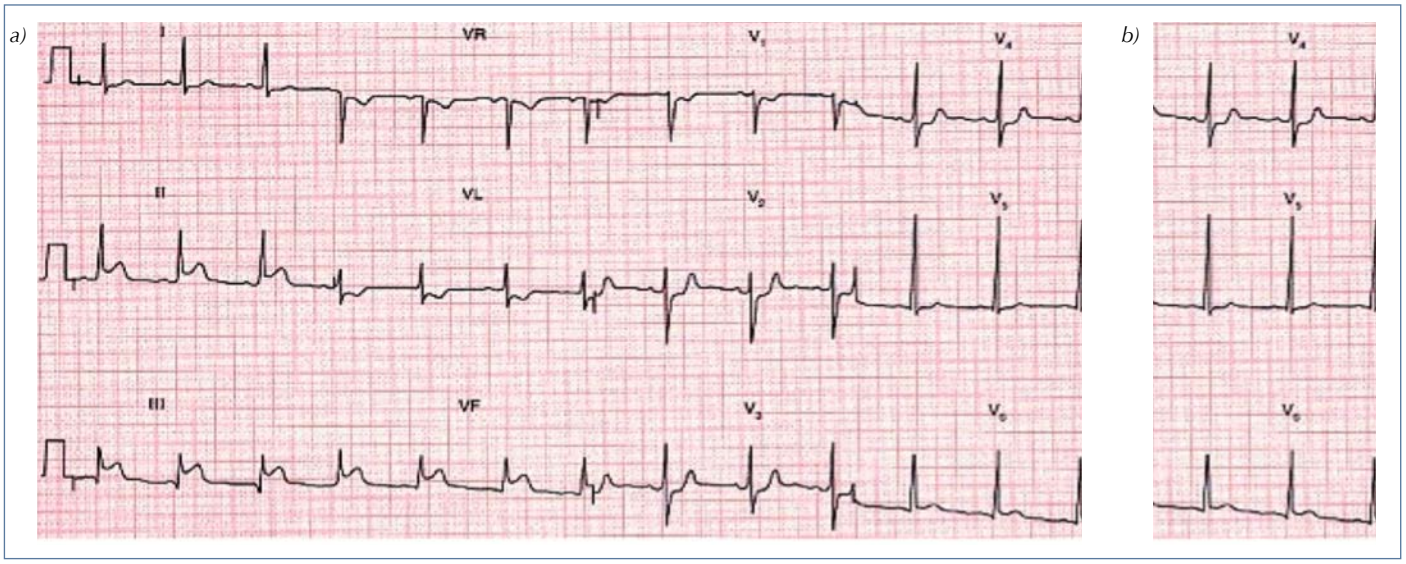

Figure 2a. The electrocardiogram (ECG) – an example of visual data interpretation of high complexity that has been universally adopted and well standardised. Following structured assessment of the projection (representing cardiac electrical activity), a diagnosis of inferior myocardial infarction is determined.

Figure 2b. A partial representation of the same ECG dataset as Figure 2a. The same diagnosis would not be made even though it is showing the same data. This highlights the importance of ensuring full data collection.

- For reassurance. This test is done by the PWD in the hope (and expectation) of a normal result. The frequency of such testing over time will usually diminish (either as a result of effective reassurance or, paradoxically, because reassurance is not achieved), or a fixed testing routine follows to maintain that reassurance. By definition, this dataset will usually appear "normal" for that individual (illustrated by green stars in *Figure 3*) and will not generally capture information of concern.

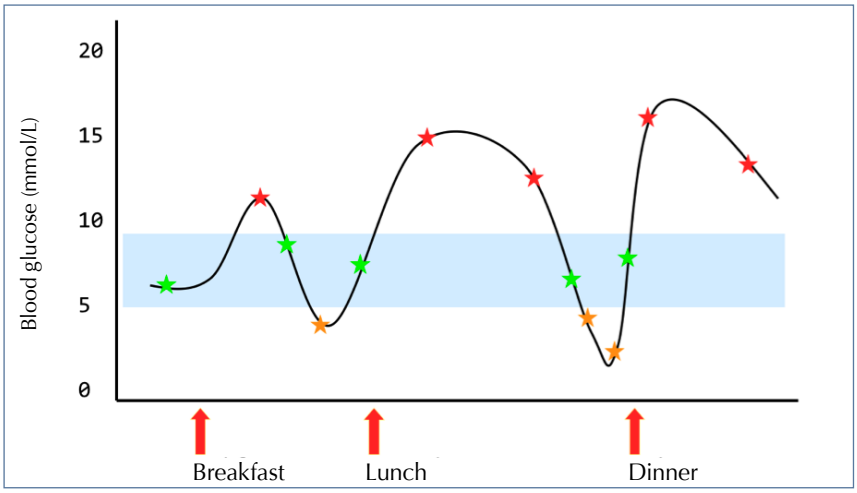

Figure 3. The challenge of self-monitoring blood glucose interpretation: 13 discrete finger-stick tests taken over a single day – while the mean of ~8 mmol/L represents "good control", the assessment of red, green and orange stars alone, as a result of less frequent testing (or particular reasons for testing) would reveal three different interpretations.

- For symptoms or circumstances. This test is done at a time when the PWD is doing something unusual or stressful, and thus is expecting abnormal results. Where the concern is hypoglycaemia, testing will identify hypoglycaemia, and, conversely, where the concern is hyperglycaemia, testing will identify hyperglycaemia, often with little or no correlation to the overall exposure. This is illustrated by red and orange stars in *Figure 3*, and tends to not be representative of what is "normal" for that individual. While it may be useful for making reactive changes and promoting educational input, it will rarely inform a proactive therapy decision, and thus rarely contribute to longer-term goal achievement.
- As part of an agreed plan involving the PWD and an HCP (or occasionally a PWD alone). These tests are done to a structured plan and without expectation of a particular result, with the aim of avoiding situational bias and with the intention of informing a longer-term, proactive planning process. Such data will produce only marginal (if any) immediate benefit, but when reviewed retrospectively they can inform the direction of future therapy decisions and, thus, change future outcomes. If such structured monitoring is undertaken without long-term

review, it has, logically, no benefit and can become the focus of frustration for both the PWD and the HCP!

The potential biases in such data can make the interpretation of SMBG in clinical care difficult unless prior planning is involved. The burden associated with undertaking SMBG can be considerable, and for data interpretation to be effective, the HCP is required to be involved in (or at least aware of) the formulation of the testing plan, as well as committed to analysing and interpreting the data afterwards.

There is no "standard of care" statement in the UK or elsewhere as to how SMBG data should be visualised. Indeed, over the last three decades, many different visualisation formats have been created, usually by meter manufacturers as a marketing strategy. This lack of uniformity, which requires interrogating over 50 different sets of software for different SMBG meters on a single clinic computer, has for a number of years acted as a barrier to appropriate utilisation of the data and provided an excuse to clinicians who are not prepared to act. However, over the last 5 years or so, the arrival of more simple-to-use, web-based multiple-device systems, such as DiaSend in the UK and Glooko in the US, has begun to bring a degree of consistency and universality to glucose data analysis, which has allowed HCPs to start systematically looking for patterns within the data that might have been overlooked before.

How patterns can be identified in datasets

Data must be approached in a structured fashion, according to the following steps:

1) Clinical goals.
2) Data validation.
3) Longitudinal review.
4) Cross-sectional review.
5) Planning.

With regard to the DiaSend monitoring device, to start with, the meter must be set correctly with the date and time, and the data collection process must follow the pattern previously agreed for data validity (i.e. right patient, right meter, right date). The next logical step in a clinic assessment is to look at the trend projection (F*igure 4a*) since the PWD was last seen, which allows a review of the overall progress and day-to-day variability, plus any periodic problems that may have occurred during the interval between clinic visits.

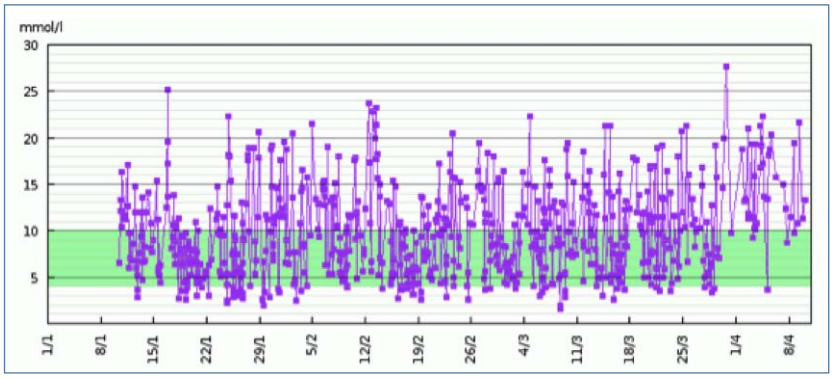

Figure 4a. A "standardised" longitudinal (trend) data projection of self-monitoring of blood glucose data using the DiaSend system, in this case highlighting change in variability that has occurred in the previous 2 weeks.

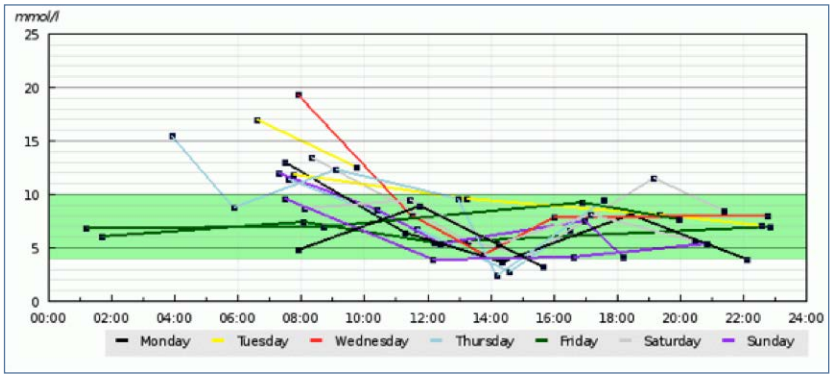

Figure 4b. A "standardised" cross-sectional (standard day) data-projection of SMBG data using the DiaSend system, in this case highlighting regular instability (fasting hyperglycaemia).

N.B. In both projections, the data are represented by the points and not by the lines drawn between them. The lines highlight the periods for which there is no data!

This should then be followed by modal day analysis (*Figure 4b*), to look for instability patterns across the day. Analysis should look at periods of hypoglycaemia risk first, then at fasting/pre-meal levels against target (associated with basal insulin), then at pre- and post-meal differences (associated with insulin/carbohydrate-related boluses), and then at situational elements, such as correction/insulin sensitivity levels (if relevant).

Developments in glucose monitoring

There are a variety of UK-available CGM and flash glucose monitoring devices, with varying features and costs. These approaches to glucose

"The use of glucose monitoring data is an evidence-based, effective interventional process, which is teachable with a structured approach."

monitoring eliminate the bias associated with SMBG and can provide greater convenience for the PWD (Pickup et al, 2015). CGM and "flash" glucose monitoring with linked ambulatory glucose profiling has allowed larger and more detailed datasets than SMBG to be collected, which are ideally suited to a computerised approach virtually identical to the approach described on the previous page.

CGM has been around for a decade but, until recently, the interpretation of these datasets has proved challenging in routine clinical consultation. This is why, in 2013, an international consensus meeting was convened between clinicians, researchers and industry to agree a standard approach to data presentation. The subsequently agreed standard, the Ambulatory Glucose Profile (AGP; *Figure 5*), has become prominent by simplifying these complex datasets into manageable snapshots that fulfil the criteria of being speedy, accurate, simple and reproducible (Bergenstal et al, 2013). The AGP allows the development of a clinical intervention hierarchy to reduce the variables of the glycaemic triad. The glucose profiles in panels (i) of *Figure 5a* and *Figure 5b* have excessive exposure and variability; however, in order to reduce both, it is the variability that needs to be addressed first (panel [ii]). Once this has been achieved, the instability becomes the next logical target (panel [iii]). Having addressed these issues, the reduction of exposure becomes a relatively trivial task that can be achieved safely without increasing the risks of hypoglycaemia. In contrast, a strategy that initially targets exposure without giving attention to measures of flux will tend to increase variability, and hypoglycaemia risk, and is thus often unsuccessful in achieving any useful change.

What: What needs to be done in consultation to allow routine analysis

To allow for data analysis to occur in a clinic setting, what needs to be done in preparation? Implementing data-led consultation requires a clinical desire to change the glycaemic experience of the PWD, which is supported by HCP training. Close liaison between the clinical team and the local IT support and governance teams is required to allow procurement of a web-based IT solution to implement cloud-stored information of each PWD that can be discussed during clinic visits. Practically, there is no system currently able to present data from all possible cloud storage systems in a unified manner. However, encouraging patients to utilise a cloud-storage system and upload data (either from home or at the clinic, directly from newer meters or via meter-linked smart-phone applications), allows for HCPs to routinely access data with high levels of simplicity and utility while data control remains with the PWD. It can also keep costs to a minimum for the clinical team as, in our experience, annual clinic subscriptions for such services tend to be significantly cheaper than the costs required to maintain any local clinical database system.

Administrative staff need to be familiar with the IT and devices, and clinical staff should be trained in the use of the software, as well as data analysis and interpretation. It is also vital that the validity of the datasets is protected by ensuring PWD have devices that are set up correctly and are not used by anyone else. Over-arching all of this will be a process that is agreed by the multidisciplinary team to ensure continuity.

Final thoughts

Historically, the use of data downloads has been undervalued by clinicians and avoided by those with an aversion to learn new computer-based techniques. It has also been burdened by cumbersome systems that are in a non-uniform manner across a variety of platforms and devices. However, with the emergence of some newer systems, utilising data is becoming simpler. The use of glucose monitoring data is an evidence-based, effective interventional process that is teachable with a structured approach. After more than 40 years, data collection and analysis is fit for purpose as a mainstay of intervention, and it should thus be considered a routine part of the specialist delivery of diabetes care. ■

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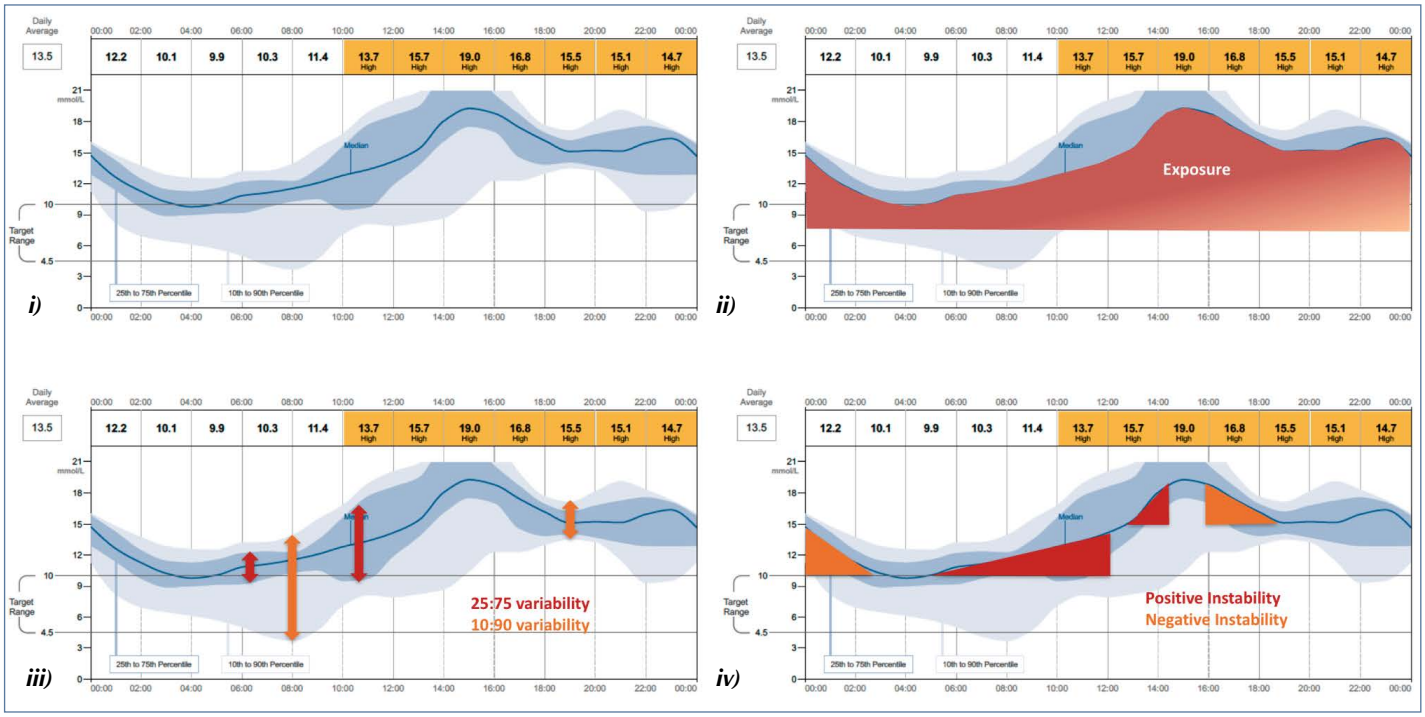

Figure 5a. i) A standardised projection of an Ambulatory Glucose Profile (AGP) produced from a continuous glucose monitor, in this case the Freestyle Libre. (ii) The same projection identifying glycaemic exposure; iii) glycaemic variability; iv) glycaemic instability.

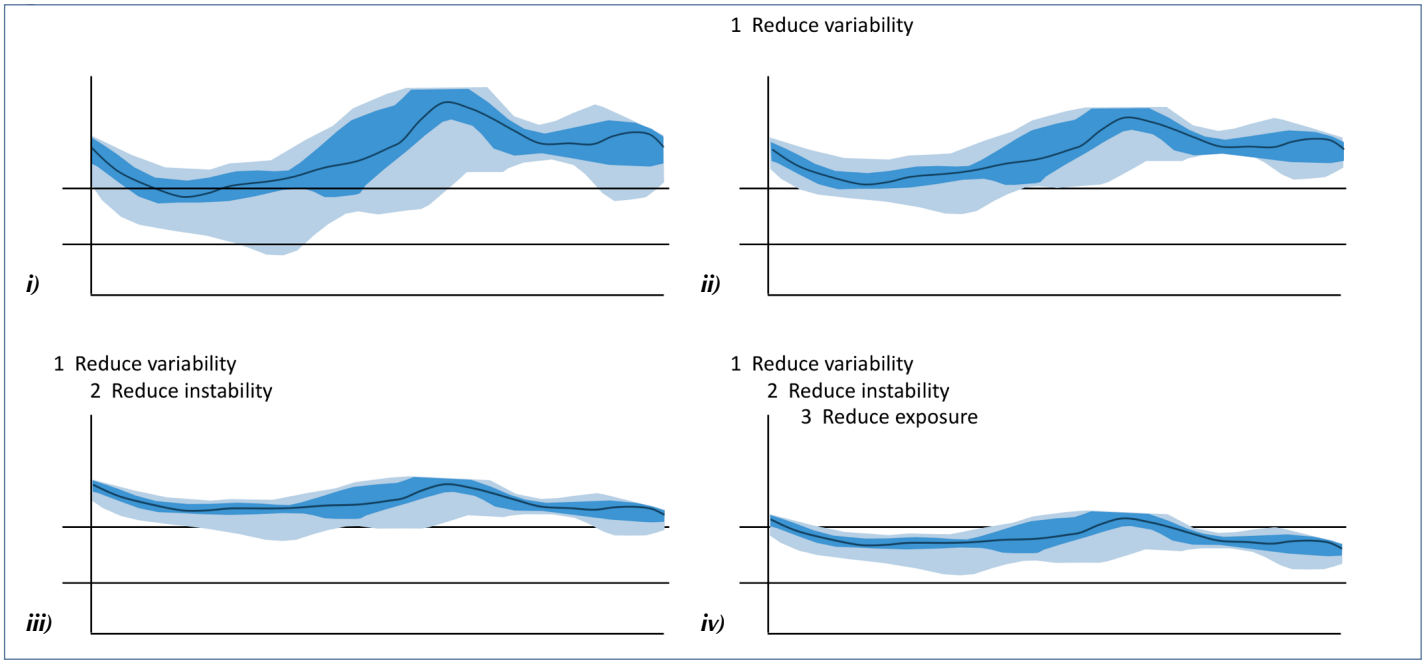

Figure 5b. A cartoon to identify step-wise clinical interventions to achieve AGP-related glycaemic therapeutic priorities from the same profile shown in Figure 5a.