# Summary of responses to PHARMAC's consultation on future funding approach to blood glucose meters and test strips

This document provides a summary of the responses PHARMAC received to consultation on the future funding approach to blood glucose meters and test strips. We received responses from 313 separate people/organisations, made up of the following groups: 275 individual consumers/users, 15 consumer organisations, 54 health professionals/health professional organisations, and 15 suppliers of meters and test strips. Some respondents identified themselves as falling into more than one category (for example, both an individual consumer and a healthcare professional) which is why the number of different groups adds up to 359.

## Functions of a blood glucose meter and test strips

### Question 1 – What functions must a blood glucose meter provide/perform?

A total of 302 people provided a response to this question.

Many people responded saying that the attributes that were listed as prompts in the questions were all must-haves. It is possible that the use of the 'prompts' may have influenced responses.

Key attributes that respondents considered were most important were (the number in brackets represents respondent numbers):

- memory capacity (178)
- ability to download readings (122)
- ability to provide averages (120)
- backlight (108)
- ISO standard/accuracy/reliability (106)
- non-coding strips (78)
- wide operating temperature range (32)
- easy to read date/time/glucose reading (32)
- ability to test ketones on the same meter (24)
- quick testing time (21), and
- ability to delete readings (21).

Other functions a few respondents suggested were having a small/discreet meter size, having a small blood sample size, having individually sealed test strips and/or in flat pack, and having coded strips. The majority of respondents said that they wanted memory capacity, ability to download and averaging functions, although they did not provide extra information about these features- for example, how big the memory should be, or what averaging functions they would be looking for. Some people responded that they needed a memory function that held at least 500 test results/over 90 days' testing capacity.

The ability to download readings provided a broad range of responses – many people wanted the capacity to just be able to download readings to software with their doctor so that

they could analyse results. Others wanted the ability to download to their own and to their doctors' software. Some respondents were very keen to have a whole range of functions within the downloadable software such as graphing against time, providing notes and memos and downloading to the 'cloud' for immediate/real time access to range of results for family members and health professionals.

Most people suggested that the averaging functions required were 1, 7, 14, 30 and 90 day averaging. Health care professionals indicated that the averaging function was useful for 'educational' purposes when trying to promote good glycaemic control.

### Question 2 – Which functions do you consider are optional (i.e. would be nice to have but are not essential)?

A total of 259 people provided a response to this question.

The top-ranked attributes of a meter/test strip that respondents considered were 'nice to have/optional' were:

- ability to download readings (66)
- ability to delete readings (57)
- backlight (52)
- ability to provide averages (41)
- non-coding strips (28)
- large memory capacity (17)
- pin/port light (11)
- ketone testing (9)
- Bluetooth/wireless/smartphone connectivity (4)
- having individually sealed test strips (4), and
- having an in-built test strip magazine with the meter (4).

## Usability

There was strong support in general to having usability testing for the blood glucose meters and test strips. However, many individuals responded to the questions along the lines of how they would like to learn to use a meter, rather than about what they thought would be the best approach for determining which meter/s to fund.

To avoid future confusion over such matters, in this and in future blood glucose meters and test strip communications, usability will now be referred to by PHARMAC as 'end-user testing' as this more accurately reflects our intention.

Three options were provided as suggested ways to approach end-user testing:

- Option A: individuals are observed performing tasks with a meter and test strips.
- Option B: individuals are sent a meter and test strips and asked to use it for a 3-4 week period. Meters are 'assessed' at an individual level.
- Option C: focus groups of people with diabetes are held where there the meter and test strips are introduced to the group. Meters are 'assessed' in a group situation.

### Question 3 – What do you consider to be the pros and cons of each of the three approaches outlined above?

A total of 282 people provided a response to this question.

| **Option A: Individual observed performing basic functions of blood glucose meter** | |
|---|---|
| **Pros** | **Cons** |
| Helpful to observe people in performing tasks | Having to travel to a clinic restricts attendees |
| Potentially quicker data collection | Not the best option for people who live rurally |
| Would help to indicate how easy the meter was to use | Time consuming |
| | Unlikely to mimic real-world situation |
| | May be costly |
| | Don't get to see how the meter performs over different times of day etc. |
| | Would not indicate preferences |
| | Would not, on its own, likely provide confidence to users in the performance of a meter |

| **Option B: Individual sent meter to use over a 3-4 week period** | |
|---|---|
| **Pros** | **Cons** |
| Considered to be easier to administer | Does not mimic how people are provided with meters in the first place, e.g. via a healthcare professional |
| Can manage in own time, don't have to attend separate appointments | Concern expressed that this might not be a good method for older adults |
| Most likely the best 'mimic' of a real world situation | People may not use the meter if it is just provided to them |
| Can use in a range of circumstances | People shouldn't have to wait 3-4 weeks to find out if they are using the meter correctly |
| Multi-choice answers would help to ensure focussed responses | There needs to be a 'helpline' with the supplier |
| | People need to be relied on to provide feedback and this may not occur |
| | There may be difficulty understanding a questionnaire for some people |
| | Would the meter be used accurately and therefore, would it reflect accurate usage? |

| **Option C: Focus groups facilitated by diabetes nurse** | |
|---|---|
| **Pros** | **Cons** |
| Learning as a group can be good for some – help to bounce off ideas from each other | Having to travel to a clinic restricts attendees |
| Likely to reflect how people were provided with support currently | Not the best option for people who live rurally |
| Groups often raise more thoughts than just individuals on their own | Time consuming |
| | Some individuals are often quiet in group situations and will not speak up |
| | Potentially costly |

| | |
|---|---|
| | Some concern that the facilitator may bias the group |
| | Diabetes nurses are not likely to have time to take part in these groups (however, other people could probably do the management of the groups) |
| | Not likely to reflect how people were provided with support currently |

The theme of health literacy, and a concern that the three possible end-user testing approaches may not be the best to support health literacy, was expressed by a number of respondents.

A number of respondents suggested that different approaches may work best for different groups of people, eg teenagers may pick up a meter and use it much more quickly than an older adult. .

Some respondents indicated that as long as people are listened to, it doesn't matter what end-user testing approach is used.

Most respondents indicated that any end-user testing must include a wide range of people, e.g. children, those who are working, active people, older adults etc.

When it came down to the primary function of a meter, i.e. testing blood glucose, there were differing views about the need for end-user testing for this. Many respondents considered that this was a simple task that most people could perform without any help, while many others considered that people still need to have support when using a meter for its primary function.

### Question 4 – Do you think that usability testing should use one of these approaches or a combination of these three approaches?

A total of 285 people provided a response to this question.

There were a range of responses, with Option B being the most popular sole approach, but most people preferring a combination of the three proposed approaches:

- 18 respondents considered option A should be used;
- 52 respondents considered option B should be used;
- 16 respondents considered option C should be used;
- 10 respondents considered a combination of A+B should be used;
- 7 respondents considered a combination of A+C should be used;
- 21 respondents considered a combination of B+C should be used;
- 40 respondents consider a combination of A+B+C should be used;
- 42 respondents considered a combination should be used but did not identify which of the options to be used in combination;
- 11 respondents considered that just one approach should be used, but did not identify which approach; and,
- 9 considered that none of the suggestions should be used.

Some further thoughts provided included:

- Allowing people their choice as to which of the end-user testing approaches they were involved with;
- Having professional instruction included in all of the options used;
- Having everybody who uses a blood glucose meter to be involved in the end-user testing;
- Some concern that if a combination of approaches is used, people will get different levels of training meaning that comparisons would be difficult; and,
- While use of a meter may be simple, concern was expressed that people seem to misunderstand the readings and what they actually mean for diabetes management.

### Question 5 - Are there any other methods of usability testing you think would be better?

A total of 216 people provided a response to this question.

The majority of respondents did not suggest any other methods for end-user testing and considered that the proposed approaches were likely to cover a range of circumstances. However, a number of respondents suggested that health professionals, including nurses and pharmacists, should be part of any end-user testing. Further, respondents made suggestions of 'clinical/accuracy' testing rather than end-user testing (note: clinical/accuracy testing is covered in question 7).

The following were suggested as potential additional methods to assess usability:

- Treat experienced and inexperienced users differently
- Have meters individually explained at a pharmacy/GP practice
- Health professionals (particularly nurses and pharmacists as they are the ones most likely to be providing the meters to consumers) understanding and assessment of meters should be tested as well
- Used district nurse visits with follow-up care
- One-on-one instruction from diabetes nurse or health professional
- Use hospitals and doctors do test on patients
- Do a simultaneous comparison of meter readings with the same drop of blood
- Use organisations such as St Johns, diabetes organisations, residential care providers etc.
- Have a non-invasive analysis
- Have instructional video/s on website
- Use a quick guide with pictures only
- Use some people without diabetes to try and use the meters (this would help to assess how easy the meters could be used in the first place)
- Have individuals assess a number of different meters
- Do usability testing at children's diabetes camps
- Use people who have been using just the CareSens and those who have had to change in the past as well

### Question 6 – What criteria should be used when assessing the usability of a blood glucose meter?

A total of 276 people provided a response to this question.

As with question 5, a number of responses related to 'accuracy' testing of the meter/assessment to the ISO standards, e.g. how correct the meter is the majority of the time etc., rather than the usability and functionality of the meter. The following were suggestions for assessment criteria for end-user testing of blood glucose meters and test strips:

*Meter related assessment criteria*

- Ease of use (this was mentioned very frequently, but it was not 'defined' as to what ease of use actually meant)
- Wait time for a result
- How much blood is needed for a test
- Easy to read/clear screen/don't have to wear glasses to read etc.
- Can read in bright/dim light
- Can use independently with little outside advice or reference to user manual
- Understanding of what error messages mean and how to address these
- Accessing functions of the meter, including averages, trends and past results/memory, and how easy to do this
- Can the meter be read and understood when reading upside down (e.g. is it clear that the reading is 5.6 mmol/L rather than 9.5 mmol/L)
- Practicality/size of carrying meter and test strips around
- The ease of doing a night-time test
- Does the meter hold the test data on display for long enough before turning off
- Are their warning buzzes/alarms and do you understand these/can you turn them off
- Can you easily set the date/time/alarms?
- Is it easy to connect/interface with other devices and GP programmes
- Ease of battery change
- Can the meter be 'individualised', e.g. with stickers etc.
- Sturdiness/robustness including water splashes, being in a hot car etc.
- Does the meter have to be removed from the case for testing
- Operating temperature range
- Simple calibration/coding of test strips (if needed)
- Is there enough time between inserting a strip and doing a blood test
- Does the meter turn on automatically when a strip is inserted?
- Back and forward buttons for reviewing blood glucose
- Don't delete settings/readings by accident
- Clear low-battery indication.

*Test strip-related assessment criteria*

- Intuitive insertion of test strips into meter
- Ease of getting right volume of blood on test strip
- Easy to handle and see test strips

- Meter feels comfortable to hold including with arthritic and/or shaky hands
- Simple instructions
- Ability to open test strip container/packaging.

*Other assessment criteria*

- Case/packaging hold all the necessary bits and pieces, e.g. meter, strips, lancing device and lancets etc.
- Finger-pricker/lancing device easy to use and with minimal pain.

Some responses to this question commented that improved blood sugar control is the only valid reason for regular testing with blood glucose meters, and that people need more education to understand what the results of the tests really mean.

## Accuracy/Clinical Assessment

### Question 7 – What further accuracy and clinical assessment criteria should be considered?

A total of 138 people provided a response to this question which suggested criteria, including 102 consumers, 28 identified health care professionals and 8 suppliers.

A further 143 people either did not respond, responded by saying they didn't know or said that they felt the question had already been covered.

The top 8 'further accuracy and clinical assessment criteria' identified by the 138 respondents included (in order of preference):

| Number in order of preference (1= most preferred) | Desirable accuracy and clinical assessment indicator |
|---|---|
| 1 | Wider temperature range use |
| 2 | Dual use to analyse ketones |
| 3 | Able to measure HbA1c |
| 4 | Able to ensure accuracy of readings |
| 5 | Ability to upload data from the meter |
| 6 | Easy to use meter for the majority |
| 7 | Ability to detect contamination from contaminants such as soap or glucose |
| 8 | Compatible with a smart phone application |

### Question 8 – Have you been involved in the testing of meters and test strips or can you suggest who could conduct testing of this type?

A total of 159 people responded to this question. 10 responders stated that they had previously been involved with the testing of meters and test strips and 149 said that they had not.

Of the respondents, 23 percent stated that people living with diabetes, particularly people living with Type 1 Diabetes Mellitus should be involved with directly testing the meters.

Six health care professionals identified that they had previously been involved with the testing of meters and test strips.

Twelve consumer respondents indicated they would be willing to be involved with the evaluation of meters and test strips this time.

In response to who could conduct this testing the following responses were provided:

| Proposed source of testing | Number of responses |
|---|---|
| People with diabetes | 38 |
| Laboratory | 8 |
| Pharmacists | 8 |
| Diabetic Clinics | 6 |
| Registered nurses | 6 |
| POCTAG | 5 |
| Elderly (people) | 3 |
| Canterbury Labs | 3 |
| Local diabetes educator | 2 |
| Suppliers | 2 |
| PHARMAC | 2 |
| Clinicians | 2 |
| International | 2 |
| Use international standards | 1 |
| NZ Diabetes Research Centres | 1 |
| Baker IDI Unit, Melbourne | 1 |
| Roche Diagnostics | 1 |
| University | 1 |
| Scientists | 1 |
| Akld School of Medicine | 1 |
| Diabetes NZ | 1 |
| SGS* | 1 |

* Société Générale de Surveillance

### Other

#### Question 9 – What support (i.e. educational, information) from suppliers of meters would be desirable?

There were 216 consumer respondents to this question. At least 50 percent of these respondents identified more than one form of desirable support.

Six noted they were happy with the status quo in terms of supplier support.

The Top 10 desirable types of support, in order of preference, are identified below:

| Number in order of preference (1= most preferred) | Number of respondents | Identified support criteria |
|---|---|---|
| 1 | 59 | Hard copy user guide |
| 2 | 49 | 0800 phone line |
| 3 | 23 | Interactive and educational website (with on-line instruction book) |
| 4 | 16 | Free battery replacement |
| 5 | 14 | Diabetic nurse education |
| 6 | 8 | Regular meter testing and |

| | | |
|---|---|---|
| | | replacement (2 yearly) |
| 7 | 7 | Log books |
| 8 | 7 | Training disc |
| 9 | 6 | Availability of smart phone applications |
| 10 | 5 | Regular newsletter to meter users |

There was significant referencing back to the attributes of the meters that were funded previously, including previous supplier support in response to this question.

At least 20 percent of respondents who wanted a hard copy user guide had stipulations about it, including the fact that it should be multi-lingual for the dominant languages that now exist in New Zealand. There was also a demand for the booklet to be in larger print for those with visual impairment and a couple of respondents noted that the booklet should be as small as possible for easy transportation.

Many respondents said that a 0800 line needed to be a 24 hour service with a person on the end of the phone line – and this person should be in New Zealand.

### Question 10 – What accessories should be provided with meters? For example, a case, lancing device etc?

There were a total of 267 respondents to this question. Respondents often identified two or more accessories that they believed should be provided with the meter.

Almost all respondents agreed on the top four desired accessories. These were a case, a robust lancing device, spare lancets and a log book.

The other desired accessories that were identified as ideal are listed below:

- An ‘extra pocket’ for disposing of used cotton wool and strips
- Bluetooth functionality
- Instruction book
- Test strips
- Replacement batteries
- A biro for recording readings
- Sharps container
- Band Aid
- Insulin pen
- Download PC cable
- QC (quality control) solutions
- Glucose tablets
- Downloadable software package
- Led-light torch

### Question 11 – Should different types of meters and test strips be funded for people who are taking different medication?

A total of 237 respondents answered this question, 78 percent of them in the affirmative.

| Number of respondents | Response |
|---|---|
| 185 | Yes |
| 25 | No |
| 27 | Cannot comment |
| 1 | Retain status quo |

Sample themes of the responses are noted below:

- A meter for the visually or hearing impaired.
- A distinction needs to be made between the needs of those with type 2 and those with type 1 diabetes.
- Dual meter required for those needing to test for ketones.
- It is dependent on clinical need, guided by the clinicians.
- I am not an expert to be able to answer this.
- The fewer meters the better – it's confusing.
- A pre-diabetic meter.

Whilst respondents said they wanted different meters to meet different end-user needs, it wasn't made clear how the meters should be different, apart from for the visually impaired. However it was clear that respondents considered a choice of meters was desirable.

### Question 12 – What software and data capabilities of funded meters are both practical and desirable?

There were 260 responses to this question.

More than a third of respondents indicated that it was important that meters had software that enabled results to be downloaded to a computer (Windows or a Mac). Five percent of respondents included that it was important for the meter to have the ability to store data for a range of between 7 days and 3 months.

The other most common responses were as follows:

- USB access is a must.
- The ability to download data via Bluetooth.
- The ability to calculate the average weekly blood glucose.
- Software that is able to produce graphs and export the data in a diabetes clinic to a printer.
- The ability to sync a smartphone via Bluetooth.

Three unique responses included:

- A colour screen
- Don't assume everyone has a computer

- There is no material difference between all the major manufacturers (supplier response).

### Question 13 – Are there any other comments you wish to make to PHARMAC?

There were 93 responses to this question.

Respondents took the opportunity to make comments regarding the outcome of the previous funding decision. Of the 93 responses, 27 detailed their disappointment with the previous funding outcome.

### Question 14 – Are there any other comments you wish to make related to this proposed approach?

There were 96 responses to this question.

The purpose of this question was to gain feedback from respondents about the proposed timeframe that was outlined in this initial consultation document, which may not have been clear from the question. None of the responses addressed the proposed timeframe.

Of the responses 45 percent were reflective of the previous funding decision. Other responses took this as an opportunity to ask questions.

For example, one respondent asked 'Will we be advised of the possible suppliers?'