

# Did the diabetes meter change in 2012 have an impact on people's health?

A report of an investigation commissioned by PHARMAC

## ***What changed?***

From September 2012 to March 2013 approximately 100,000 people changed the brand of their diabetes blood glucose meters and test strips to one of three CareSens meters.

PHARMAC commissioned an independent evaluation on the clinical impacts of the meter change to answer the questions:

1. Was there anything wrong with the three CareSens meters?
2. Did the change in meters have any clinical impacts?

Other important changes were happening at exactly the same time. These included the transition of the Ministry of Health's Diabetes "Get Checked" programme and establishment of DHB-led Diabetes Care Improvement Package; and PHARMAC's funding of insulin pumps and consumables which could only be prescribed for people having experienced unpredictable and significant variability with low blood sugar.

## ***How were the answers found?***

This was quite a difficult study with a lot of complex data, meaning care needs to be taken as it is not possible to draw firm conclusions. Using such data, researchers can never demonstrate that one action actually caused another.

The report looked at the rate of hospital admissions for every person with diabetes in New Zealand before, during and after the changeover. While there may be other things that would ideally be examined, hospitalisation data is the best information that could be obtained.

The data relating to question 1 looked at people with the same stage of diabetes from two completely different time points (before and after the change). This was people who had first received a meter in 2011 (who would have almost all used another brand of meter) compared to people who received their first meter in 2014 which would have been one of the CareSens meters.

The data most relevant to answering question 2 looked at all people with diabetes to see if there was any change to the number who were hospitalised over time. Within that group it also looked at whether there were changes in the reason for hospitalisation, particularly for either high or low blood sugar.

The report also looked at other analyses, including comparing the rates of hospitalisation in each patient over the entire time period, and then aggregating the results. That hasn't helped to answer either of the two questions, but does confirm that diabetes can have progressive health implications over time and we can expect the number of hospitalisations to increase in any group of people with diabetes, in addition to the number of people with diabetes continuing to increase.

## What were the answers?

### 1. Was there anything wrong with the three CareSens meters?

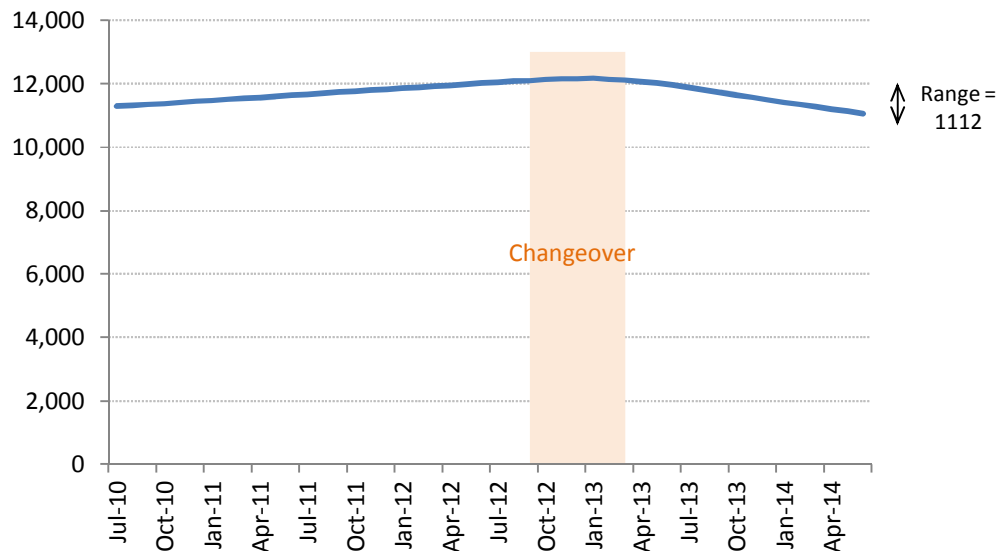
No, that is unlikely. The comparison did not show a difference in the number of people hospitalised. Of 18,640 people of similar ages, those who received their first (previous brand) meter in 2011 had 228 hospitalisations, whereas those who received the new brand in 2014 had 186. This was over their first five months of using a meter.

This is consistent with the laboratory testing of the CareSens meters' accuracy, and investigations by Medsafe and reviews by the manufacturer of nearly 2,000 returned meters finding no faults in the accuracy of the meters.

### 2. Did the change in meters have any clinical impacts?

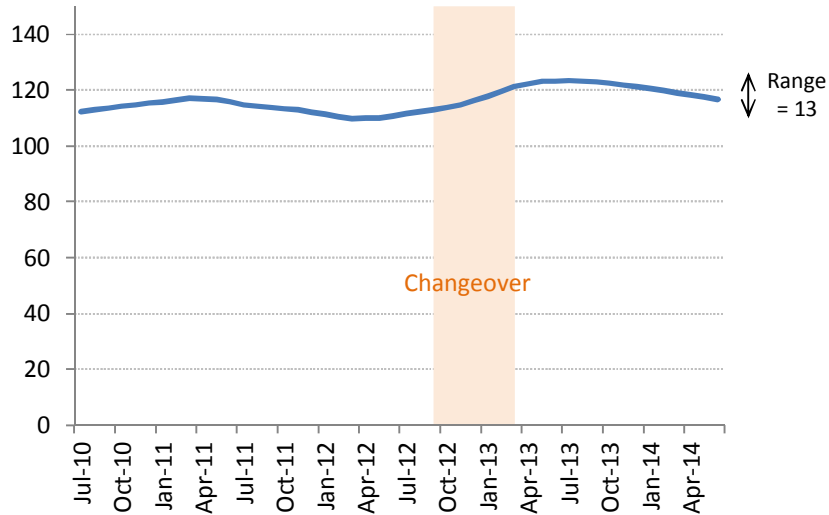
Possibly. Well before the change to meters, the trend was that more hospitalisations were occurring amongst people with diabetes, even after taking into account that more people are usually hospitalised in winter. This trend continued throughout the change and declined afterwards. Whether this downward trend was a result of the meter change or other changes in the health system, disease, or treatment, is unknown. This is shown in the Figure 1 below.

Figure 1. Seasonally adjusted trend - hospitalisations per month for people with diabetes

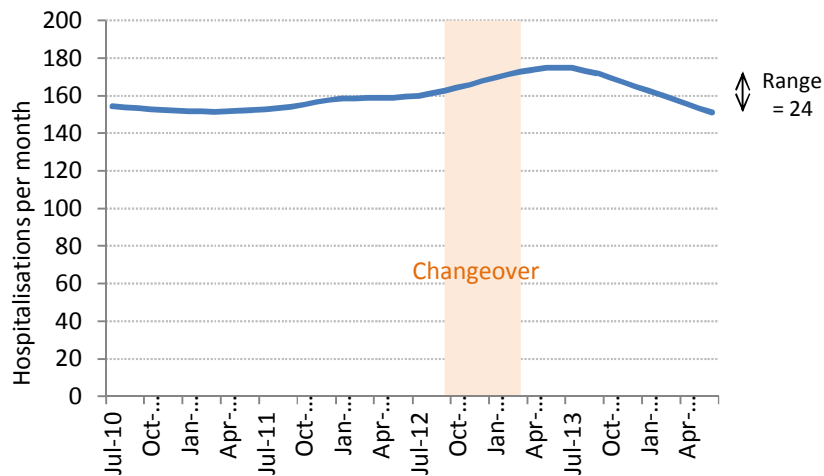


Over the same period of the analysis, New Zealanders were being hospitalised for reasons other than diabetes at a growing rate. For all people this went from 2.6% to 4.8%, whereas the rate of people with diabetes being hospitalised for any reason went from 3.7% to 4.7%. This raised an additional question: was there a change in hospitalisations as a result of low or high blood sugar episodes or was the change due to other factors? Compared to previous summers, the trend indicates there wasn't the usual summer decrease in hospitalisations between October 2012 and April 2013 for both low and high blood sugar. However changes in the trend line can also be seen at other times not associated with the meter change (figures 2 and 3).

**Figure 2. Seasonally adjusted trend - hospitalisations for low blood sugar (hypoglycaemia) in people with diabetes**



**Figure 3. Seasonally adjusted trend - hospitalisations for high blood sugar (hyperglycaemia) in people with diabetes**



**What will PHARMAC learn from this?**

Change in the health sector can have an impact on patient health. We want to maximise the beneficial impacts and minimise actions which have negative consequences. PHARMAC recognises that it has to be very careful when making change. An earlier report, looking at how it managed the change process in this case, showed some room for improvement. PHARMAC has taken this on board in managing its current consultation process and will continue to take this information into account in future decisions.