HEALTH PARTNERS
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Hospitalisations for diabetes in New Zealand: measuring the impact of the change in subsidy to glucose monitoring test strips.

An investigation commissioned by PHARMAC

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Acknowledgments

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Note on report layout

The documentation for this project consists of two reports. This first report outlines the study, main results and conclusions drawn. The second report is in the form of a statistical annex, going into more detail on the statistical approaches used, and co-factor and other analyses performed. Detailed data tables are provided in the second paper to back up the mainly graphical approach taken in the first paper.

Executive summary

Blood glucose monitoring is a key facet of diabetes management, allowing people with diabetes to vary medication dosage to meet their changing circumstances. Glucose monitoring meters and test strips are provided as part of health funding in New Zealand, with over 116,000 patients accessing subsidised test strips. PHARMAC undertook a process in 2012/13 to change suppliers for the test meter and test strips, affecting the majority of people with diabetes using publically funded test strips. Significant effort went into the management of the changeover and the change process, and the extent of the success of this is being evaluated.

This report aimed to measure whether or not there was any measureable health impact of the changeover by using nationally collected hospitalisation data for every person with diabetes in New Zealand, assessing the rates of admission before, during and after the changeover. Hospitalisation is a relatively significant health event, and has the advantage of being measurable and being collected independently of the meter changeover process.

The key measure used was hospitalisation for a principal diagnosis of either *hypoglycaemia*, or low blood glucose, or *hyperglycaemia*, or high blood glucose. Two different studies were carried out. The first took a total population view of all people with diabetes in New Zealand, measuring their incidence of hospitalisation over time. The second used a cohort of people with diabetes starting at 1 January 2012. A within-person change in rate of hospital treatment analysis was used, with each person effectively acting as their own control in comparing the hospitalisation rate for that individual during or after the intervention to that before. These individual comparisons were then summed over the cohort, and were carried out separately for within diabetes-related medication categories.

For the total population view, both hyper- and hypoglycaemia hospitalisations (as the primary cause of the admission) showed similar patterns with a small increase occurring during the changeover period, returning to baseline thereafter. The within-person analysis showed similar increases for each of the medication groups, with no change in trajectory during or after, suggesting the increases were unlikely to be related to the test meter changeover. A separate analysis compared 'new-to-meter' people with diabetes in periods before and after the changeover. Comparing people with diabetes initiating meter testing in 2014 with an age-matched cohort from 2011 showed no change in the risk of hypoglycaemia or hyperglycaemia.

The small increase in admissions due to hypo- or hyperglycaemia over the changeover period seems plausibly to be related to the meter change process, as people and their clinicians learned how to handle their new meters. This hospitalisation rate then fell following the changeover. We speculate that the additional publicity that surrounded the consultation efforts, increased information about home monitoring of blood levels, and the likely increased linkage to general practitioners and pharmacists by people with diabetes, may all have contributed to an overall improvement in diabetes management, mitigating some of the effects of the changeover. The changes together may have led to increased interest in and awareness of the need for testing, and the importance of managing the results.

1. Background

Blood glucose monitoring is a key facet of diabetes management, allowing people with diabetes to vary medication dosage to help prevent potential hypoglycaemic (low blood sugar) events and manage their disease. Subsidised glucose monitoring meters and test strips are provided as part of health funding in New Zealand.

PHARMAC's role in funding of blood glucose monitoring meters and strips began in 2005. Test strips comprised a large component of PHARMAC spend – $22m in 2010/11 – that was growing. A wide range of diabetes management products was funded by PHARMAC. Suppliers provided high levels of support to patients and clinicians, and attracted high brand loyalty.

From mid-2011 PHARMAC sought proposals from suppliers of blood glucose testing meters and strips. Then during early-mid 2012 PHARMAC consulted on its preferred option for supply, which was to fund a range of CareSens meters and strips, supplied by Pharmaco, no longer fund other meters, and widen clinical eligibility criteria. PHARMAC's aims in its funding proposal were to ensure:

- Consistent access
- Widened funded access
- Safe and effective products
- Choice
- Security of supply
- Savings for reinvestment

Key milestones were:

- Funding of CareSens from 1 September 2012, including a high-specification meter
- Cessation of funding of other meters from 1 December 2012, and other strips from 1 March 2013
- Extension of the changeover period to June 2013, though by April 2013 over 70,000 people with diabetes were using CareSens meters, from a target of the 120,000 who had been accessing publicly funded strips prior to January 2012..

PHARMAC has commissioned two independent evaluations of the meter changeover. The first examined the process of the changeover, including the reactions of patients and their health care providers, and provides much more detail on the background and processes involved in the changeover. That report has been published:

Allen + Clarke. *Evaluation of the implementation of a decision to change the funding and supply of blood glucose meters and test strips.* 1 Sep 2014, 108pp. Accessible from www.pharmac.govt.nz

This report follows on from that earlier evaluation and aims to examine whether there were any observable health impacts following the changeover To address this, we examined the rate of hospital admissions for every person with diabetes in New Zealand, and compared these rates between the three periods: before, during, and after the changeover. While hospitalisation is a relatively significant health event, meaning other more subtle changes are not being tested, it has the advantage of being a clear measure, and as it is collected through the national health collections, the measurement of this outcome is independent of the meter changeover process.

2. The study method

The study population is all people with diabetes in New Zealand as at 31 December 2013 as defined by the New Zealand Virtual Diabetes Register (VDR).[1] The VDR includes all people identifiable in the national health collections as being likely to have diabetes, and is described in more detail in Section 3. Note that this includes all people with diabetes whether or not they are users of test strips. Using encrypted data to maintain privacy, this was linked with public hospital (NMDS) and community pharmaceutical data for the period 1 July 2010 to 30 June 2014, allowing hospitalisations for all people with diabetes to be linked to which medication they were dispensed.

The initial analysis examines the dispensing of test strips over time, and is shown in Section 4. Chapters 5 and 6 then cover the hospitalisation data. Three key hospitalisation measures were defined.

1. Hospitalisations with a principal diagnosis[2] of *hypoglycaemia*, or low blood glucose. Here we are particularly concerned with people who might be over-treating themselves, driving their blood glucose down. Regular blood testing can assist in avoiding this.
2. Hospitalisations with a principal diagnosis of *hyperglycaemia*, or high blood glucose. Here we are concerned about potential lack of treatment – regular blood testing might assist the patient in achieving better control.
3. *All medical or surgical hospitalisations.* Diabetes has significant effects on many systems – heart and circulation, renal (kidneys) etc – so this analysis broadens the focus from blood glucose state to overall health.

While hypo- and hyperglycaemia have clearly different mechanisms of harm, in addition to presenting them separately we used their combined totals as being the most direct measure with regard to blood testing control, and hence the most relevant to the study. 'All hospitalisations' as a category was intended as a cross-check to assess the wider impacts of treatment changes or health changes.

By linking to the community pharmaceutical data we were able to group people with diabetes by the type of diabetes medication they were dispensed.[3] Each diabetes medication has a different risk profile for blood glucose testing, and hence different testing regimes and potential response to changes. The grouping allowed for a stratified analysis of the diabetes population. Those on two or more different medication types were prioritised in the following order:

1. long-acting/intermediate insulin (LONG)
2. rapid/short-acting insulin (SHORT)
3. no insulin but oral sulphonylureas (ORAL SULPH)
4. no insulin nor sulphonylureas, but use of metformin, acarbose or glitazones (OTHER ORAL)
5. no pharmaceutical treatment of diabetes (NONE).

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[1] Jo E, Drury P. *Development of a Virtual Diabetes Register using Information Technology in New Zealand.* Healthc Inform Res. 2015 (Jan); 21(1):49-55.

[2] The principal diagnosis is the main cause of the admission to hospital. Any other condition contributing to the hospital event is recorded as secondary diagnoses. The principal diagnosis is the outcome most able to be directly linked to the intervention – secondary diagnoses may relate to happenings in hospital, or to other secondary effects from different illnesses.

[3] Note the terminology here. We use 'dispensing' throughout the report as that is what the data represents – the issuing of the medication to the patient from community pharmacies. While this will be strongly related to prescriptions written, and medication actually taken, it is not quite the same thing.

The period July-Dec 2011 was used to assign people to medication groups. The first three groups all have potential for hypoglycaemia to occur; the latter two much less so. All groups have potential for hyperglycaemia to occur. Prior to analysis it was considered that the SHORT group would be the most likely to show any change as a result of the meter changeover, so in the presentation of results the group ordering has SHORT last.

2.1. Study design

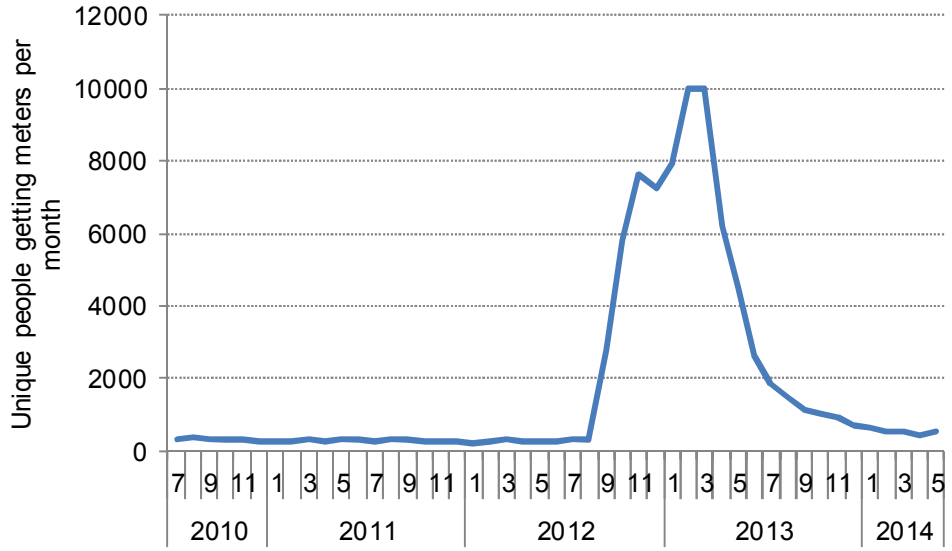
Two levels of analysis were carried out. The first took a population view, looking at the overall change in test strip use or hospitalisation with the different groups, while controlling for seasonal effects. It used an 'open cohort' - people with diabetes were able to enter (through new diagnosis) and exit (through death) throughout the duration of the study. We termed this the 'VDR' or population view, and it used all data from 1 July 2010 to 30 June 2014. All people with diabetes in the VDR as at 31 December 2013 are included.

The second was an interrupted before-and-after longitudinal observational study. It used a within-person change in rate of hospital treatment analysis, within a 'closed cohort' of people with diabetes aged 5-84 in the VDR as at 31 December 2013 who were alive on 1 January 2012 (the beginning of the 'before' period). Three periods were defined:

- BEFORE: 1 Jan to 31 Aug 2012
- DURING: 1 Sep 2012 to 31 Mar 2013
- AFTER: 1 Apr 2013 to 30 Jun 2014

Essentially each person acted as their own control in comparing hospitalisation rates for that individual during or after the intervention with that before. By including data across all three periods at the individual level, we were able to examine whether each person with diabetes had a higher or lower rate of hospitalisation during or after the changeover to CareSens. These individual comparisons were then summed to the population level, comparing the average rate of outcome DURING and AFTER with the BEFORE period.

Figure 1. Meter dispensing July 2010 to May 2014



Individual claims for meters in the Pharmaceutical Benefits data system. Note that many people may have received meters directly other than through dispensing at a pharmacy (if they did not meet funding criteria for a subsidised meter).

Note that the first few months of the 'after' period would have included people still transitioning to a CareSens meter, (as well as people newly diagnosed), but the majority of people with diabetes (~80%) who were using a meter and test strips would have received a CareSens meter by this date (31 March 2013, as seen in Figure 1). To 7 December 2013 116,000 different people had been dispensed a CareSens meter and test strips[4], with the majority of people for whom meters would be beneficial thought likely to have changed over.

This is an observational study; that is, we did not randomise people to categories like in a clinical trial. This means that we are reporting on associations that we observed, and cannot be as clear on potential causation as would be possible in a randomised controlled trial. On the other hand it involves a very large cohort of people covering the entire country, and the main potential confounders were able to be controlled for.

More details on the analysis design and statistical approach are given in the statistical annex.

[4] Personal communication, PHARMAC.

3. The people with diabetes

The study population consists of people identified in the VDR as likely to be diagnosed with diabetes in New Zealand as at 31 December 2013. The VDR captures information from the national collections data for the years July 1999 to June 2014 and uses an algorithm to estimate the number of people in the population who have diagnosed diabetes. This algorithm is progressively modified to improve sensitivity and specificity, and has been validated against primary care registers.

Six major national databases are used by the VDR to define this population of people with diabetes. An individual is classified as having diabetes if they meet one or more of the following criteria:

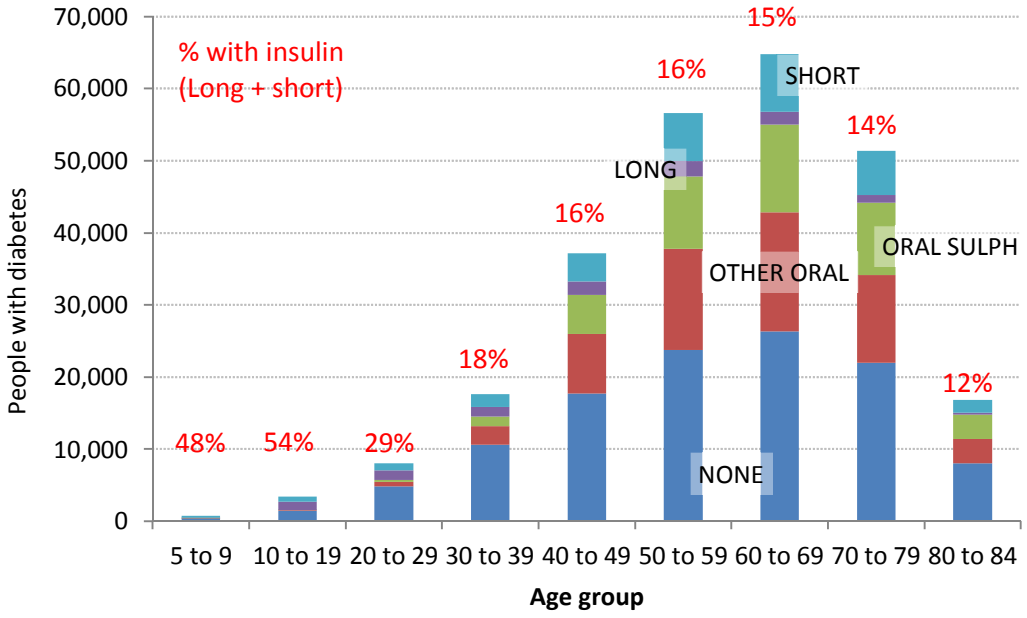
- any diagnosis code of diabetes in a hospital admission
- Any outpatient attendance for diabetes retinal screening
- dispensing of specific anti-diabetic therapies (insulin, metformin, sulphonylureas etc)
- four or more laboratory tests for HbA1c in 2 years indicating likely monitoring of diabetes

Each person is only counted once. The VDR also links with the mortality data to capture the date of death if this has occurred.

As the VDR is linking data across time it makes the explicit assumption that a person is never 'cured' of diabetes. So if a person alive in 2012 had, for example, a hospital admission in 2004 that had a diagnosis code of diabetes, or had been prescribed with metformin in 2007, they would be included in the register, even if they have had no admissions or medications since then.

The VDR as at 31 December 2013 had 269,021 individuals, of which 256,454 were included in the cohort analysis – ie were aged 5-84 years and alive as at 1 January 2012. Details of this group are shown graphically below, with further data available in the statistical annex.

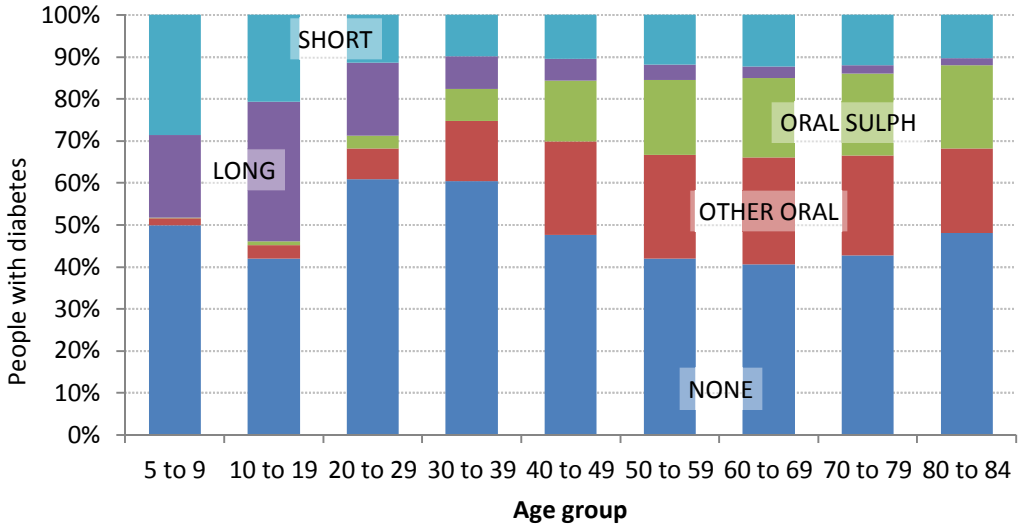
Figure 2. People with diabetes by medication group and by age group, 2013



Source: VDR 2013, all people alive as at 1 Jan 2012 aged 5 – 84 years. Medication groups for Jul-Dec 2011 as described on page 6. N=256,454.

For type 2 diabetes prevalence rates increase strongly with age, explaining the age distribution seen in Figure 2. There were around 65,000 60-69 year olds with diabetes, the modal point making up a quarter (25%) of the diabetes population. Those aged 50 and over made up three-quarters (74%). Overall 16% of people with diabetes were on insulin in some form, with the highest numbers of users in the older age groups – two-thirds of insulin users are aged 50+ (67%). Figure 3 shows the same data but as a proportion at each age, highlighting the higher proportion of insulin use in the largely type 1 younger people, and higher oral medication use in the largely type 2 older people.

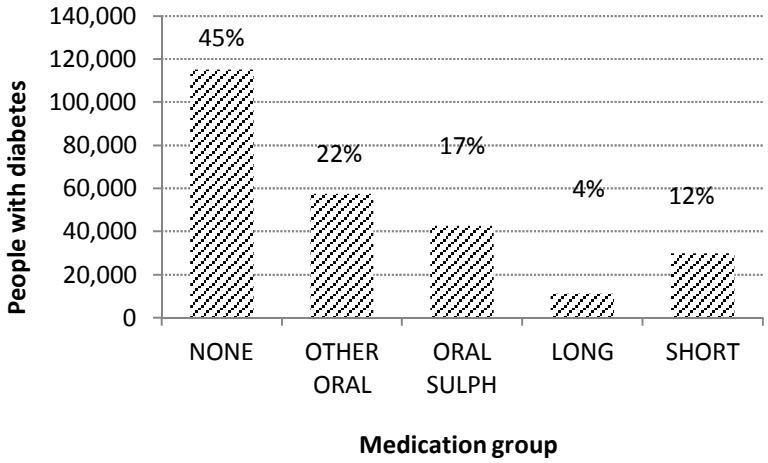
Figure 3. Proportion of people with diabetes by medication group by age group, 2012



Source: VDR 2013, all people alive as at 1 Jan 2012 aged 5 – 84 years. Medication groups for Jul-Dec 2011 as described on page 6. N=256,454.

Note that the VDR is unable to distinguish between people with type 1 or type 2 diabetes. While all people with type 1 diabetes will be on insulin, some people with type 2 diabetes people also require insulin. People on insulin (ie, in the SHORT and LONG groups) may thus be either type, while those in the other three medication groups will likely have type 2 diabetes.

Figure 4. People with diabetes by medication group, 2012



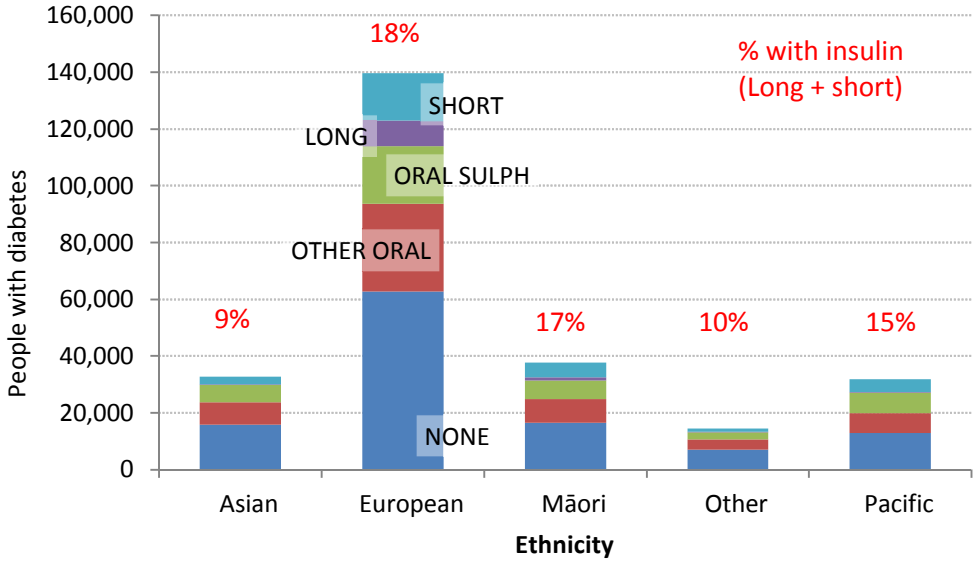
Overall 45% of the VDR-identified people were on no anti-diabetes medication in the latter half of 2011 (Figure 4) – they might have been 'diet-controlled', otherwise not controlling their diabetes, still to have got their formal diabetes diagnosis, or potentially mislabeled or 'pre-diabetic'. For a person in any of these situations they could potentially start medication and/or testing throughout the study

period, and were considered to be part of the population potentially affected by the blood glucose testing meters and strips changeover.

In this VDR population, gender was almost equally distributed, with the proportion on insulin slightly higher for males – 16.5% compared with 15.6% for females.

Those of Pacific or Asian[5] ethnicity had higher rates of diabetes than Māori, while those of European or Other ethnicity (Other being those ethnically Middle Eastern, African or American ethnicities) have had much lower rates. By dint of population numbers though, European comprised the majority (54%) of those with diabetes in New Zealand (Figure 5). Europeans had the highest proportion on insulin (18%), followed by Māori (17%) and Pacific (15%).

Figure 5. People with diabetes by ethnicity and medication group, 2013

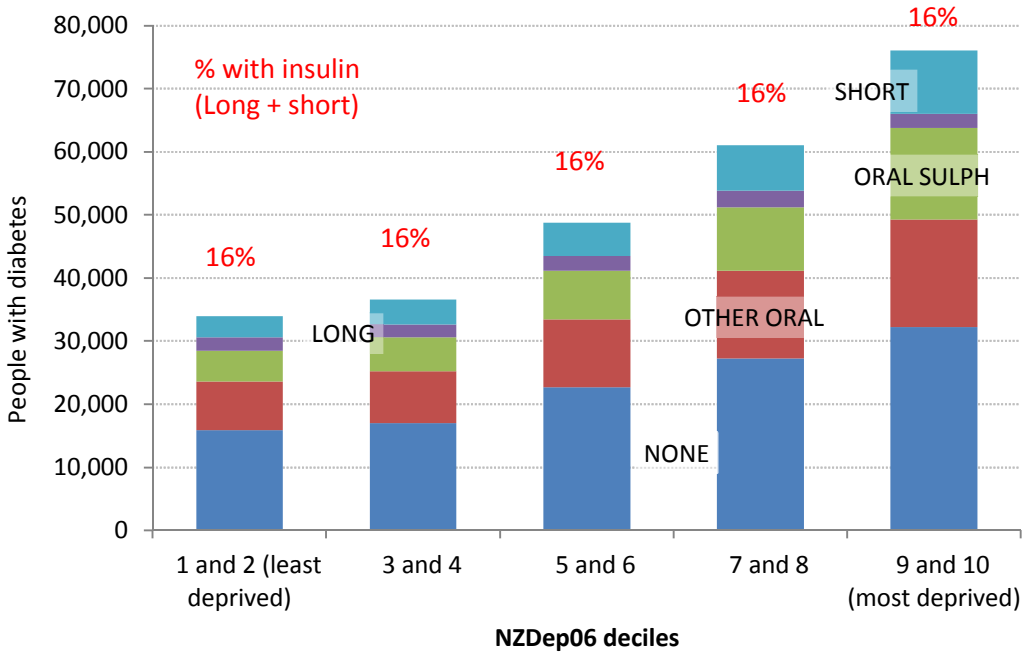


Source: VDR 2013, all people alive as at 1 Jan 2012 aged 5 – 84 years. Medication groups for Jul-Dec 2011 as described on page 6. Ethnicity prioritised Māori, Pacific, Asian, Other, then European. Other refers to Middle East, Africa and America in the main.

People living in geographical areas of more socioeconomic deprivation are more likely to have diabetes than those in less deprived areas. Figure 6 shows people with diabetes by deprivation quintile, with those in 9 and 10 (the most deprived areas) having more than twice the prevalence of diabetes as those in the least deprived two quintiles (deciles 1+2 and 3+4) (where if rates were even then each group would have 20%). The proportion of insulin use was about the same across all deprivation levels.

[5] People of Indian ethnicity in New Zealand have a high rate of diabetes, while those of Chinese ethnicity have a low rate. For this study all Asian ethnicities were considered together, providing ana possible intermediate rate

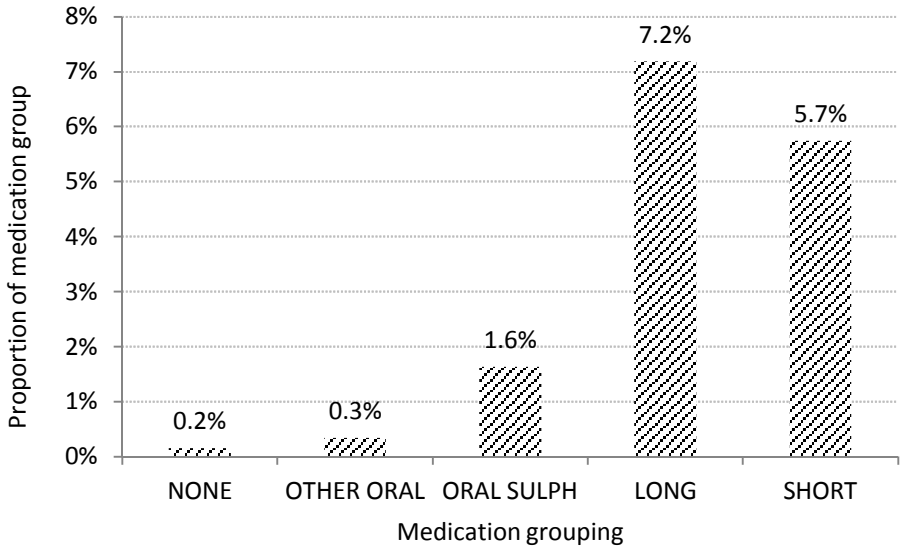
Figure 6. People with diabetes by deprivation and medication group, 2013



Source: VDR 2013, all people alive as at 1 Jan 2012 aged 5 – 84 years. Medication groups as at Jul-Dec 2011 as described on page 6. NZDep06 deciles combined to make quintiles

Of this diabetes cohort, 33,624 (13%) had been admitted to a public hospital in 2011 (the year prior to the start of the study), with 3,590 of those (around 10% of the admitted group) due directly to impaired blood glucose control – ie, having a principal diagnosis of hyper- or hypo-glycaemia. That is, around 1.4% of the total VDR cohort was admitted in any one year (2011) for hypo- or hyper-glycaemia. However this risk was not evenly distributed, with those on insulin medication having a higher risk (Figure 7). It is in the groups ORAL SULP, LONG and SHORT that any changes that clinical effects occurred due to the test strip meter change would be expected to show.

Figure 7. People with diabetes proportion admitted for hyper- or hypo-glycaemia, 2011



Source: NMDS; all people in VDR 2013 alive as at 1 Jan 2012 aged 5 – 84 years, with a hyper- or hypo-glycaemia admission for 2011. Medication groups as described on page 6.

The wide variation in incidence of admission for hyper- or hypo-glycaemia (by drug-treatment category) contrasts with that for any diagnosis which shows less variation (Figure 8). Of interest the NONE group – ie, those people in the VDR but not on anti-diabetic medication for Jul-Dec 2011 – had a similar rate of hospital admission as the others. Only those on short-acting insulin appeared to be at higher risk of admission.

Figure 8. People with diabetes proportion admitted for any reason, 2011

Source: NMDS; all people in VDR 2013 alive as at 1 Jan 2012 aged 5 – 84 years with a medical-surgical admission for 2011. Medication groups as described on page 6.

Around one-third (35%) of the people identified as having diabetes on the VDR and included in the cohort were using test strips – or at least had had a publicly-funded dispensing of a test strip in the period July to December 2011, prior to the commencement of the cohort study. This varied by medication group, with around 90% of those using insulin to 8% of those on no specific anti-diabetes medication accessing subsidised test strips (Table 1).

Table 1. People with diabetes by medication group, proportion getting test strips, 2011

Group	number	Had at least 1 strip dispensed Jul-Dec 11	% dispensed
NONE	115,141	8,924	8%
OTHER_ORAL	57,573	20,490	36%
ORAL_SULPH	42,602	25,071	59%
LONG	11,217	10,284	92%
SHORT	29,921	26,043	87%
Total	256,454	90,812	35%

Source: Community pharmaceutical dataset; all people in VDR 2013 alive as at 1 Jan 2012 aged 5 – 84 years dispensed test strips at least once. Medication groups as described on page 6.

One could consider the NONE group – those identified as having diabetes, but not currently on medication for diabetes – as a kind of control group for the current study in that they are less likely to be using test strips to start with, and any increase in strip use will likely relate to disease progression. One would expect less changes in their diabetes hospitalisation rates as a result of changes in test strip dispensing or distribution.

Further detail on blood glucose test strip use can be found in Metcalfe S et al *Self-monitoring blood glucose test strip use with diabetes medicines in people with types 1 and 2 diabetes in New Zealand,* available at https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2014/vol-127-no-1406/6371.

4. Change in number of test strips dispensed

This analysis is based on the data supplied from the community pharmacy data set. Each test strip dispensing (including for the visually impaired) was counted as a data point.

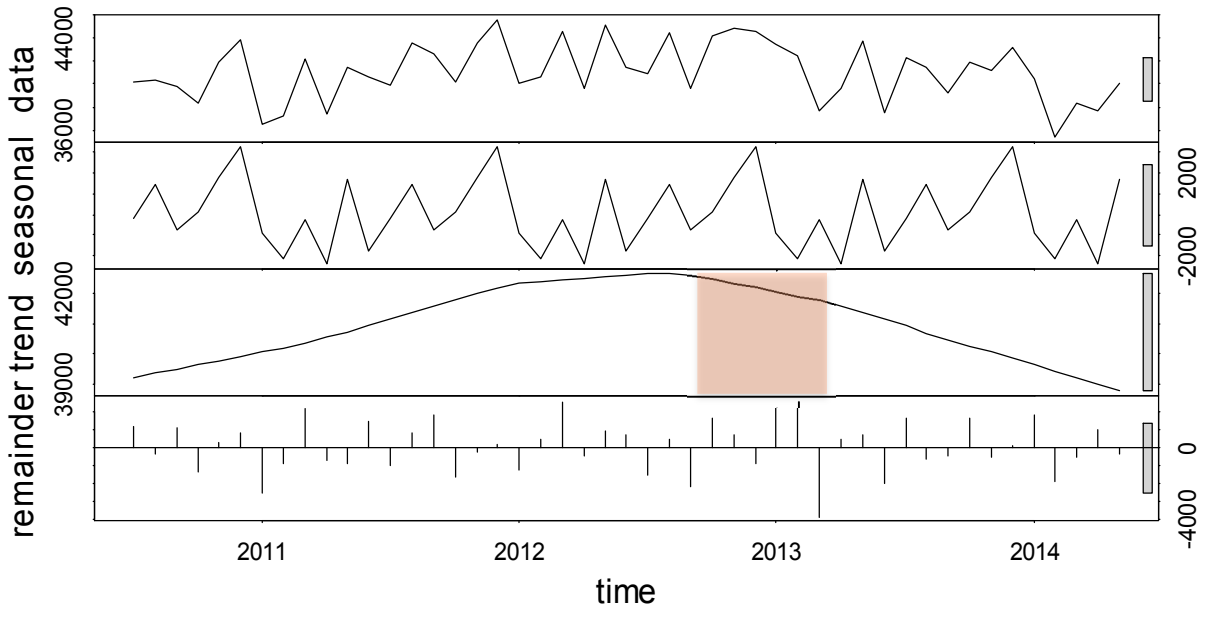
Seasonal decomposition graphs – how to read

The analysis used produces a smoothed trend line while controlling for normal monthly variations. A 4-way graph is used to show each element of the analysis. Each is lined up by month as noted by the years at the foot of the graph, running from Jul 2010 to June 2014.

1. Data. This presents the actual data used as monthly counts. The minimum and maximum for the whole period are shown in the left axis
2. Seasonal. This shows the variation by month seen – termed 'seasonal' statistically, but perhaps better described as monthly variation – for example community dispensing is often low in January, not because it is summer but because people are more likely to be away on holiday and to have picked up their pharmaceutical needs in December. The 'swing' from highest month to lowest month is shown in the right axis.
3. Trend. The key results of the analysis. This subtracts the monthly variation from the original data, then smooths to estimate the underlying trend. The minimum and maximum for the whole period are shown in the left axis.
4. Remainder. This shows the difference for each month between the adjusted result and the smoothed trend, showing the 'unexplained' variability. The size of the lowest remainder compared to the higher is given in the right axis.

The shaded box in the 'trend' graph indicates the changeover period.

Figure 9 Monthly trend in number of dispensed prescriptions for glucose test strips, July 2010 to May 2014



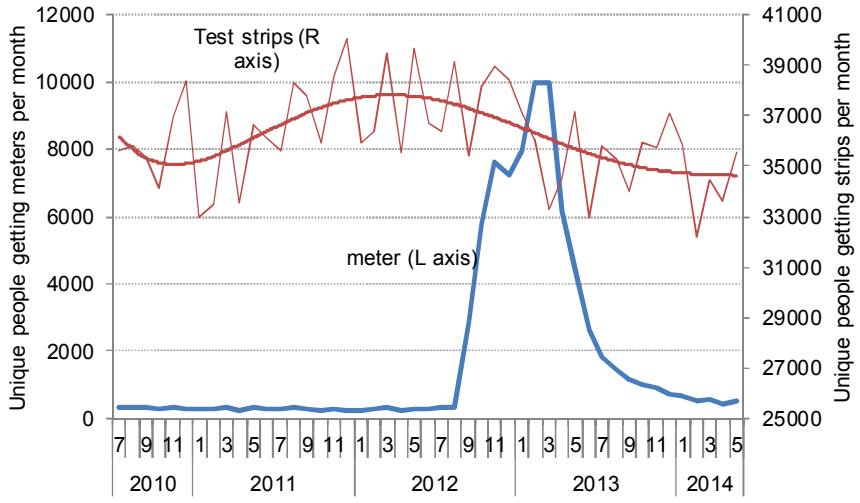
Source: VDR 2013 linked with community pharmaceutical dataset. All people with diabetes included, see text box for graph description. Note pharmaceutical data was only available to 31 May 2014

Throughout the duration of the study, there was a mean rate of 41,104 test strip dispensings per month (standard deviation: 2,542; range: 35,347 to 45,652). The trend component of Error! Reference source not found.Figure 9 shows that the total number of redeemed prescriptions per month grew from an average of ~39,000 claimed in mid-2010 to a peak of ~42,000 per month in mid-2012. The rate of dispensing steadily declined from this point to just less than the mid-2010 figure - ~39,000 by June 2014. A changing monthly pattern in the rate of dispensing is also evident, with a peak occurring in December, and a trough in April. The 'seasonal' variation is about 2,000 dispensings per month, comparing the peak months with the troughs.

There was an increase in test strip dispensing prior to the start of the meter changeover. This could have been due to people (and their health professionals) being reminded of the benefit of blood glucose testing with the publicity of the changeover. It may also be due to people 'stockpiling' strips for their old meter. In addition over the period Sep 2012 to Jun 2013, some test strips were made available with the new meters, with the new meters on prescription including 10 test strips. People may have also have been purchasing strips privately – these will not be captured in this data. This may have contributed slightly to the apparent fall off from September 2012.

Figure 10 shows similar data on test strips but restricts it to unique individuals per month, and compares it to the meter dispensing. Again the increase is before the changeover period, and the number of people getting strips dispensed in 2014 appears to be returning to the pre-2012 levels. Thirty-four per cent of the cohort received at least one blood glucose strip dispensing in the last six months (Dec 2013 to May 2014) compared with 35% in July-Dec 2011 (Table 1, page 13).

Figure 10 Monthly numbers of dispensed prescriptions for glucose test strips or meters, July 2010 to May 2014



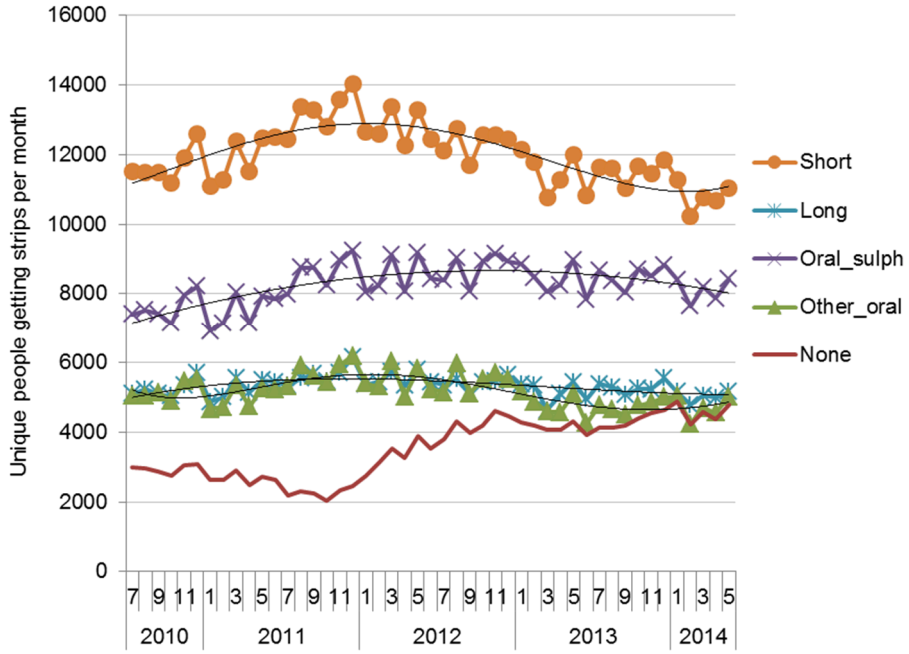
Source: Community pharmaceuticals data set and all people in VDR 2013 alive as at 1 Jan 2012 aged 5 – 84 years. Medication groups as at Jul-Dec 2011 as described on page 6.

It is thus a little difficult to interpret the before-after changes – these are shown in the Annex for those interested. All medication use cohorts showed an increase in test strip dispensing prior to the changeover, but for the 'after' compared to 'before' there is a divergence, with people using insulin reducing the quantity dispensed. This is shown in Figure 11. Note again that dispensing is what is being measured, not strip usage or prescriptions written. The overall pattern seems to be driven by the short-acting insulin users in particular.

An interesting small rise in the 'NONE' category is evident. There is considered to be a low clinical need for testing in this group. The increase might arise from:

- people switching from diet-controlled to medication ('natural history')[6]
- people being inspired by the publicity of the changeover to start testing (not a feature of the other groups, apart from perhaps people using sulphonylureas)
- people newly diagnosed (in 2013 and 2014), possibly starting medication, starting testing.

Figure 11 Monthly trend in number of dispensed prescriptions for glucose test strips by medication group, July 2010 to May 2014



Source: Community pharmaceuticals data set and all people in VDR 2013 alive as at 1 Jan 2012 aged 5 – 84 years. Medication groups as at Jul-Dec 2011 as described on page 6.

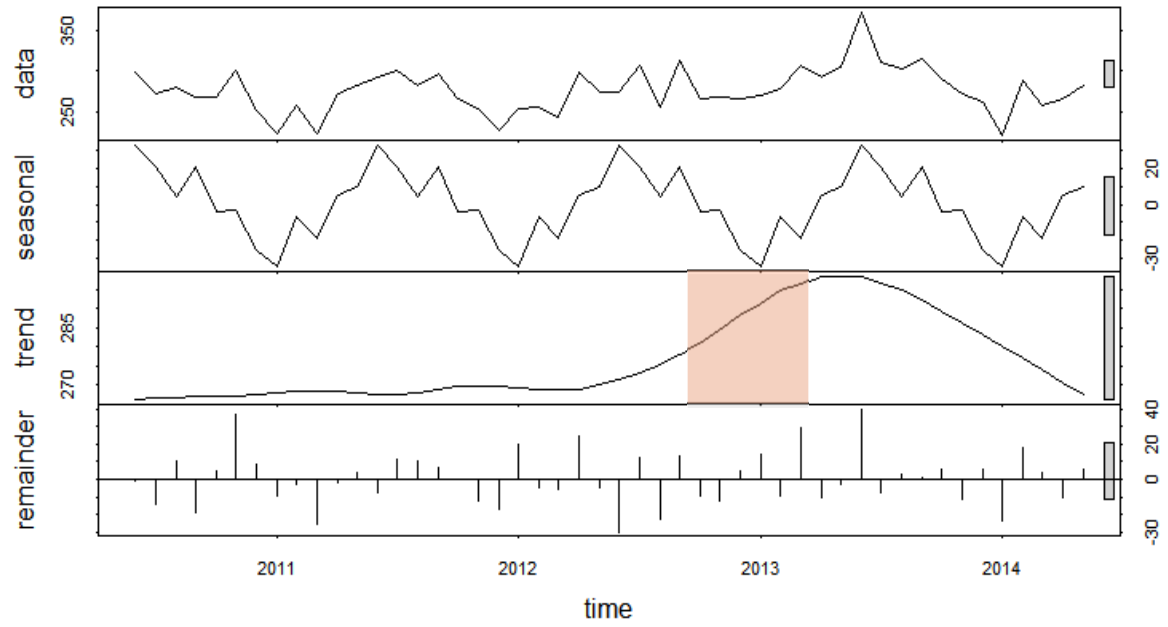
[6] Remembering that medication groups were assigned for the July-Dec 2011 period and held throughout the study period – even if a NONE person switches to insulin use they still belong to the NONE category for the study

5. Hospitalisations for poorly controlled blood glucose

5.1. VDR population analysis

Throughout the duration of the study (1 Jul 2010 to 30 June 2014) there was a mean of 274 hospitalisations per month with hyper- or hypo- glycaemia as the principal diagnosis. The trend component of Figure 12 shows that the number of hospitalisation per month started to increase from an average of 265 to 270 per month before May 2012, to a peak of about 300 per month between May and June 2013, before declining thereafter. By June 2014 levels were similar to those observed before 2012. Note that the trend line has been 'zoomed in' to highlight the rise – at maximum the peak represents 30 additional episodes per month, a ~10% increase from the baseline. There is also evidence of a seasonal pattern in the number of admissions, with an average of 30 fewer hospitalisations occurring in summer months, with peaks of 20 greater than average per month in winter. This might represent an excess of respiratory infections occurring in winter leading to people with diabetes developing steroid-induced ketoacidosis.

Figure 12. Monthly hospitalisations in New Zealand public hospitals with principal diagnosis of hyper- or hypo-glycaemia for people with diabetes, July 2010 to June 2014

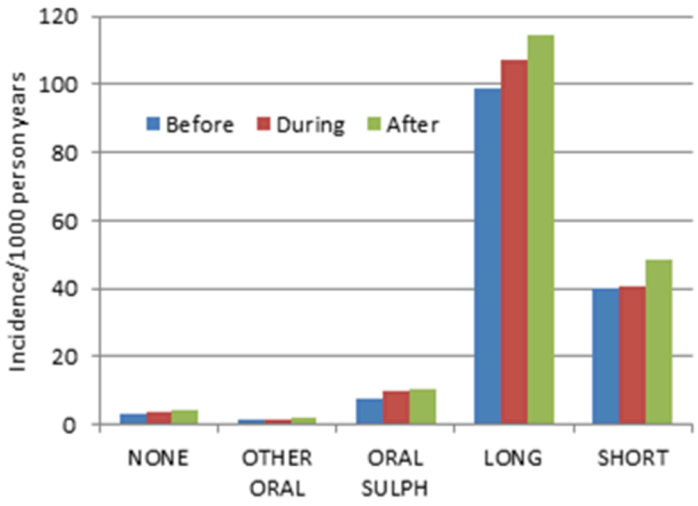


Source: VDR linked with NMDS. All people with diabetes included, principal diagnosis only (ICD codes used shown in the appendix of the Annex). Data = actual hospitalisation numbers per month, seasonal = the seasonal component; trend = what is left after subtracting the seasonal component, smoothed (highlighted area = the 'during' period); remainder = the difference month by month from the fitted trend curve. See notes in text box, page 14 for more explanation on the graph layout.

5.2. Per person

The person-specific analysis showed a small increase in the hyper- or hypo- glycaemia principal-diagnosis hospitalisation rate for the DURING period for the overall cohort of 5%, followed by a further 4% increase in the AFTER period (Figure 13). As expected the insulin-using groups had the highest risk of admission, with the 11,000 on long acting insulin highest (99/1000 persons per year BEFORE), followed by the nearly 30,000 on short acting insulin (40/1000) and then the 42,600 on sulphonylureas much lower (8/1000). The long/short groups both have large absolute increases in hospitalisations but the other groups also had increases. While hardly visible even the NONE group has an increase across periods, where the test strip introduction was hypothesised to have a null effect. This perhaps gives an indication about the "background" change in hospitalisation.

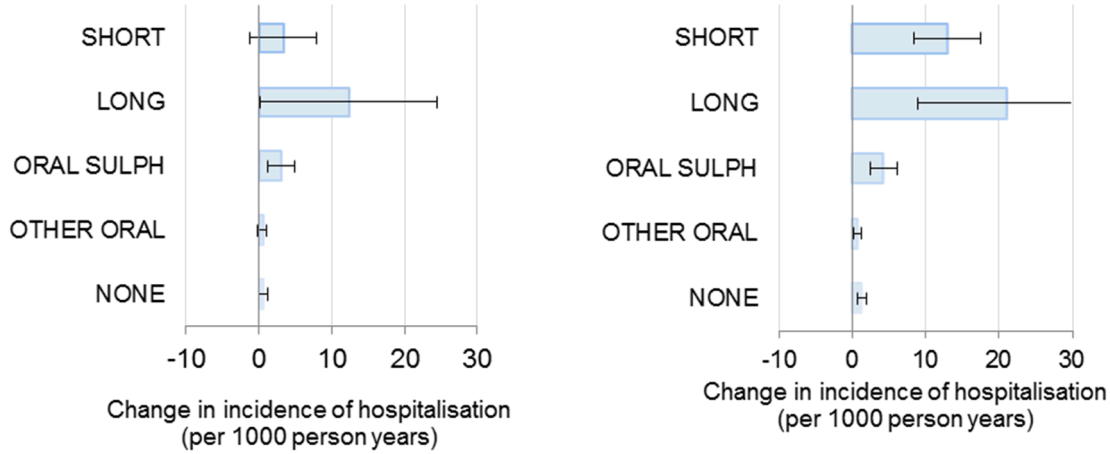
Figure 13. Hospitalisation with principal diagnosis of hyper- or hypo-glycaemia for people with diabetes before, during and after the meter changeover



Source: VDR linked with NMDS, cohort study. Rates per 1000 person years in each medication group

Figure 14. Change in principal diagnosis of hospitalisation rates for hyper- or hypo-glycaemia for people with diabetes

a) DURING compared with BEFORE **b) AFTER compared with BEFORE**



Source: VDR linked with NMDS, cohort study. Change in rates per 1000 persons in each medication group. Within-person analysis summed, so controlled for all individual characteristics.

The detailed within-person analysis is summarised[7] in Figure 14. The zero mark on the horizontal axis indicates no overall change in incidence of hospitalisations, compared with the BEFORE period. The left panel graph (Figure 1214a) shows the absolute increase in hospitalisation rate DURING the changeover, relative to the BEFORE period; the right hand panel (Figure 1214b) the AFTER time-period compared to BEFORE. The means of the different diabetes groups are to the right of this line indicating increases in incidence for each group. The 95% confidence limits are indicated on the plot by horizontal black lines. If they either include or are close to the null value of 0 this indicates no or

[7] All data values are given in the statistical annex.

marginal statistical significance. The DURING period showed increases in all medication groups, mostly non-significant. In contrast the AFTER graph sees increases that are statistically significant, or unlikely to be due to chance, in each group, with the LONG group and the SHORT group having the largest absolute change. In terms of numbers for the 2012 cohort overall, this would be equivalent to an extra 17 hospitalisations per month during the changeover, or 120 over the 7-month period, and further increase of 18 a month (to 35 a month) for the 15 months following the changeover.

We were puzzled by the apparent difference in the cohort view (Figure 14b) compared with the population view (Figure 12) in the risk of hospitalisation in 2014 compared to 2011-12. The main difference in methodology is that with the cohort view we are unable to control for the consequence of the natural history of diabetes, which usually involves increased risks of hospitalisation as the disease progresses. We also cannot rule out other clinical or policy changes that may have occurred over the same time period, but it is this natural history that appears most important. To test this further we stratified the cohort into a subset that might be considered of equivalent risk, people starting meter testing for the first time.

5.3. New-to-meter testing

For this analysis we took all people who had test strips dispensed in the first 5 months of 2011 who had not had strips dispensed in the 6 month period prior to that (Jul-Dec 2010). A similar cohort who had not had a strip dispensed in Jul-Dec 2013 but did in the first 5 months of 2014 was selected, and age-matched to the 2011 cohort. These groups represent people with diabetes either taking up blood testing for the first time, or re-establishing blood testing after a break of more than 6 months. As such we might expect them to be comparable in risk for hospitalisation. We matched for age, but did not further control for ethnicity, deprivation, gender or comorbidity.

Overall 18,640 people were able to be matched at an average age of 57. The 2011 cohort had 228 hypo- or hyperglycaemia hospitalisations Jan-May 2011, while the 2014 cohort had 186. This gave a rate difference of -5/1000/year (paired t-test = 0.07, non-significant).

This new-to-meter side analysis supports the VDR population view that hypo- or hyperglycaemia hospitalisations in 2014 had returned to 2011 levels. It suggests that the effects seen in the cohort view are more likely to be related to the natural history of diabetes than being due to any effect of the changeover in blood test meters.

6. Hospitalisations for hypoglycaemia

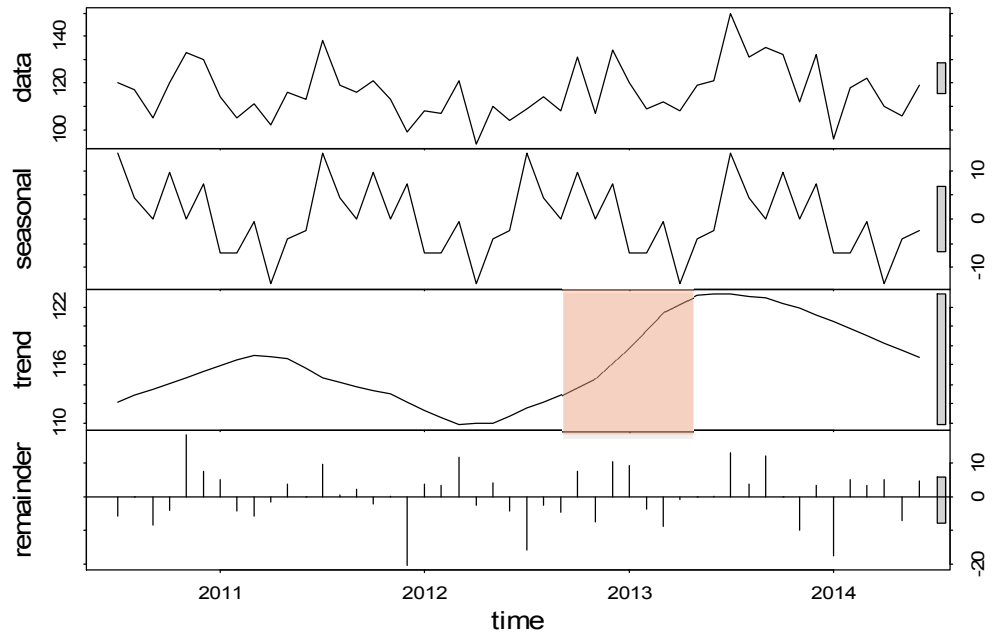
In examining hospitalisations for hypoglycaemia (low blood sugar) we are particularly concerned with the potential for insufficient blood monitoring of glucose, leading to overuse of insulin or excess sulphonylurea doses. Dose sizes required for blood glucose control can vary from day to day, for example with other behaviours like binge drinking of alcohol (a hypoglycaemic agent). While generally hypoglycaemia episodes are self-correcting, or can be dealt with by family members, or by ambulance officers/staff at an emergency department, more severe episodes, or those with co-morbidities, may necessitate hospital admission.

Detailed descriptions of the analyses used are given in Section 5 above. This section concentrates on the differences between hypoglycaemia hospitalisations analysed separately compared with the composite hypo- and hyperglycaemia analysis in Section 5.

6.1. VDR population analysis

There were around 110 hospitalisations a month for hypoglycaemia in the VDR population across the whole study period, so it comprises slightly less than half the composite indicator discussed in the previous section. The same increase as seen in the composite indicator (Figure 12) is present for hypoglycaemia (Figure 15), albeit smaller. Note the 'zoomed in' nature of the figure – the peak represents an increase of 12 hospitalisations a month. The rates fall in a similar fashion to the composite indicator.

Figure 15. Monthly hospitalisations in New Zealand public hospitals with principal diagnosis of hypoglycaemia for people with diabetes, July 2010 to June 2014



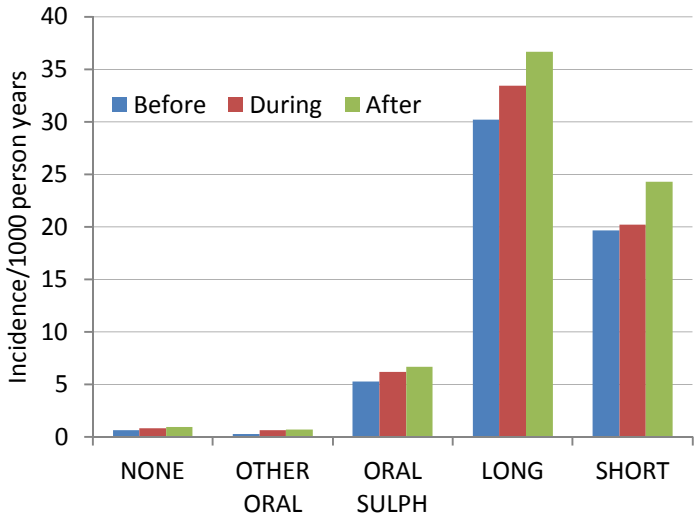
Source: VDR linked with NMDS. All people with diabetes included, principal diagnosis only (ICD codes used shown in the appendix of the Annex). 'data' = actual hospitalisation numbers per month, 'seasonal' = the monthly variation component; 'trend' = what is left after subtracting the seasonal component, smoothed (highlighted area = the 'during' period); 'remainder' = the difference month by month from the fitted trend curve. See notes in text box, page 14 for more explanation on the graph layout.

6.2. Within-person

Rates for hospitalisation with a principal diagnosis of hypoglycaemia were 8% higher in the DURING period, and a further 4% higher in the AFTER period (Figure 16). In a similar fashion to the composite

indicator, while the insulin groups had the highest absolute increase in hospitalisation, they had a lower relative increase than those on oral or no medications. This increase across all categories suggests an underlying trend rather than an effect only due to the blood test meter changeover.

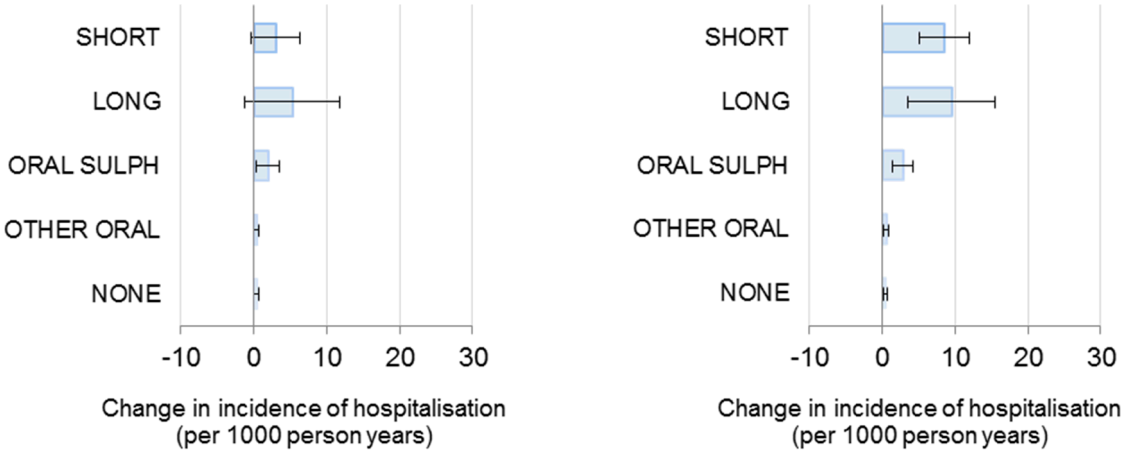
Figure 16. Hospitalisation with principal diagnosis of hypoglycaemia for people with diabetes before, during and after the meter changeover



Source: VDR linked with NMDS. Rates per 1000 persons in each medication group, annualised.

Little statistical significance was seen for the DURING period, while the sulphonylurea, long and short acting insulin groups showed statistically significant increases in the AFTER period compared with the BEFORE (Figure 17).

Figure 17. Change in principal diagnosis of hypoglycaemia hospitalisation rates for people with diabetes
a) DURING compared with BEFORE **b) AFTER compared with BEFORE**



Source: VDR linked with NMDS, cohort study. Change in rates per 1000 persons in each medication group. Within-person analysis summed, so controlled for all individual characteristics

For the 2012 cohort this would be equivalent to an extra 10 hospitalisations per month over the changeover (70 in total over the 7-month period), and an added 7 per month (making 17 extra per month) for the 15 months following (255 extra hospitalisations in total).

6.3. New-to-meter testing

In the analysis as described in Section 5.3 the new-to-meter cohort had 74 hypoglycaemia hospitalisations in 2011 compared with 61 in 2014 (p= 0.31, non-significant).

7. Hospitalisations for hyperglycaemia

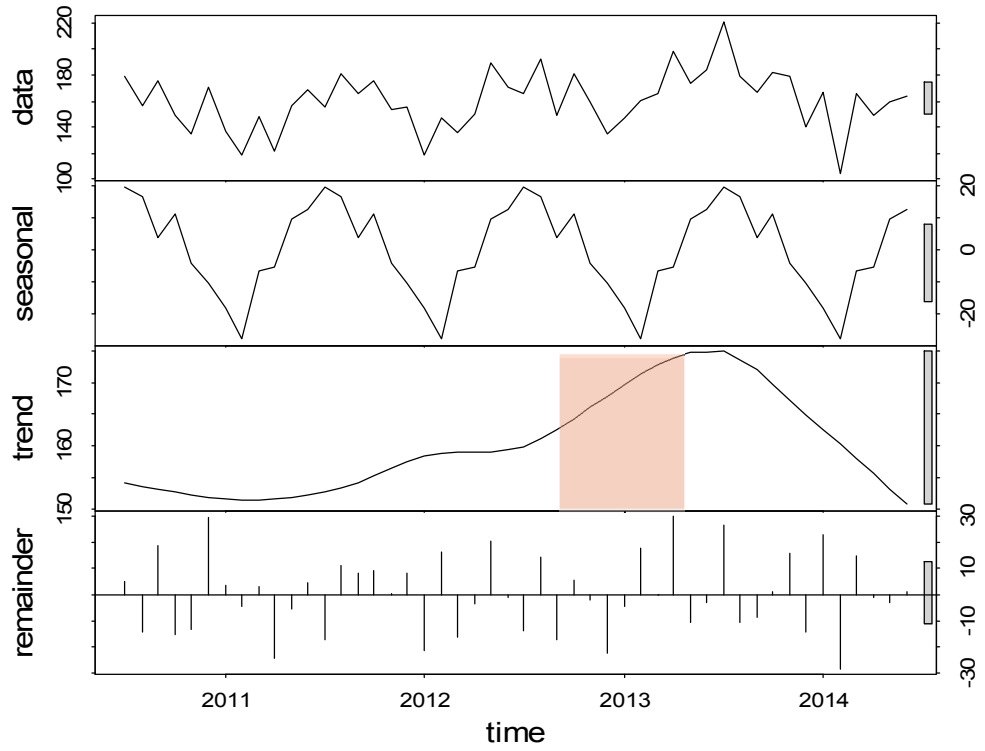
In examining hospitalisations with a principal diagnosis of hyperglycaemia we are particularly concerned with the potential for insufficient blood monitoring of glucose, leading to people with diabetes not realising their blood glucose levels are too high, and under treating any hyperglycaemia that they may develop. This could affect any of the groups but, given the relative stability of oral regimes, changes in testing are most likely to affect insulin-users.

Detailed descriptions of the analyses used are given in Section 5 above. This section concentrates on the differences between hyperglycaemia hospitalisations analysed separately compared with the composite hypo- and hyperglycaemia analysis in Section 5.

7.1. VDR population analysis

There were around 150 hospitalisations per month with a principal diagnosis of hyperglycaemia in the VDR population across the study period. The seasonal decomposition curve looked similar to that for the composite and hypoglycaemia analyses above, with a small peak just after the time of the DURING period of around 20 extra hospitalisations per month at its highest (Figure 18). It drops back to the previous baseline over the course of the following year.

Figure 18. Monthly hospitalisations in New Zealand public hospitals with principal diagnosis of hyperglycaemia for people with diabetes, July 2010 to June 2014



Source: VDR liked with NMDS. All people with diabetes included, principal diagnosis only (ICD codes used shown in the appendix of the Annex). 'data' = actual hospitalisation numbers per month, 'seasonal' = the seasonal component; trend = what is left after subtracting the seasonal component, 'smoothed' (highlighted area = the 'during' period); 'remainder' = the difference month by month from the fitted trend curve. See notes in text box, page 14 for more explanation on the graph layout.

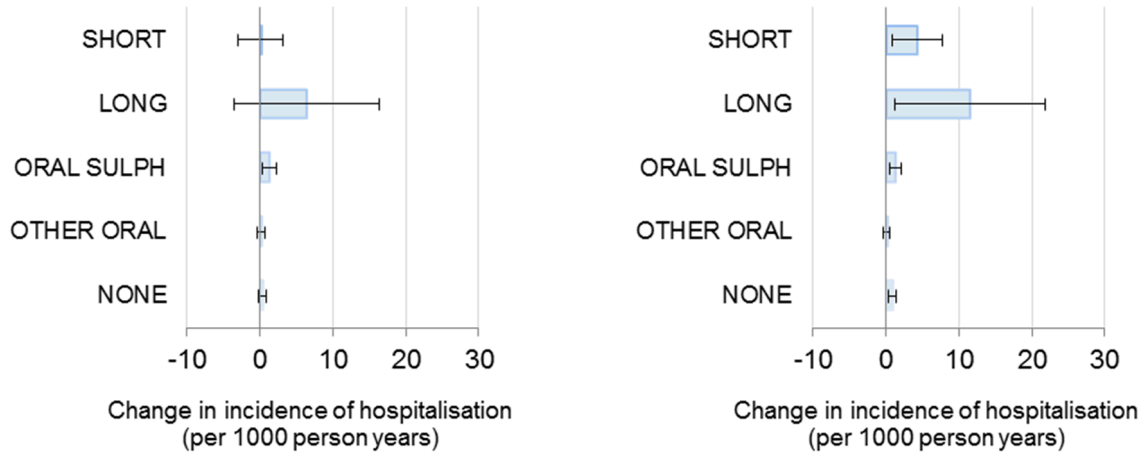
7.2. Per person analysis

Increased hyperglycaemia hospitalisations (principal diagnosis) were seen during the study, in a similar fashion to the composite and hypoglycaemia indicators discussed above (Figure 19).

Figure 19. Hospitalisation with principal diagnosis of hyperglycaemia for people with diabetes before, during and after the meter changeover
Source: VDR linked with NMDS, cohort study. Rates per 1000 persons in each medication group, annualised.

In the DURING period no statistically significant change in hyperglycaemia hospitalisations was seen in the within-person analysis (Figure 20). In the AFTER period the LONG and SHORT groups had increases that just reached statistical significance, though their proportionate increase at 18% was less than that of the other groups (29%).

Figure 20. Change in hyperglycaemia hospitalisation rates for people with diabetes
a) DURING compared with BEFORE **b) AFTER compared with BEFORE**



Source: VDR linked with NMDS, cohort study. Change in rates per 1000 persons in each medication group. Within-person analysis summed, so controlled for all individual characteristics.

For the 2012 cohort this would be equivalent to an extra 8 hospitalisations per month 'during', or 60 over the 7-month period, and a further 11 per month (19 in total per month) for the 15 months following up to 30 June 2014.

7.3. New-to-meter testing

In the analysis as described in Section 5.3 the new-to-meter cohort had 154 hyperglycaemia hospitalisations in 2011 compared with 125 in 2014 (p= 0.12, non-significant).

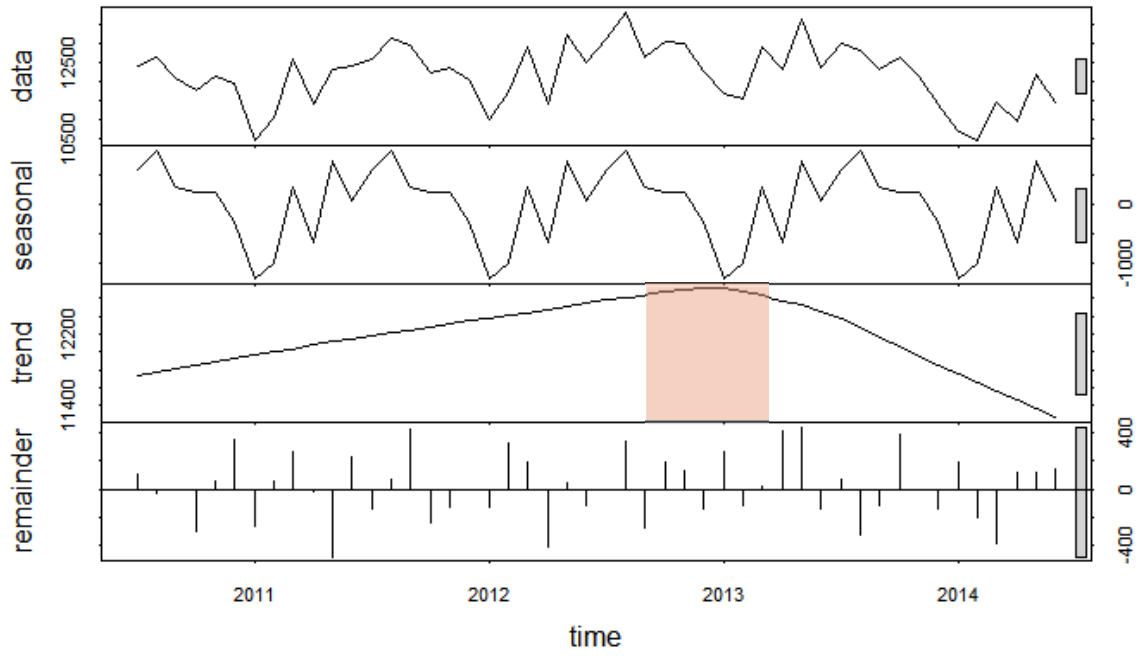
8. All hospitalisations

Long term good diabetes control should slow the onset of complications of diabetes, and thence potentially slow the increase in the incidence of hospitalisation. Short-term lapses in control are less likely to result in increased hospitalisation outside the hyper- and hypo-glycaemia main cause, but could do so. For this reason we examined the incidence of all hospitalisations within the VDR population to see if there was any effect over the course of the study period. We were particularly looking to see if there was any difference across medication groups.

8.1. VDR population analysis

Throughout the duration of the study a mean monthly rate of 10,008 medical-surgical hospitalisations occurred for the population with diabetes, ranging from 8,530 to 11,123. The trend component of Figure 21 shows an average of 11,600 hospitalisations per month occurred in the latter part of 2010 to the end of 2012, with a gradual rise to about 12,200 per month by June 2013 before declining again to 11,400 by Jun 2014 (Figure 21). There is also evidence of a seasonal pattern in the number of admissions, with an average of about 800 more hospitalisations than average occurring in August, compared with the lowest point occurring in January with an average of 1,000 fewer hospitalisations. The seasonal variation is about 1,800 hospitalisations per month, comparing the peaks with the troughs.

Figure 21. All hospitalisations at New Zealand public hospitals for people with diabetes by month, July 2010 to June 2014

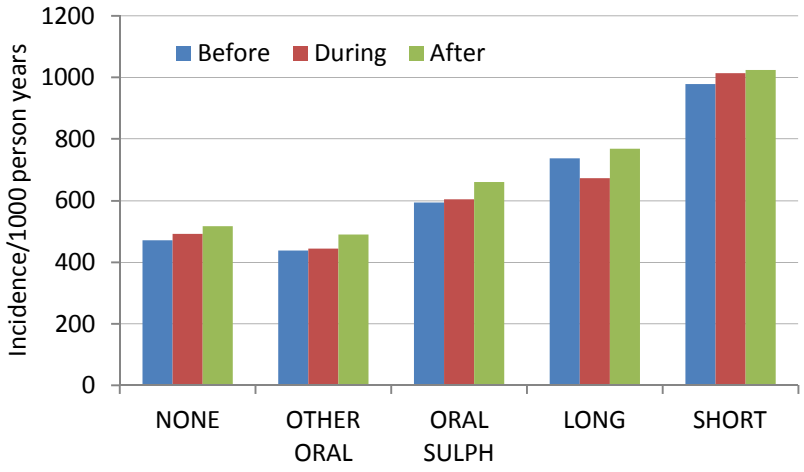


Source: VDR linked with NMDS. All people with diabetes included, 'data' = actual hospitalisation numbers per month, 'seasonal' = the seasonal component; 'trend' = what is left after subtracting the seasonal component, smoothed (highlighted area = the 'during' period); 'remainder' = the difference month by month from the fitted trend curve. See notes in text box, page 14 for more explanation on the graph layout.

8.2. Within-person

A steady increase in all hospitalisations was seen across most drug groups (Figure 22).

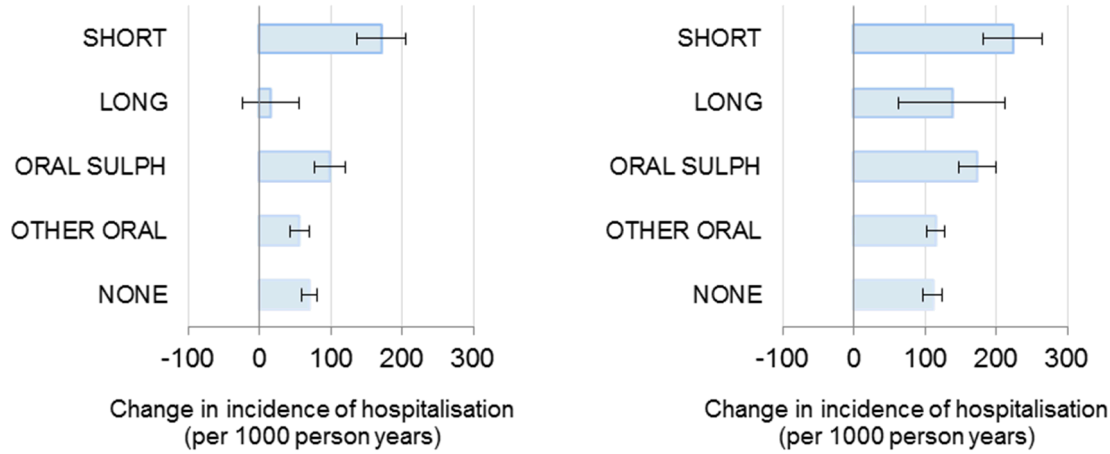
Figure 22. All hospitalisations for people with diabetes before, during and after the meter changeover



Source: VDR linked with NMDS, cohort study. Rates per 1000 persons in each medication group, annualised.

In the DURING period all groups except for LONG had statistically significant increases in hospitalisations compared with the before period (Figure 23). This increase persisted in the 'after' period, now including LONG – ie, all groups showed increases compared with the 'before' period. While the ORAL_SULPH, LONG and SHORT groups had higher absolute increases, their proportionate increase (25%) was much the same as that of the other two groups (24%).

Figure 23. Change in all hospitalisation rates for people with diabetes
a) DURING compared with BEFORE **b) AFTER compared with BEFORE**



Source: VDR linked with NMDS. Change in rates per 1000 persons in each medication group. Within-person analysis summed, so controlled for all individual characteristics. Note difference in scale to those above.

In terms of numbers for the 2012 cohort overall, this is equivalent to an extra 290 hospitalisations per month in the changeover period, or 2000 over the 7-month period. This dropped back a little with a decrease of 70 per month for the 15 months following up to 30 June 2014, but still represents an increase of ~200 a month compared to the 2012 baseline.

8.3. New-to-meter testing

In the analysis carried out as described in Section 5.3 the new-to-meter cohort had 3,250 medical-surgical hospitalisations in 2011 compared with 4,239 in 2014 ($p<0.001$, significant). This is a rate

increase of 127 hospitalisations per 1000 people with diabetes per year. For those admitted this represented 1.48 admissions per person in 2011 and 1.65 admissions per person in 2014. Taking individuals having at least one admission the figures are 2,190 compared with 2,571, still a significant increase with a rate increase of 49 people per 1000 people with diabetes per year, a 17% increase. This is quite a different pattern to the hypo-and hyperglycaemia hospitalisations seen in Chapters 5-7, and may represent a shift in the pattern of care for people for diabetes. It warrants further exploration, but is outside the bounds of this work.

9. Discussion

9.1. Summary of findings

The analysis of public hospital data over the past four years for all people in New Zealand with known diabetes has revealed some intriguing trends. The study concentrates on hospitalisations where the main reason for being admitted relates to blood glucose control – either low (= hypoglycaemia) or high (= hyperglycaemia). If the change in the test meter were to have an effect on hospital admissions, it is likely to be for these diagnoses. At the whole VDR population level we see a small increase in hospitalisation in the changeover period, followed by a return to the previous rate in the period following the changeover. This seems consistent with the changeover having caused some disruption in diabetes care, with the disruption settling in the period following changeover.

At the individual level the within-person analysis shows an apparently contrasting effect, with a gradual increase in hypo- or hyperglycaemia hospitalisation seen throughout the study time period, with a 7% increase in these hospitalisations while the changeover takes place, and a continuing increase thereafter. Perhaps the most important thing to note is that all medication groups had similar proportionate increases. If it were the meter change only that was causing the increase we would have expected higher proportionate changes in the insulin groups, which was not the case. We undertook an additional analysis which examined people with diabetes who were newly starting use of a meter, comparing 2011 and 2014. This group which should have an equivalent risk of hospitalisation showed no change in hypo- or hyperglycaemia hospitalisation over the period. This also makes it less likely that the increase seen in the cohort study was a result of the meter change policy only.

Our interpretation then is that the small increase in the 'during' period seen at the VDR level is then influenced at the per person view by disease progression. We cannot distinguish between the meter change and other clinical or policy changes that may have occurred over the same time period.

To give an idea of the size of the change from the likely disease progression, in terms of numbers of hospitalisations for hypo- or hyperglycaemia, the cohort for the BEFORE period averaged 247 hospitalisations per month. For the DURING period the incidence increased by 17 to an average 264 per month (a 6.8% increase over BEFORE's rate), then in the AFTER period a further rise of 17 hospitalisations per month occurred (a 6.2% increase over DURING's rate).

The 'all hospitalisations' category showed similar proportionate increases to the analysis of hospitalisations due to hyper- and hypoglycaemia events, lending further weight to this change being related to the natural history of diabetes where this is an increasing risk of complications as the disease progresses. By way of comparison, taking an age-weighted[8] view of all New Zealanders' medical-surgical hospital admission rates (ie people with and without diabetes) for the same timeframe as this study shows a 2.6% increase over the DURING phase, and a 4.8% increase for the AFTER compared with the period before the changeover. Comparable figures for the diabetes cohort are 3.7% and 4.7% - similar increases.

9.2. What may be the cause?

The pattern seen is consistent with the idea that the change process was disruptive, with some test strip users suffering some loss of glucose control. Mechanisms that have been suggested include:

- Some people testing less with the new meter than their old meter, leading to less tight blood control and increased hyper- or hypoglycaemia episodes

8 Age-adjusted to match the age structure of the diabetes population. Data from NMDS, all New Zealand medical-surgical casemix hospitalisations analysed in the same way as for the diabetes cohort.

- Some people testing *more* with the new meter, perhaps leading to more enthusiasm for tight blood control, thereby increasing hypoglycaemia episodes
- People newly testing becoming aware of high blood glucose readings and seeking medical attention as a result
- Some people getting less accurate readings/more variability in readings with the new meter, and getting poorer control as a result; or conversely people *perceiving* the results as less accurate and seeking care attention earlier
- People testing with the old and new meters in parallel, and getting differing results leading to irregular dosing and less control
- People who otherwise were not testing starting testing; as a new tester attempting overly tight blood control and getting increased hypoglycaemia episodes
- People who were testing becoming non-testers; potentially increasing the risk of hyper- or hypoglycaemia episodes
- People becoming more likely to attend hospital during the changeover period in response to test results or symptoms due to the publicity surrounding the change, and concern about the meter readings
- People had the same chance of presenting to hospital with diabetes-related conditions throughout, but due to their awareness of the new meters and test strips, and clinician(s) potential increased awareness of glucose control, the admission was more likely to be attributed on that, and coded as being due to hyper- or hypoglycaemia rather than some other presenting cause.

Probably some mixture of all these has occurred. If one was to investigate further a specific-cause, audit of individual hospitalisations would be needed. Whatever the underlying explanation, it appears that the risk reduced to baseline levels following the changeover, which is reassuring.

We were particularly interested in the idea that the increase might have come about through changed care-seeking behaviour rather than the mechanics of testing and dose titration. The slowed increase in all hospitalisations in the 'after' period is of note here. We could speculate that the combined impact of additional publicity that surrounded the consultation efforts, increased information about home monitoring of blood levels, and the likely increased linkage to general practitioners and pharmacists by people with diabetes, may have contributed to an overall improvement in timely care. The changes together may have led to increased interest in and awareness of the need for testing, and the importance of managing the results. As noted in the recent evaluation of the process:

> *"For some consumers, the opportunity to interact with the health system during the change to CareSens appears to have led to positive impacts by enabling them to access advice to improve the management and monitoring of their illness. Other positive diabetes management impacts were also documented, including the improved ability to test correctly.* p10*"* [9]

Alternatively, it may just be that people got used to their new meters, and care returned to what it was before.

9.3. Strengths

The study represents the whole population of people with known diabetes in New Zealand (ie, a 100% sample), giving a large cohort and a complete view with little risk of selection bias, and random error due to sampling. Every publicly-funded medication is captured, as is every public hospitalisation as

[9] Allen + Clarke. *Evaluation of the implementation of a decision to change the funding and supply of blood glucose meters and test strips.* Report to PHARMAC, 1 Sept 2014.

long as the coding is correct. Data covers the lead-in period well, and includes over a year of post-change data. The VDR population view analysis provided a clear picture of the likely trend over the changeover period. For the cohort study analysis is by individual. Each person acted as their own control with 256,000 separate before-and-after comparisons which were then summed to estimate the change in hospitalisation rates over the whole cohort. Stratifying by drug type allows the change to be more closely linked to the meter change intervention. The analysis by individual also mitigates any effect of broadening the diabetes definitions – for example, in having a larger pool of more mild disease or even 'pre-diabetes' in the virtual diabetes register in later years compared with earlier. Regression modelling allows major risk factors to be examined in detail, though not the main thrust of analysis here (details of the modelling are shown in the Annex).

9.4. Limitations

In this before-after design it is difficult to disentangle effects of the underlying disease and the intervention under study. As an observational study it cannot answer causation questions in the same way a clinical trial might be able to do. There are also many changes occurring in the health system simultaneously, and it is difficult to establish cause and effect, particularly with a progressive chronic condition like diabetes. For example, a mild winter or relatively low influenza rates may affect acute hospitalisation rates, or the increasing use of insulin pumps might have affected rates. It is also not possible to disentangle the effects of the change in the meter alone, compared with the effects of other elements of the education and awareness campaign. As the whole country was changed, it was not possible to compare areas with and without the change, leaving the need for a before-after study design.

While having more than a year of data after the intervention is very useful, it may be that a longer time period is needed to determine the full extent of the effects of the changes. The changeover may have been dragged out for some people – for example, the effect of stockpiling of previous brands test strips means that the previous meters may have been used for a longer time than the period used in the study. The analysis of the dispensing of test strip volumes suggests a large increase in test strip dispensing before the changeover, and a significant reduction following the changeover, indicating a possible stockpiling effect. There is also a possibility that not all hospital coding was completed for May/June 2014 (data was extracted in September 2014), though total hospitalisations for people with diabetes in May/June 2014 were only 400 less than the corresponding period in 2013 – within 2%.

While stratifying by drug category allows those individuals most sensitive to likely adverse effects to be identified, there are many other changes going on in the health system all the time, so direct attribution of cause and effect is not possible. Overall the natural history of diabetes would suggest that control becomes poorer with greater duration of the disease.

Further analyses are suggested by this work. One could look to update the study when a further years-worth of data becomes available. Also a closer look at hospitalisation rates for people with diabetes and the apparent increases in risk over time would be potentially important. It may be that people with type 2 diabetes are become increasingly likely to reach the maximum of their oral medication and require starting insulin for example.

9.5. Conclusion

Changes in the incidence of hospitalisations for people with diabetes were likely to be temporally related to the changeover of blood glucose testing meters. The small rise in hyper- and hypo-glycaemia hospitalisations in people with diabetes seen during the changeover period reduced following the changeover, and is likely to have been a time-limited effect of the change process. The report also illustrates the increasing impact of diabetes on our health system but this is not related to the type of test strips and meters in use.