

ALLEN+CLARKE

**EVALUATION OF THE IMPLEMENTATION
OF A DECISION TO CHANGE THE
FUNDING AND SUPPLY OF BLOOD
GLUCOSE METERS AND TEST STRIPS**

1 September 2014



This report has been prepared by:

Marnie Carter, Lead Evaluator

Ned Hardie-Boys, Evaluation Advisor

Dr John Marwick, Primary Care Expert

Jessie Wilson, Evaluation Analyst

CONTENTS

Acknowledgements.....	7
Executive summary.....	8
1 Introduction	12
1.1 Purpose	12
1.2 Audience	12
1.3 Structure of this report	13
2 Background and context	14
3 Methodology.....	15
3.1 Evaluation approach	15
3.2 Evaluation objectives	15
3.3 Information sources and methods.....	17
3.4 Analysis	19
3.5 Strengths and limitations	19
4 Key findings	20
4.1 Decision making, procurement and consultation.....	20
4.2 Planning for implementation	28
4.3 Information and communications	34
4.4 Education and support.....	40
4.5 Transition to the new meters	51
4.6 Impact of the funding decision on consumers.....	70
4.7 Impact of the decision on health professionals.....	74
4.8 Impact of the decision on PHARMAC.....	79
4.9 Impact of the decision on the pharmaceutical market.....	82
5 Conclusions and recommendations.....	85

Appendix A: Detailed evaluation questions.....	95
Appendix B: Online survey.....	97
Appendix C: Timeline of key events.....	106

LIST OF FIGURES

Figure 1: Process map of the development and implementation of PHARMAC’s funding decision	16
Figure 2: Health professionals’ survey responses regarding information sources	35
Figure 3: Health professionals’ quality ratings of information sources	36
Figure 4: Survey respondents’ awareness and use of education and support resources	41
Figure 5: Survey respondents’ ratings of education and support resources they used	42
Figure 6: New CareSens meter dispensing by provider type	47
Figure 7: Survey respondents’ perceptions of how patient groups transitioned to the new meters	54
Figure 8: CareSens brand change notification to Medsafe reporting patterns	63
Figure 9: Fluoxetine brand change adverse reaction reporting patterns	63
Figure 10: Overview of PHARMAC transition activities	67
Figure 11: Health professionals’ use of the transition to discuss patients’ diabetes management	74

LIST OF TABLES

Table 1: Number of blood glucose meter units dispensed by brand 2008-2010	21
Table 2: Trigger factors likely to incur negative reactions to brand changes	30
Table 3: Calls received by PHARMAC/Pharmaco free phone lines September 2012 – September 2013...	43
Table 4: Percentage of CareSens N POP, N and II models prescribed by pharmacists by DHB region.....	48
Table 5: Health professionals’ perceptions of what went well with the implementation of CareSens meters (N = 102)	52
Table 6: Overview of meter and strip functionality concerns across focus groups.....	55
Table 7: Concerns related to patient choice and brand loyalty.....	59
Table 8: Health professionals’ perceptions of what could have been improved with the implementation of CareSens meters (N = 105)	75
Table 9: Blood glucose meters and test strips annual costs 2010-2013.....	79
Table 10: Conclusions related to development of the decision	85
Table 11: Conclusions related to the effectiveness of implementation	87
Table 12: Conclusions related to the transition to the new meters and test strips	90
Table 13: Conclusions related to the impacts of the change to CareSens.....	91
Table 14: Detailed evaluation questions.....	95

ACKNOWLEDGEMENTS

The *Allen + Clarke* evaluation team would like to thank all those who participated in this evaluation, including PHARMAC personnel, users of blood glucose meters, clinicians, consumer and healthcare organisations and pharmaceutical industry suppliers. The time and support provided, and knowledge and experiences shared, was invaluable to the evaluation process. We would particularly like to thank the consumers, health professionals, organisation representatives and other stakeholders for their participation in the key informant interviews, survey and focus groups. The evaluation team would also like to acknowledge the PHARMAC staff who attended advisory meetings for their support, guidance and feedback on the findings, and for their collaboration with us throughout this project.

EXECUTIVE SUMMARY

The change to the funding and supply of blood glucose meters and test strips

In August 2012 the Pharmaceutical Management Agency (PHARMAC) entered into a single supplier agreement with Pharmaco NZ Ltd for blood glucose meters and test strips. The decision to change the funding of blood glucose meters sought to ensure that people with diabetes have access to accurate meters while achieving savings of approximately \$10 million per year over the three-year contract period. This was the first time PHARMAC had implemented a funding decision that required a change of device and associated consumables. The decision has affected around 120,000 diabetes patients using blood glucose meters and has gained a high level of public interest.

Evaluation objectives

The objective of the evaluation was to assess the implementation of the single supplier funding arrangement. Specifically, the evaluation sought to:

- determine what worked well with the implementation of the decision and what did not
- ascertain if there were unintended or unexpected effects that occurred as a result of the decision
- identify any 'lessons learned' for PHARMAC's future decision making and implementation.

The evaluation addressed four overarching themes related to the chronological progression of PHARMAC's single supplier funding decision. These evaluation themes focused on the (1) development of the decision, (2) effectiveness of the implementation, (3) transition to the new meters and strips and (4) the impacts of the funding decision on consumers, health professionals, PHARMAC and the market.

Methods

The evaluation involved multiple information sources and mixed methods, including:

- review of PHARMAC documents and data related to the decision
- key informant interviews with PHARMAC personnel and other relevant stakeholders
- focus groups with consumers
- an online survey of health professionals.

Key findings

Development of the decision

The blood glucose test strips market represented a substantial cost for PHARMAC, and the agency had been seeking savings in this area for some years. When the multiple supplier agreement for blood glucose meters ended in 2011, PHARMAC issued a request for proposals for sole, dual or standard supply of meters and test strips.

PHARMAC analysed the proposals it received against a range of dimensions including PHARMAC's nine decision criteria, modelling of the shortlisted bids to determine cost savings for PHARMAC, and the timing at which savings were likely to be achieved. However, PHARMAC did not substantially consider the large scale change which would be required if single or dual supply was awarded to a supplier other than Roche (i.e., over 80 percent of the market would be required to change brands).

Once a preferred supplier had been selected, clinical testing of the meters was undertaken but, despite attempts, no 'usability testing' (i.e., testing the functionality of the meter when used by the patient in a real world setting) was completed. This could have helped to pre-empt and mitigate issues with functionality that were subsequently experienced by consumers and clinicians and the challenges some patient groups had in learning to operate the meter.

Effectiveness of the implementation of the change

PHARMAC heeded health professional and consumer advice that a 'one-size-fits-all' communications approach would not be suitable for consumers, and planned for a comprehensive range of information channels and touch points. Activities included direct communications from PHARMAC and Pharmaco, notices in professional journals and newsletters, websites and phone numbers. The communications channels were generally considered effective by health professionals, who reported having achieved a high level of awareness of the coming changes. Consumers' perceptions of the effectiveness of PHARMAC's communication were mixed, with those belonging to patient groups and support organisations generally having greater awareness of the change.

PHARMAC's education and support strategy was premised on the idea that education and training materials would be provided to health professionals to support them in teaching their patients to use the new meters. The materials provided to health professionals by PHARMAC were generally well received, and overall the evaluation findings suggest that health professionals were well informed about the changes. However, the quality of education consumers received from health professionals was variable. The majority of consumers learned to use their meters with minimal support; many simply picked up the new meter and did not want or need additional education. Others received high quality education and support from their health professional (mainly pharmacists), but for some the education did not meet their needs.

Throughout the implementation process PHARMAC monitored rates of uptake of the new meters, as well as the concerns raised by consumers and health professionals during the change process. PHARMAC was responsive in adapting its implementation approach to address any identified issues.

Transition to the new meters and strips

The majority of consumers and health professionals transitioned to the new meters without a large degree of difficulty. Assisting over 100,000 people in transitioning successfully to the CareSens meters is a key accomplishment for PHARMAC.

Despite the majority of individuals transitioning successfully to the new meters, some individuals experienced barriers with the changeover. These challenges included adapting to the different strip and meter functionality, loyalty to previous meter brands and perceived lack of choice. Apprehension over perceived CareSens inaccuracies remains an ongoing barrier to successful transition for some

individuals. Type 1 diabetics and parents of young Type 1 diabetics are particularly concerned about perceived inconsistent meter readings and perceived discrepancies between their old meters and the new meters.

Impacts of the funding decision on consumers

The majority of the 120,000 consumers who have acquired the new CareSens meters did not experience any significant positive or negative impacts. 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. A negative impact felt by some individuals relates to distress and mistrust in the CareSens meters due to concerns over the accuracy or validity of the meters. For some, this has impacted the way in which they monitor their illness, for example more frequent testing motivated by perceptions of inaccurate CareSens meter readings.

Impacts of the funding decision on health professionals

Health professionals reported both positive and negative impacts of PHARMAC's funding decision to move to a single supplier of diabetes management products. A key positive consequence of the implementation related to health professionals having used the changeover as an opportunity to discuss monitoring, self-management strategies and improved testing techniques with their patients.

Opportunity costs were seen as an adverse effect of the switch to CareSens products. This impact was particularly experienced by those health professionals working in secondary care who were required to spend time providing education and reassurance to patients at the expense of clinical activities. Other health professionals believed that their relationships with patients were negatively impacted by the need to 'front' an unpopular change.

Impacts of the funding decision on PHARMAC

Interviews with PHARMAC staff indicate that the expected savings resulting from the change to a single supplier arrangement have been achieved: The annual cost of blood glucose meters was \$23 million in 2012, whereas the annual cost post-implementation of the change to CareSens meters decreased to just over \$14 million in 2013. It is estimated that PHARMAC has achieved an estimated savings of over \$10.1 million in the 2013 calendar year.

Evaluative evidence does suggest, however, that funding could have been spent more efficiently had some of the transition difficulties experienced been identified and planned for earlier. PHARMAC has acknowledged some opportunity costs associated with implementation of the funding decision. The initial stages of the implementation process required a higher than anticipated amount of PHARMAC staff resources, and staff time was diverted to supporting the implementation at the expense of other work. The evaluation team also heard examples of stress PHARMAC staff experienced during the transition period, with reports of long working hours and difficulties in dealing with concerns raised by the health sector consumers.

Impacts of the funding decision on the pharmaceutical market

The move to a single supplier arrangement for blood glucose meters is likely to have ongoing impacts in reducing the cost of blood glucose meters and test strips, as suppliers wishing to enter the market after the single supplier period ends would need to match the price offered by CareSens. The change may also have wider impacts in the pharmaceutical market (i.e., in relation to other medicines or devices) by sending a message to suppliers that PHARMAC is willing to make a significant change in order to use public resources more efficiently.

Evidence suggests that a single supplier arrangement is unlikely to pose a risk to the blood glucose meter supply chain as mitigation strategies are in place, such as the requirement for Pharmaco to have four months' worth of stock and immediately notify PHARMAC if stock falls below this. The single supplier agreement also includes provisions for new meters to be introduced to the market, allowing for continued innovation in meter technology, suggesting that concerns about negative impacts on innovation in the pharmaceutical devices market are unlikely to be realised.

Recommendations

Based on the findings of the evaluation of PHARMAC's funding decision to change the funding and supply of blood glucose meters and test strips, we have identified a number of recommendations relating to the implementation of future funding decisions of a similar nature:

1. develop criteria for determining whether a medical device change under consideration is likely to be a 'standard' or 'major' funding decision.
2. clarify the purpose of future consultations in request for submission documents, and ask that submitters respond to specific questions.
3. include and plan for face-to-face meetings as a core part of consultation for major changes.
4. planning for implementation of major decisions should include a focus on identifying likely patient concerns and objections, and providing key messages and resources to support health professionals to reassure consumers.
5. seek specialist advice and employ specialist communications personnel early in the planning stages.
6. support the development a more formalised health system referral approach and multiple support pathways depending on need.
7. undertake early planning and implementation of transition support activities targeted at patient groups likely to struggle with the transition.
8. work with other health agencies to identify and promote activities to target the broader contextual and behavioural factors influencing condition management.

1 INTRODUCTION

The Pharmaceutical Management Agency (PHARMAC) appointed Allen and Clarke Policy and Regulatory Specialists Ltd (*Allen + Clarke*) to evaluate the implementation of a major funding decision that resulted in a change to the funding and supply of blood glucose meters, the devices used by people with diabetes to measure their blood glucose. This report presents the findings of the evaluation, which was undertaken between July 2013 and April 2014. The findings and conclusions presented in this report are the result of *Allen + Clarke*'s independent inquiry and do not necessarily reflect the views of PHARMAC.

1.1 Purpose

PHARMAC commissioned this evaluation in order to continuously improve its approach to implementing its funding decisions. PHARMAC will use the evaluation findings to identify key lessons related to the implementation of the change of blood glucose meters, and to inform the implementation of other funding decisions in the future.

The evaluation assessed both the process and the implementation of the funding decision. The purpose of the evaluation was to:

- determine what worked well with the implementation of the decision and what did not
- ascertain if there were unintended or unexpected effects that occurred as a result of the decision
- identify any 'lessons learned' for PHARMAC's implementation planning to support future decisions.

Overarching themes that the evaluation addressed were (1) development of the decision, (2) effectiveness of implementation, (3) transition to the new meters and strips and (4) impacts on consumers, health professionals, PHARMAC and the market.

This report is the first part of a twostage evaluation of the implementation of the change to the funding and supply of blood glucose meters and test strips. The first stage, the results of which are presented here, focused on the implementation of the change process and does not attempt to assess clinical impacts of the change. Clinical impacts will be analysed during the second stage of the evaluation.

1.2 Audience

The main audience for the report is PHARMAC staff involved with the development and implementation of the funding decision, as well as those PHARMAC staff likely to be involved in future similar transactions. The report may also be useful to share with the PHARMAC Board, which has overall responsibility for all of PHARMAC's funding decisions and the Pharmacology and Therapeutics Advisory Committee of PHARMAC (PTAC), which provides clinical advice to the Board.

1.2.1 Other relevant stakeholders

The evaluation findings will also be of interest to organisations involved with the development and implementation of PHARMAC's decision. While this report in its entirety may not be relevant to this

audience, there is likely to be significant interest in specific evaluation findings, and it will be important to ensure that key findings are disseminated to the sector.

These organisations include but are not limited to MTANZ (the primary industry body representing medical device suppliers and manufacturers in New Zealand); DHBs, diabetes and medical clinics, pharmacies and Primary Health Organisations (PHOs) (agencies providing diabetes management services including advice, information and the prescription of diabetes devices and consumables); the New Zealand Society for the Study of Diabetes or NZSSD (national advisory body on scientific and clinical diabetes care and standards); the Diabetes Nurse Specialist Section of the New Zealand Nurses Organisation or the NZNO (representation of nurses who specialise in diabetes); the Royal New Zealand College of General Practitioners or RNZCGP (the professional body which sets standards for general practice and provides training and ongoing professional development for general practitioners and hospital generalists); the Pharmacy Guild of New Zealand and the Pharmaceutical Society of New Zealand (organisations providing support, representation and services to pharmacists); and Medsafe (New Zealand Medicines and Medical Devices Safety Authority responsible for ensuring the meters funded by PHARMAC are of an acceptable standard).

Further audiences for the evaluation findings include consumer groups and consumers affected by the change. This includes non-government organisations and charities such as Diabetes New Zealand, Diabetes Youth New Zealand, Grey Power and Te Rōpū Mate Huka, which support people and their families affected by diabetes.

1.3 Structure of this report

The remainder of this report is structured as follows:

- **Section 2** provides a contextual background for the funding decision
- **Section 3** sets out the evaluation methodology, including the overall approach to design, the evaluation objectives and questions, and the specific methods
- **Section 4** presents the main evaluation findings based on the overarching evaluation themes of development of the decision, implementation of the funding decision, transition to the new meters and strips and impacts on consumers, health professionals, PHARMAC and the pharmaceutical market
- **Section 5** includes concluding comments on the evaluation findings, and our recommendations for key lessons related to the implementation in order to better inform future funding decisions.

2 BACKGROUND AND CONTEXT

PHARMAC was created in 1993 in response to rapid increases in healthcare expenditures and the resultant need for active management of Government spending on medicines. PHARMAC's central objective was to introduce price competition between pharmaceutical companies operating within the New Zealand market in order to obtain improved value for medicines, and to increase New Zealanders' access to these medicines. This included organisation of the range of subsidised pharmaceuticals, review of therapeutic groups of medicines and development of price-reduction strategies such as contractual arrangements, multiproduct agreements and tendering.

PHARMAC first assumed responsibility for funding blood glucose testing products in 2005, at which time dual supply contracts for the subsidised devices were awarded to Roche and Medica, suppliers of the Accu-Chek and FreeStyle brands of meters. A multiple supply arrangement was introduced in 2008 once the dual supply contracts with Medica and Roche had ended, aimed at creating a more cost effective supply model through the introduction of further meters. Six meters were listed in the Pharmaceutical Schedule by 2011, which included two CareSens blood glucose meters distributed by Pharmaco and manufactured by i-SENS.

In August 2011 PHARMAC issued a request for proposals (RFP) for the supply of diabetes management products. The RFP led to a successful bid by Pharmaco for the single supplier of CareSens diabetes products, which required approximately 120,000 people with diabetes to switch to a CareSens meter in order to continue to access subsidised test strips. The transition to CareSens meters commenced on 1 September 2012, with only the CareSens range available from 1 March 2013.

Although PHARMAC has previously implemented major changes to pharmaceuticals, this was the first time that a decision necessitating a change in a medical device and associated consumables had been implemented. Given the novelty and scale of the funding decision and the substantial amount of public interest the decision received, PHARMAC is interested in an evaluation of the process around the decision and implementation of the change. It is anticipated that the review will help PHARMAC to develop appropriate strategies for implementing other potential device changes in the future.

3 METHODOLOGY

This section sets out our approach to the evaluation, the evaluation objectives and questions, a summary of the information sources, how methods and analysis were undertaken, and an overview of the strengths and limitations of the evaluation.

3.1 Evaluation approach

PHARMAC appointed *Allen + Clarke* to evaluate the implementation of a major funding decision, resulting in a change of the supply of blood glucose test strips and meters. The focus of the evaluation assessed the process and the implementation of the decision rather than the decision itself (i.e., it does not seek to determine whether single supplier should have been implemented in the first place). The findings of the evaluation will be used to identify key lessons related to the implementation of this decision and to inform the development and implementation of future funding decisions.

Allen + Clarke approached the evaluation in four key phases, including Scoping and Design (Phase 1), Evidence and Data Collection (Phase 2), Analysis and Development (Phase 3), and Reporting and Recommendations (Phase 4). The specific methods used to collect evidence are described in section 3.3 below.

The evaluation team engaged with PHARMAC throughout the evaluation. PHARMAC provided input into the selection of stakeholders for interviews and focus groups, and the development of evaluation tools such as the quantitative survey. *Allen + Clarke* provided regular progress reports to PHARMAC outlining tasks completed, next steps, issues and risks, and any other relevant information. The evaluation also included face-to-face meetings at key stages of the process, including a presentation of interim findings in October 2013 and a ‘sense making’ workshop in February 2014. The purpose of these engagements was to present the emerging findings to PHARMAC, provide an opportunity for feedback and discussion, and engage in participatory interpretation of the implications of the findings.

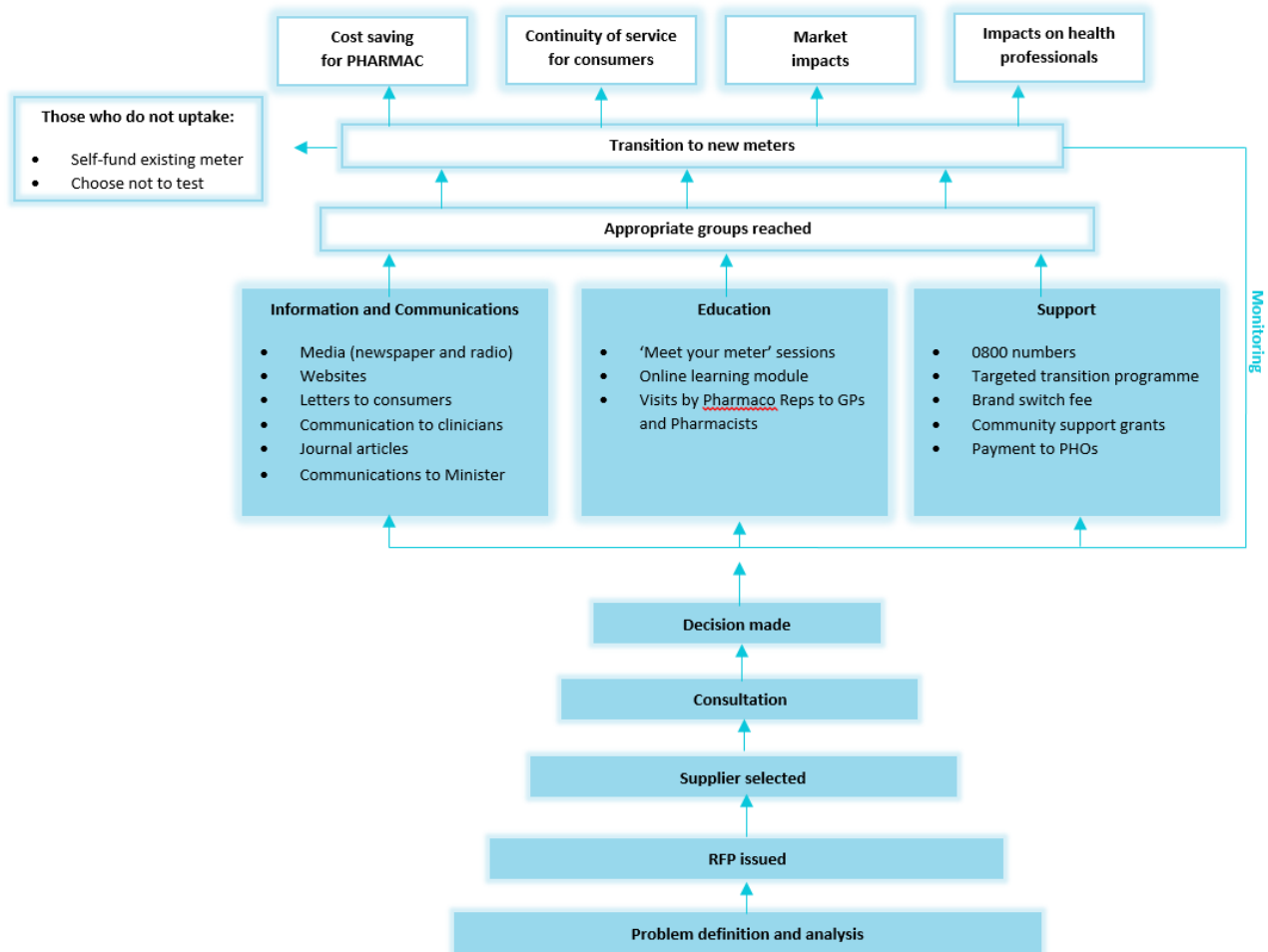
3.2 Evaluation objectives

The evaluation considered the processes PHARMAC used to implement the decision to change to single supplier of blood glucose meters. As the decision making processes (such as pre-procurement analysis, supplier selection, and consultation) impacted on the later implementation of the decision, these have been included within the scope of analysis. The evaluation centred around three key questions:

- What worked well with the implementation of the decision and what did not?
- Were there any unintended or unexpected effects that occurred as a result of the decision?
- What are the key ‘lessons learned’ for PHARMAC’s future decision making?

The evaluation team developed a process map to sequence the events involved in the development and implementation of PHARMAC’s decision to move to a single supplier of blood glucose meters and test strips. This is provided as figure 1 below.

Figure 1: Process map of the development and implementation of PHARMAC's funding decision



The process map was presented to key PHARMAC stakeholders during an initial workshop to check its validity. The stages of implementation articulated in the map have formed the foundation of how the evaluation has been structured. This includes four central evaluative themes based on the chronological progression of PHARMAC's implementation of the funding decision:

1. **development of the decision** considers the appropriateness of PHARMAC's analysis, supplier selection and consultation processes, as well as its planning for implementation
2. **implementation of the decision** includes the effectiveness of the information, communication, education and support mechanisms employed by PHARMAC
3. **transition to the new meters and test strips** focuses on the success or otherwise of various consumer groups in making the transition to CareSens meters
4. **impacts of the funding decision** examines how the decision affected consumers, health professionals, PHARMAC and the pharmaceutical market.

A full set of evaluation questions corresponding to these themes is located in Appendix A.

3.3 Information sources and methods

The information and evidence required to answer the evaluation questions was gathered from multiple sources and through multiple methods. These included:

- review of PHARMAC documents and data related to the decision
- key informant interviews with PHARMAC personnel and other relevant stakeholders
- focus groups with consumers
- online survey of health professionals.

Further details of the methods are provided below.

3.3.1 Document and data review

We undertook a comprehensive review and critical analysis of documents, resources and data related to the implementation of the decision, including:

- weekly reports to the Director-General of Health
- PHARMAC board papers
- minutes of the Diabetes Subcommittee of PTAC meetings
- the RFP and other procurement documentation
- consultation documents
- stakeholder websites (e.g., PHARMAC, CareSens, Pharmaco)
- health professional education resources such as those provided by Goodfellow Learning and BPAC
- consumer resources such as factsheets, 'how to' videos, and website resources
- Medsafe data on incidents related to blood glucose meters and test strips.

The results were used to form the process map detailed in figure 1. The documents and data were also used to highlight key issues and assumptions that were tested through the evaluation, and to provide evidence related to the key evaluation findings.

3.3.2 Key informant interviews

We interviewed informants from PHARMAC as well as health professionals, suppliers who submitted bids on the proposal, and medical organisation representatives with knowledge of and experience with the funding decision. These interviews were held with:

- 6 PHARMAC employees (e.g., Managers, Team Leaders, communications staff)
- 6 clinicians (Pasifika Diabetes Nurse Specialist, Māori Diabetes Nurse Specialist, Diabetes Nurse Specialist, General Practitioner, Policy Pharmacist, Community Pharmacist)
- 6 medical, nursing and pharmacy organisations (Aotearoa College of Diabetes Nurses, Pharmacy Guild of New Zealand, Pharmaceutical Society, Royal New Zealand College of General Practitioners, Medsafe, Diabetes New Zealand)
- 3 consumer groups and NGOs (Diabetes New Zealand, Grey Power, Te Rōpū Mate Huka)

- 4 suppliers and supplier bodies (Pharmaco, Roche, Medica/Abbott, and the Medical Technology Association of New Zealand).

The interviews collected qualitative information on the development of the decision, the effectiveness of the implementation, and impacts on consumers, health professionals and the market.

3.3.3 Focus groups with consumers

Six focus groups were held with a sample of people with diabetes from a range of different demographic groups and regions around the country. This included representation of Māori, Pasifika and Asian peoples, adult and youth Type 1 diabetics and older adults (aged 60 years plus). Interested consumers who could not participate in focus groups (e.g., due to the timing of the event) were given the option of participating in a one-on-one interview, mini-group interview with their family/whānau, or submission of written consumer feedback.

Between eight to sixteen people participated in each of the focus groups across six sites nationwide. The focus groups were facilitated using a semi-structured format, and checklists were developed to ensure the key evaluation themes were discussed. During the focus groups, we sought to better understand:

- consumers' understanding of the changes to the funding and supply of blood glucose meters
- what opportunities were available to consumers to provide input into the decision
- consumers' experiences and views of the consultation process
- consumers' perceptions of the implementation of the decision (including information, education and support provided to consumers)
- how the decision impacted on consumers and how widespread the impacts were.

3.3.4 Online survey of health professionals

An online survey was conducted with health professionals including pharmacists, nurses, and general practitioners. The survey included questions to obtain quantifiable data testing the prevalence of views, issues and impacts regarding PHARMAC's decision. Topic areas included:

- awareness of the changes to funding and supply
- the effectiveness of communications regarding the consultation process and the changes
- perceptions of opportunities to participate in the consultation
- satisfaction (and dissatisfaction) with the changes
- impacts on opportunities to discuss diabetes management with clientele.

The survey was open for a four-week period and included 15 questions. The majority of the survey questions were close-ended (e.g., participants were asked to rate various factors on a scale of 1–5), with a few open-ended questions to allow for additional comments. The survey was developed in collaboration with PHARMAC's project team and piloted with a small group of participants. Adjustments were then made to the survey as necessary.

A total of 195 completed responses were received. However, 70 of the responses were from consumers rather than from health professionals, and therefore have not been included in the analysis. One hundred and thirty-six responses were received from health professionals; of these, 20 were doctors (15

percent), 30 were pharmacists (22 percent), and 86 were nurses (63 percent). A copy of the survey is provided in Appendix B.

3.4 Analysis

The analysis focused on synthesising and triangulating information from the various data sources and evaluation methods. We took an iterative approach based on grounded theory that allowed for key findings to emerge from the data within each of the four overarching evaluation themes.

Evidence to address each of the evaluation objectives was compiled from a variety of data sources. We analysed qualitative information from interviews, literature, and open-ended survey responses, and corroborated key findings with quantitative information such as analysis of the survey data and data provided from organisations such as Medsafe. Findings were constantly revisited to determine whether and how the supporting and relevant evidence supported the emerging findings.

3.5 Strengths and limitations

The main strength of the evaluation approach and methodology is its detailed consideration of the context of the decision, including how it has impacted a wide range of stakeholders, consumers, and the market. The key informant interviews and focus groups allowed for the collection of context-rich information from multiple stakeholders with frequently divergent opinions and perceptions of the funding decision. The evaluation approach allowed for *Allen + Clarke* to maintain frequent interaction with PHARMAC.

One limitation of the evaluation methodology relates to the fact that a relatively small number of focus groups were run. While the data collected gave in-depth insight into the experiences of consumers, the small number poses some limitations on generalisability of the findings to the population of people with diabetes in New Zealand as a whole. Additionally, the impacts of the funding decision on consumers identified are based largely on consumers' perspectives (i.e., how they saw the decision as impacting them). The reported clinical impacts have not been independently verified and should be interpreted with caution.

4 KEY FINDINGS

4.1 Decision making, procurement and consultation

This evaluation focused on the implementation of the changes to the funding and supply of blood glucose meters and test strips, and is not intended to be a review of PHARMAC's decision making processes. However, as the implementation of the change was influenced by what occurred during PHARMAC's decision making, procurement and consultation processes, we have included observations related to these initial steps of the change process.

PHARMAC followed its standard procedure (i.e., that used for pharmaceuticals) during the decision making and procurement process. This involves initial analysis of the proposal by PHARMAC staff, advice from the Pharmacology and Therapeutics Advisory Committee (PTAC), consultation on the proposed arrangement and a final decision made by the PHARMAC Board, after which planning for implementation commences.

However, this was the first time a decision had been made to implement a single supplier arrangement for the funding of a medical device and it appears that the standard decision making process did not lead PHARMAC to anticipate and plan for the challenges associated with single supplier of blood glucose meters. Based on the evaluation findings, it appears that the implementation of the decision is likely to have been smoother if issues including the size of market change required, patient expectations regarding the functionality of the meters, and non-clinical issues such as patient reluctance to change meter brands had been identified and planned for. A different decision making and procurement process, such as a request for expressions of interest followed by a request for proposals and earlier engagement with clinicians and consumers, may have been more appropriate.

4.1.1 Analysis prior to and during procurement did not give adequate consideration to the potential implications of single supplier

Blood glucose meters, and particularly test strips, represented a significant cost for PHARMAC, and the agency had been aware for some years that this market had the potential to achieve savings. PHARMAC first assumed responsibility for funding blood glucose testing products in 2005 at which time dual supply was awarded to Roche (supplier of Accu-Check meters) and Medica (supplier of Abbott Laboratory's FreeStyle Optium meters). During the three year contract, the two suppliers were able to achieve a dominant position in the market and appear to have successfully created substantial brand loyalty amongst consumers.

After the dual supply contracts ended in 2008 an arrangement in which multiple blood glucose meters were listed was introduced. Interviews with PHARMAC officials indicated that this was seen as a first step towards moving to a more cost effective supply model for the blood glucose meters market by increasing acceptance of other brands of blood glucose meters. By the time the request for proposals (RFP) for the supply of diabetes management products was issued in August 2011 there were six brands of meters listed in the Pharmaceutical Schedule: Accu-Chek Performa, Freestyle Lite, Optium Xceed, CareSens POP, CaseSens II, and On Call Advanced. However, Roche and Medica were still heavily dominant in the market. The table below provides details of the number of blood glucose meters dispensed by brand from 2008 to 2010. As shown, 83.1 percent of the units dispensed in the 2010

calendar year were Roche meters and 14.3 percent were Medica. Together, CareSens II and POP meters represented just 2.5 percent of the total units distributed in 2010.¹

Table 1: Number of blood glucose meter units dispensed by brand 2008-2010

Company	Meter brand	2008		2009		2010	
		No.	Percent	No.	Percent	No.	Percent
Roche	Accu-Chek Advantage	63	0.9%				
	Accu-Chek Performa	6,156	86.3%	4,591	85.1%	4,161	83.1%
Pharmaco	CareSens II			23	0.4%	76	1.5%
	CareSens POP			3	0.1%	52	1.0%
Acon Labs	On Call Advanced					3	0.1%
Medica	FreeStyle Lite			41	0.8%	147	2.9%
	Optium	12	0.2%				
	Optium Xceed	899	12.6%	734	13.6%	570	11.4%

Source: PHARMAC, 2011. Letter to RFP Recipients Providing Additional Information Regarding Blood Glucose Test Strips and Meters.

It is also noteworthy that the dominant incumbent supplier had invested considerable resources in maintaining market share, such as providing training about diabetes for clinicians, exhibiting at clinician and consumer organisations' conferences, and supporting camps for children with diabetes. The resultant size of market share and brand loyalty is important context for the later implementation of the single supplier arrangement.

The RFP for diabetes management products was issued in late August 2011. Interviews with PHARMAC staff noted that the analysis prior to issuing the RFP had largely focused on standard pre-procurement issues such as defining the market, deciding the period of supply and identifying what products would be sought in the procurement. The RFP stated that PHARMAC was willing to consider proposals for single, dual or standard supply. There was a perception amongst some health sector informants that PHARMAC had proceeded on the assumption that a dual supply or status quo arrangement was likely to result from the RFP and that the incumbent supplier with the largest market share (Roche) was likely to be part of the winning tender. PHARMAC informants have stated that the agency was open to all options at this point and, as one staff member pointed out, it would be difficult to identify and estimate all potential outcomes prior to a decision actually being made and the effort required on PHARMAC's part to undertake such analysis would unlikely be worth the advantages gained. Nevertheless it does appear that the large scale change which would be required if single or dual supply was awarded to a supplier other than Roche (i.e., over 80 percent of the market would be required to change brands) was not substantially considered by PHARMAC prior to issuing the RFP.

Analysis undertaken by PHARMAC staff during the supplier selection process also followed normal procedure. PHARMAC's nine decision criteria formed the basis of the decision, and shortlisted bids were modelled to determine cost savings as well as the timing at which savings would likely be achieved (interview, PHARMAC personnel). Based on these parameters, Pharmaco's bid offered the greatest opportunity to achieve substantial savings.

¹ PHARMAC, 2011. Letter to RFP recipients providing additional information regarding blood glucose test strips and meters.

During the procurement process there was some attention paid to meter functionality (see section 4.1.2 below), but factors including the size of the change, potential challenges with such a large market shift, and the extent to which consumers were reluctant to change from a meter which they saw as meeting their needs, does not appear to have been given serious consideration until consultation began.

4.1.2 The selected meters were subjected to clinical accuracy testing, but no consumer testing was undertaken

All the meters put forward in Pharmaco's proposal had been tested for accuracy by the Christchurch Diabetes Service. Despite an attempt by PHARMAC, no usability testing was carried out, and non-clinical factors such as patient expectations of meter functionality and patient satisfaction with their current meters appear to have not been fully considered. This could have been picked up through field testing of the meters.

4.1.2.1 Clinical testing of the meters

While there is no legislative obligation to undertake pre-market testing of medical devices in New Zealand, it is a requirement of the Diabetes Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) that any new meter pass a clinical evaluation of its performance. One of the proposed meter models (CareSens II) was already in use in New Zealand and had been previously tested in 2009.² The CareSens N meter was tested in late 2011, and the results state that the meter performed satisfactorily under controlled conditions and complied with international guidelines, concluding that it is "*acceptable for operational use for point of care testing*".³ The CareSens N POP, added in response to consultation feedback, was tested in May-July 2012 and also complied with the criteria set by the National Committee for Clinical Laboratory Standards.

The testing was implemented in line with the protocols set out in PHARMAC's *Guidelines for Funding Applications* and aimed to "*compare the analytical performance of the blood glucose meter on capillary whole blood samples versus reference laboratory analysis of venous plasma glucose*".⁴ The testing was designed to ensure that the blood glucose results given were within an acceptable margin of error (plus or minus 20 percent variance) in readings from capillary samples—a blood sample collected by pricking the skin measured using a meter—compared to a reference method of laboratory venous plasma samples (blood taken from a vein).

PHARMAC bases its clinical testing on New Zealand standards which do not require testing against the International Organization for Standardization (ISO) Standards. However, the manufacturer itself is required to have evaluated meter accuracy according to the relevant ISO Standard. At the time of listing, the 2009 ISO Standard for blood glucose meters required accuracy to within plus or minus 20 percent of a laboratory test result, 95 percent of the time. The manufacturer-reported accuracy of the CareSens meters meets this standard. In June 2013 the ISO Standard was tightened to require meters to

² Lunt H, Kendall H and Florkowski C, 2009. Evaluation of four capillary glucose meters. *Report Prepared on Behalf of PHARMAC*. Available at www.pharmac.health.nz/assets/diabetes-four-meters-evaluation.pdf

³ Lunt H, Logan F and Florkowski C, 2011. Evaluation of capillary glucose meter: CareSens N. *Report Prepared on Behalf of PHARMAC*. Available at www.pharmac.govt.nz/2012/02/28/CareSensN%20evaluation.pdf

⁴ PHARMAC, 2010. Appendix 2 –Protocol and evaluation of self monitoring blood glucose systems. *Guidelines for Funding Applications to PHARMAC*, pp. 51-52.

perform within a margin of error of plus or minus 15 percent, and Pharmaco states the CareSens meters meet the 2013 ISO Standard.

Based on these findings we would conclude that PHARMAC undertook sufficient clinical testing to have confidence in the accuracy and performance of the CareSens meters. However, the testing was carried out in controlled conditions, which *“limits the generalisability of the findings to the real world setting of more extreme testing conditions and variable use of meters by patients”*.⁵ As discussed below, field testing could have been beneficial to identify and mitigate functionality and usability issues that were later raised by consumers and clinicians.

4.1.2.2 Consumer testing of the meters

PHARMAC sought advice from the Diabetes Subcommittee of PTAC regarding the functionality of the meters. Minutes from a meeting held on 8 December 2011 note that opinions were sought regarding the CareSens N meter, which was part of the Pharmaco proposal but not currently on the market. The Subcommittee:

- considered that the meter offered acceptable functionality and was intuitive to use
- advised that confirmation be sought from the supplier as to whether the device offers the ability to detect faulty or damaged test strips, and
- noted that it would be useful if the date and time did not need to be reset when the battery was removed.

It is noted that the Diabetes Subcommittee is comprised of clinicians, including diabetologists, a general practitioner, a diabetes specialist nurse, a general physician/clinical pharmacologist and an oncologist (the chairperson). Members are all practising senior clinicians who are tasked with providing *“objective advice to PHARMAC on health needs and clinical benefits”* of the proposal under consideration.⁶ In line with this role, committee members approached the discussion of meter functionality from a clinical lens. The advice did not consider ‘intangibles’ such as patient attachment to meters and the functionality requirements of specific groups such as older adults or those with low health literacy.

Issues with functionality that were subsequently experienced by consumers and clinicians and the challenges some patient groups had in learning to operate the meter (see section 4.5.3) could have been pre-empted and mitigated through consumer testing of the meters. PHARMAC did attempt to undertake consumer testing after concerns were raised through the consultation process and by the working group set up to assist with implementation (section 4.2.2.2). A memorandum to the PHARMAC Board dated 29 June 2012 notes that the working group highlighted concerns regarding the lack of consumer experience with the CareSens meters, and that in response PHARMAC was working with Diabetes NZ to undertake “usability testing” (i.e., testing the functionality of the meter when used by the patient in a real world setting) with approximately 25 patients. The purpose was to gain feedback from consumers on how the meters operate in New Zealand. However, interviews with Diabetes NZ suggest that when the organisation was informed that the testing would not affect the outcome of the

⁵ Lunt H, Logan F and Florkowski C, 2012. Evaluation of the CareSens N POP capillary glucose meter. *Report of Study Undertaken on Behalf of PHARMAC*. Available at www.pharmac.health.nz/assets/diabetes-caresens-n-pop-evaluation.pdf

⁶ PHARMAC, 2012. PHARMAC’s decision criteria consultation document.

decision (i.e., whether single supplier of CareSens meters would go ahead) it subsequently refused to undertake the testing. PHARMAC did not approach another provider and no usability testing of the meters was done. Usability testing could have helped PHARMAC to anticipate and mitigate some of the concerns that were subsequently raised about the meters' functionality such as operating temperature, and the fact that the meter tends to produce higher readings on average than other meter brands. These issues led to consumer dissatisfaction (and in some cases distrust) of the meter and, had they been identified earlier, these messages could have been communicated to clinicians and users.

4.1.3 The purpose of consultation was misinterpreted by some patients and clinicians

PHARMAC's guidelines for funding applications note that prior to making a decision on a proposed change to the Pharmaceutical Schedule and when applicable, PHARMAC will "*consult with people that may be affected by the proposed change... consultation responses are considered by PHARMAC with an open mind and, if appropriate, the proposal may be amended*".⁷ A consultation paper was released on 23 February 2012 stating that PHARMAC had entered into a provisional agreement with Pharmaco to be the only supplier of subsidised blood glucose test strips and meters to the New Zealand market. The document did not ask specific questions, instead noting that PHARMAC "*welcomed submissions on the proposal*".⁸

The purpose of consultation was to seek feedback on the proposal to inform PHARMAC's Board as to whether the provisional agreement for the single supplier of CareSens meters should be approved and/or amended before approval. PHARMAC personnel reported that the key intent was to identify any issues or potential impacts that had not yet been considered or any modifications that should be made to the proposed arrangement. This was the final step before the Board could then approve the proposal, decline it, approve the proposal subject to modifications, or require further consultation or information.

The consultation document was distributed through PHARMAC's usual channels, which included sending notices of consultation to individuals and organisations who had previously expressed an interest in diabetes products and medications. At least one supplier of another meter brand also emailed their customer lists and encouraged consumers to submit a response.

The evaluation found that clinician knowledge and awareness of the consultation process was high. Many clinicians heard about the consultation through a variety of channels. For example, a Māori diabetes nurse heard about the consultation through the Aotearoa College of Diabetes Nurse Specialists, a newsletter from the PHO, through Ngā Manakura (a Māori nursing and midwifery leadership and workforce development organisation), and through the incumbent supplier's representatives. A general practitioner heard about the consultation through an email from PHARMAC, and then through a request from the PHO for contribution to their submission.

In contrast, most consumers we spoke with as part of the evaluation had not heard about or contributed to the consultation. However, many users of diabetes meters did make a submission: Of the 2,645

⁷ PHARMAC, 2010. Guidelines for funding applications. Available at www.pharmac.health.nz/assets/funding-applications-guidelines.pdf

⁸ PHARMAC, 23 February 2012. Consultation document on proposals relating to multiple diabetes management products.

submissions received, over ninety percent (2,418) were from individual consumers, with six percent (167) from clinicians/DHBs, two percent (48) from patient groups and less than one percent (12) from suppliers/industry.

Interviews with clinicians, patient groups and consumers suggest that the open format, written consultation process worked well for most patient groups. There was some concern from Māori and Pasifika stakeholders that this consultation method was not appropriate for their communities, and the later addition of face-to-face meetings was appreciated (see section 4.1.4 below).

The consultation process was the first time most clinicians and consumers had heard about the single supplier proposal, and many expressed concern. The evaluation found that many stakeholders thought the consultation was an exercise to determine whether or not to go ahead with a single supplier arrangement, and this led to some feeling ignored when such an arrangement was implemented. Several clinicians and consumers spoken to during the evaluation expressed a perception that consultation was “window dressing” of a “done deal”:

*“It was clear that the consultation was about **how** to implement the CareSens meters, rather than **whether** to implement them... it seems the decision to go with a single supplier had already been made and nothing that was submitted would make a difference.”*

- Interview, General Practitioner

It may be useful if future request for submission documents clearly identify the consultation’s purpose. PHARMAC’s consultation process could also be enhanced by asking submitters to respond to questions to identify specific parts of the proposal that are being consulted on (and what may change as a result of stakeholder feedback). This approach would also make it easier to analyse the submissions received.

4.1.4 PHARMAC responded to concerns raised during the consultation by adapting the consultation format and making amendments to the proposal to address some functionality and clinical concerns

Interviews with PHARMAC personnel have suggested that it was not until the consultation document was released that the high level of public and media interest in the change to a single supplier of meters became apparent. PHARMAC was responsive to the higher than expected interest and adapted the standard consultation approach by adding a series of public meetings when it became clear that written feedback was insufficient to gather the perspectives of all relevant groups. The consultation meetings were held in Auckland, Christchurch, Porirua and Wellington and were generally well attended. For example, 78 people attended in Christchurch and 56 in Auckland, including a large number of consumers. A PHARMAC Medical Director led each meeting, which included a short presentation of the rationale for the proposed change, followed by an opportunity to provide feedback. Notes were taken and added to the analysis of submissions process. The face-to-face consultation meetings received largely positive feedback from evaluation informants who had attended. A practice nurse noted that the meeting she went to was attended by a cross section of consumers and clinicians and, although emotionally charged, the PHARMAC representative had listened well to the concerns raised. A Māori diabetes specialist nurse felt that the meetings were a more appropriate means for members of the Māori community to input into the consultation process than through written submissions.

Evidence from interviews with PHARMAC staff, health professionals and consumers suggest that this was a challenging time for PHARMAC and those affected by the decision. As outlined above, PHARMAC's standard decision making process did not lead it to fully consider the likely repercussions involved with such a significant market transition, and a lack of consumer testing meant many of the issues raised during the meetings had not been anticipated. This meant the agency was not well prepared to address the concerns raised during the consultation process, and PHARMAC staff reported feeling stressed. For example, the regional consultation meetings were described by one staff member as very hard, as PHARMAC could not assure attendees that all their concerns would be addressed.

As stated above, PHARMAC received a total of 2,645 written submissions. PHARMAC produced a summary document analysing the issues raised, providing representative comments on the issues, and outlining PHARMAC's response. The analysis shows ten key themes emerged from the consultation: technical issues relating to both meters and test strips; software; lancets; clinical; service and support; moving to a single supplier; process; financial/resource; implementation; and supplier/industry responses.

Interviews with PHARMAC staff noted that little clinical feedback was received, and that the issues raised were primarily related to meter functionality and challenges likely to be faced by patients and clinicians in transitioning to a new meter brand. PHARMAC made several changes to the proposal in response to consultation feedback. The CareSens N POP meter was added to the agreement, replacing the CareSens POP. This had no clinical benefit (interview, PHARMAC official), but was added to address some of the functionality concerns raised, specifically the ability to provide 30 day averaging, backlighting, larger memory capacity (the ability to store up to 500 readings), and the ability to recognise expired strips. PHARMAC also amended the proposal to continue funded access to the Freestyle Optium meter for those who had been prescribed one to dual test for blood ketones and blood glucose prior to the decision date.

The amended proposal was presented to the PHARMAC Board on 29 June 2012 in a paper which recommended that the Board resolve to approve the agreement with Pharmaco and list the CareSens N, CareSens N POP and CareSens II meters and test strips. The Board approved the agreement on the condition that the new meter (the N POP) passed a clinical evaluation of its performance by the Christchurch Diabetes Service (see also section 4.1.2).

4.1.5 Use of a registration of interest process, followed by a request for proposals from shortlisted suppliers, is recommended for major future funding decisions

Based on the above findings, we conclude that PHARMAC's standard decision making and procurement procedure may not have provided for adequate identification of the likely challenges associated with a single supplier of blood glucose meters, which in turn limited PHARMAC's ability to plan for and mitigate risks. In summary, analysis prior to the RFP focused on defining the market, deciding the period of supply and identifying what products would be sought in the procurement. Despite requesting proposals for single, dual and multiple supply arrangement, PHARMAC did not give substantial consideration to the size of market change that would be required should a single supplier contract be awarded to the non-dominant incumbent supplier; over 83 percent of the units dispensed in the 2010 calendar year were Roche meters. The standard procurement process provided for clinical testing of meter accuracy, but did not mandate field testing of the meters. Finally, the consultation process did

not ask specific questions and appears to have led some submitters to believe that the purpose of the consultation was to determine whether the decision should go ahead or not.

Some adjustments to the decision making and procurement process could be considered for future funding decisions regarding medical devices. It may be beneficial to PHARMAC to develop criteria to determine whether a change under consideration is likely to be a 'standard' decision or a 'major' decision. A good starting point would be the trigger factors listed in table 2 under section 4.2.1, which could be adapted to account for medical devices by including factors such as whether the device is primarily used by patients or clinicians.

These criteria could be applied to a potential decision prior to issuing a request for proposals. If the results indicate that the change is likely to be 'major', we recommend that an initial registration of interest (ROI) is issued, which would allow for shortlisting of interested parties and then more substantial analysis of impacts of a small number of full proposals, including undertaking field testing of the device. We note that PHARMAC is currently undertaking some work to review its operating policies and procedures, and that this will include consideration of how the process of making decisions for medical devices need to be adapted, and that PHARMAC has begun to consider the points outlined above.

PHARMAC could also consider involving consumers at an earlier stage in the process for 'major' decisions. This could include engaging with users prior to the ROI to identify the critical parameters required from the device (for example, in this case eyesight is an issue for diabetics, so large screen size could have been identified as a key feature that potential suppliers must be able to demonstrate they can meet). We note that PHARMAC has recently made some changes to its organisational structure, including the establishment of a new Engagement and Implementation directorate in December 2013. The directorate's approach to decision making and implementation includes a focus on increased stakeholder engagement throughout the process, including engaging with relevant stakeholders, under confidentiality, as an input into decision making.

4.2 Planning for implementation

PHARMAC's approach to implementing the change to CareSens meters was guided by an implementation plan⁹ which set out a range of communication, information and education processes and activities. The objectives of the implementation plan were to ensure that:

- consumers and health professionals understood the timing and occurrence of various changes
- health professionals were confident and competent in training patients to use the CareSens products, and
- consumers affected by the change were provided with consistent and appropriate information about funded meters and strips in a variety of formats as well as options for provision of the new meters that best suited their needs.

In line with advice from the working group (see section 4.2.2.2 below), the implementation plan provided for a staged approach which outlined three overarching phases and specific activities for each:

1. **the consideration phase**, which covered the period prior to the decision being finalised. Activities in this phase were intended to maintain links with key stakeholder groups (e.g., through the establishment of the working group) and manage the flow of information to the media.
2. **the decision phase**, which covered processes for notifying stakeholders that the decision to change to CareSens meters had been confirmed. Communication strategies and activities developed by PHARMAC included media protocol and strategies for media engagement, a dedicated page on PHARMAC's website with links to documents related to the decision, and the establishment of a free phone number (0800 66 00 50) to provide information about the decision to consumers.
3. **the post-decision implementation/transition phase**, which focused on providing education and training materials to the health sector to support patient transition to the new meters. The plan did not provide detailed information about activities to be implemented in this phase, noting that this would not occur until a decision had been made.

PHARMAC's implementation strategy included the identification of relevant audiences and development of a tailored plan with multiple communication channels to reach those audiences. Targeted audiences identified by PHARMAC included diabetes patients; health professionals (e.g., clinicians, nurses, diabetes specialists) and associated organisations including Te Rōpū Mate Huka and various Pasifika organisations; consumer organisations; government partners and impacted government agencies; and media channels. The planned approach to the third phase involved a tailored strategy to ensure nurses, pharmacists and prescribers were able to educate their patients on the new meters, as well as a range of information channels to provide consumers with information on changes to, and use of, the funded meters.

⁹ PHARMAC, June 2012. Proposed implementation plan for a change in diabetes management products. *Memorandum of Board Meeting*.

4.2.1 PHARMAC's implementation planning focused on how consumers and health professionals would access and be taught to use the device

PHARMAC listened to health professional and consumer advice that a 'one-size-fits-all' approach would not be suitable for consumers and attempted to plan for a comprehensive range of information channels and touch points. For example, the implementation plan notes that face-to-face communication would be prioritised for Māori and Pasifika consumers:

*"It is anticipated that a complementary series of 'road show' events would occur in Māori and Pacific communities at the same time as more 'mainstream' events. These events would occur at, for example, churches, community halls, Māori health provider locations, which best suit Māori and Pacific consumers. PHARMAC recently appointed a preferred provider for event management ... to augment and support the knowledge that PHARMAC staff already has in connecting with Māori and Pacific communities."*¹⁰

While PHARMAC carefully planned how it would disseminate information on how to access and use the meters, it does not seem to have undertaken substantial planning to support health professionals and consumers to navigate non-clinical challenges associated with the change.

PHARMAC had previous experience in changing from products with strong brand loyalty to other products with similar functionality but a different brand. Pertinent examples highlighted by informants included changing from Prozac to generic fluoxetine and from Ventolin brand asthma inhalers to Salamol brand inhalers. While these were changes to medications rather than devices, the experiences provide relevant insights into the type of issues that need to be planned for when implementing a single supplier arrangement for products with strong brand loyalty (see also section 4.5.6 concerning resistance to change). A study of patient change from Ventolin to the Salamol inhaler, published in the New Zealand Medical Journal, found that patients moving from a trusted brand to another product may experience anxiety, apprehension, and caution, and cites evidence that patients' assessment of the efficacy of the product appears to be influenced by factors such as different appearance and functionality.¹¹ The study concluded that:

"...if the physical delivery features of a device are different, and patients are not adequately reassured, educated, and safely trialled, then it is highly likely any new [device] introduction will face difficulties no matter how bioequivalent it may pharmaceutically turn out to be."

A special issue of the Best Practice Journal, noted that the introduction of a different brand of medicine to the market is often met with suspicion and concern by health care providers and patients, and that concerns mainly involve issues of effectiveness and safety.¹² An article in the journal, contributed by PHARMAC, stated that PHARMAC is aware of a number of 'trigger factors' for negative reactions to

¹⁰ PHARMAC, June 2012. Proposed implementation plan for a change in diabetes management products. *Memorandum of Board Meeting*.

¹¹ Reti S, 2006. Ventolin to Salamol: A crossover study in New Zealand to assess asthma stability in adults converted from Ventolin to Salamol. *New Zealand Medical Journal*, 119(1244), pp. 1-7. Available at <http://www.journal.nzma.org.nz/journal/119-1244/2276/content.pdf>

¹² Cannons C, Duffull S, Jessamine S, Rasiah D and Tatley M, 2009. Medicine brand changes. *Best Practice Journal (BPJ)*, Special Edition: Generics, pp. 12-13. Available at http://www.pharmac.govt.nz/2009/08/25/bpjse_generics_2009.pdf

brand changes.¹³ The identified triggers, and comment on the extent to which these were present in the change to CareSens meters, are outlined in table 2 below.

Table 2: Trigger factors likely to incur negative reactions to brand changes

Trigger factor	Relevance to CareSens change
Does the medicine have a large patient population (over 50,000 patients)?	Approximately 120,000 people use blood glucose monitoring devices.
Is the current brand well-known with high brand loyalty (e.g., Ventolin, Panadol, Losec)?	Roche Accu-Chek was used by over 80 percent of the market. Interviews with consumers and clinicians suggested strong brand loyalty. At the time of the change, CareSens had about 2.5 percent market share.
Is the medicine heavily marketed to patients and doctors?	While direct marketing was limited, Roche sponsored a range of clinician and patient focused events such as diabetes education seminars, children's camps and stands at conferences.
Does the new brand have a different colour, shape or taste?	The CareSens meters are different in appearance and functionality compared to both common existing meters in terms of aspects such as colour, test strip packaging, size and operational temperature.
Is the medicine primarily used by children or elderly people?	Children and elderly were not the primary users of blood glucose meters. However, parents of diabetic children tend to be an engaged and informed group with high interest in any proposed change.
Has there been negative feedback to consultation, or political lobbying around the change?	The consultation process received 2,645 submissions, many of which raised concerns regarding the technical differences between the meters, clinical implications of switching meters and supply chain risks associated with a single supplier arrangement. The issue was discussed on the Labour Red Alert blog by Maryan Street in December 2012, and raised through Oral Parliamentary Questions by Brendan Horan in June 2013.

As shown in the table above, the change to CareSens involved many of the 'trigger factors' that suggested implementation would likely be met with concern by consumers. We therefore suggest that PHARMAC's planning for implementation would have been enhanced by consideration of how to mitigate patient and clinician concern regarding the effectiveness and safety of the meters. Potential strategies could have included providing resources for pharmacists and other health professionals to not only train patients how to use the new meter, but also to help them understand the rationale for change, likely patient objections, and how to provide positive reinforcement of the facts during the first interaction with the patient. A PHARMAC pamphlet titled *My Medicine Looks Different*, which provides

¹³ Rasiah D, 2009. How does PHARMAC assess if a brand change is appropriate? *Best Practice Journal (BPJ)*, Special Edition: Generics, pp. 21-22. Available at http://www.pharmac.govt.nz/2009/08/25/bpjse_generics_2009.pdf

common questions and answers on medicine brand changes (e.g., addressing patient concerns about whether the new medicine is a 'cheap alternative', if the new brand will work the same way), could be adapted to be used for changes of medical devices.

It is also apparent that many of the planned education activities were premised on the assumption that most people were using meters correctly, and focused on educating consumers to adapt to the new one. However, as it turned out many people were not well-educated about meter use. During discussions with PHARMAC staff, the agency agreed that it underestimated people's understanding and knowledge around 'what a meter does' and what is considered normal in terms of meter readings, accuracy and variance. Advice from the diabetes working group meeting held in May 2012 notes that the group viewed the implementation of the change as *"a valuable opportunity for health professionals to provide education to patients about appropriate testing"*.¹⁴ While many individual health professionals appear to have taken this opportunity (see section 4.7.1) it may have been beneficial for PHARMAC to link with other health agencies to use the opportunity presented by the meter change to promote wider education on diabetes management.

4.2.2 The time available for detailed planning for implementation was limited; greater engagement with stakeholder groups may have enhanced the planning process

The ability for PHARMAC to undertake the detailed planning recommended above may have been compromised by the short time frame between the finalisation of the decision and the listing date. While efforts were made to engage with consumers and clinicians during the planning process, greater engagement with representatives of the specific groups likely to be most affected by the change may have helped to better ensure that messages were developed and delivered in a culturally appropriate and effective manner.

4.2.2.1 Timing of implementation planning

PHARMAC's implementation strategy was presented to the PHARMAC Board in late June 2012, but the strategy only provided details of activities to be implemented during phase one (the consideration phase prior to the decision being finalised) and the decision phase (during which stakeholders would be notified that the decision to change to CareSens meters had been confirmed). As noted in the Board paper, no detailed planning or activities to support the implementation and transition to the new meters could occur until the decision had been made.

The paper states that PHARMAC intended to undertake detailed planning for implementation during July and August 2012. However, the CareSens N POP meter had been added to the agreement as a response to consultation feedback, and this needed to be tested. The testing process took longer than expected and PHARMAC did not receive the report until late July 2012 for a 1 September Pharmaceutical Schedule listing date. Due to this delay, the announcement of the changes was made only three weeks before the listing, and as a result the detailed planning stage appears to have been substantially shortened. This may have meant issues such as how to mitigate likely consumer and clinician concerns were not given adequate consideration in the planning stages.

¹⁴ PHARMAC, 17 May 2012. Notes from the Diabetes Working Group meeting.

The listing date had already been delayed from that originally planned: the consultation document specified listing on the Pharmaceutical Schedule from 1 June 2012, with CareSens becoming the only subsidised brand of meters and test strips from 1 December 2012. The extended consultation timeframe and volume of submissions that needed to be analysed meant that the dates for implementing the changes were postponed to a listing date of 1 September 2012 and a single supplier of the meters from 1 March 2013. In hindsight, the further delay in getting the results of the N POP clinical performance evaluation should have prompted PHARMAC to re-negotiate with Pharmaco to have the 1 September date for implementing the changes shifted to a later date. Re-negotiation of the implementation date would have enabled more detailed activity planning to occur before the listing date, although it is noted that re-negotiation of this date may have incurred unwanted opportunity costs.

It is also noted that PHARMAC employed a specialist communications person about half way through the implementation process who was “very good” and “*helped to achieve higher rates of awareness*” about the transition (interview, consumer organisation representative). In future we recommend that PHARMAC seeks specialist advice earlier in the planning stages, as stakeholders noted communications improved markedly once this happened.

4.2.2.2 Engagement with stakeholders during planning

It was suggested by many clinicians and consumers spoken to as part of this evaluation that earlier communication with representatives from specific groups of stakeholders that were likely to be impacted by the change may have enabled PHARMAC to anticipate and mitigate some of the concerns later raised by these groups.

As a vehicle to gather consumer and clinician input into the planning stages, PHARMAC set up a working group to assist with the implementation of the change to CareSens meters and test strips. The group totalled about eighteen members, and was comprised of PHARMAC personnel, clinicians (including doctors, pharmacists and nurses), and representatives of consumer organisations and community groups who would be affected by the change (including Māori and Pasifika representatives). The first meeting was held in May 2012, after the consultation had finished but prior to finalisation of the decision. The purpose of the meeting was “*to discuss how PHARMAC would best implement any change in meter supplier should a significant change be required*”.¹⁵ Meeting notes show that discussion was held regarding the wider health sector environment (for example changes to the ‘Get Checked’ programme and the recently increased patient co-payments for dispensed items) and how this might impact on implementation activity, as well as consideration of the information currently available to patients around diabetes care and management and education on meter training. The meeting minutes note that the working group emphasised that “*there needs to be multiple contact points for patients to reinforce and ‘back up’ training that had been received*”, and that the working group recommended a staged approach with different activities for different patient groups, including multiple information and education channels.¹⁶

Interviews with members of the working group suggest that they appreciated the opportunity to provide PHARMAC with direct feedback from a consumer and/or health professional perspective. Development

¹⁵ PHARMAC, 17 May 2012. Notes from the Diabetes Working Group meeting.

¹⁶ Ibid.

of the implementation plan appears to have been strongly influenced by the recommendations of the working group. For example, in line with the group's advice, the key health professional focus for information and resources was directed at nurses (who provide training in the clinical setting) and pharmacists (who dispense meters) rather than general practitioners and specialists (who are not involved with training and supporting patients to use the meters).

A second working group meeting was held on 4 September 2012 after the listing of the CareSens meters. Discussion at this meeting focused more on detailed implementation activities, including key messages that needed to be disseminated (such as timelines for the change and advice on meter entitlement for various groups of patients), resources that had been developed (including the Goodfellow online learning module and a comparison chart of the three CareSens meters), and actions that would be taken to support implementation (such as sending demonstration models to clinics).¹⁷ The working group also discussed specific communication channels, noting that PHARMAC would investigate working with organisations such as Grey Power and the Māori Women's Welfare League to disseminate information to patients, and would look into the use of media channels including radio, television and print media.

The evaluation results show that these efforts appear to have been successful in creating awareness of the change amongst clinician groups (see section 4.3). However, several consumer groups interviewed during this evaluation felt that the planned activities did not give enough consideration to how specific groups, particularly Māori and Pasifika, would be guided through the transition. As outlined in section 4.1.4, the implementation plan notes that face-to-face communication would be prioritised for Māori and Pasifika consumers, and suggested that a series of road show events (i.e., Meet Your Meter sessions) would occur in Māori and Pasifika communities. However, interviews with Māori and Pasifika clinicians and consumers suggested that community knowledge of, and attendance at, Meet Your Meter events was low, and the times and venues were not always suitable. Several informants felt that the working group was not an adequate forum to plan engagement with Māori and Pasifika communities, as much of the time was dedicated to 'mainstream' issues. It was suggested that establishing sub-groups of representatives of these communities, including meter users and Iwi or church leaders with "*good networks that are close to the ground and people*" (interview, Māori diabetes nurse) would have helped to better ensure that messages were developed and delivered in a culturally appropriate and effective manner.

Finally, we recommend that the planning process for the implementation of major decisions uses documented evidence from previous product changes, engagement with affected groups, and specific contractual requirements with suppliers related to implementation support, to identify concerns likely to be raised by users. Furthermore, future medical device implementation planning should focus on providing support to health professionals to not only teach consumers to use the new device, but also to understand likely patient objections and provide positive reinforcement of the facts during patient interactions.

¹⁷ PHARMAC, 4 September 2012. Notes from the Diabetes Working Group meeting.

4.3 Information and communications

The following section offers evaluation findings concerning the information and communications provided by PHARMAC to health professionals and consumers during the implementation of the change to CareSens meters and test strips. Communications with health professionals appears to have provided good clinician awareness of the changes, but the overall effectiveness of the communication and information strategies varied for consumers. These findings are described in further detail in the following sections.

4.3.1 PHARMAC's information and communications ensured that health professionals were aware of the coming change to CareSens meters

PHARMAC's approach to disseminating information about the change to CareSens meters was guided by its implementation plan, which set out a range of processes and activities intended to provide for *"effective communication of the changes to all affected and interested parties"*.¹⁸ As outlined in section 4.2, this included the identification of target audiences and development of a tailored plan with multiple communication channels to reach each of these audiences. Interviews with PHARMAC personnel suggest that the agency placed importance on ensuring that health professionals were aware of the changes, including key dates and milestones and what would be expected of them during the change.

PHARMAC implemented a number of activities intended to inform health professionals of the change to CareSens meters and test strips. These information channels included but were not restricted to direct communications from PHARMAC and Pharmaco such as letters, phone calls, and e-mails, and notices in professional journals and newsletters. The media played a key role in PHARMAC's communications strategy. There had been high levels of media attention during the consultation period and this was anticipated to continue once the decision to switch suppliers had been announced. PHARMAC's communications approach mitigated this anticipated reaction in the sector by holding a media conference to announce the changes, and by developing a list of communication and information processes, protocol and strategies for media engagement.

A number of additional information resources were implemented after the initial announcement. A CareSens website was launched in late August 2012, and PHARMAC also developed a dedicated page on its website with links to documents related to the decision (e.g., the diabetes management products proposal,¹⁹ minutes of Diabetes Subcommittee discussions of diabetes management products,²⁰ and Board papers related to the decision²¹). PHARMAC and Pharmaco free phone numbers were also available to provide information about the decision.

¹⁸ PHARMAC, June 2012. Proposed implementation plan for a change in diabetes management products. *Memorandum of Board Meeting*.

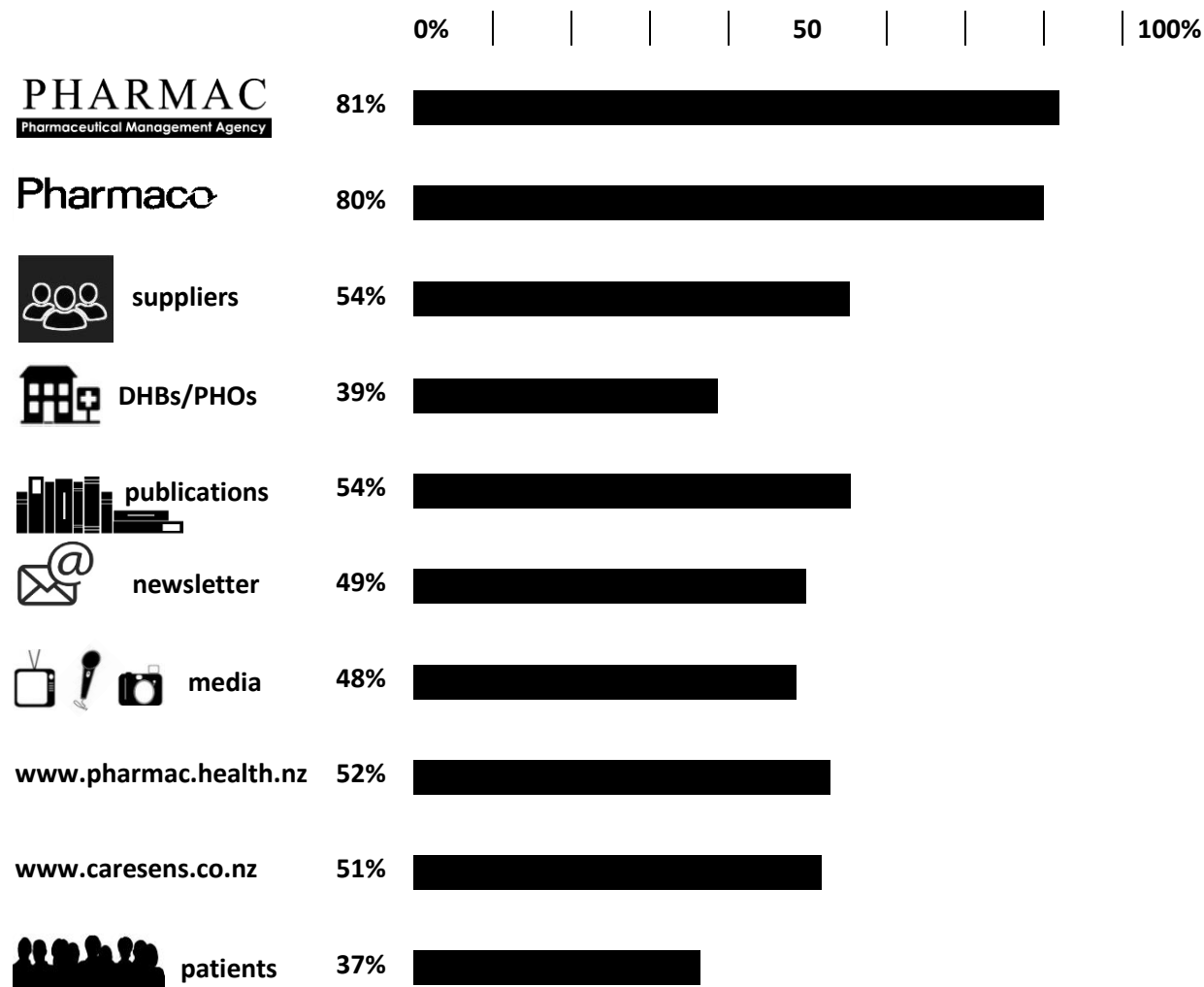
¹⁹ PHARMAC, 2012. Proposals relating to multiple diabetes management products. Available at <http://www.pharmac.health.nz/assets/diabetes-blood-glucose-meters-proposal.pdf>

²⁰ PHARMAC, 3 March 2011. Diabetes Subcommittee of PTAC meeting (minutes for web publishing). Available at <http://www.pharmac.health.nz/assets/diabetes-subcommittee-minutes-2011-05.pdf>

²¹ PHARMAC, June 2012. Proposed implementation plan for a change in diabetes management products. *Memorandum of Board Meeting*.

Results of the online survey outline the various communication channels that health care providers were aware of during the change to CareSens products. Figure 2 illustrates the surveyed health professionals' responses to the following question: *"Which of the following information sources did you see on the change to CareSens meters and strips?"*

Figure 2: Health professionals' survey responses regarding information sources



Based on these results and information provided by key informants, the most common means through which clinicians heard about the changes was via official PHARMAC communications including e-mails, letters and notifications of updates to the Pharmaceutical Schedule. This was an effective approach that took advantage of pre-existing communication channels, and meant that the messages' relevance could be tailored to different clinician groups. Other common sources of information included communications from Pharmaco, suppliers of other meters (e.g., Roche) and notices in professional publications.

Overall, the evaluation findings suggest that health professionals were well informed about the changes. In an open text question, survey respondents were asked to describe what went well with the change to CareSens meters. Of the 122 responses, 13 highlighted advance notice of the change as a key

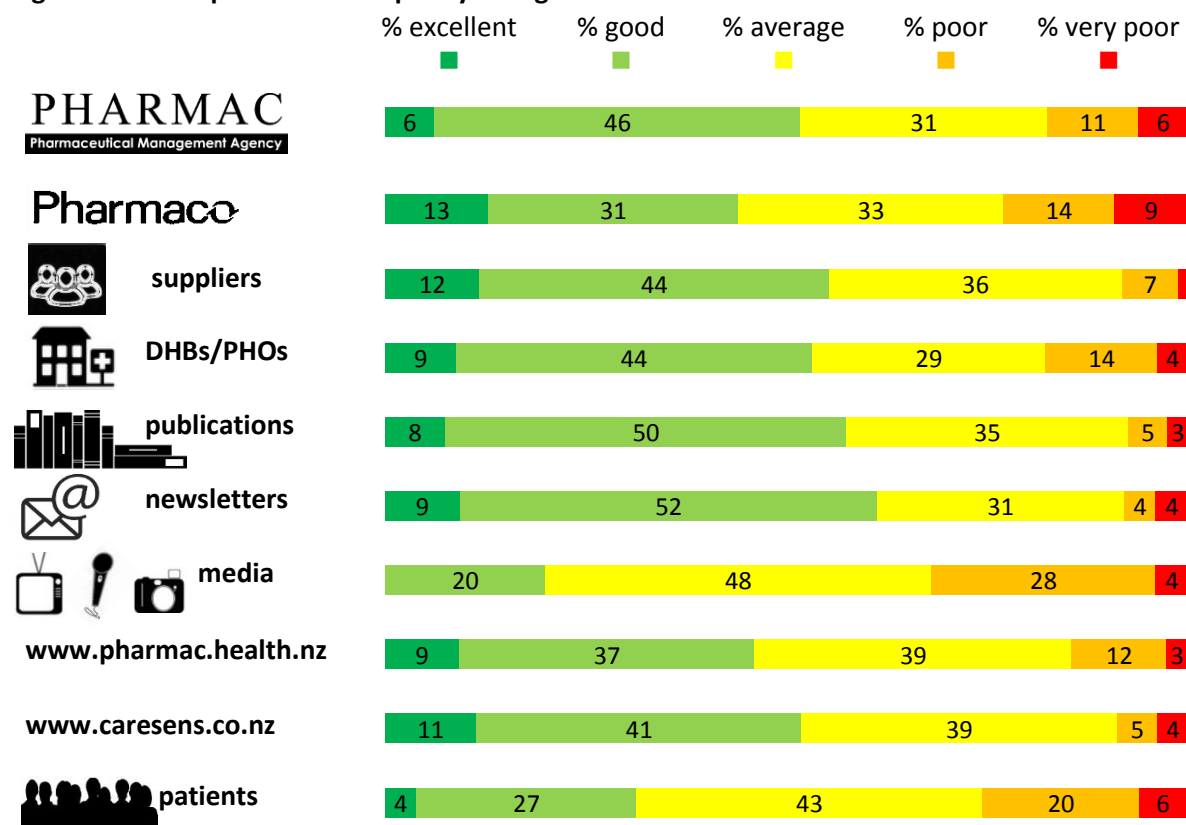
achievement, noting that there was “widespread advertising of the changes”, “adequate lead in time”, and “plenty of material” provided to health professionals. Interviews with clinicians indicated that this advance notice had given them time to seek out more detailed information and prepare themselves to educate their patients about the meters.

Once initial awareness of the changes had been achieved, PHARMAC’s approach to keeping the sector informed was generally considered useful and effective for establishing understanding of the changes. In particular, the ongoing flow of information from PHARMAC was well received, with one pharmacist commenting:

“PHARMAC did well at keeping the sector informed and engaged with us at every step. They tried to be transparent and released information as it came to hand... most [pharmacists] knew the change was coming and we got regular reminders and updates.”

Those health care providers who completed the survey also rated the quality of information sources they saw regarding the change to CareSens meters and strips as excellent or good as displayed in figure 3.

Figure 3: Health professionals’ quality ratings of information sources



According to the percentages outlined above, health professionals perceived the quality of communications about the change to be highest (a combination of excellent/good) for newsletters (61 percent), notices in professional publications (58 percent) and communications from other suppliers (55 percent). Conversely, survey respondents believed the quality of communications concerning the change to be lowest (a combination of poor/very poor) through channels offered by media coverage (32

percent), patients (25 percent) and Pharmaco (23 percent). The poor media ratings likely reflect the negative coverage the change initially received, rather than the quality of PHARMAC's communications through media channels.

In general, these survey and qualitative findings suggest that the means and methods of communication used by PHARMAC for health professionals were effective in providing awareness of the changes. Based on this, we believe the organisation should continue to provide information related to future changeovers to health professionals utilising similar communication channels.

4.3.2 The effectiveness of communications to consumers was variable

The general satisfaction expressed by health care providers with the communications and information about the switch appears not to have translated through to consumers, despite PHARMAC having provided a wide range of communication channels to consumers about the change to CareSens meters and test strips. These methods included nationwide radio and newspaper advertising; patient brochures with a covering letter dispatched to all general practices; and targeted newspaper and radio communications to various media sources intended for minority groups such as migrant populations.²²

Consumers who could be described as 'active' in diabetes advocacy generally had high awareness of the changes; many had contributed to the consultation process, and had been continuously monitoring developments in PHARMAC's decision making process. Other, less active, consumers spoken to during the evaluation remembered receiving letters from their GP, seeing advertisements, or receiving newsletters from their local diabetes association. These communications were described by consumers as "adequate", giving them a "heads up" that a change was coming.

Despite the efforts to provide information across a range of channels, evidence suggests that several of the targeted consumer groups may not have been sufficiently informed of the change. For example, none of the Chinese Asian (Asian) focus group participants recalled seeing any information about the change and were unaware that a change was coming prior to being told about it by their doctors and pharmacists, although they acknowledged that they would be unlikely to pay attention unless the communications were in a Chinese language. A number of the Asian focus group participants also expressed annoyance that they had not been better informed of the change prior to visiting their doctor, and many felt that the change had come with no warning:

"I was shocked that I went to get my strips as usual, and all of a sudden the chemist said 'here's a new meter.' I didn't expect that as it was the first I had heard of it. I should have been told earlier. I complained to the chemist but was told I didn't have a choice and this is now the only free option."

- Asian man told through interpreter

Similar responses were observed in focus groups with older adults (60+ years old) and adult Type 1 diabetics. Many of the older adult and Type 1 diabetic group participants first heard of the change when they approached their pharmacist for strip refills or on a visit to the doctor.

A Māori practice nurse/diabetes volunteer coordinator stated that many of her clients do not own computers or have limited access to computers; others do not receive newspapers and some have low

²² PHARMAC, 21 February 2013. Diabetes implementation report to Director-General of Health from PHARMAC.

literacy and health literacy skills. The nurse felt that face-to-face communication was best for Māori. It is noted that the PHARMAC implementation plan anticipated that road show events (i.e., Meet Your Meter sessions) would be held in Māori communities, but it is not clear whether these occurred. One diabetes nurse specialist expressed concerns at low Māori participation at a mainstream Meet Your Meter session she attended (two out of 20 people were Māori).

PHARMAC had ongoing engagement with support organisations such as Diabetes New Zealand throughout the communications process, and regularly fed information to consumers through organisations' newsletters, websites, and social media pages. This approach appears to have been effective; focus group interviews show that consumers who were members of these organisations were better informed about the changes than those who were not. Consumer organisations' knowledge of their members' particular interests and concerns meant that PHARMAC's messages could be tailored to be more relevant and understandable to the different user groups they served (such as communicating with younger diabetics through Diabetes Youth). A number of focus group participants praised the quality of support provided by these organisations, and it is clear that consumer trust in them is strong. The use of these organisations to disseminate information should be seen as a core communications channel to provide information to consumers. Similarly, use of Māori and Pasifika diabetes networks would enhance communications to these communities. As was mentioned in section 4.2.2.2, establishment of community representative sub-groups (e.g., meter users, Iwi, church leaders with good networks) would have helped to develop and deliver messages in the most culturally appropriate way possible.

4.3.3 Information and communication processes during the implementation were responsive and adaptive

PHARMAC actively monitored and put in place interventions to mitigate the concerns raised by consumers and health professionals during the change process. For example, a consumer organisation spokesperson shared that PHARMAC had been "responsive to concerns" by facilitating discussions with Māori, Pasifika and youth to take on board feedback about how communications could be improved. The spokesperson also mentioned PHARMAC's having employed a specialist communications person about half way through the implementation process who was "very good" and "*helped to achieve higher rates of awareness*" about the transition.

Further, it appears that PHARMAC and Pharmaco successfully engaged with health professionals and consumer organisations to improve communications about the change. One informant from a consumer organisation stated that they were in "constant contact" with PHARMAC during the early stages of the change. The informant praised PHARMAC's efforts to reach all relevant groups, noting that if the organisation became aware of a consumer group that was not being adequately reached by the communications, they would inform PHARMAC, who would in turn implement actions to reach these consumers. For example, when it was identified that many Pasifika individuals were unaware of the need to change devices, advertisements about the upcoming switch to CareSens meters were played on various Pacific radio programmes and stations.

Similarly, a practice nurse working for a centre that services a high percentage of Māori diabetics said she had had frequent contact with PHARMAC to engender communications throughout the changeover:

“They were pretty good about keeping in touch through the process of informing whānau, and usually listened to our advice. I’d be on the phone [to PHARMAC] about once a week in the early days and they always took the time to discuss and talk it out.”

Throughout the implementation process, PHARMAC regularly informed the Director General of Health of ‘issues to flag’ around consumer concerns raised through media coverage, and provided approaches to how these concerns could be mitigated. Such strategies involved additional Meet Your Meter sessions and face-to-face meter training with various medical centres and pharmacies²³; development of a talking-points sheet directed at pharmacists in response to reports of patients being provided new meters with inadequate or no explanation from their pharmacist²⁴; a ‘direct to patient contact initiative’ funding offer to PHOs to support efforts in contacting patients who had not yet transitioned; media responses via letters to various newspapers; and at times personal correspondence from PHARMAC’s Medical Director to concerned consumers.²⁵ The communication strategies PHARMAC implemented appear to have assisted some consumers, enabling an increased sense of support and understanding about the change to the new devices. For example, some Pasifika consumer interviewees mentioned hearing about the switch through media outlets such as radio advertisements.

Based on these findings, we would conclude that an implementation plan detailing communication and information processes, active monitoring of the effectiveness of communications strategies, and the ability to make adjustments to communication processes as necessary are essential components in both planning for and implementing change. PHARMAC is advised to continue this approach.

²³ PHARMAC, 6 December 2012. Diabetes implementation report to Director-General of Health from PHARMAC.

²⁴ PHARMAC, 20 December 2012. Diabetes implementation report to Director-General of Health from PHARMAC.

²⁵ PHARMAC, 4 July 2013. Diabetes implementation report to Director-General of Health from PHARMAC.

4.4 Education and support

PHARMAC's approach to educating consumers and health professionals about the CareSens meters involved the provision of resources directed at health professionals, who would then train their patients to use the meter. This section provides an overview of the education resources available, and discusses the effectiveness of the training provided to consumers.

4.4.1 Short and easily accessible forms of education appear to have been most effective for health professionals

According to a consultation feedback analysis document²⁶, PHARMAC was aware of concerns about the potential impact of the funding decision on health professionals. Specifically, the consultation feedback document suggests that the proposed implementation plan activities should support health professionals in providing the information they need and reduce *"the administrative burden on sectors of the health-care community"*.

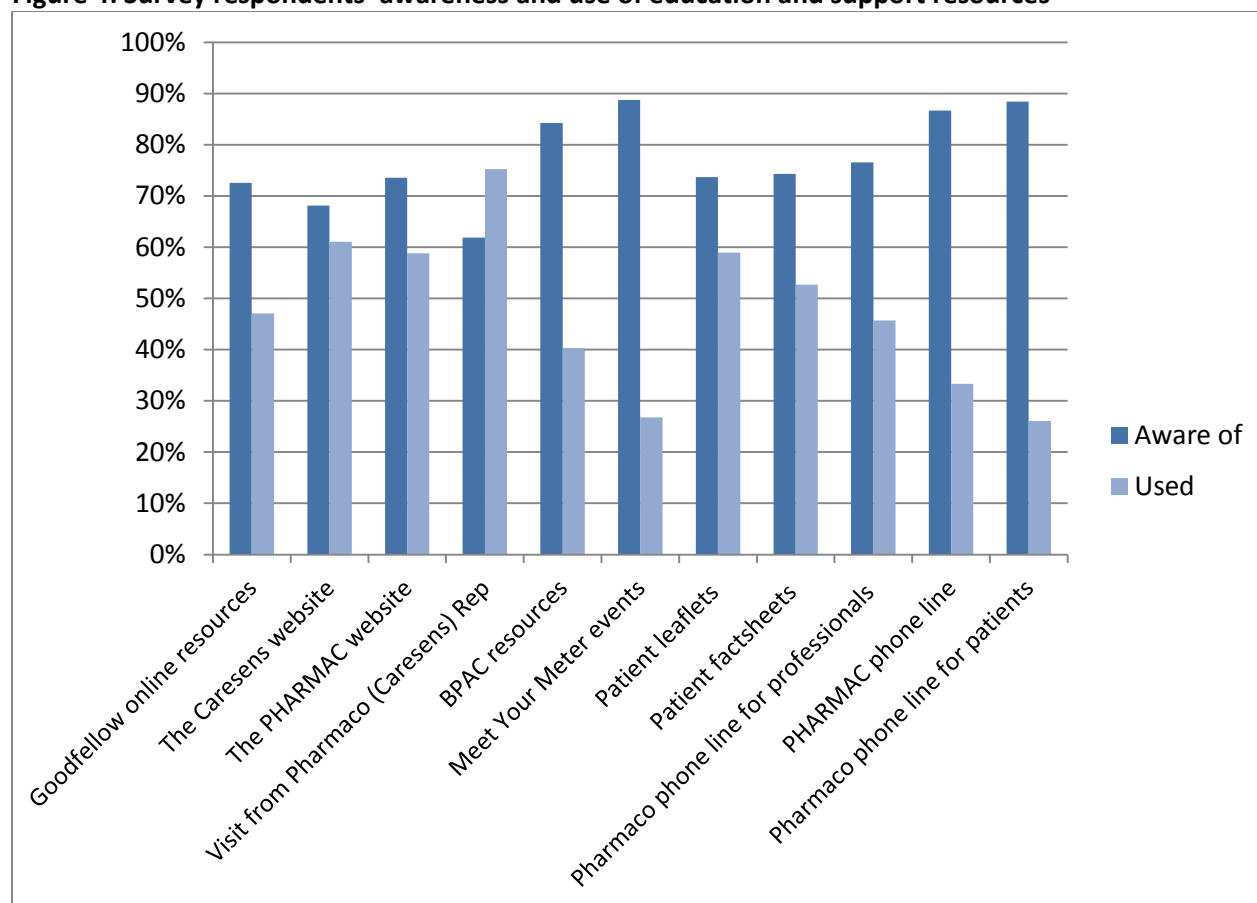
As outlined in PHARMAC's implementation plan, key activities in the post-decision implementation phase were to provide education and training materials to the health sector in order to *"support patients in transitioning from one brand of meter to another in a timely and coordinated way"*.²⁷ PHARMAC provided a range of education resources, primarily targeting pharmacists and nurses, to support them in engaging with their patients. These resources included the development of a Goodfellow online learning module, information on the PHARMAC website, patient-facing hard copy leaflets and online fact sheets, articles in the Best Practice Advocacy (BPAC) journal, a national road show of Meet Your Meter events, and the PHARMAC free phone line. In addition, PHARMAC negotiated with Pharmaco to provide a range of education and support services as part of the single supplier agreement. These included phone lines for health professionals and patients, a website, and visits to health professionals from Pharmaco representatives.

The survey of health professionals asked respondents to identify which of the education and support services they were aware of, and which they had used. The results are shown in figure 4 below and are discussed further in relation to specific education resources later in this section.

²⁶ PHARMAC, June 2012. Analysis of issues raised in consultation: Blood glucose meters and test strips. *Executive Summary*.

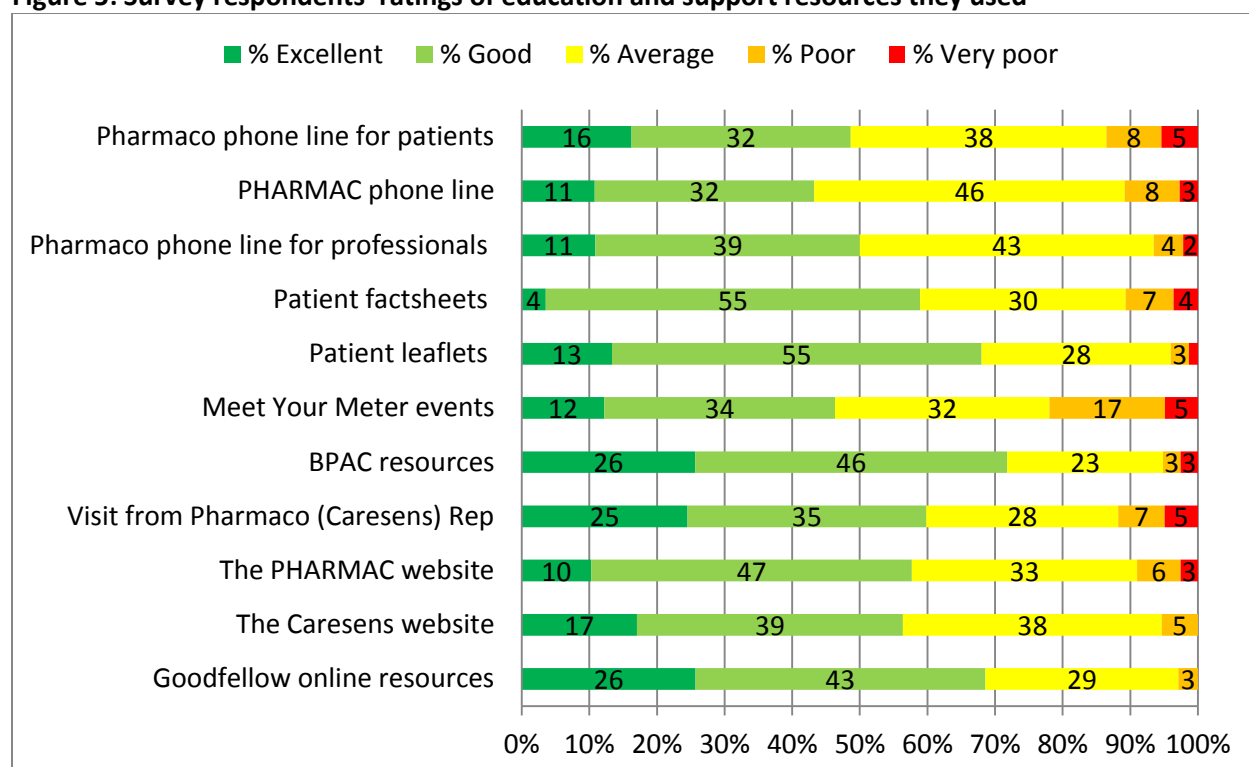
²⁷ PHARMAC, June 2012. Proposed implementation plan for a change in diabetes management products. *Memorandum of Board Meeting*.

Figure 4: Survey respondents' awareness and use of education and support resources



Survey respondents were also asked to rate the information and support resources that they used. The results are displayed in figure 5 below. The results show that resources which received the highest ratings (combining 'excellent' and 'good') were the BPAC resources, Goodfellow online learning module, and patient leaflets and fact sheets. Further details of clinician and consumer perceptions of the specific education resources, gathered through key informant interviews, are discussed below.

Figure 5: Survey respondents' ratings of education and support resources they used



PHARMAC provided a hard copy leaflet targeted at patients as well as a downloadable factsheet (both titled *"New blood glucose meters for people with diabetes"*). The leaflet explained the reason for changing meters, provided information about downloading test results, and directed patients to other sources of information and education. The factsheet also provided this information as well as an overview of the three CareSens meter models. Survey results show high clinician ratings for these resources: 68 percent of respondents rated the leaflet as good or excellent, with 59 percent good/excellent for the factsheet. Interviews with health professionals suggested that clinicians struggled to find the time to educate themselves about the new meters, and "quick, snappy" ways of accessing information such as leaflets were effective means of education. Consumers with whom the evaluation team spoke to had mixed views; some praised the leaflet and factsheet as a useful overview and pointer of how to obtain further assistance. Others felt the resources had *"clearly been written by a doctor"* and were not written in a consumer-friendly manner suitable for patients.

Several free phone numbers were available throughout the transition to CareSens. The PHARMAC number (0800 660 050) was intended for any funding, implementation or support queries, while Pharmaco set up two numbers to support the change: a free phone line for health professionals (0508 CARESENS), and a phone line for consumers (0800 GLUCOSE). Calls to all three lines peaked in March 2013, when the CareSens meters became the only subsidised brand available, and numbers are now tapering off. Table 3 below shows the average number of calls per month to each line from September 2012 to September 2013, the peak number received, and the number of calls received in September 2013 (six months after the change to a single supplier).

Table 3: Calls received by PHARMAC/Pharmaco free phone lines September 2012 – September 2013

Phone line	Number of calls per month		
	Average	March 2013	September 2013
PHARMAC (0800 660 050)	60	151	45
Pharmaco line for health professionals (0800 CARESENS)	395	729	145
Pharmaco line for patients (0508 GLUCOSE)	284	643	133

Pharmaco reported that their call centre had been made permanent, and in October 2013 was reported to have received about 150 to 170 calls per week. Clinicians and consumers who had used the service generally found it to be helpful and responsive to their queries.

Information on both the CareSens and PHARMAC websites was generally perceived as effective. The PHARMAC website appears to have been primarily accessed by clinicians (very few focus group participants had accessed this). Several clinicians and patient group representatives interviewed commented that they appreciated PHARMAC's transparency in placing documents such as Board papers and PTAC meeting minutes on the website. Another stated that the 'questions and answers' section was a useful resource that they had referred to several times. The CareSens website's overview of the features of the new meters was described as useful:

"I referred to the website quite often during the early days of the change. The videos demonstrating how to use the meters were useful to educate myself and to direct patients to if they needed additional training on the meters."

- Pharmacist

Feedback from consumers about the quality of the CareSens and PHARMAC websites was mixed. Several focus group participants liked the overview of the three models provided on the CareSens website and had used this to determine which model was appropriate for them. For example, one person had been given a particular model, but did not like its functionality (the display was too small, and it was difficult to access past readings). This person looked at the CareSens website, gathered information about the three different models and made a self assessment about which model would be best for them, then asked for this meter from their doctor and was provided with it.

Some consumers had looked at the PHARMAC website but had found the amount of information overwhelming. Various participants in the older adult diabetic focus group felt the information and communications about the change was "very dense" with "lots to read". These participants believed that the website was too technical, with one participant admitting *"I couldn't be bothered reading it all even though I wanted to know more about the change to the new meters."* It is noted that the PHARMAC website is primarily targeted at clinicians, and the information it contained was tailored to the needs of this audience.

While only 40 percent of survey respondents had used the BPAC journal resources, those that had rated them highly (72 percent stated that the resources were good or excellent). Two BPAC articles were

published: a supplement in February 2013²⁸ provided information about the change process and key dates; and a second article in June 2013²⁹ provided key message for clinicians regarding issues that had occurred during the implementation process. The latter article also included guidance for responding to patients who were comparing meter readings and raising accuracy concerns, a reminder the meter change was a good opportunity to review whether self-monitoring was appropriate for patients, and information about special authority funding for patients using insulin pumps and ketone testing meters. The BPAC articles were particularly praised by doctors: the survey results show 91 percent of respondents who identified as being a doctor rated the BPAC resources as good or excellent.

Similarly, the Goodfellow online learning module received positive reports from clinicians who had used it. This online training module provided education on the features of the CareSens meters, the key things clinicians needed to explain to patients when demonstrating the meters, and tips for training patients in meter use. The module contributed 0.5 hours towards continuing professional development requirements. The Goodfellow unit was described by clinicians who had used it as “useful”, “clear and accessible” and “easy to follow”. Several informants also noted that the learning module had not been well publicised, remarking that many of their colleagues had been unaware of it. This triangulates with the survey results, which show comparatively low awareness and use compared to other education methods.

The visits made by Phamaco representatives were one of the more successful education methods. The visits appear to have achieved very good coverage, with representatives reported to have visited almost all general practices, community pharmacies and hospital diabetes centres in New Zealand to deliver education and training on the meters. Representatives also attended Meet Your Meter sessions (see below) and provided consumer education through sessions run with organisations such as Diabetes NZ and through marae, Pasifika churches, and in some cases private homes. The overall survey results show high levels of awareness (76 percent), use (75 percent) and excellent/good ratings (60 percent) for visits. Clinicians interviewed for the evaluation also generally perceived the Pharmaco visits as effective, with some informants noting that the representatives faced a challenging task in having to deal with scepticism and concern from health professionals and consumers:

“I found [the Pharmaco reps] helpful and very flexible. They were doing their best to turn a tough crowd... in many ways they were the ‘face’ of an unpopular swap out and I think they did well in not only providing training but also ‘selling’ the decision.”

– Pharmacist

While primarily focusing on educating clinicians (who would in turn educate their patients) PHARMAC did provide some direct-to-consumer education. A nationwide series of Meet Your Meter events took place at two key periods: in November and December 2012 (soon after the listing of CareSens meters), and in February and March 2013 (prior to CareSens meters being the only funded meters available). Providing direct-to-consumer events is not within PHARMAC’s usual scope of practice; however, interviews with PHARMAC staff suggested that more direct consumer interaction would be beneficial due to the high levels of public interest in the change. The events were intended to:

²⁸ BPAC, February 2013. It is now time to change your patient’s diabetes meter. Available at http://www.bpac.org.nz/Supplement/2013/February/docs/Diabetes_Meter_update.pdf

²⁹ BPAC, June 2013. Comparing results between different blood glucose meters. Available at <http://www.bpac.org.nz/BPJ/2013/June/docs/BPJ53pages-40-41.pdf>

“...give people a chance to choose which of the three funded meters is right for them, learn about the best way to use meters, and have any other questions they might have about diabetes management answered”.³⁰

The Meet Your Meters sessions were run in collaboration with general practices, diabetes support groups and pharmacies. PHARMAC staff noted that the best attended were those promoted by Diabetes New Zealand. The events were initially scheduled between 10am and 2pm, with evening events added later in response to consumer and clinician requests for after work sessions. A typical four hour programme included two 45 minute seminar style education sessions as well as ‘drop in’ education.

Although clinician awareness of the events was high (89 percent of survey respondents were aware of the events, and the majority of clinician key informants had heard about them), clinician attendance was low (27 percent of survey respondents had ‘used’ the events). This statistic is likely to be low because the sessions were primarily targeted at consumers. Interviews with PHARMAC staff and key informants suggested that attendance was patchy, with some events well attended and others attracting very small audiences. Some informants questioned the location of the events (one was held “*in the middle of nowhere*” in a large city; another, targeting Māori diabetics, was held in a location which was not well served by public transport). Overall, most clinicians agreed that even though the events were a good idea, they were not always well executed (e.g., not always adequately advertised, or consumers were not given enough notice).

The Meet Your Meter events received mainly positive feedback from consumers engaged with as part of the evaluation. Several focus group participants had attended the events, and felt that the sessions had provided a good overview of the functions of the three different meter models and offered an opportunity to ask questions about the meters. After attending, these consumers felt empowered to request the model they wanted from their health professional:

“After attending the [Meet Your Meter] event I felt like I knew about the meters and could ask my doctor for the one I wanted.”

- Older adult

In addition to the Meter Your Meter events, the implementation of the small grants scheme—intended to enable the provision of targeted information and education to communities which were slow to transition to the new meter—was very well regarded by informants we spoke to. These were a one-off grant allocation of up to \$5,000 available to Māori, Pasifika, and diabetes health and welfare organisations to provide information and education about the change to their communities. PHARMAC was praised for listening to feedback from targeted group representatives and recognising that those working directly with communities were best placed to implement strategies that would work for their members. The “quick and easy” application process was also commended. However, it was suggested that the grants could have come earlier in the process, and that there could have been more publicity around their availability. Examples of how funding was used includes a Pasifika organisation that held a session on a community radio station to talk about the changes and answer the questions of members of the public, and kaupapa Māori education sessions such as that outlined in box 1.

³⁰ PHARMAC, 29 November 2012. Diabetes meters change reaches next milestone. *Media Release*. Available at <http://www.pharmac.govt.nz/2012/11/29/2012.11.29%20diabetes%20meters%20change.pdf>

Box 1: Example of use of a community support grant

A Māori health trust identified that just before March 2013 approximately 85 percent of the trust's patients had not yet transitioned to the new meters. The trust was so concerned that they contacted PHARMAC, and were told about the community grants scheme which would enable them to run their own awareness campaigns and education sessions.

The trust recognised that the education being provided by pharmacists was not "hitting the mark" for their community members, and felt that kaupapa Māori education in a group setting would be more effective.

The trust used the grant to run a series of education sessions for community members. These were run at the trust's facilities "*where whānau felt comfortable*", and food and drinks were offered. A 'kanohi ki te kanohi' approach was employed, whereby whānau taught each other to use the new meter with support from the trust's staff. People were able to come to multiple sessions, giving them an opportunity to practise with the meter and then come back for further advice.

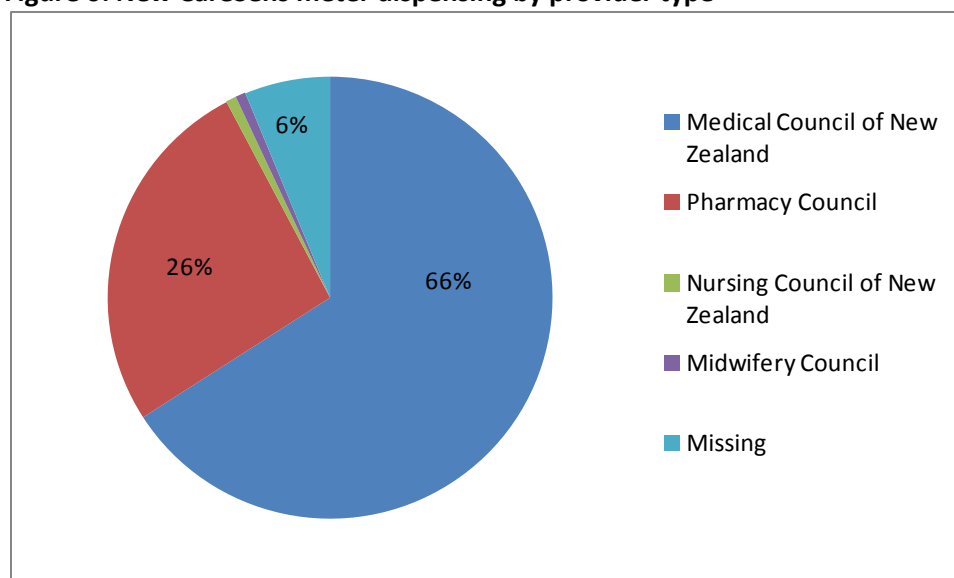
A trust spokesperson reported that this approach resulted in much higher uptake of the new meters, and people felt more comfortable in making the transition.

4.4.2 Some health professionals may not have adequately educated themselves on all three CareSens meter models

PHARMAC's approach to dispensing the CareSens meters was that consumers would uptake their meter through their general practitioner or pharmacist, with education and training being provided primarily by pharmacists and practice nurses (interview, PHARMAC personnel). Analysis of PHARMAC data on diabetes meter dispensing by initiating 'prescriber'³¹, displayed in figure 6, shows that about two thirds of prescribers were doctors (i.e., those registered with the Medical Council of New Zealand), and a quarter were pharmacists (registered with the Pharmacy Council). The remaining meters were dispensed by those registered with the Nursing Council and Midwifery Council, although together these accounted for less than two percent of all meters dispensed. The data were missing in six percent of cases.

³¹ Meters were able to be dispensed by pharmacists without prescription.

Figure 6: New CareSens meter dispensing by provider type



About half of the focus group participants had initially picked up their meter from their general practitioner, with the remaining half having received it from the pharmacist when they went to pick up their prescription of test strips. The use of pharmacists as an avenue for consumers to access the meter and receive training was in line with advice from the Diabetes Subcommittee of PTAC, which stated that the pharmacy should be a key point of contact with patients to facilitate the meter swap out and that pharmacists should be able to undertake patient education on the use of the new meter.³²

Pharmacists were able to dispense a subsidised meter without a prescription for the six month transition period (from 1 September 2012 to 1 March 2013) to their clients with diabetes who had obtained diabetes medications from them in the past. This arrangement was highly praised by clinicians through interviews and in the survey; when asked what went well with the implementation of the changes, 15 respondents (out of 122) highlighted arrangements for prescribing and dispensing the meters as a key positive:

“It was a fantastic scheme to allow [pharmacists] to dispense the meter without prescription, it makes changes easier.”

“Pharmacists being able to dispense the meters made it much simpler for patients, they could come back to us for training rather than having to refer patient back to their GP for a second appointment.”

However, interviews with health professionals and consumer organisations suggested that, despite the range of education resources available, some clinicians may not have educated themselves on all three meter options, resulting in some health professionals *“prescribing the meter that they knew, rather than the best fit for the patient”* (interview, consumer organisation spokesperson). The evaluation found examples of clinicians who admitted that they had not been familiar enough with all three meter models to make a robust assessment of which model was most appropriate for each patient. For example, a

³² PHARMAC, 8 December 2011. Diabetes Subcommittee of PTAC meeting.

pharmacist involved with the dispensing of meters did not feel well educated on the meters and had not had time to read fliers and handouts. She remembered receiving a brochure describing the meters and their differences, but thought it probably “*got shoved in the corner*” because pharmacists “*get bombarded with so much you don’t know what’s worth retaining for future use*”. This meant she did not feel confident in matching meter to consumer and “*ended up dispensing the same meter to ninety percent of patients*”.

Many of the consumers spoken to during focus groups had not been given a choice about the CareSens model they were prescribed, and were surprised to learn that there was more than one model available. In many cases this is likely to be because the clinician assessed the patient’s needs and dispensed the most appropriate meter model without informing the patient that other models were available. Others may have been provided a model (e.g., CareSens II) due to specific diabetes management circumstances.³³ However, in other cases it appears the meter dispensed did not match well with the patient’s needs, which may be due to their pharmacist (or other health professional) not being familiar with all three of the CareSens models. For example, a participant in the Māori focus group had been prescribed the CareSens N POP but struggled to read results from the small screen size. A nurse who was present at the focus group stated that, in her opinion, the CareSens N would have been a more appropriate model for this patient.

The evaluation team analysed data provided by PHARMAC on meter uptake by prescriber to examine potential patterns in the meter model prescribed by pharmacist across the DHB areas in which the focus groups were held. The results, displayed in table 4 below, do appear to show regional differences. For example, the Bay of Plenty (where the Māori focus group was held) shows a higher than average percentage of pharmacist prescriptions for the N POP model. Capital and Coast DHB, where a group discussion with Pasifika consumers was held, also shows higher than average rates for N POP prescriptions. The varying patterns in meter model prescription may be due to factors such as different demographics between DHB regions, but it does appear that there are regional ‘preferences’ in terms of the meter models that were dispensed by pharmacists.

Table 4: Percentage of CareSens N POP, N and II models prescribed by pharmacists by DHB region

Area	N POP	N	CareSens II
Auckland	18.2%	79.6%	2.2%
Canterbury	20.5%	78.0%	1.4%
Capital and Coast	39.1%	60.1%	0.8%
Bay of Plenty	44.7%	53.4%	1.9%
Counties Manukau	26.0%	70.9%	3.1%
All DHB areas	25.4%	72.7%	1.9%

The different meter dispensing patterns do not appear to have had a substantial, negative impact on consumers, but some users’ dissatisfaction with the functionality of their meter may have been due to not receiving a meter best suited to their needs (see section 4.5.3).

4.4.3 The level and quality of support provided to consumers by health professionals was variable

³³ Pharmaco made the CareSens II meter available to GPs to provide free of charge to consumers considered in need of continued blood glucose monitoring (e.g., those consumers who manage their diabetes with diet or metformin, typically Type 2 diabetics).

Most consumers engaged with during the focus groups received initial education on the meter through pharmacists. It was anticipated that pharmacists would spend an average of thirty minutes per patient (interview, PHARMAC staff) and this appears to have been about right; a pharmaceutical association representative stated that pharmacists spent between 5 minutes and 45 minutes per patient.

Consumer perceptions of the quality of education provided by pharmacists were variable. Some focus group participants highly praised the education that they had received: for example, a Māori focus group participant recounted how their pharmacist had spent 30 minutes going over how to use the meter in a one-on-one session, and had been available when the person had come back later to ask questions. Education through pharmacists was also rated highly by Pasifika consumers, who noted that they would be unlikely to go to their general practitioner if they required additional support due to the cost of a consultation; the fact that a pharmacy was located in their community and free to access enabled them to return to the pharmacy to 'have a longer talk' about their meter.

Others stated that they received little or no education on how to use the meter. For relatively experienced diabetics this was fine; reading the information booklet that came with the model was enough to enable them to teach themselves, and they did not feel that they needed a great deal of education and support around using the new meters. Most of the participants in the focus groups of Type 1 diabetics and youth, and about half of the older adults and Māori focus group participants fell into this category.

However, some consumers stated that they had not received enough education on the meter to enable them to use it successfully. One person had received training on the meter in a group setting with approximately six other people and had not felt comfortable asking questions. The person left without really understanding how to use the meter. Others had not received any training, but instead had been told to read the instruction booklet or had been referred to the phone line. This was particularly an issue for participants in the Asian focus group, many of whom were not able to communicate well in English. Several members of the Pasifika focus group felt that phone lines and instruction booklets were not a useful means of education and stated that they learned best through face-to-face methods. Clinicians spoken to noted that one-off training from the pharmacist was not appropriate for many Type 2 diabetics with various co-morbidities where establishing a pattern of proper testing is difficult.

A representative of a pharmacy association believed that pharmacists' ability to provide quality education may have been limited by the rushed time frame from decision to the listing date, when the change to CareSens meters began. This meant that pharmacists had often had not had time to train themselves on the new meters and test strips, yet were required to educate their patients. The informant also noted that pharmacists were largely unaware of how patients were finding the devices and the functionality issues that some were experiencing. It would have been useful for PHARMAC to have communicated about the concerns patients were raising so that they could have been better prepared to help. It also appears that there may have been confusion amongst some pharmacists regarding their role in educating patients. For example, one pharmacist the evaluation team spoke with believed that they *"didn't really have a role in educating patients"* and that their primary focus was checking they had the right meter and test strips. This pharmacist would tell people to call the helpline if they needed training and support.

People who struggled with using their new meter after the initial education session were generally referred to a diabetes specialist nurse/kaitiaki for further training and support. This worked very well

from the perspective of consumers as it allowed them to receive detailed education in a one-on-one setting. A number of participants in the Māori focus group had received education this way, and found the training resonated with them and made them feel comfortable:

“Sometimes it takes me a while to get my head around new things and new technology. I went back to [Māori diabetes nurse] a few times before I really got how to use the new meter. I liked that I could talk to a person I know and can trust.”

These informants stated that the education on how to use the meter was delivered in the context of wider advice on diabetes management (including advice on diet and exercise) and that their overall management of their diabetes had improved as a result. However, some diabetes specialist nurses raised concerns about the amount of time they were required to spend teaching patients how to use the meter, and that this took time away from clinical activities (see also section 4.7.2). Many in secondary care did not see educating patients as a formal part of their role, and felt that better education systems should have been in place in primary care.

4.4.4 Education and support pathways could be more targeted to need

As outlined above, different groups of consumers have different education and support needs. The majority of consumers learned to use their meters with minimal support; many simply picked up the meter and did not want or need additional education. Others required a thorough programme of education and multiple interactions with the health system in order to adapt to the new meters. Not all of the approximately 120,000 people who changed to CareSens meters needed the expected 30 minutes of training; however, it is important to target resources at those who struggle to adapt.

We suggest that there may be value in working with relevant agencies, particularly the Ministry of Health, DHBs and health professional organisations, to ensure that appropriate referral pathways through the health system are available depending on need. This would involve an initial entry point for uptake and education with most people provided with a free phone number for additional support. Those who need further education and support could then be referred to a nurse educator, and this could also offer multiple layers of support ranging from a single session to a broad programme of education. Resources could then be targeted to the higher intensity support pathways. The financial implications of this would need to be considered (e.g., determination of whether payments to clinicians offering more comprehensive education pathways would be appropriate).

4.5 Transition to the new meters

The following section discusses key findings regarding the transition to use of CareSens diabetes management products. The first finding proposes that the majority of consumers and health professionals transitioned to the new meters without a large degree of difficulty. However, evaluative evidence indicates some individuals experienced transition barriers, particularly older adults, children and speakers of English as a second language. These barriers included issues related to strip and meter functionality, challenges in overcoming brand loyalty to the incumbent supplier, and perceptions related to lack of meter choice. We also discuss barriers to successful transitions related to concerns about the accuracy of CareSens meters. In the concluding sections, we explore the possibility that more thorough analysis of and attention to change management stages of the transition process, and earlier planning and implementation of transition activities, may have gone some way in mitigating the identified barriers.

4.5.1 The majority of consumers and health professionals transitioned without difficulty

A total of 97 percent of patients eligible for a subsidised meter were reported to have acquired CareSens meters by 30 June 2013.³⁴ Our evaluation findings indicate the transition phase occurred without difficulty for the majority of these patients as well as for the health care community.

Many of the health professionals spoken to by the *Allen + Clarke* team were of the opinion that the transition had gone relatively smoothly overall. While noting that there had been some patient reluctance to change meters, there was acknowledgement that *“the new meters presented a general learning curve that most people handled without problem”* (interview, general practitioner). A community pharmacist we interviewed considered that the transition had been smoother than other pharmaceutical brand switches she had experienced, and did not create as many problems as she had expected; she could recall only two or three patients from her pharmacy who had experienced issues transitioning to the CareSens meters. A nursing organisation representative also agreed that, as of October 2013 when the interview was conducted, most people who had made the transition were now *“more or less”* happy with their new meters.

Health professionals' perceptions of a generally successful transition to the new meters were confirmed by several focus group participants. For example, approximately 80 percent of participants in our adult Type 1 diabetes focus group were successfully using the CareSens meters (predominantly the CareSens N), and Māori focus group participants also reported adapting relatively easily to the new meters: *“They’re not that different to the old ones. I just needed to figure out how to use the thing, and once [diabetes nurse] had shown me I was away”*, one participant noted. Out of the 16 participants in the Māori focus group, a total of 14 reported having successfully transitioned to the new meter and were relatively comfortable using it (*“we just had to accept it and learn fast”*). The majority of consumers in the Asian focus group also appear to have transitioned relatively easily, with one participant observing:

“There is a slight difference in readings, which seems to depend on where I take the blood sample from. But it’s not a big deal and I am able to use the meter with no problems.”

³⁴ PHARMAC, 4 July 2013. Diabetes implementation report to Director-General of Health from PHARMAC.

Evaluation participants identified several factors that had assisted with the smoothness of transition. For example, several individuals in the adult Type 1 focus group stated that the CareSens changeover had occurred with adequate forewarning, allowing them the opportunity to prepare for the switch. These individuals were more satisfied with the CareSens transition when compared to prior device transitions they had experienced in the past, such as the wholesale replacement of the Accu-Chek Advantage. This had occurred when it was identified that the meter was not reading correctly, resulting in the recall and replacement of all Accu-Check Advantage meters. Several focus group participants felt that this change had been poorly managed, and felt that they had received more notice and better information on the reasons for the change during the transition to CareSens.

The evaluation survey also highlighted advance notice of the change as a key positive achievement. In response to a question regarding what went well with the implementation, 13 out of the 102 responses received nominated the adequate notice period as something that 'went well' with the change. Other positive factors were the quality of information and communications (17 out of 102 responses) and arrangements for dispensing meters (15 out of 102 responses). Table 5 conveys various commentaries we received from health care providers regarding positive perceptions of the transition (negative impacts of the transition on the health care community are explored in section 4.7.2).

Table 5: Health professionals' perceptions of what went well with the implementation of CareSens meters (N = 102)

Theme	Number of responses	Examples of respondents' comments
Quality of information and communications	17	<p><i>"Lots of useful information"</i></p> <p><i>"The videos on the CareSens website are very helpful, and the fact that the information sheets are available in different languages helps the patients who have English as their second language"</i></p> <p><i>"Excellent phone support from CareSens 0800 number and clear, easy to read brochure handouts from Pharmaco"</i></p>
Arrangements for dispensing or prescribing meters	15	<p><i>"Fantastic scheme to allow us to dispense meters without prescription, it makes changes easier"</i></p> <p><i>"Being able to give out meters to people opportunistically enabled me to swap and provide individualised teaching of the device"</i></p>
Advance notice of the change	13	<p><i>"Plenty of advance warning about changeover and transition"</i></p> <p><i>"It was generally well advertised and most patients were aware of the impending change"</i></p> <p><i>"Adequate lead-in period for change to be managed"</i></p>
Supply chain maintenance	13	<p><i>"Good supply of meters and easy to obtain"</i></p> <p><i>"Quick response to the need for more meters"</i></p>
Support from Pharmaco	8	<p><i>"Pharmaco was very good with providing info and/or personal assistance when required"</i></p> <p><i>"Staff training done by the CareSens representative was well"</i></p>

Theme	Number of responses	Examples of respondents' comments
		<i>received by staff"</i>
Functionality of new meters	6	<i>"No programming or changing the chip for new strips so much easier for some patients, some of them began testing where previously they wouldn't"</i>
No charge to patients to change meters	5	<i>"Free meters - our patients would not have been able to afford to buy new meters"</i>
Opportunity to improve diabetes' diabetes management	4	<i>"Being able to talk to us at the pharmacy about their meters, and it being an opportunity to discuss diabetes management in general"</i> <i>"The opportunity to stop testing for some patients and reduce testing for others"</i>
Other	10	<i>"The actual changing of meters seemed to go well between GP practices and pharmacies"</i> <i>"I personally had no problems; my patients were quite happy to change"</i>

Note. Theme responses are not mutually exclusive, therefore there were >102 theme responses.

Overall, these findings highlight PHARMAC's accomplishment in assisting the majority of New Zealanders to transition successfully to the CareSens meters. More than 100,000 people have obtained the new meters and transitioned through a large-scale change:

*"When you look at what we have undertaken - which is over 100,000 people using equipment they are used to and moving them to new equipment that not many have much experience with - overall, it has been successful and a good change."*³⁵

- PHARMAC CEO

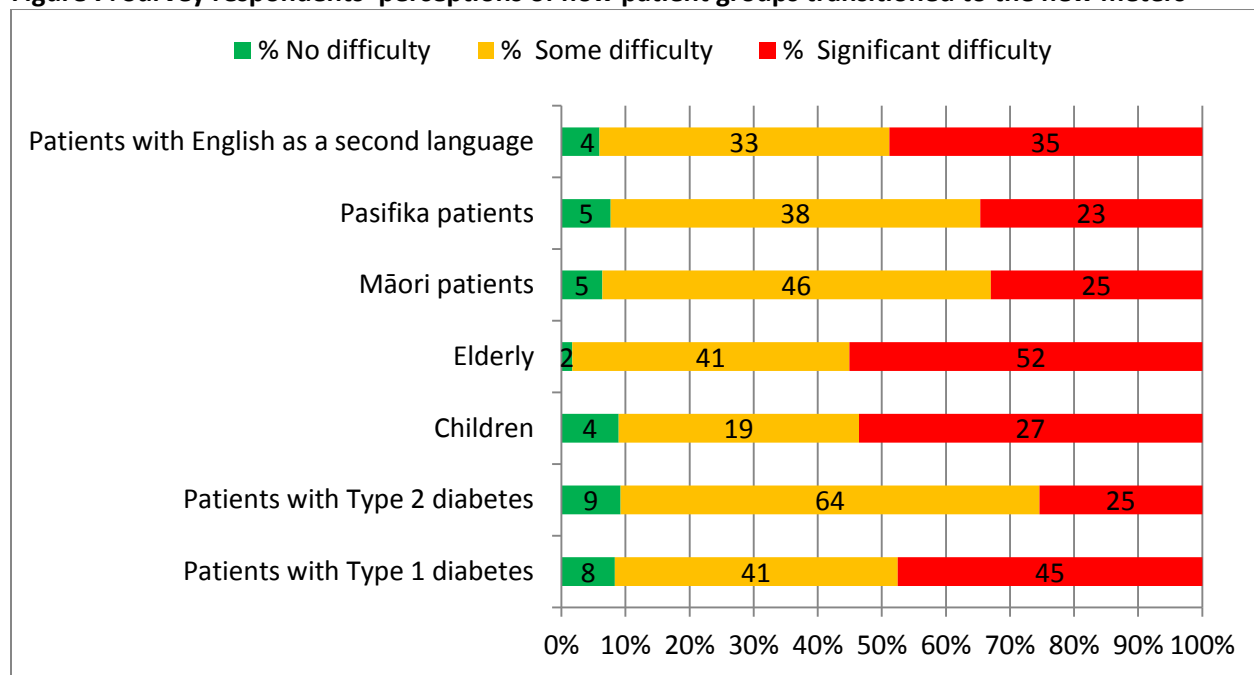
4.5.2 Some patients experienced challenges in making a successful transition to CareSens meters

There is evidence to suggest that while the majority of consumers and health professionals made the transition to CareSens meters without difficulty, other individuals—including some elderly consumers, individuals with English as a second language, and children—struggled to make a successful transition.

The survey of health professionals asked respondents to indicate the degree of difficulty that various groups of patients experienced with the transition process. The results, displayed in figure 7, show that respondents identified elderly and children as the groups who experienced the most difficulty with the transition. Patients with English as a second language, and those with Type 1 diabetes were also seen as experiencing a high degree of difficulty.

³⁵ Pharmacy Today, 2013. Meters don't measure up, diabetics say. Available at <http://www.pharmacytoday.co.nz/in-print/2013/september-2013/september-2013/meters-don%E2%80%99t-measure-up-diabetics-say.aspx>

Figure 7: Survey respondents' perceptions of how patient groups transitioned to the new meters



Information gathered through the focus groups largely corresponds with these findings. Of the 10 participants in the older adults (aged 60 plus) focus group, all were using CareSens meters but only four felt that they had transitioned easily. Another four had concerns about meter functionality and accuracy and stated that the process of adapting to the new meters had been fraught. The remaining two patients raised substantial concerns about the CareSens meters and, although they were using the meters, also continued to use their previous meter as a backup and did not feel that they had transitioned successfully. Similar patterns were apparent amongst the 10 participants of the Asian focus group, all of whom spoke English as a second language. While most stated that there were some initial challenges in adapting to the new meter, primarily due to the different functionality, seven out of the 10 had transitioned relatively easily. Of the three participants who had not successfully transitioned, two were self-funding their previous strips and one person had stopped testing.

Participants in the child and youth focus group appeared to have struggled most with the transition. Of the five children and youth represented in the group, all of whom had been issued the N POP meter, only two were successfully using the meter with the other three self-funding their previous meter. The transition was reported to be particularly difficult for parents of younger children, who stated that the inconsistency in readings between the CareSens meters and their previous device had led to uncertainty, compounded by the fact that younger children are often unable to communicate their diabetes-related symptoms or how they are feeling; the parents stated that they need to rely solely on the accuracy of the meter to determine their children's blood glucose levels. Further discussion on meter inconsistency and accuracy as barriers to transition is outlined in section 4.5.5.

In contrast to the survey findings, all the participants in the adult Type 1 focus group had made a successful transition to the new meters. This may have been because the focus group participants were all relatively 'experienced' diabetics (having had their diagnosis for several years) and had been through

previous meter changes. These participants reported being strongly impacted by later accuracy concerns (see section 4.5.5), but most had made the initial transition without major difficulties.

Interviews with PHARMAC staff suggested that uptake of the new meters amongst Māori and Pasifika consumers was higher than for other groups, and the survey findings suggest that health professionals perceived that there were fewer transition difficulties for these groups. Discussion with Māori and Pasifika patients during focus groups found that the majority were successfully using CareSens meters, albeit with some initial challenges in learning to use a meter different to the one they were used to. However, it appears that Māori consumers' overall successful transition may have been largely due to having access to good education and support (see section 4.4 for detailed information about education and support during the transition). Those living in rural areas and/or without internet and telephone access appear to have struggled more with the transition. For example, a diabetes nurse specialist working for a Māori health provider stated that, although the organisation received a community support grant to educate their community, some of her clientele were not able to access this due to living in remote locations without public transport. A separate informant we interviewed in the Bay of Plenty also mentioned rural isolation as a cause of transition difficulties amongst Māori.

4.5.3 The different functionality of the CareSens meters was a barrier to successful transition for some consumers

According to our evaluation results, difficulties associated with meter and test strip functionality were a reoccurring theme across the focus groups. These issues include difficulties with error messages, problems downloading test results, reduced meter functionality in colder temperatures and various issues with strip storage and use. Table 6 summarises functionality issues reported across each of the focus groups.

Table 6: Overview of meter and strip functionality concerns across focus groups

Meter issues	Focus group					
	Asian	Adult Type 1	Māori	Older adult	Youth Type 1	Pasifika
Temperature sensitive; does not function well in cold weather	✓	✓		✓	✓	✓
Buttons used for scrolling do not work well or have malfunctioned		✓				
Clock on meter runs slow; cannot be used reliably for testing times		✓				
Error messages appear often (e.g., "E4", "LO") and sometimes take multiple test strips to resolve		✓			✓	✓
Difficulty downloading test results		✓	✓	✓		
Meter memory issues					✓	
Strip/strip canister issues						
Strip canister difficult to open		✓		✓		

Meter issues	Focus group					
	Asian	Adult Type 1	Māori	Older adult	Youth Type 1	Pasifika
Test strips fall out of canister easily		✓		✓	✓	
Test strips are “flimsy”, making it difficult to insert into meter			✓	✓	✓	✓
Test strip canister is too large					✓	
Strips less portable since not individually packaged					✓	
Cannot ‘top up’ blood amount on strip					✓	
Other functionality issues						
The needle is difficult to insert into the pricking device	✓			✓		
The spring on the CareSens lacer is poor	✓	✓				
The lacer is painful			✓			✓

These frustrations were shared by many of the health professionals who responded to the survey. One respondent felt that the “small but important” differences from the Accu-chek meter most of their patients had previously used resulted in the transition process being more difficult than it needed to be. Another believed the need for coding in the CareSens II meter was a “backward step” which had led to confusion amongst patients, and had unnecessarily added an extra layer of difficulty to the transition process.

Various barriers to a successful transition were reported as a consequence of these functionality difficulties. Some consumers attributed the functionality issues they experienced to the CareSens meters being ‘cheap’ and an ‘inferior’ product in comparison to their previous meters (adult Type 1 focus group, Māori focus group). This perceived inferiority has caused reluctance amongst some to use it, and a loss of confidence in the meters for others (adult Type 1 focus group, Pasifika focus group). Other focus group participants reported that having to learn about the new meter features was a challenging, time-consuming and stressful exercise (Māori focus group). Patients undergoing a brand change are generally most concerned about potential changes in therapeutic effects, adverse effects and practical issues relating to use (e.g., size, shape, appearance). Some of the consumers we spoke with have elected to continue to use their previous meter and self-fund their test strips due specifically to the difficulties they experienced with CareSens device functionality (Asian focus group, youth Type 1 focus group).

Others consumers were frustrated that the functionality issues they experienced with the new meters and test strips were not better anticipated by PHARMAC, and highlighted how ‘real-world’ field tests could have helped thwart some of these problems (adult Type 1 focus group). These perceptions are

echoed by two medical researchers who authored an article regarding the CareSens changeover.³⁶ The authors noted that many of the functionality issues could have been easily anticipated, including the fact that patients with reduced dexterity were likely to struggle with the small test strips, and that those living in colder parts of the country were likely to experience problems with a meter that is not able to read in lower temperatures. As was raised in section 4.1.2, these issues could have been better prepared for by undertaking consumer testing during the procurement period, particularly prior to release of the Supply of Diabetes Management Products RFP.³⁷ This would have enabled earlier identification of key functionality issues, and PHARMAC could have used the information garnered from consumer testing as a part of their communications and marketing planning to better anticipate and prepare for public response. Such preparation may have offered more reassurance to consumers that the functionality of the CareSens meters is different from their previous meters but that they are still adequate devices. Consumer testing around meter and strip functionality and incorporation of this testing into PHARMAC's communications strategy would have also helped to assist health professionals to better support patients with a ready response to functionality concerns.

Although issues with functionality posed barriers to a successful transition for some consumers, the majority of those individuals eligible for funding learned about and adapted to the new meters to overcome initial functionality obstacles.

4.5.4 Brand loyalty and perceived lack of choice led to a reluctance to change in some consumers

Trust in and loyalty to previous suppliers was a barrier to the CareSens transition for many of those who struggled with the transition. As was reported in the consultation feedback document:

"...many Māori patients with Type 2 diabetes use Accu-Chek due to it being very user friendly and the support is excellent. Generations of whānau members have used Accu-Chek."

Our evaluation work with consumers found similar sentiments. Some of the Type 1 youth said they found it difficult to transition to a new meter, as they had always had an Optium and the readings from this meter were their 'normal'. Participants in the Asian and Māori focus groups liked their Optium and Accu-Chek meters, saying that they felt 'comfortable' with them and were annoyed by having a change they perceived as unnecessary, especially since they believed they had been provided an inferior product. Similarly, many of the adult Type 1 participants found the new meters 'cheap', and thought that the transition was like going from a "BMW meter to a KIA meter".³⁸ These views related to trust and brand loyalty may also be one of the factors related to the high prevalence of parallel testing and accuracy concerns (section 4.5.5).

Brand loyalty was also expressed by individuals in the health sector. A key informant stated that a previous supplier, Roche, had an "incredible back-up and support system", with a team of specialised nurses providing comprehensive support (interview, medical agency spokesperson). Roche was also reported to sponsor diabetes clubs, publish information, and provide a variety of consumer-focused

³⁶ Lunt H and Florkowski CM, 2014. Transitioning to a national (New Zealand) single supplier scheme for glucose meters: Lessons learned, problems yet to be solved. *Journal of Diabetes Science and Technology*, pp. 1-4. DOI: 10.1177/1932296814524860

³⁷ 4 March, 2014. PHARMAC sense-making session with Allen + Clarke.

³⁸ 12 February 2014, Dunedin. Type 1 diabetic focus group.

activities. As such, the spokesperson stated that their level of knowledge and support was well recognised by both the medical community and consumers.³⁹ He commented that it has not been “an easy road” for Pharmaco in this regard. From the perspective of a practice nurse/diabetes volunteer coordinator, Roche had done an excellent job in providing good support and building strong client relationships to her and her clientele. She felt that the Roche representative had gone “the extra mile” and had a clinical background, whereas she believed Pharmaco representatives do not have the same level of clinical experience and found this a barrier in her work with patients.

Lack of choice is also seen to have presented difficulties for some consumers. A number of diabetics in the consumer focus groups expressed annoyance that they were no longer able to choose from a range of meter brands but were now ‘forced’ to use CareSens meters. A consumer organisation representative we interviewed believed that this was particularly prevalent amongst Type 1 diabetics who did not ‘choose’ to get diabetes, and were dissatisfied that one of the choices they did have available to them (i.e., choosing their preferred meter brand) was now being taken away. A health professional raised concerns about limiting meter availability to one brand, stating that each of the previously available meter brands had offered different features that enabled more precise matching of meter to patient; the change to a single brand limited clinicians’ ability to select a meter that best met their clients’ needs.

A PHARMAC employee stated that the organisation had hoped to increase patients’ sense of choice by adding the CareSens N POP a result of consultation feedback and thus increasing the CareSens range to three meters. However, despite three different CareSens models being available many patients were not offered a choice when the meter was dispensed; rather, pharmacists or general practitioners often told patients which meter was right for them, thereby making the choice to issue a certain CareSens meter on behalf of their clientele (see section 4.4.2).

It is noted that PHARMAC received submissions regarding concerns related to lack of consumer choice, trust and brand loyalty during the consultation, and publicly responded to these concerns in their consultation feedback summary.⁴⁰ PHARMAC’s responses to these concerns have been extracted from the summary document and outlined in table 7 below. Commentary is also provided around ways in which PHARMAC may have better anticipated and addressed these concerns during the transition period.

³⁹ We acknowledge Roche charged a higher rate for the meters and as such were able to provide this level of support.

⁴⁰ PHARMAC, June 2012. Analysis of issues raised in consultation: Blood glucose meters and test strips. *Executive Summary*.

Table 7: Concerns related to patient choice and brand loyalty

Concern 1: Lack of patient choice	
What was the specific concern raised during consultation?	<i>"One meter doesn't suit everyone."</i> The ability to select which meter fits best is important.
Who raised the concern?	Clinicians, patients and patient groups
What was PHARMAC's response?	Three different meters will be offered. Patients are able to choose to ensure the meter fits their requirements.
How could have this response been improved to better address the concerns?	Clearer communications with pharmacists around providing a choice to all consumers or asking if they were aware of what meters were available may have also increased consumers' ability to choose between the meters.
Concern 2: Trust/Lack of confidence/Brand loyalty	
What was the specific concern raised during consultation?	Incumbent suppliers had successfully achieved a large market share and brand loyalty. <i>"I have come to depend on my Accu-Chek meter and know that I can trust this system. My meter is my best friend... it tells me if I'm safe to drive, safe to play sport, safe to go surfing..."</i> Further comments included, <i>"We have a history of using Accu-Chek and Optium products-we have not used CareSens products and therefore have no confidence in them."</i>
Who raised the concern?	Clinicians, patients, patient groups and suppliers
What was PHARMAC's response?	Existing suppliers were provided with equal opportunity to submit bids for supply of funded meters. PHARMAC is confident that Pharmaco is a capable supplier and able to build trust over time. Consumer confidence in Pharmaco needs to be established, but PHARMAC is confident in Pharmaco's capability/commitment to supporting healthcare professionals and patients/patient groups. Pharmaco has supplied pharmaceuticals in NZ for many years and has a good supply record.
How could have this response been improved to better address the concerns?	PHARMAC's planning for transition could have specifically addressed how confidence in the CareSens meters would be established to help quell consumer reluctance to switch brands (e.g., specific implementation activities provided by Pharmaco, focusing more communications on the functionality of the meters and offering sound empirical and usability evidence that they are "as good as" the existing meters, advertising visits made by Pharmaco representatives to the different pharmacies and DHBs).

In summarising the information provided above, development of specific plans to help ensure consumers were given choice between the CareSens meters (i.e., more specific and directed communications with pharmacists around offering consumers a choice) may have enabled a greater

sense of choice in the diabetic community. This could have involved a focus on earlier and more targeted support and education for pharmacists (e.g., a concise summary or flowchart resource to support matching meter to patient). More communications could also have focused on the different functionality of the meters and offering evidence that they are of a similar quality to other meter brands.

While these steps may have helped to ease the transition, overall the need to change from a trusted brand and lack of choice were largely seen as an annoyance or inconvenience by most consumers, and represented a minor barrier to transition that was relatively easily overcome.

4.5.5 Concerns related to the accuracy of CareSens meters was a key transition barrier for some patients

The most significant barrier to successful transition for some patients involves concerns over the accuracy of the CareSens meters. Although PHARMAC considered and responded to patient and clinician concerns regarding CareSens meter accuracy during the consultation period⁴¹, our findings indicate continuing concerns over the accuracy of the new meters. The evaluation team heard numerous examples from both consumers and clinicians of the CareSens meters producing variable results, leading to a perception that the meters were inaccurate. Others reported that the meter reading did not match the user's expected results based on the way that they were feeling. For example, participants in the Māori focus group indicated that sometimes their CareSens readings seemed overly high, when nothing that they had eaten or done with regards to their testing behaviours should have led to a higher reading.

Evaluation findings suggest that various accuracy concerns have caused psychological distress in some consumers, leading to reluctance to use the new meters. For example, one 16 year-old diabetic and her mother were concerned about the inconsistency in readings they were receiving from their CareSens N POP meter and replaced all of the consumables, including the lancing device and test strips. They continued to receive inconsistent results despite having a replacement meter, and have now begun re-testing with an Optium meter whenever they are unsure of the CareSens reading. Other consumers stated that they *"do not feel confident in the accuracy of the readings"* and have begun to doubt their ability to safely manage their diabetes. Detailed discussion of the impact on consumers of the variation in meter readings is provided in section 4.6.2, but overall it is clear that perceptions of meter inaccuracies are continuing to cause stress and concern for some diabetics.

It appears that at least some of the reported inaccuracy is driven by users comparing readings derived from their CareSens meter with that of their previous model, with the assumption that the previous model was correct and the CareSens reading was therefore wrong. Meter comparison associated with accuracy concerns was a widespread practice across all diabetic consumer groups spoken to as part of this evaluation. For example, an adult Type 1 diabetic reported having trialled his CareSens meter against his Accu-Chek meter for several months and found that the CareSens read lower—particularly with lower blood sugar levels—which he reports would have changed the way he treated himself,

⁴¹ PHARMAC, June 2012. Analysis of issues raised in consultation: Blood glucose meters and test strips. *Executive Summary*. Available at <http://pharmac.govt.nz/2012/08/08/Summary%20of%20responses%20to%20test%20meters%20and%20strips%20proposal.pdf>

should he have been going solely off the CareSens readings. Concern about meter accuracy due to inconsistent results from parallel testing was not an isolated issue amongst consumers: concerns were also expressed by health professionals about different readings between meters. One clinician asked for PHARMAC to further explain *“the difference in the readings between the old and new meters which can be dramatic.”* Additional comments from health professionals included appeals to PHARMAC to *“ensure the meter is similar to the old meters... A meter should not be changed to one that reads significantly higher than older meters.”*

Engagement with consumers during the focus groups found relatively widespread knowledge that meters were expected to read within a plus or minus 20 percent accuracy range; however, many consumers believed that this variance related to the expected difference in readings between meters rather than between a meter and a laboratory test. For example, a mother of a teenager with Type 1 diabetes reported that the CareSens N POP meter readings were often higher than the expected 20 percent variability compared to the Optium meter, while other consumers in the youth Type 1 diabetes focus group perceived that the N POP readings were sometimes 20 percent higher than Optium readings, especially when sugars are extreme (both low and high levels).

Other evaluation informants stated that they had observed large variation in meter readings taken one after the other with the same meter. Some of this reported variation may be attributable to patient factors such as incorrect hand washing, improper coding or internal/external interference from other substances.⁴² This appears to have been the case with some of the consumers engaged with as part of this evaluation; for example, several participants in the Māori focus group reported that after approaching their diabetes educator with concerns about the meter, they had realised that their previous testing practices were incorrect and had made changes, such as washing hands before testing and not squeezing the finger to draw blood.

On the other hand, according to a recently published article on the transition to CareSens meters, some patients described irregular but highly variable test results despite demonstrating good meter testing technique to their clinicians.⁴³ These inaccuracies may be attributable to issues with test strips (e.g., strip storage, ageing, manufacturing variances) or environmental factors may impact on measurement accuracy such as altitude, humidity and temperature. Some researchers have in fact cautioned that blood glucose testing in high altitudes or low temperatures *“may give totally unreliable false low or high readings.”*⁴⁴

An alternative scenario is that there may be an issue with the accuracy of the device itself. While it is beyond the scope of this evaluation to consider the clinical accuracy of the meters, published evidence has not identified any evidence of accuracy problems in the CareSens meters. A recent study on

⁴² Ginsberg H, 2009. Factors affecting blood glucose monitoring: Sources of error in measurement. *Journal of Diabetes Science and Technology*, 3(4), pp. 903-913.

⁴³ Lunt H and Florkowski CM, 2014. Transitioning to a national (New Zealand) sole supply scheme for glucose meters: Lessons learned, problems yet to be solved. *Journal of Diabetes Science and Technology*, pp. 1-4. DOI: 10.1177/1932296814524860

⁴⁴ Öberg D and Östenson CG, 2005. Performance of glucose dehydrogenase- and glucose oxidase-based blood glucose meters at high altitude and low temperature. *Diabetes Care*, 28(5), p. 1261.

PHARMAC's implementation of the change included clinical testing of meter accuracy.⁴⁵ The research used the Accu-Chek Performa as the reference value, allowing a direct comparison of Performa capillary results with those of the CareSens N POP meter. Study findings based on 105 adult participants' capillary samples showed that, on average, the CareSens N POP meter read approximately 0.6mmol/L higher than the Accu-Chek Performa. The researchers emphasise that this difference is not likely to result in errors in clinical decision making, but that it "*was generating anxiety amongst some individuals and/or their caregivers*". The authors also included caveats about these findings, such as sampling and testing having occurred without a "real world element" and an absence of results from hypoglycaemic patients, which limited comparisons in the critical glucose range of <5.6mmol/L.

Accuracy of the CareSens meters has also been considered by Medsafe, the agency responsible for ensuring that medicines and medical devices are acceptably safe. From October 2012 to February 2014 there were 122 incident reports to Medsafe. Out of the total number of issues reported (N = 152), 115 included meter readings inconsistency or differences between two or more meters as issues. Of these, none of the meters were found to be faulty in reading blood glucose levels.

Nearly 200,000 meters had been distributed to the New Zealand market from August 2012 to May 2014. As at 24 July 2014, a total of 1192 meters had been returned to Pharmaco that were considered faulty by the user. From the 1192, 70 were faulty but none were determined to be reading blood glucose levels incorrectly.⁴⁶

A special edition of the Best Practice Journal on medication brand transitions posits that the implementation of product changes often precipitates an increase in reports of patients' adverse experiences.⁴⁷ An article by Dr Michael Tatley from the Centre for Adverse Reactions Monitoring (CARM) notes that reports of adverse reactions typically follow a predictable pattern that begins within the first few weeks following a brand change. The number of reports then typically peaks in the range of 15-40 reports and then declines over a three month period. While it is noted that the change to CareSens meters relates to a change in device, rather than a medicine, and is therefore not directly comparable, the pattern of reports to Medsafe appears to closely align with the expected trend.

Figure 8 on the following page shows the pattern of reports to Medsafe following the change to CareSens meters. As a comparison, figure 9 shows the pattern of reported notifications to CARM following a change from Prozac to a generic version of the antidepressant fluoxetine.

⁴⁵ Thompson H, Chan H, Logan F, Heenan H, Taylor L, Murray C, Florkowski C, Frampton C and Lunt H, 2013. A glucose meter evaluation co-designed with both health professional and consumer input. *The New Zealand Medical Journal*, 126(1386), pp. 90-97.

⁴⁶ PHARMAC, 26 September 2013. Diabetes implementation report to Director-General of Health from PHARMAC.

⁴⁷ Cannons C, Duffull S, Jessamine S, Rasiah D and Tatley M, 2009. Medicine Brand Changes. *Best Practice Journal (BPJ)*, Special Edition: Generics, pp. 12-13. Available at http://www.pharmac.govt.nz/2009/08/25/bpjse_generics_2009.pdf

Figure 8: CareSens brand change notification to Medsafe reporting patterns

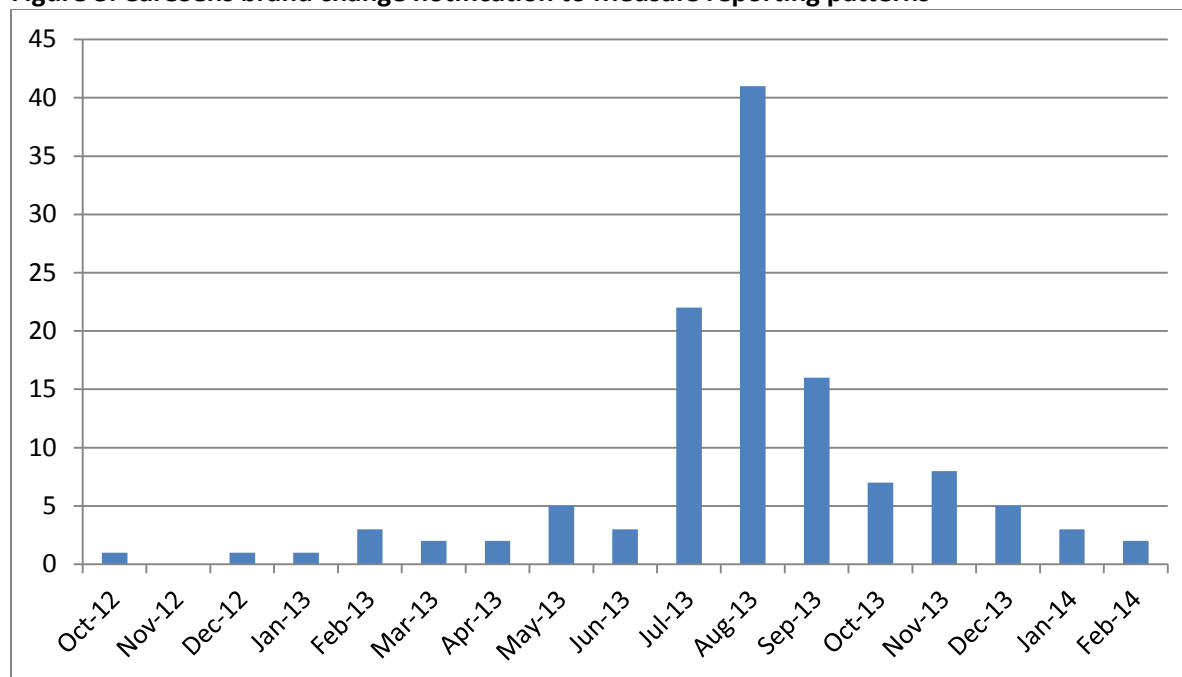
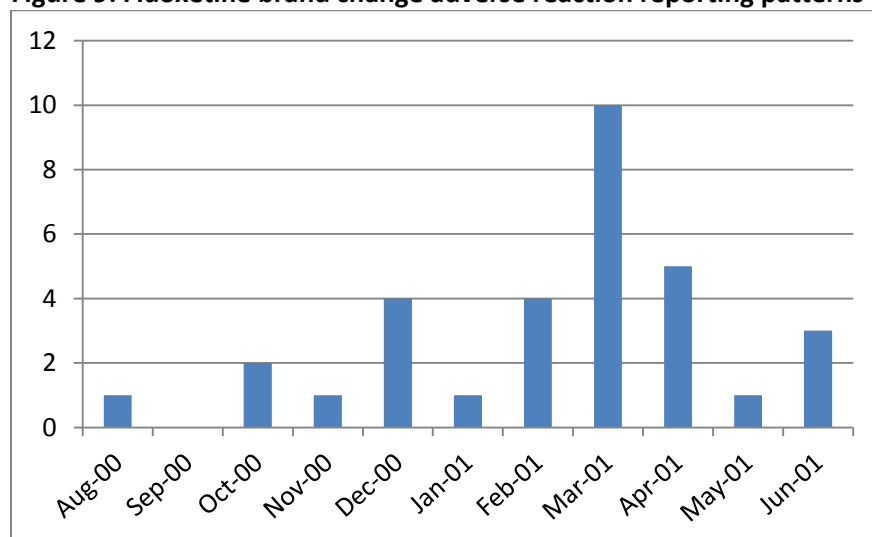


Figure 9: Fluoxetine brand change adverse reaction reporting patterns



The article posits that the commonly observed pattern of a peak in notifications followed by a decline, despite the new medicine continuing to be available, suggests that the adverse reaction reports may be a phenomenon of the change process rather than medicine per se. In the case of the CareSens brand change, the decline in reports may be due to other factors, such as consumers learning to ‘manage’ using the meters despite continuing inaccuracies, or those experiencing ongoing accuracy issues may be self-funding other meter brands. However, it is worth noting that the number of accuracy complaints has decreased substantially in recent months.

While there is as yet no clinical evidence that the meters are providing incorrect readings, the variable readings and related accuracy concerns have nonetheless acted as a barrier for some consumers to make a successful transition to the CareSens meters and are continuing to cause ongoing stress in some. With this in mind, some learning for PHARMAC's consideration include the possibility that more thorough consumer group engagement and usability testing would have helped to better identify and plan for accuracy issues and concerns. Development of criteria to assist with a thorough assessment of potential patient impacts would have also helped flag early concerns about meter accuracy. Further, PHARMAC could have focused more exclusively on increasing individuals' understanding and knowledge around 'what a meter does' and what is considered normal in terms of meter readings, accuracy and variance by placing more emphasis on meter variance and measurement error in educational resources. More detailed suggestions for PHARMAC's consideration are provided below regarding ways in which these issues relating to meter accuracy may be overcome.

- **Method comparison testing, field studies, post-marketing surveillance and/or usability testing done in addition to clinical testing, and designed and conducted in collaboration with consumers:** Additional accuracy testing of the CareSens meters utilising any of these methods—and ideally as many of these methods as possible—designed in conjunction with diabetic patients could help increase consumer trust in the new meters as well as in PHARMAC as the managing organisation. Providing consumers with the opportunity to assist with development of additional testing designs and/or to participate in the testing itself would strengthen the sense that PHARMAC understands and is willing to address their concerns.
- **Carefully consider the needs and vulnerability of different consumer groups:** It is suggested that PHARMAC carefully consider accuracy concerns in relation to differing levels and types of consumer vulnerability, and to develop specific communication strategies about meter accuracy tailored to these groups. As the aforementioned findings indicate, individual factors such as diabetes type (e.g., Type 1), age, hypoglycaemia awareness, and other individual patient concerns appear to be associated with some consumers' increased need for accurate meter readings.
- **Increase awareness and understanding around potential causes of error:** Provision of a specific information checklist⁴⁸ to those experiencing variable results (or those newly-diagnosed patients) may go some way in increasing understanding of correct testing technique and therefore enhancing consistency of readings. This checklist could include questions such as have the strips expired? Have hands been thoroughly cleaned? Is there enough blood on the strip? Have the strips been affected by climate, heat or light?

4.5.6 A more thorough understanding of change management may have helped to prepare for transition

⁴⁸ National Diabetes Services Scheme, September 2013. Blood glucose monitoring: What if the test result doesn't sound right? Available at www.diabetesaustralia.com.au/NDSS-Content/Diabetes-Information-Sheets/Blood-Glucose-Monitoring1/#Importance

Allen + Clarke posits that PHARMAC could have better prepared for the transition process by undertaking more detailed analysis of the likely stages of change. This first requires an understanding of the psychology of change, followed by careful planning for the management of the change process.

Box 2 below presents further information about change management and the psychology of change, including some approaches and resources to understanding change, change management and change resistance with a specific lens applied to PHARMAC's implementation of the CareSens funding decision.

Box 2: Understanding resistance to change and change management

Understanding resistance to change and change management

Why does resistance to change occur and what can organisational 'change agents' such as PHARMAC do to mitigate it? Organisational management researchers⁴⁹ have considered the possibility that some change agents may contribute to the occurrence of "resistant behaviours"—examples of which are provided in the Change Curve Model section below—themselves by:

- failing to build trust before a change, and
- not adequately communicating the change to change recipients (consumers, health professionals).

There is evidence to suggest that these potential contributors to change resistance may have occurred during PHARMAC's implementation of the CareSens funding decision. Issues related to trust and communication are described in sections 4.3, 4.4, and 4.5.4.

The Change Curve Model

The Change Curve Model⁵⁰ is a popular managerial tool used to understand the stages of change, anticipate how change recipients may react to change, and plan for how negative impacts can be minimised. Below, we relate the model to the CareSens changeover, providing examples of consumer and health professionals' reactions to the transition across each stage of change.

Stage 1: Some individuals' initial reactions upon learning about the changeover may have been shock or denial in reaction to the challenge to the status quo: *"Almost all patients expressed their concern about switching from their current supplier as they were extremely happy with the service and support they have received..."*⁵¹

Stage 2: Once the reality of the brand change began to hit, some individuals reacted negatively: they may have feared the impact, felt angry, and actively resisted or protested against the changes. Various media sources portrayed these different reactions.^{52,53}

⁴⁹ Ford JD, Ford LW and D'Amelio A, 2008. Resistance to change: The rest of the story. *Academy of Management Review*, 33(2), pp. 362-377. Available at

http://www.communicationcache.com/uploads/1/0/8/8/10887248/resistance_to_change-the_rest_of_the_story.pdf

⁵⁰ Mind Tools. The Change Curve: Accelerating change, and increasing its likelihood of success. Available at http://www.mindtools.com/pages/article/newPPM_96.htm

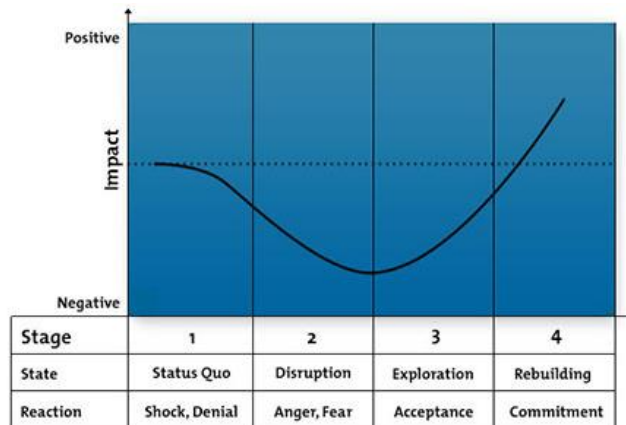
⁵¹ PHARMAC, June 2012. Analysis of issues raised in consultation: Blood glucose meters and test strips executive summary.

⁵² Mathewson N, November 2012. Diabetics confused by testing equipment. Available at <http://www.stuff.co.nz/the-press/news/8017451/Diabetics-confused-by-testing-equipment>

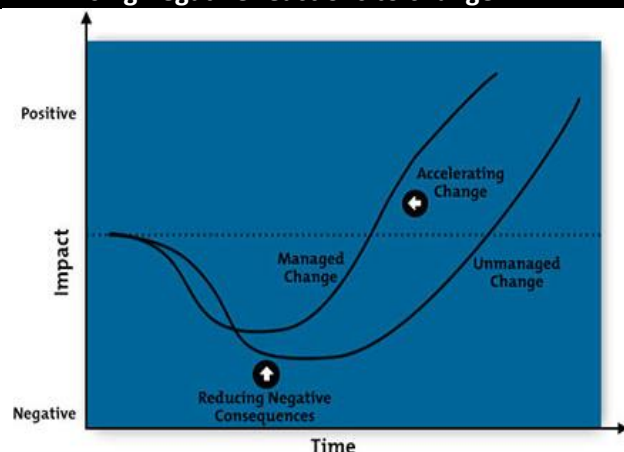
⁵³ Stop PHARMAC taking away the choices of people with diabetes! Available at <https://www.facebook...30150197030591/>

Stage 3: The transition to CareSens is currently at this stage of the Change Curve Model. Most individuals have accepted the transition, and perhaps some individuals who once resisted the change are now beginning to accept and adapt to the changes. Various focus groups we held found evidence of acceptance and adaptation to the new meters.^{54,55}

Stage 4: In the future, the overwhelming majority of people will have hopefully accepted the changes implemented by PHARMAC and will have rebuilt ways to operate successfully with the transition.



Minimising negative reactions to change



We pose the following questions regarding how PHARMAC could have better minimised negative reactions to change.

Stage 1: Did PHARMAC communicate often without overwhelming people and ensure individuals knew where to go for more information if they needed it? Did PHARMAC take enough time to respond to concerns that arose?

Stage 2: How carefully did PHARMAC consider, plan, and prepare for the impacts and objections people may have experienced during the change? Were the issues people raised addressed early with clear communication and support, and did PHARMAC take action to minimise and mitigate problems people experienced?

Stage 3: How well did PHARMAC set the foundation for this stage by ensuring staff and health professionals affected by the change were well trained/equipped? Did PHARMAC provide early opportunities to the health care community and consumers to understand what potential changes the transition would bring? Was contingency time for extra resourcing and support anticipated and prepared for?

Stage 4: Are the current benefits of the funding decision being clearly communicated to both PHARMAC staff and those medical and consumer groups affected by the change?

⁵⁴ 24 February 2014, Auckland. Chinese Asian diabetic focus group.

⁵⁵ 12 February 2014, Tauranga. Māori diabetic focus group.

4.5.7 Earlier planning and implementation of transition activities may have provided for a smoother transition process

As suggested in the above section, greater analysis of and attention to the stages in the change process likely to be experienced by consumers may have improved mitigation of the aforementioned barriers through earlier implementation of transition activities. The following section provides an overview of PHARMAC-led or supported transition activities, and then offers potential learnings for PHARMAC regarding the planning and implementation of the changeover.

Figure 10 illustrates a number of specific transition events PHARMAC engaged in between July 2012 and July 2013.⁵⁶ A full timeline, including all transition events, is provided as appendix C.

Figure 10: Overview of PHARMAC transition activities

Pre-implementation period	Jul 2012	
	Aug 2012	Public notification that single supplier proposal was approved
CareSens products available; previous meters still funded	Sep 2012	Communications sent to health professionals Transition to new meters begins
	Oct 2012	
	Nov 2012	Meet Your Meter events begin
Previous meters defunded; strips still available	Dec 2012	
	Jan 2013	Development of direct-to-patient contact initiative begins
	Feb 2013	Nationwide newspaper and radio advertising Direct-to-patient contact initiative finalised
Only CareSens products funded and available from 1 March	Mar 2013	Additional activities/advertising targeted at slower uptake DHBs Targeted Transition Programme established Grants approved to support advertising activities targeting Māori and Pacific communities
	Apr 2013	
	May 2013	
	Jun 2013	
	Jul 2013	Implementation considered complete ⁵⁷

⁵⁶ Some activities (e.g., communications to professional groups) are not included in the figure.

⁵⁷ PHARMAC, 25 July 2013. Diabetes implementation report to Director-General of Health from PHARMAC.

As highlighted in the above figure, dedicated activities to support the transition process in specific groups did not commence until January 2013; four months after the change to CareSens meters had commenced. In December 2012, PHARMAC provided a revised implementation plan to the Director-General of Health and began “*scoping options for writing directly to individuals with diabetes*”⁵⁸ at the end of January 2013, finalising this revised approach on 28 February 2013.⁵⁹ As recorded in the Director-General report, the initiative’s objective was for PHARMAC to provide a total of \$550,000 in grants across New Zealand and implementation resources (e.g., instructions for extracting a target patient list, template letter, brochures, information on how to access the online training tool) to participating PHOs in order to support general practices in contacting people using a blood glucose meter directly who had not yet switched to the new meters via letter, phone or text message. February 2013 also saw the initiation of nationwide advertising of the meter change, including newspaper and radio advertisements.

In March 2013, after the CareSens meters and strips became the only subsidised products available, PHARMAC implemented a number of activities to enhance the transition process. This included region-specific uptake initiatives. For example, the Taranaki and West Coast DHBs were identified as having lower meter uptake in comparison to other DHBs. In collaboration with Diabetes New Zealand, PHARMAC arranged additional activities and advertising in those regions’ newspapers to help encourage uptake.

In December 2012 PHARMAC began the ‘small grants scheme’ for Māori, Pasifika and consumer organisations, providing financial assistance for organisations to support their communities to change to the CareSens meters. PHARMAC approved 24 grants, totalling just under \$44,000 with a \$5,000 maximum per grant.

The Targeted Transition Programme came into effect in March 2013, once CareSens was the only subsidised brand of meters available. The programme allowed “*for extra strips from patients’ old brand to be issued, giving them time for a visit with their health professional to help them feel comfortable with the new meter*”⁶⁰. Patients received a one-off supply of their old strips to give them more time to engage with their health care professional to make the transition.

By the end of July 2013, PHARMAC reported to the Director-General⁶¹ that the changeover process to CareSens products was complete, though the support and monitoring of individual patients, stock levels, number of 0800 calls, meter returns, incident reports and media responses continued.

In consideration of the timing of the aforementioned transition events, we raise the possibility that earlier planning and implementation of various transition activities could have mitigated some of the difficulties reported during this period of the implementation process. Specifically, the earlier roll-out of the community support grants programme may have fostered earlier and more responsive uptake from diabetics belonging to these communities. As was previously noted, lack of access to or awareness of support and education services about the transition was cited by some health professionals and consumers as a barrier to successfully switching to the CareSens meters. PHARMAC could have better

⁵⁸ PHARMAC, 31 January 2013. Diabetes implementation report to Director-General of Health from PHARMAC.

⁵⁹ PHARMAC, 28 February 2013. Diabetes implementation report to Director-General of Health from PHARMAC.

⁶⁰ PHARMAC, 14 March 2013. Diabetes implementation report to Director-General of Health from PHARMAC.

⁶¹ PHARMAC, 25 July 2013. Diabetes implementation report to Director-General of Health from PHARMAC.

utilised its awareness of likely transition barriers gathered from the consultation phase and pre-empted these by establishing the grants programme back in September 2012, when the CareSens products first became publically funded. Contact with relevant health providers and community organisations could have been made at that time, informing these organisations of the availability of grants and additional resources should they have required additional support.

4.6 Impact of the funding decision on consumers

This section addresses the impact PHARMAC's decision to move to a single supplier of diabetes management products has had on consumers. Evaluation findings indicate the funding decision concerning CareSens meters and consumables has had positive effects on the diabetic community in terms of enhancing their diabetes management, as well as negative impacts such as stress and anxiety.

4.6.1 Most consumers successfully managed the change to CareSens meters with minimal impact on their diabetes management

Our evaluation findings indicate that the majority of the diabetic community did not experience significant negative effects of PHARMAC's funding decision; or, if they did experience initial difficulties, have now adjusted to using the CareSens meters. As outlined in section 4.5.1, most of the participants in the consumer focus groups were successfully using the CareSens meters.

The opportunity to interact with the health system during the change to CareSens appears to have led to positive impacts for some consumers by enabling them to access advice to improve the management and monitoring of their illness. For example, a number of Type 2 diabetics in the Māori focus group had received education about the CareSens meters from a Māori diabetes nurse educator or *kaitiaki* (see also section 4.4.3). These participants said that the CareSens meter education was delivered in the larger context of diabetes management including advice on diet, meal timings, and exercise regimes. As a result, several patients had incorporated changes into their lifestyle, with one Māori participant noting:

"When I got the education from [diabetes nurse educator] I learned a lot about eating healthier and making sure I go for [regular] walks...of course I knew it already but the support from whānau helped me to actually make some changes."

Other positive diabetes management impacts were also documented, including the improved ability to test correctly. Some Māori focus group participants realised their previous testing practices were incorrect after having received education on the new meters, and have made changes to their testing techniques (see section 4.4.3).

The aforementioned evidence, paired with the findings detailed in section 4.5.1 (that the majority of consumers and health professionals transitioned without difficulty), suggests PHARMAC's funding decision to move to a single supplier of blood glucose devices and consumables had minimal impact on most of the 100,000 consumers who have acquired the new CareSens meters.

4.6.2 Some consumers experienced negative impacts such as stress and mistrust, which have led to changes in their diabetes management practices

Findings from the evaluation suggest that although the majority of consumers have transitioned successfully to CareSens devices, a small number of individuals experienced negative impacts related to concerns over the accuracy or validity of the meters. As first raised in section 4.5.5, reports of meter inaccuracy and uncertainty have resulted in significant stress and insecurity for both patients and their families. One health professional who responded to the survey stated that:

"Clients are angry and stressed about a new product that is not comprehensively sold to them as reliable... There is an element of distrust with the use of the CareSens meter which is impacting negatively on patients' wellbeing."

In our discussions with consumers, Type 1 diabetics and parents of Type 1 diabetics were particularly concerned about inconsistent readings and perceived meter inaccuracies. Parents stated that they were still experiencing a "large amount of stress" and doubt about the accuracy of the CareSens meters, and that the perceived inaccuracy of their children's CareSens meters makes them feel that their children are unsafe. One parent said, "You question yourself and you think you're doing a rubbish job taking care of your kids." Another parent described feeling stressed and nervous:

"It's terrifying... It makes you feel anxious as a parent. You feel inadequate. When they give you something that's not doing the job as well as what you've already got, you feel like you can't win."

Adult Type 1 focus group participants also provided examples of the negative lifestyle impacts that perceived meter inaccuracy had led to. Some participants stated that they are afraid to drive (diabetics are not covered by insurance should they have a diabetic-related driving incident), another noted that fear of a hypo- or hyperglycaemic incident had led to her not wanting to be alone with her children when her husband was away.

Results from the evaluation indicate that specific consumer groups have experienced more substantive impacts related to PHARMAC's funding decision than others. As suggested by the above findings, Type 1 diabetics (including adults, children/youth, and caregivers of children) appear to have experienced greater levels of stress related to perceived meter inaccuracies. Given important differences between the two diabetes types such as differences in cause, symptoms and management regimes, this finding is not unexpected. With regard to management regimes, for example, a recent survey commissioned by the American Association of Diabetes Educators⁶² found that 65 percent of participants with Type 1 diabetes considered their blood glucose meter to be extremely important in helping them manage their diabetes, which was a significantly higher percentage compared to Type 2 diabetics (44 percent).

In addition, some key informant interviewees expressed concerns about the effects of the change on more 'isolated', vulnerable consumer groups such as minority populations (e.g., Pacific Islanders) with co-morbidities and difficulties accessing education and support services; or the elderly, who were seen by some of the health care community to be more adverse to technological change.

The reported mistrust of the CareSens meters due to perceived inaccuracies has impacted on the way in which some consumers manage and monitor their illness. More frequent testing was a common occurrence amongst the focus group participants, which was motivated by perceptions of 'overly high' CareSens meter readings. These participants would often take one test, find that the reading was higher than anticipated, and then consequently retest to determine if the higher reading was 'correct' using a second (or sometimes more) test strip. Similarly, the majority of participants in the adult Type 1 focus group continue to use their previous meters as a 'fall-back' measure: these participants said they now

⁶² Harris Interactive, 2013. Survey to gauge knowledge regarding blood glucose meter accuracy. *Executive summary*. Available at http://www.diabeteseducator.org/export/sites/aade/_resources/Advocacy/Executive_Summary_Meter_Acc_2014.pdf

test more frequently and with greater regularity using their old Optium meters. We also found the opposite situation, whereby some consumers have stopped testing as frequently if an initial reading appears to be inaccurate. For example, one Asian focus group participant struggling to transition had visited his pharmacist several times to express his concerns about the meter. The meter was found to be testing normally, but the participant did not believe the CareSens was providing an accurate reading. His mistrust of the meter has led to reluctance to use it and he tests much less frequently now.

PHARMAC has suggested that, for some consumers, management of their diabetes may be focused on the exact numerical reading displayed on the meters, rather than seeing the reading as an indication of approximate blood glucose levels.⁶³ It was further suggested that patients are managing their diabetes by responding to the reading given by the meter instead of using the meters as part of a broader diabetes management process. This suggests that for future change transition processes, greater consideration should be given to providing information to consumers about diabetes self-monitoring.⁶⁴ We encourage PHARMAC to work in partnership with other health-related agencies and health care providers to increase optimal diabetes management. This may include, for example, partnering with nationwide diabetes organisations to enhance patient education and self-management strategies.⁶⁵

4.6.3 There have been anecdotal reports of adverse impacts related to the use of CareSens meters

Despite the fact that the CareSens range has successfully passed clinical performance evaluations, some consumers reported experiencing adverse impacts related to the change. It is beyond the scope of this evaluation to verify the validity of these reports and the following examples are anecdotal in nature, but these examples have been included to provide an indication of the types of incidents being reported and to illustrate their impacts on consumers.

Some consumers reported experiencing inaccurate meter readings which they believed led to their non-recognition of hypoglycaemia as well as the overtreatment of hyperglycaemia for others. An older Type 1 diabetic recounted an incident in which a CareSens blood glucose reading was taken shortly before undertaking a car journey that took approximately 20 minutes. The reading had indicated that his glucose levels were high enough to drive; however, the man became unconscious while pulling into his driveway. Subsequent testing by ambulance personnel with a different meter model showed a substantially lower blood glucose reading at which the man would not have attempted to drive. This incident caused substantial stress and uncertainty for the man and his wife, who then kept a record of both CareSens and Optium meter readings from the same drop of blood. This recorded differences between the meters as great as 10mmol/L, further undermining the couple's confidence in the meter.

Another participant, a mother of two young diabetic girls, voiced concern about the accuracy of the CareSens meters and described the impact this perceived inaccuracy has had on her family. After both children switched to the new CareSens meters, one of the daughters experienced a hypoglycaemic fit that the mother perceived to be the result of an inaccurate meter reading. The mother made comparisons between her daughters' CareSens meters and their previous Accu-Chek devices, and found

⁶³ 4 March, 2014. PHARMAC sense-making session with *Allen + Clarke*.

⁶⁴ 4 March, 2014. PHARMAC sense-making session with *Allen + Clarke*.

⁶⁵ Lin D, Hale S and Kirby E, 2007. Improving diabetes management. *Canadian Family Physician*, 53(1), pp. 73-77. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1952559/>

discrepancies in the meter readings. Because the amount of insulin given to her children is based on meter readings, the mother voiced her concern that trusting the CareSens meters' results may lead to her accidentally inducing a hypoglycaemic fit and has continued to use the previous meters for managing her daughters' diabetes.

As noted previously, the above reports are anecdotal only and their accuracy has not been confirmed; they are provided as only examples of the impacts on consumers' confidence in their ability to manage their diabetes. PHARMAC's planned clinical evaluation of the impact of the change to CareSens meters will be an important input to clarify the validity of such reported impacts, and it is recommended that the results of the evaluation are publicised to consumers.

4.7 Impact of the decision on health professionals

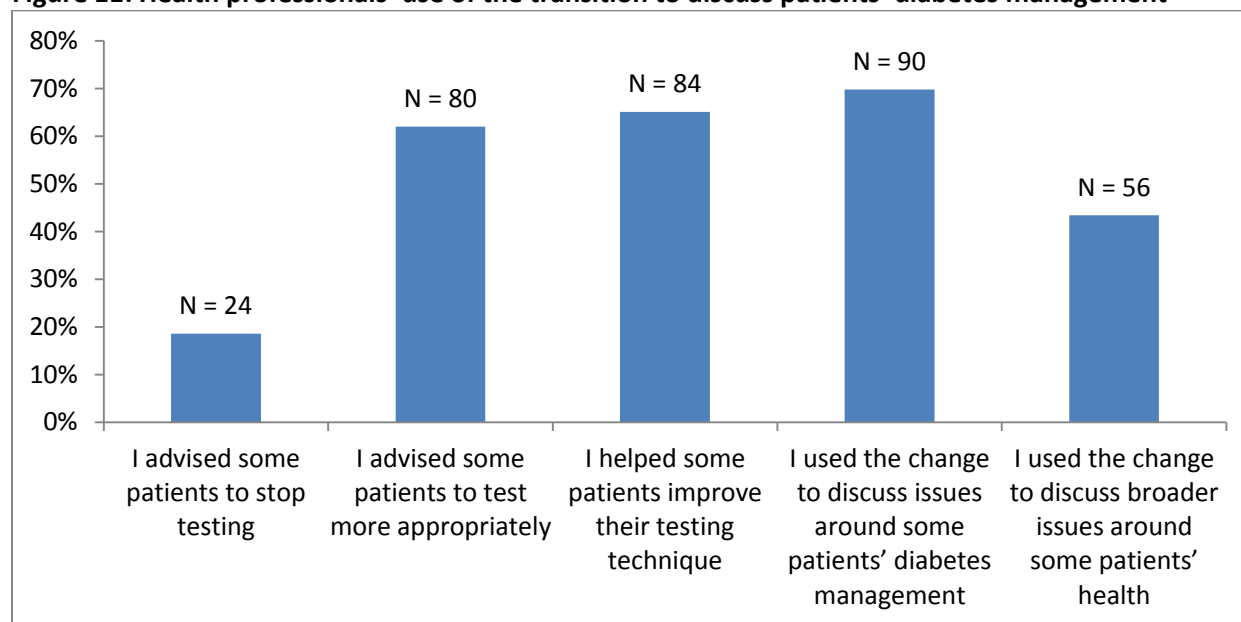
This section addresses the impact of the funding decision on health professionals. The evaluation found evidence of both positive impacts such as the opportunity to interact with patients to improve diabetes management, as well as negative impacts such as opportunity costs and, in some cases, potential damage to health professionals' relationship with their clients.

4.7.1 The change to CareSens meters provided an opportunity for health professionals to help improve their patients' diabetes management

A key positive impact of PHARMAC's funding decision relates to health providers having used the changeover as an opportunity to discuss monitoring, self-management strategies, and improved testing techniques with their patients.

The considerable extent to which health professionals had used the opportunity to discuss diabetes management was a key finding from the evaluation survey. In reply to a question about their use of the transition to discuss patients' diabetes management, figure 11 shows that 70 percent of the 129 respondents reported having used the change to discuss issues around some clients' diabetes management, with 65 percent using the change to help some patients improve their testing technique, and 62 percent of respondents advising their patients to test more appropriately.

Figure 11: Health professionals' use of the transition to discuss patients' diabetes management



Interview data also found that health professionals had acted as *“advocates for the meters through educating patients about meter use and self-management strategies”* (interview, diabetes nurse). Health professionals reported observing resultant improvements in testing practices. For example, one nurse reported a decrease in home testing, with her patients now coming to the clinic to have their readings monitored, which she felt was a more appropriate method for some clients. Another health professional stated that he had *“audited”* patients' testing practice and had observed much better technique in subsequent visits with these clients.

These findings are particularly encouraging, given research showing significant associations between regular reviews and discussions about diabetes management (Type 2 diabetics, in these instances) with primary care providers and improved glycaemic control and management of diabetes-related complications (e.g., blood pressure).^{66,67}

These positive impacts could be further enhanced in subsequent changes by a specific focus on using the changeover to target some of the broader contextual and behavioural factors that influence diabetes management. This could involve adapting a community or group health approach by which people in the diabetes community could be brought together to discuss diabetes management issues as a whole (e.g., the factors that contribute to and determine successful diabetes management), and then discuss use of the new meters (e.g., support and education) as a secondary conversation.

4.7.2 Negative impacts experienced by health professionals included opportunity costs and damage to relationships with patients

Evaluation results garnered from the quantitative survey and key informant interviews found health care providers experienced some adverse effects of the decision, both within their own professional roles and their observations of how the decision has impacted on their clientele. In response to a survey question regarding what could have been improved with the implementation of changes to the subsidised test meters and strips, health professionals highlighted issues surrounding education, information, and support; functionality concerns; and opportunity costs. Selected responses related specifically to the perceived impacts of the decision on the health care providers themselves are provided in table 8.

Table 8: Health professionals' perceptions of what could have been improved with the implementation of CareSens meters (N = 105)

Theme	Number of responses	Examples of respondents' comments
Education, information, and support	42	<p><i>"A practical session could have been held for pharmacists (and other health professionals) on the types of meters available and their use. 'Problem solving' should have been implemented well in advance as many other pharmacists I spoke to, like myself, had never even seen a CareSens meter. We were also unaware free 'demo' meters could be obtained from the company"</i></p> <p><i>"More education for health professionals was needed on tips for using this meter, including potential problems, their causes, and how to remedy these"</i></p> <p><i>"Greater clarity around access to other funded meters, test strips, and ketone testing was needed"</i></p>

⁶⁶ Agban H, Raina Elley C, Keneal, T and Robinson E, 2008. Trends in the management of risk of diabetes complications. *Primary Care Diabetes Europe*. Available at http://www.diabetes.org.nz/news/nz_news/trends_in_the_management_of_risk_of_diabetes_complications

⁶⁷ BPAC, February 2014. Getting to know patients with Type 2 diabetes and poor glycaemic control: One size does not fit all. *Best Practice Journal*, 58. Downloaded from <http://www.bpac.org.nz/BPJ/2014/February/docs/BPJ58-diabetes.pdf>

Theme	Number of responses	Examples of respondents' comments
Functionality issues	24	<p><i>"Some small but important safety aspects were not highlighted to us, such as the fact that the CareSens II and the CareSens N need different strips. And more importantly, that if the patient uses the strip in the wrong meter it won't warn them with an error message – it just gives them an inaccurate reading. This and the fact that the CareSens N and CareSens II will not warn patients if expired test strips are being used are both matters of patient safety and of great concern to us"</i></p> <p><i>"We have discovered that several patients have been prescribed the wrong CareSens strips for their meters as well as there being no indication that calibration for some meters is required"</i></p>
Accuracy and reliability issues	20	<p><i>"More information for patients around meter accuracy is needed as we still are having ongoing issues with families not trusting the accuracy of the CareSens meters"</i></p> <p><i>"A better review of the science before the consultation behind accuracy-precision tests should have predicted issues, especially around accuracy in the borderline hypoglycaemic range"</i></p>
Consultation and usability testing	13	<p><i>"More consultation with patients and specialist groups (diabetologists) was needed before this whole scale change happened"</i></p> <p><i>"I would have liked PHARMAC to have taken more note of consumers' and stakeholders' feedback regarding making the change"</i></p>
Implementation timing	9	<p><i>"A longer crossover period would have been good to assure patients and clinicians that the new meters and strips were not inferior to the older ones"</i></p> <p><i>"A longer period for pharmacists to prescribe the meters"</i></p> <p><i>"The changeover should have been staggered with T2DM diet control first, leaving our most vulnerable clients as the last to have to switch over"</i></p>
Opportunity costs	9	<p><i>"There was a failure to appreciate and compensate for the additional workload on those members of Diabetes Teams"</i></p> <p><i>"The funding went to pharmacies to do the education but nurses everywhere ended up doing a great deal of it. Nurses should have been funded to provide the education. Patients picked it up from the pharmacy and then came and asked us how to use them"</i></p>

Theme	Number of responses	Examples of respondents' comments
		<i>"I was very disappointed with the process and the fact that we as diabetes nurse specialists had to deal with a large proportion of the education and provision of the new meters. We were in many cases the front line when there were problems"</i>
Other	28	<i>"There was and continues to be SO much wastage. Perfectly useful meters simply go to the landfill because strips no longer available - this seems completely against any gains in changing over. Surely these meters could be used somehow by someone"</i>

Note. Theme responses are not mutually exclusive, therefore there were >105 theme responses.

4.7.2.1 Opportunity costs

Key informant interviews found recurring themes that mirrored those expressed by health professionals who participated in the online survey. Opportunity costs were particularly seen as a negative impact by health professionals working in secondary care. For example, a diabetes specialist nurse believed that education on the new meters should be provided in a primary care setting (such as a general practice or pharmacy) and that secondary care should not be involved in switching patients to the new meters unless a clinical opportunity arose. However, the nurse found that feedback from patients suggested that the quality of education provided by pharmacists was inadequate for many of her patients, which resulted in the need to use clinic time to reassure patients and explain the reasons for change. This was an opportunity cost, as this time could have been better used for clinical work. Similarly, a diabetes nurse specialist commented:

"Secondary care had many queries and patients 'popping in'. We were implementing the changeover and providing education about the new kits. The concern that this would occur was raised repeatedly before the changeover and our concerns were not taken seriously. The changeover resulted in increased workloads of already busy health professionals..."

There was a perception amongst some health professionals that PHARMAC had failed to appreciate the amount of time required to educate and support patients through the transition, particularly for more vulnerable patient groups. One key informant, a diabetes nurse educator who worked primarily with Māori consumers, noted that she spent up to three sessions per patient providing education on the new meter and felt that this was at the expense of providing broader information on diabetes management practices.

PHARMAC provided some compensation to health professionals for the time and effort taken to support the change. Pharmacists received brand switch payments per the Pharmacy Services Agreement, which recognises additional counselling required for switching patients between brands of certain medicines and devices⁶⁸, and from February to April 2013 payments were made to PHOs to distribute to general practices in recognition of the time taken for practices to undertake tasks such as contacting patients

⁶⁸ PHARMAC. Pharmacy brand switch payments. Available at <http://www.pharmac.health.nz/assets/pharmacy-claiming-brandswitch.pdf>

about the change. Other health professionals, such as diabetes nurses and educators, did not receive specific compensation for what was seen as a “huge piece of work”. Other diabetes nurse specialists said they would have been uncomfortable taking payments for one-on-ones because their health providers had existing contracts with the Ministry of Health. Several nurses believed protocols for the provision of additional funding to health organisations or alternative compensation schemes (i.e., less funding for general practitioners as many consumers do not visit a GP, and more funding to the specialists and nurses who provide the education) are needed for any future large-scale changeovers.

4.7.2.2 Impact on relationship with patients

Some health professionals believed that their relationships with patients were negatively impacted upon by the need to ‘front’ the change to CareSens meters. This appears to have been particularly prevalent amongst some diabetes specialist nurses and pharmacists. For example, one diabetes specialist nurse had a large number of patients reporting accuracy concerns related to the CareSens meters. The nurse contacted PHARMAC and was provided with reassurances that the meters had been tested and proven to be accurate, which the nurse then passed on to her patients. She reported that many of these patients continued to experience substantial variation in meter readings and did not trust her reassurances of accuracy as these conflicted with their experiences. The nurse was concerned that this had undermined her credibility with patients and contributed to a perception that she was not ‘on their side’.

Some pharmacists also felt their patient relationships had been damaged by PHARMAC’s funding decision. This appears to be primarily due to the fact that pharmacists’ role was to dispense and provide education on the meters, yet many consumers expected pharmacists to respond to concerns regarding the rationale for the change, or deal with patient reports of inconsistent meter readings. One pharmacist stated that she and her colleagues “*copped a lot of flak*” from patients and found it hard to say, “*No, I can’t help you, call the 0800 number.*” She considered the possibility that patient’s negative reactions towards her as a pharmacist may have been driven by the perception that pharmacists are “*just a part of PHARMAC*”, and so unduly blamed the pharmacy community for the decision despite the fact that pharmacists were not responsible for the change. Further, a pharmacy group spokesperson reported that pharmacists were wary of PHARMAC’s decisions, as they are generally the ones who must operationalise them. He went on to say that carrying out PHARMAC’s funding decision in this instance made many pharmacists feel like they were “*Pharmacops*”, in that they had to “*enforce*” the change in the face of consumer reluctance, which in turn made relationships with clientele challenging.

Clearer messaging to the public and pharmacists around pharmacists’ roles—what services they would and would not provide during the implementation—could have helped alleviate some of the difficulties pharmacists faced dealing with disgruntled or confused patients.

4.8 Impact of the decision on PHARMAC

This section describes the impacts that the change to CareSens meters had on PHARMAC and its staff, and suggests that a key impact involved the opportunity costs and staff stress associated with the change process.

4.8.1 Estimated cost savings of approximately \$10 million have been achieved

As noted in section 4.1, blood glucose meters and test strips represented a substantial cost to the Combined Pharmaceutical Budget, funded by DHBs and managed by PHARMAC. At the time of the funding proposal, PHARMAC reported that the Combined Pharmaceutical budget subsidised approximately \$22 million worth of diabetes test strips per year and approximately \$33 million worth of diabetes medicines.⁶⁹ Over the period during which CareSens are the only subsidised brand of meters, the estimated savings were estimated to total about \$10 million per year to the Combined Pharmaceutical budget. This was calculated based on the net present value (NPV) of the CareSens subsidy over five years at a discount rate of 8 percent to be paid by DHBs and the forecast demand, taking into account any effect of the decision on that demand, versus the status quo. Based on this, the CareSens proposal offered savings of \$20.56 million (3 Year NPV) over the period until July 2015.⁷⁰

The expected cost savings have been achieved. Figures provided by PHARMAC, displayed in table 9, show that the annual cost of blood glucose meters and test strips from 2010 to 2012 rose from just over \$21 million in the 2010 calendar year to just over \$23 million in 2012. In 2013, after the implementation of the change to CareSens meters, the annual cost dropped to just over \$14 million.

Table 9: Blood glucose meters and test strips annual costs 2010-2013

Year	Meter	Meter (50 lancets, lancing device, 10 test strips)	Blood glucose test strips	Blood glucose test strips x 50 and lancets x 5	Blood glucose test strips x 50 and lancets x 5	Total
2010	\$81,419	-	\$21,011,828	-	\$164,375	\$21,257,622
2011	\$73,685	-	\$21,906,668	\$94,498	\$18,533	\$22,093,384
2012	\$50,873	\$476,000	\$22,534,135	\$144,234	-	\$23,205,242
2013	-	\$1,009,680	\$13,092,531	\$4,102	-	\$14,106,314

The figures show that the total cost of meters and test strips rose by an average of 4 percent per annum. Assuming that a similar increase was likely in 2013, had the supplier arrangements not changed, it is estimated that the cost of meters and test strips would have totalled \$24,245,316. Based on this assumption, estimated savings of \$10,139,002 have been achieved in the 2013 calendar year.

⁶⁹ PHARMAC. Diabetes management products proposal: Why is PHARMAC making this proposal? Available at <http://www.pharmac.health.nz/medicines/your-health/diabetes/blood-glucose-meters-changes/diabetes-management-products-proposal>

⁷⁰ PHARMAC, 2013. Annual report for the year ended 30 June 2013. *Report presented to the House of Representatives*. Available at <http://www.pharmac.health.nz/assets/annual-report-2012-2013.pdf>

It was also reported that the savings are likely to last beyond the end of the single supplier period. This is due to the fact that the savings offered by CareSens have become the 'status quo' and once the agreement expires in 2015 other suppliers wishing to re-enter the market will need to be competitive on price and match, or offer further discounts to the status quo. Further discussion of ongoing market impacts is provided in section 4.9.

4.8.2 Direct implementation costs were slightly lower than expected

According to PHARMAC's website, the training, education and implementation of the change to CareSens meters was expected to incur a total one-off cost of approximately \$1 million.⁷¹ The total direct cost of implementation was slightly lower than this figure, with PHARMAC having spent a total of \$889,033.92 to the end of May 2014. This figure was achieved despite the extension of the consultation process and the addition of further implementation activities such as newspaper advertising. Expenditure included costs related to communications and advertising, education, PHO payments, and support mechanisms such as Meet Your Meter sessions and the community grants programme. The largest cost incurred was related to PHO payments, at just under \$306,000, with Meet Your Meter sessions another substantial cost at just over \$186,000.

There was acknowledgement amongst PHARMAC personnel that the funding could have been spent more efficiently had some of the transition difficulties experienced been identified and planned for earlier.⁷² As outlined in section 4.3.3, PHARMAC was responsive and adaptive in its implementation activities, but it is likely that the initiatives that were put in place were less efficient than they could have been. For example, the addition of public meetings to the consultation process was resource intensive, and due to these being added once consultation had commenced it was not possible to seek out cost effective venues, flight costs, etc. Despite these additional costs, the total expenditure on implementation was approximately 10 percent lower than budgeted for and the financial costs to PHARMAC appear reasonable.

4.8.3 Additional costs to PHARMAC included opportunity costs and staff stress

The implementation of the change to CareSens meters, particularly in the initial stages, required a large amount of PHARMAC staff time to be devoted to the project. According to a senior PHARMAC staff member, the implementation of the decision required a higher allocation of staff resources than initially expected due to factors such as the amount of additional work required to respond to reactions from the sector and the level of reporting requested (e.g., weekly reports to the Director-General of Health, regular media engagement). This meant that PHARMAC's internal resources had to be reallocated to the project, which resulted in some staff being unable to dedicate substantial time to other work, signifying an opportunity cost for PHARMAC. While it is difficult to quantify these opportunity costs, several illustrative examples were provided by PHARMAC personnel:

⁷¹ PHARMAC. Diabetes management products proposal: What are the costs of switching patients from one brand to another? Available at <http://www.pharmac.health.nz/medicines/your-health/diabetes/blood-glucose-meters-changes/diabetes-management-products-proposal>

⁷² 4 March, 2014. PHARMAC sense-making session with *Allen + Clarke*.

- one PHARMAC staff member reported that for a period of nearly 18 months they had primarily focused on diabetes, despite their role being intended to include other projects during the implementation process
- the large volumes of submissions received required another staff member to work long hours, and the staff member was not able to attend to other parts of their work programme
- senior managers held weekly steering group meetings throughout the implementation process. While these were short (between 15 – 30 minutes), the frequency of meeting (i.e., every week) mean that total time spent by senior staff over the implementation period was high.

The evaluation team also heard numerous examples of stress that PHARMAC staff experienced during the transition period. One staff member reported working at least six days per week for long hours during the consultation period, as PHARMAC was not prepared for how resource intensive the process would be. The staff member reported receiving over 300 emails per day, as well as letters and phone calls. Another staff member that they had experienced some stress in dealing with concerns raised by the health sector consumers in what was often a 'fraught' process.

During a 'sense-making' session with *Allen + Clarke*, PHARMAC acknowledged that the opportunity costs and staff stress could have been better managed. The attendees stated that PHARMAC has made several changes to its management and business processes, including the establishment of a separate email address for consumer and health professionals to provide feedback, meaning one staff member is not burdened with responding to all queries. It was also noted that the experience in implementing the CareSens change had provided lessons regarding the amount of resource (both in terms of time and financial resources) required to support such a change process, and that these lessons would be applied to future decisions. PHARMAC has already begun to make changes to better support change processes. In December 2013 a new Engagement and Implementation directorate was established. This was created in response to PHARMAC's expanded role to include the management of all hospital medicines and medical devices, and its development incorporated lessons from the change to blood glucose monitoring devices. The directorate takes a change management approach to implementation projects, assigning a designated project lead supported by a team of personnel from across the organisation, ensuring that adequate capacity and expertise is available to the project. Discussion with PHARMAC staff suggested that this approach has proven to be effective. For example, the recent implementation of changes to the brand and distribution of growth hormone (a potentially controversial change) was described as well managed with better clarity around roles and responsibilities.

4.9 Impact of the decision on the pharmaceutical market

This section considers the impact that the decision to move to a single supplier of blood glucose meters has had on the pharmaceutical market. The single supplier arrangement for CareSens meters has been in place for just over a year, and it is unlikely that any impacts on the pharmaceutical market will be apparent within this short timeframe. However, several potential impacts were raised by informants during the evaluation, which are discussed below.

4.9.1 Ongoing cost savings are likely in the blood glucose device market

As was stated in section 4.8.1, the move to a single supplier arrangement for blood glucose meters is likely to have ongoing impacts in reducing the cost of the meters, as it is possible that suppliers wishing to enter the market after the single supplier period ends may need to match the price offered by CareSens. During interviews with two pharmaceutical companies, for example, it was stated that PHARMAC *“would be looking for even more cost savings”* and that the single supplier agreement was likely to mean lower overall prices in this market.

Several informants believed that it was unlikely that PHARMAC would receive many bids once the single supplier arrangement with CareSens expired. One of the pharmaceutical companies interviewed stated that they would be unlikely to re-enter the market after the single supplier period had ended, as they had undertaken modelling on different scenarios and it looked *“unattractive”* to re-enter the market due to the high set up costs that would be required. Another company stated that they would consider putting in a bid, but would need to carefully consider whether it would be economic for them to provide meters at the price that PHARMAC was likely to seek. A scenario under which no alternative bids are received once the single supplier period ends presents two possibilities in relation to market impacts. There was a perception amongst some informants that the lack of competition may result in price rises, as the supplier could essentially charge whatever they wanted. On the other hand, PHARMAC informants suggested that, based on experience, a price becomes the new ‘status quo’ once it is established, and price rises are less likely even if a single supplier is dominant in the market. On balance, it appears likely that the cost savings achieved through the change to CareSens meters are likely to be retained.

It is also noted that the change may have wider impacts in the broader pharmaceutical market (i.e., in relation to other medicines or devices) by sending a message to suppliers that PHARMAC is willing to make a significant change in order to use public resources more efficiently. There was a perception amongst PHARMAC informants that the fact that the agency had gone through with the single supplier arrangement indicated it is not afraid to make the ‘big calls’: it was hoped that PHARMAC’s implementation of a single supplier agreement would therefore encourage suppliers to place more competitive bids for future single supplier procurements.

4.9.2 Risks to the supply chain and stock management appear to have been adequately mitigated

Some informants, including health professionals and representatives of consumer organisations, raised potential supply chain issues as a risk of moving to a single supplier arrangement. It was suggested that a single supplier agreement meant the supply chain would be vulnerable to disruptions, whereas multiple suppliers with multiple storage points could provide for continuity of supply. The Christchurch

earthquake was highlighted as an example of the type of event which could lead to these issues. If such an eventuality occurred, this would have a substantial, negative impact on users.

Evidence suggests that adequate mitigation strategies have been put in place to minimise this risk. Under the terms of its contract, Pharmaco is required to have four months' worth of stock. PHARMAC receives regular stock reports from Pharmaco which must include immediate notice if stock falls below four months' supply.⁷³ This means that PHARMAC would have a substantial notice period if stock shortages were likely to occur, and contingency plans could be activated meaning minimal disruption to the supply chain. The Pharmaco website lists further risk mitigation strategies, including that the meters are manufactured in three separate locations, with contingency back-up production in other countries. It also states that back-up stock is available from Australia and the USA, and the company has the ability to access urgent air shipments of stock if needed.

As was noted by PHARMAC personnel, single supplier arrangements may in fact provide greater certainty in terms of supply chain maintenance, as the agreement contains legal responsibilities in relation to supply which are greater than that expected under a dual or multiple supply agreement. In addition, the blood glucose devices market was previously dominated by one supplier yet did not experience any supply chain issues. Based on this evidence, we conclude that supply chain risks are adequately prepared for and it is unlikely that disruption of consumer access to meters will occur as a result of the single supplier agreement.

4.9.3 While the change has resulted in the withdrawal of market support from incumbent suppliers, alternative support activities have been implemented by CareSens

A further market impact discussed by several informants was the withdrawal of support systems provided by the incumbent suppliers of the meters. As noted previously in this report (see section 4.1.1), the dominant suppliers had invested substantial resources in creating and maintaining market share, which included the establishment of extensive support systems for clinicians. This included a team of representatives and clinicians who could provide advice to health professionals and a technical support enquiry line, as well as sponsorship of medical conferences and the provision of training on diabetes-related topics. The companies also provided consumer resources such as brochures, guides for using the software to download meter readings, and sponsorship of diabetes camps for children. However, it is noted that the provision of this support was made possible through the higher price paid for these meter brands and, therefore, was essentially provided through the use of taxpayer funds.

As part of the single supplier agreement, Pharmaco was required to set up a call centre, develop hard copy and website-based support resources, and to undertake visits to all healthcare providers.⁷⁴ Feedback from health professionals suggested that Pharmaco achieved good awareness of these support mechanisms, with largely positive feedback reported (see section 4.4.1).

⁷³ Diabetes Management Products Proposal. Available at: www.pharmac.health.nz/medicines/your-health/diabetes/blood-glucose-meters-changes/diabetes-management-products-proposal

⁷⁴ PHARMAC, Summary of consultation feedback.

4.9.4 The agreement with CareSens includes provisions for technological innovation

A final concern raised by evaluation participants related to the change to CareSens meters is the potential impact of a single supplier arrangement on innovation in the pharmaceutical devices market. Informants raised concerns that the lack of competition in the market would not incentivise technological innovation, and that New Zealand may miss out on advancement in meters such as Bluetooth and internet capability.

Evidence suggests that these concerns are unlikely to be realised. The single supplier agreement with Pharmac includes provisions for new meters to be introduced to the market and it was through this provision that the CareSens N POP meter was added to the agreement. During interviews with Pharmac personnel, the company outlined several projects currently underway to enhance meter technology, such as research into ways in which information technology could be used to enter meter readings directly onto clinicians' patient records.

In a related issue, concerns were raised that if further single supplier arrangements were introduced this may impact on the ability for New Zealand medical device companies to break into the international market. It was stated that selling product into the local market was a key mechanism for then moving to export of devices. If more single supplier arrangements are enacted, concerns were raised that New Zealand firms may find it more difficult to establish a market presence that could then be leveraged for export. It is difficult to determine the extent that this impact might be realised, as at this point no further single supplier arrangements have been introduced. However, the point is reported for PHARMAC's information.

Overall, despite several concerns being raised by informants, it appears likely that few negative market impacts will be observed through the change to CareSens. Further, the positive impacts of ongoing cost reductions to the pharmaceutical budget for blood glucose meters seem likely to extend beyond the conclusion of the single supplier period.

5 CONCLUSIONS AND RECOMMENDATIONS

The evaluation addressed four overarching themes related to the chronological progression of the funding decision. These evaluation themes focused on the (1) development of the decision, (2) effectiveness of the implementation, (3) transition to the new meters and strips and (4) impacts of the funding decision on consumers, health professionals, PHARMAC and the market.

This section sets out our conclusions related to each of these evaluation themes and provides a summary of the key evidence on which the conclusions are based. Each theme area also contains recommendations for PHARMAC's consideration to enhance the implementation of future funding decisions.

5.1.1 Development of the decision

PHARMAC followed its standard procedure (i.e., that used for medicines) during the decision making and procurement process. However, this was the first time a decision had been made to implement a single supplier arrangement for the funding of a medical device and its associated consumables, and as such the standard decision-making process used for pharmaceutical medicines did not adequately enable PHARMAC to anticipate and plan for the challenges associated with a single supplier of blood glucose meters. If issues such as the size of market change required and patient expectations regarding the functionality of the meters had been sufficiently identified and planned for, the implementation of the decision is likely to have been smoother. Further details are provided in table 10.

Table 10: Conclusions related to development of the decision

Evaluation criteria	Conclusions	Evidence
Effectiveness of analysis during supplier procurement	PHARMAC's analysis prior to and during procurement did not give adequate consideration to the scale of change that would be required under a single supplier arrangement.	<ul style="list-style-type: none"> CareSens II and POP meters represented only 2.5 percent of the total units distributed in 2010, while 83.1 percent of the units dispensed in the 2010 calendar year were Roche meters and 14.3 percent were Medica. Interviews with key informants suggested that the large-scale change which would be required if single or dual supply was awarded to a supplier other than the incumbent with the largest market share was not substantially considered by PHARMAC prior to issuing the RFP or when analysing supplier bids.
	PHARMAC undertook sufficient clinical testing to have confidence in the accuracy and performance of the CareSens meters.	<ul style="list-style-type: none"> Testing of the analytical performance of the CareSens meters was implemented in line with the protocols set out in PHARMAC's Guidelines for Funding Applications. All three CareSens models complied with the required standard, providing blood glucose readings within plus or minus 20 percent of a reference laboratory test.
	Consumer testing, which could	<ul style="list-style-type: none"> In line with their designated role, the Diabetes

Evaluation criteria	Conclusions	Evidence
	have helped PHARMAC to anticipate and mitigate some of the concerns that were subsequently raised about the meters' functionality, was not undertaken.	<p>Subcommittee of PTAC provided advice regarding the functionality of the meters from a clinical lens, and did not consider 'intangibles' such as patient attachment to meters.</p> <ul style="list-style-type: none"> • PHARMAC attempted to undertake consumer testing with Diabetes NZ, but did not approach another provider when this was unsuccessful.
Appropriateness and effectiveness of consultation	The purpose of consultation was misinterpreted by some patients and clinicians.	<ul style="list-style-type: none"> • The consultation document did not ask specific questions, and it was not clear to all consumers and clinicians what the consultation was intended to test. • This led to a perception amongst clinicians and consumers interviewed for the evaluation that the consultation was an exercise to determine whether or not to go ahead with a single supplier agreement. • In turn, this left some individuals feeling ignored when a single supplier arrangement was later implemented.
	PHARMAC responded appropriately to concerns raised during consultation.	<ul style="list-style-type: none"> • PHARMAC adapted the standard consultation approach by adding a series of public meetings when the high level of public interest became apparent. • The CareSens N POP meter was added to address functionality concerns and funded access to the Freestyle Optium meter to dual test for blood ketones and blood glucose was continued.

Based on the above findings, we conclude that the implementation of the change to the supply of blood glucose monitoring devices would have been smoother if small adjustments had been made to PHARMAC's standard decision making and procurement procedure, and as such we present the following recommendations for PHARMAC's consideration.

Recommendation one: develop criteria for determining whether a medical device change under consideration is likely to be a 'standard' or 'major' funding decision. This may include criteria such as:

- the size of the patient population that may be required to change
- the extent to which incumbent suppliers have strong brand loyalty
- the extent to which the device is directly marketed to patients and clinicians
- whether the device is patient-operated or clinician-operated
- the frequency of device use (i.e., is it used daily, weekly, infrequently?)
- whether the device is primarily used by certain groups, such as children or elderly people.

If application of the criteria indicates that the funding decision is likely to be ‘major’, we recommend that an initial registration of interest (ROI) is issued, which would allow for short listing and then more substantial analysis of a small number of full proposals.

Major funding decisions should also include consumer input, including:

- consumer-based field testing at an early stage in the procurement process to identify and mitigate functionality and usability issues
- establishment of a committee comprised of representatives from communities likely to be affected by the decision, to consider and prepare for non-clinical reactions to medical devices, including how the impact of these intangibles may affect specific consumer groups.

Recommendation two: clarify the purpose of future consultations in request for submission documents, and ask that submitters respond to specific questions in order to clarify what parts of a proposal are being consulted on.

Recommendation three: include and plan for face-to-face meetings as a core part of consultation for major changes. This will ensure that consumers groups, such as Māori and Pasifika, are able to contribute to the discussion through a format that is appropriate for these communities.

5.1.2 Effectiveness of the implementation of the decision

The evaluation found that PHARMAC developed a comprehensive implementation approach which outlined how messages on the change and the new meters would be provided to a range of different audiences. However, while PHARMAC carefully planned how it would disseminate information on how to access and use the meters, it does not seem to have undertaken substantial planning to support health professionals and consumers to navigate non-clinical challenges associated with the change. Information channels to health professionals were generally effective, but the information to consumers received mixed responses. Further details of our conclusions related to the effectiveness of implementation are provided in table 11.

Table 11: Conclusions related to the effectiveness of implementation

Evaluation criteria	Conclusions	Evidence
Effectiveness and appropriateness of planning for implementation	PHARMAC’s planning for implementation provided targeted information to consumers and health professional groups on how to access and to use the device.	<ul style="list-style-type: none"> • A comprehensive implementation plan was developed and provided to the PHARMAC Board on 29 June 2012. • The plan included the identification of a range of different groups, including diabetes patients, health professionals, consumer organisations, government partners and impacted government agencies, and media channels. • The plan articulated a strategy to ensure nurses, pharmacists and prescribers were able to educate their patients on the new meters, and a range of information channels to provide consumers with

Evaluation criteria	Conclusions	Evidence
		information on changes to, and use of, the funded meters.
	PHARMAC could have undertaken more planning to support health professionals and consumers to navigate non-clinical challenges associated with the change.	<ul style="list-style-type: none"> • PHARMAC had previously experienced changes from products with strong brand loyalty to other products (e.g., Ventolin to Salamol inhalers) and was aware that patients' assessment of the efficacy of the product appears to be influenced by factors such as different appearance and functionality. • The change to CareSens involved many of the 'trigger factors' that suggested implementation would be likely to be met with apprehension by consumers. • The implementation plan does not articulate any strategies to mitigate these non-clinical impacts.
	The time available for detailed planning for implementation was limited.	<ul style="list-style-type: none"> • Testing of the CareSens N POP meter took longer than expected and PHARMAC did not receive the report until late July 2012. • This left just over one month to plan for a listing date on the Pharmaceutical Schedule of 1 September 2012. • The detailed planning stage was therefore substantially shortened.
Effectiveness of information and communications channels	PHARMAC's information and communications ensured that health professionals were aware of the coming change to CareSens meters.	<ul style="list-style-type: none"> • Clinicians who responded to the survey highlighted advance notice of the change as a key positive aspect of the change. • Direct communication from PHARMAC and Pharmaco were the most common sources of information for health professionals.
	The effectiveness of communication to consumers was variable.	<ul style="list-style-type: none"> • The majority of focus group participants reported being unaware of the change until they approached their chemist for strip refills or on a visit to the doctor. • Key informant interviews and focus groups show that consumers who were members of these organisations were better informed about the changes than those who were not.
	PHARMAC was responsive and adaptive in its information and communications processes.	<ul style="list-style-type: none"> • PHARMAC responded to concerns that certain groups were not aware of the change by implementing targeted communications activities. • These included advertisements on Pacific radio, additional Meet Your Meter sessions, and funding for PHOs to directly contact patients. • A communications specialist was employed to

Evaluation criteria	Conclusions	Evidence
		midway through the implementation to support better information dissemination.
Effectiveness of education and support	Health professionals found short and easily accessible forms of education most effective.	<ul style="list-style-type: none"> While awareness of more comprehensive education resources such as Meet Your Meters sessions, BPAC resources and phone lines was high, actual use was low amongst survey respondents. Interviews with clinicians found a preference for easily accessible resources such as websites, leaflets and fact sheets.
	Some health professionals may not have adequately educated themselves on all three CareSens meter models.	<ul style="list-style-type: none"> Interviews with clinicians and consumer organisations found examples of clinicians having not educated themselves on all three meters, and dispensing primarily one model. Analysis of the rates of prescription of each meter model by pharmacists shows some variation in prescription patterns across DHB areas.
	The level and quality of support provided to consumers by health professionals was variable.	<ul style="list-style-type: none"> Focus group information found that some consumers received comprehensive education on how to use the meters, others had not received enough education on the meter to enable them to use it successfully.

We conclude that comprehensive planning for implementation, and using a range of communication and education channels, is vital in implementing a planning for a major change. Overall, PHARMAC's information and education channels were effective in ensuring that the majority of health professionals and the patient population were well prepared to make a successful transition. The following recommendations would assist in further enhancing the process.

Recommendation four: planning for implementation of major decisions should include a focus on identifying likely patient concerns and objections, providing key messages and resources to support health professionals to reassure consumers. This would complement the resources currently provided to not teach consumers to use the new device. Likely patient concerns could be identified through evidence from previous brand changes, field testing of the device, and engagement with affected groups.

Recommendation five: seek specialist advice and employ specialist communications personnel early in the planning stages to provide ensure effective communications with health professionals and consumers.

Recommendation six: support the development of a more formalised health system referral approach with multiple support pathways depending on need. This would involve an initial entry point for accessing the device and receiving basic education (such as through pharmacists), with those consumers who require further education and support being referred to additional resource and support layers. It is recommended that development of this approach could involve collaboration between PHARMAC and other health agencies to delineate various roles, responsibilities and activities in order to enable and

promote new or existing linkages within health system referral pathways (see also recommendation eight).

5.1.3 Transition to the new meters and strips

The transition process presented few problems for the majority of the over 100,000 patients who were required to change to CareSens meters. For a minority of consumers, however, the transition was a fraught process, largely due to perceptions of inaccuracy of readings provided by the CareSens meters. This is discussed in table 12.

Table 12: Conclusions related to the transition to the new meters and test strips

Evaluation criteria	Conclusions	Evidence
Effectiveness of the transition	The majority of consumers and health professionals transitioned without difficulty.	<ul style="list-style-type: none"> By 30 June 2013 a total of 97 percent of patients eligible for a subsidised meter were reported to have acquired CareSens meters. Health professionals reported that the transition had gone relatively smoothly overall. Most focus group participants had successfully transitioned to the new meter.
	Minor barriers to transition included the different functionality of the CareSens meters, brand loyalty and perceived lack of choice.	<ul style="list-style-type: none"> Difficulties associated with meter and test strip functionality were a reoccurring theme across the focus groups. Issues include difficulties with error term readings, problems downloading test results, reduced meter functionality in colder temperatures and various issues with strip storage and use. Interviews with health professionals and consumers revealed strong brand loyalty to the previous dominant supplier. Consumers and health professionals expressed annoyance that they were no longer able to choose from a range of meter brands but were now “forced” to use CareSens meters. These issues led to reluctance to change and some perceptions of inferiority related to the CareSens meters. Overall these issues were an annoyance or inconvenience for most consumers, and represented minor barriers to transition that were relatively easily overcome.

Evaluation criteria	Conclusions	Evidence
	Concerns related to the accuracy of CareSens meters was a key transition barrier for some patients.	<ul style="list-style-type: none"> The evaluation found numerous examples from both consumers and clinicians of the CareSens meters producing variable results, leading to a perception that the meters were inaccurate. This was exacerbated by users comparing readings derived from their CareSens meter with that of their previous model, with the assumption that the previous model was 'correct' and the CareSens reading was therefore 'wrong'. Clinical studies have not identified any evidence of accuracy problems in the CareSens meters. Evaluation findings suggest that various accuracy concerns have caused psychological distress in some consumers, acting as a barrier to use of the meters.

There is documented evidence to suggest that the transition from well known brands to similar products with a different brand name will be difficult for some patients, and that factors such as different appearance and functionality commonly lead to consumer perceptions of reduced efficacy of the product. To enhance the transition process, it is therefore important to provide support to help users overcome these barriers. Recommendation four (identifying likely patient concerns and planning how to support health professionals reassure patients) would assist in providing for a smoother transition.

Recommendation seven: undertake early planning and implementation of transition support activities targeted at patient groups likely to struggle with the transition. This would include initiating successful schemes, such as the community support grants programme, when the product is first listed rather than in the later stages of transition. This should be accompanied by increased publicity of the availability of the support initiatives.

5.1.4 Impacts of the funding decision on consumers, health professionals and the market

The funding decision concerning CareSens meters and consumables has had a range of impacts. For consumers, these included positive impacts in terms of enhanced diabetes management and negative impacts such as stress. Various impacts were also observed on health professionals, PHARMAC and the pharmaceutical market. These are discussed in table 13.

Table 13: Conclusions related to the impacts of the change to CareSens

Evaluation criteria	Conclusions	Evidence
Impacts on consumers	The opportunity to interact with the health system during the change to CareSens enabled some consumers to improve the management and monitoring of their illness.	<ul style="list-style-type: none"> Some focus group participants reported receiving advice on diabetes management as part of their education on the CareSens meters, including advice on diet, meal timings, and exercise regimes. Other focus group participants realised their testing practices were incorrect after having received education on the new meters, and have made

Evaluation criteria	Conclusions	Evidence
	<p>Some consumers experienced negative impacts such as stress.</p>	<p>changes.</p> <ul style="list-style-type: none"> • Consumers and health professionals reported that concerns over the accuracy or validity of the meters had resulted in significant stress and insecurity for patients and their families. • Type 1 diabetics (including adults, children/youth, and caregivers of children) experienced greater levels of stress, anxiety and distrust of the CareSens meters related to perceived meter inaccuracies. • Some consumers have changed their diabetes monitoring practices, such as through more frequent testing. Others have made lifestyle changes such as no longer driving.
Impacts on health professionals	<p>The change to CareSens meters provided an opportunity for health professionals to improve their patients' diabetes management.</p>	<ul style="list-style-type: none"> • 70 percent of survey respondents reported having used the change to discuss issues around some clients' diabetes management, 65 percent used the change to help some patients improve their testing technique, and 62 percent advised their patients to test more appropriately.
	<p>Some health professionals experienced opportunity costs and damage to their relationships with patients.</p>	<ul style="list-style-type: none"> • The survey and key informant interviews found reported opportunity costs, such as the need to use clinic time to reassure patients and explain the reasons for change at the expense of clinical work. • Some health professionals reported that their relationships with patients were negatively impacted by the need to 'front' the change to CareSens meters, which was unpopular with many patients.
Impacts on PHARMAC	<p>The expected cost savings to the Combined Pharmaceutical Budget have been achieved</p>	<ul style="list-style-type: none"> • Figures provided by PHARMAC show that the annual cost of blood glucose meters dropped from \$23 million in 2012 to \$14 million in 2014 • Based on an average annual increase of 4 percent, it is estimated that savings of just over \$10 million have been achieved in the 2013 calendar year
	<p>The direct costs of implementing the change were lower than expected</p>	<ul style="list-style-type: none"> • The training, education and implementation of the change to CareSens meters was expected to incur a total one-off cost of approximately \$1 million. • Figures provided by PHARMAC show a total of \$889,033.92 was spent to the end of May 2014

Evaluation criteria	Conclusions	Evidence
	The change to CareSens resulted in some opportunity costs and staff stress.	<ul style="list-style-type: none"> The resource costs of implementing the decision were higher than expected due to the amount of additional work required to respond to reactions from the sector. This resulted in some staff being unable to dedicate time to other work, signifying an opportunity cost for PHARMAC. Numerous examples were reported of stress that PHARMAC staff experienced during the transition period, including long hours and stress in dealing with concerns raised by the health sector consumers in what was often a 'fraught' process.
Impacts on the pharmaceutical market	Ongoing cost savings in the blood glucose device market are likely.	<ul style="list-style-type: none"> The savings offered by CareSens have become the 'status quo' price for blood glucose meters and strips. In the future, other suppliers may need to be competitive on price and match or offer further discounts to the status quo.
	Risks to the supply chain and stock management appear to have been adequately mitigated.	<ul style="list-style-type: none"> Pharmaco is required to have four months' worth of stock. PHARMAC receives regular stock reports from Pharmaco which must include immediate notice if stock falls below four months' supply. PHARMAC would have substantial notice if stock shortages were likely to occur, and contingency plans could be activated meaning minimal disruption to the supply chain.
	The agreement with CareSens includes provisions for technological innovation.	<ul style="list-style-type: none"> The single supplier agreement with Pharmaco includes provisions for new meters to be introduced to the market and it was through this provision that the CareSens N POP meter was added to the agreement. During interviews with Pharmaco personnel, the company outlined several projects currently underway to enhance meter technology.

A few small adjustments could be made to the implementation of future changes to medical devices to enhance positive impacts and mitigate negative ones. Recommendations already provided, such as undertaking field testing of products, early engagement with consumers, and targeted support activities would help to reduce negative impacts for health professionals, consumers and PHARMAC. .

Recommendation eight: work with other health agencies to identify and promote activities to target the broader contextual and behavioural factors influencing condition management. This could include discussions with national organisations, including both government entities and NGOs, to identify

relevant programmes or interventions that could be promoted during the implementation of the change to enhance patient education and self-management strategies.

APPENDIX A: DETAILED EVALUATION QUESTIONS

The overarching themes that the evaluation addressed included (1) development of the decision, (2) effectiveness of implementation, (3) the transition to new blood glucose meters and test strips and (4) the impacts of the funding decision on consumers, health professionals, PHARMAC and the pharmaceutical market. The table below presents the specific evaluation questions under each of these themes.

Table 14: Detailed evaluation questions

Theme	Evaluation questions
Development of the decision	<ul style="list-style-type: none"> • What processes did PHARMAC undertake to make the decision? How effective were these? • To what extent were the potential risks and benefits of the decision considered? • How was the supplier (i.e., Pharmaco) selected? Was this appropriate? • How were stakeholders engaged with during the decision making process? • To what extent was stakeholder feedback considered in the final decision?
Effectiveness of implementation	<ul style="list-style-type: none"> • What activities did PHARMAC undertake to support the implementation of the decision? • How effective were these activities in reaching the target groups? • Was the timeframe for implementation appropriate? • How effective was the overall implementation of the decision?
Transition to the new meters	<ul style="list-style-type: none"> • How effective was the transition process for the various target groups? • To what extent did the target groups transition to and use the new meters? • Who did not take up the new meters? Why?
Impact on consumers	<ul style="list-style-type: none"> • What impacts has the decision had on patients (excluding clinical impacts)? • Have there been any unexpected impacts? • Have there been any disproportionate impacts on particular groups of consumers (e.g., elderly, low socio-economic groups, non-English speaking people, those with Type I or Type II diabetes)?
Impact on health professionals	<ul style="list-style-type: none"> • What impacts has the decision had on health professionals?
Impact on PHARMAC	<ul style="list-style-type: none"> • What were the costs to PHARMAC related to the implementation of the decision? • Were there any unexpected costs? • What benefits or efficiencies has PHARMAC gained as a result of the implementation of the decision? • Were there any inefficiencies or opportunity costs?

	<ul style="list-style-type: none"> • To what extent are further efficiencies expected in the future? • What other impacts has the decision had on PHARMAC?
Impact on pharmaceutical market	<ul style="list-style-type: none"> • What impacts has the decision had on the market and environment of pharmaceutical supply? • What impacts has the decision had on supply-chain management? • Have there been any unexpected impacts?
Overarching questions	<ul style="list-style-type: none"> • What has worked well with the implementation of the decision and what has not? • Are there any unintended or unexpected effects occurring as a result of the decision? • What are the key 'lessons learned' for PHARMAC's future decision making?

APPENDIX B: ONLINE SURVEY

Diabetes Glucose Meters/Test Strips Survey



PHARMAC has appointed Allen + Clarke to evaluate the implementation of a funding decision that resulted in a change in brand of the PHARMAC subsidised blood glucose meters and test strips.

The purpose of the evaluation is to assess the implementation of the decision. As part of this, the evaluation examines:

- implementation of the decision
- the impact on service providers, patients and the pharmaceutical market and supply chain
- overall costs and benefits of the decision.

We would be grateful if you could answer some questions based on your experience of the changes to the funding and supply of the meters and test strips. Please note that the survey questions look at how PHARMAC implemented the change to CareSens diabetes meters and test strips. It does not consider the decision itself or clinical impacts of the change.

Please complete the survey by 14 February 2014. It will take no longer than 10 minutes to complete.

Your responses will be grouped with others who complete the survey so that individual responses cannot be identified. Your participation in this survey is completely voluntary.

To complete the survey, please select the options that best describe your experience, and provide any comments in the boxes provided. Your answers will be saved automatically once you have finished.

All completed surveys will go into a draw for a \$200 grocery voucher.

If you have any questions about the survey please contact Marnie Carter on 04 890 7322 or email mcarter@allenandclarke.co.nz.

Diabetes Glucose Meters/Test Strips Survey



Section A: Implementation of PHARMAC's funding decision

1. What specific role(s) did you play in the change to CareSens meters and strips? Please tick all that apply.

- ☐ Prescribed the new meter and/or test strips
- ☐ Dispensed the new meter and/or test strips
- ☐ Gave out new meters/strips without prescription
- ☐ Taught individual patients/parents/caregivers how to use new meters
- ☐ Taught groups of patients/parents/caregivers how to use new meters
- ☐ Referred individuals to resources about new meters (e.g., brochures, phone line, website)
- ☐ Discussed meter results with individuals
- ☐ Discussed accuracy of new meters with individuals
- ☐ Talked with, advised or sought advice from another health practitioner
- ☐ Ordered meters/strips from wholesaler
- ☐ Had direct engagement with Pharmaco (suppliers of CareSens) about meters/strips

Other (please specify)

2. Please indicate which of the following information sources that you saw on the change to CareSens meters and strips.

- ☐ Direct communication from PHARMAC (e.g., e-mails, phone, letters, Pharmaceutical Schedule)
- ☐ Direct communication from Pharmaco (suppliers of CareSens)
- ☐ Direct communication from suppliers of other meters (Roche, Medica/Abbott)
- ☐ Direct communication from the PHO, hospital, clinical team, etc. with which you work
- ☐ Notices in professional publications (e.g., NZ Doctor, Pharmacy Today, Nursing Journal)
- ☐ Newsletter (e.g., from professional, special interest or patient groups)
- ☐ Media coverage (e.g., television, radio, newspaper, internet news site)
- ☐ Pharmac website: www.pharmac.health.nz
- ☐ CareSens website: www.caresens.co.nz
- ☐ From patient
- ☐ Don't know

3. How would you rate the information you saw about the change to CareSens meters and strips?

	Excellent	Good	Average	Poor	Very poor
Direct communication from PHARMAC (e.g., e-mails, phone, letters, Pharmaceutical Schedule)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Direct communication from Pharmaco (suppliers of CareSens)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Direct communication from suppliers of other meters (Roche, Medica/Abbott)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Direct communication from the PHO, hospital, clinical team, etc. with which you work	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Notices in professional publications (e.g., NZ Doctor, Pharmacy Today, Nursing Journal)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Newsletter (e.g., from professional, special interest or patient groups)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Media coverage (e.g., television, radio, newspaper, internet news site)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmac website: www.pharmac.health.nz	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
CareSens website: www.caresens.co.nz	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
From patient	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify below and rate the information source here)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other:

4. Please indicate which of the following educational and support resources you were aware of and/or used.

	Aware of	Used
The Goodfellow online learning resources	<input type="checkbox"/>	<input type="checkbox"/>
The Caresens website	<input type="checkbox"/>	<input type="checkbox"/>
The PHARMAC website	<input type="checkbox"/>	<input type="checkbox"/>
Visit from Pharmaco (Caresens) Rep	<input type="checkbox"/>	<input type="checkbox"/>
BPAC resources	<input type="checkbox"/>	<input type="checkbox"/>
Meet Your Meter events	<input type="checkbox"/>	<input type="checkbox"/>
Patient leaflets (hardcopy)	<input type="checkbox"/>	<input type="checkbox"/>
Patient factsheets (for download)	<input type="checkbox"/>	<input type="checkbox"/>
Pharmaco free phone line for professionals (0508 CARESENS)	<input type="checkbox"/>	<input type="checkbox"/>
PHARMAC free phone line (0800 660 050)	<input type="checkbox"/>	<input type="checkbox"/>
Pharmaco free phone line for patients (0800 GLUCOSE)	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify below)	<input type="checkbox"/>	<input type="checkbox"/>

Other:

5. How would you rate the educational and/or support resources you used?

	Excellent	Good	Average	Poor	Very poor
The Goodfellow online learning resources	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The Caresens website	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The PHARMAC website	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Visit from Pharmaco (Caresens) Rep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
BPAC resources	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Meet Your Meter events	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient leaflets (hardcopy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient factsheets (for download)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmaco free phone line for professionals (0508 CARESENS)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
PHARMAC free phone line (0800 660 050)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmaco free phone line for patients (0800 GLUCOSE)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify below and rate the resource here)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other:

Diabetes Glucose Meters/Test Strips Survey



Section B: Transition to and use of meters and test strips

6. Overall, given your experience, how do you think each of the following patient groups transitioned to the new meters?

	No difficulty	Some difficulty	Significant difficulty	Don't know	Not applicable
Patients with Type 1 diabetes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients with Type 2 diabetes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Children	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Elderly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Māori patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pasifika patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients with English as a second language	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other:

7. Did you use the change to CareSens meters and strips as an opportunity to discuss your patients' use of blood glucose monitoring?

- ☐ I advised some patients to stop testing
- ☐ I advised some patients to test more appropriately
- ☐ I helped some patients improve their testing technique
- ☐ I used the change to discuss issues around some patients' diabetes management
- ☐ I used the change to discuss broader issues around some patients' health
- ☐ Other (please specify below)

Other:

8. In your opinion, what went well with the implementation of changes to the subsidised brand of test meters and strips?

9. What would you have liked to have seen improved with the implementation of changes to the subsidised brand of test meters and strips?

Diabetes Glucose Meters/Test Strips Survey



Section C: You and your organisation

10. What sort of health practitioner are you?

- ☐ Doctor
- ☐ Nurse
- ☐ Pharmacist

Other (please specify):

11. Do you mainly work with people with diabetes?

- ☐ Yes
- ☐ No

12. Which of the following options describes your main workplace?

- ☐ General medical practice
- ☐ Other community-based general health service
- ☐ Hospital-based service
- ☐ Kaupapa Māori Service
- ☐ Pacific Island Service
- ☐ Specialist diabetes service
- ☐ Community pharmacy
- ☐ Hospital pharmacy

Other (please specify):

13. Around 5% of the New Zealand population (225,000 individuals) has been diagnosed with diabetes. Within your organisation do you generally see:

- ☐ A higher percentage of diabetes patients compared to the national average
- ☐ A lower percentage of diabetes patients compared to the national average
- ☐ An equal percentage of diabetes patients compared to the national average
- ☐ Don't know

14. From the 5% of the population diagnosed with diabetes, 10% (22,500 individuals) has been diagnosed with type 1 diabetes. Compared to this national average, do you generally see:

- ☐ A higher percentage of type 1 diabetes patients
- ☐ A lower percentage of type 1 diabetes patients
- ☐ An equal percentage of type 1 diabetes patients
- ☐ Don't know

15. Which DHB region is your practice/clinic/pharmacy located in?

- ☐ Northland
- ☐ Waitemata
- ☐ Auckland
- ☐ Counties Manukau
- ☐ Waikato
- ☐ Lakes
- ☐ Bay of Plenty
- ☐ Tairāwhiti
- ☐ Taranaki
- ☐ Hawke's Bay
- ☐ Whanganui
- ☐ MidCentral
- ☐ Hutt Valley
- ☐ Capital and Coast
- ☐ Wairarapa
- ☐ Nelson Marlborough
- ☐ West Coast
- ☐ Canterbury
- ☐ South Canterbury
- ☐ Southern

Diabetes Glucose Meters/Test Strips Survey



16. Thank you for completing the survey. If you would like to enter the draw for a \$200 grocery voucher please enter your email address below.

We will email you only if you have won the voucher. Your email address will not be saved or used for any other purpose.

APPENDIX C: TIMELINE OF KEY EVENTS

3 March 2011: Diabetes subcommittee of Pharmacology and Therapeutics Advisory Committee (PTAC) meeting held and included discussion of diabetes test meters and test strip review.

26 August 2011: PHARMAC released a request for proposals for the supply of diabetes management products, including blood glucose meters and test strips to see whether we could achieve better value for money. Offers for sole, dual and multiple supply were sought.

20 October 2011: Request for proposals closes.

8 December 2011: Diabetes subcommittee of Pharmacology and Therapeutics Advisory Committee (PTAC) meeting held and included discussion of RFP for blood glucose strips and meters.

23 February 2012: Consultation letter is circulated to all parties that in the view of PHARMAC may be affected by the decision. The consultation process involved public meetings in Auckland, Porirua, Wellington and Christchurch.

14 March 2012: Consultation closes.

15 March 2012: [Media release](#) is published announcing close of submission process and receipt of 3000 submissions.

April 2012: Paper provided to PHARMAC Board detailing consultation process.

15 May 2012: Diabetes Working Group Meeting.

2 – 4 May 2012: NZSSD conference. PHARMAC sponsored and attended.

25-27 May 2012: Diabetes New Zealand conference. PHARMAC sponsored and spoke at the conference.

29 June 2012: PHARMAC Board resolves to approve the 13 June 2012 agreement with Pharmaco NZ Ltd.

8 August 2012: PHARMAC publishes public notification that the proposal relating to sole supply of blood glucose meters and test strips has been approved. Media conference is held (including representatives of PHARMACo and NZ Medical & Scientific) to announce the funding for blood glucose meters & strips and insulin pumps. New page on the PHARMAC website, with information about the CareSens meters and test strips, goes live.

The most significant changes made to the proposal as a result of the consultation were:

- The introduction of a high-tech meter, called CareSens N POP. The N POP meter includes increased memory, backlighting for night-time use, averages and other advanced functions sought by consumers in consultation.
- Patients who were using an Accu-Chek Performa meter with an Accu-Chek Combo insulin pump prior to 1 June 2012 will be eligible for funded Accu-chek test strips for the next 5 years.

- Patients who were using a Freestyle Optium as their only meter for both blood glucose and ketone testing prior to 1 June 2012 will be eligible for continued funding of the Optium blood glucose test strip for the next 5 years.

1 September 2012: PHARMAC begins funding CareSens N and CareSens N POP meters and continues to fund the CareSens II meter. Funding for other meters and strips (FreeStyle Lite, On Call Advanced, Freestyle Optium, Accu-Chek Performa) continues. Patients can begin transition to CareSens brand meters.

4 September 2012: Diabetes Working Group Meeting (notes attached to email).

November 2012 –February 2013: *Meet your Meter* sessions are held. PHARMAC provides information to all pharmacies and GP surgeries about the events about a month before they are held in the area.

29 November 2012: Media release is published reminding people with diabetes about the changes and about the *Meet Your Meter* sessions.

1 December 2012: Only CareSens meters funded, test strips for all other meters still funded.

6 December 2012: PHARMAC reported that in response to complaints about incorrect meter readings they had updated their website in consultation with Diabetes NZ and diabetes specialists to provide information about the variance of readings.

December 2012: PHARMAC starts the 'small grants scheme' for Māori, Pacific and consumer organisations, providing financial assistance to organisations to provide support to consumers changing to a CareSens meter.

17 December 2012: Reporting to DG office on PHARMAC's revised implementation approach.

13-20 December 2012: PHARMAC meets with Diabetes NZ and seeks views from NZSSD (clinicians group).

31 January 2013: PHARMAC is developing protocol for writing to individual patients who have not switched meters.

10 February 2013: Nationwide advertising begins.

10-24 February 2013: Nationwide radio advertisements run.

15-16 February 2013: Newspaper advertisements run.

18-19 February 2013: A detailed information sheet goes to all GPs through BPAC's *Best Tests* magazine (4,500 copies), and patient brochures are also distributed to all practices.

28 February 2013: Approach for achieving direct contact with patients who have not yet switched meters is finalised (details in the 28/2/2013 Weekly report to DG).

1 March 2013: Only CareSens test strips funded.

1 March 2013: PHARMAC established a targeted transition programme for patients struggling to make the change to the CareSens meters.

7-14 March 2013: PHARMAC has approved 12 small grants. The grants are largely to local diabetes groups and Māori and Pacific health providers, to support activities targeting their communities.

8 March 2013: Letter, contract and resource kit dispatched from PHARMAC to PHOs for direct communication by general practice to patients who have not yet changed. PHARMAC wrote to all PHOs detailing the initiative and requesting a “yes or no” response by Monday 18 March.

9 March 2013: PHARMAC has presence at the Creek Fest health festival in Canons Creek.

13 - 16 March 2013: PHARMAC has presence at Polyfest in Auckland.

18 March 2013: PHARMAC provides a written briefing on the CareSens switch to the National Diabetes Service Improvement Group. This information was provided via NZSSD Chair Dr Paul Drury.

6 May 2012: PHARMAC provides a written update on the CareSens switch to the New Zealand Society for the Study of Diabetes (NZSSD) and the Diabetes Nurse Specialty Section of the New Zealand Nurses Organisation in time for their conference/AGM. This information was provided via NZSSD Chair Dr Paul Drury.

8 – 10 May 2013: NZSSD Conference. PHARMAC sponsored and attended.

June 2013: Article on meter comparisons appeared in *Best Practice Journal* (BPJ).

6 June 2013: It is reported that 28 of the 25 PHOs have directly contacted patients.

25 July 2013: PHARMAC considers it has completed the major implementation of the CareSens meters, and is now in a monitoring and support stage where activities are focussed on supporting individual patients, continuing to monitor stock levels, monitoring 0800 number calls, monitoring meter returns and incident reports, and responding to media queries.

2 August 2013: PHARMAC publishes media release announcing that 100,000 people have picked up their new meters and the CEO is quoted as saying “the change process is now complete...”

21 August 2013: PHARMAC provides a written briefing on the CareSens switch to the National Diabetes Service Improvement Group. This information was provided via NZSSD Chair Dr Paul Drury.

4 September 2013: Diabetes Christchurch hosts a public forum with Pharmaco and PHARMAC.

20 – 22 September 2013: Diabetes New Zealand conference. PHARMAC sponsored and had a trade stand.