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Transitioning to a National (New Zealand) Sole Supply Scheme for Glucose Meters: Lessons Learned, Problems Yet to Be Solved

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Abstract

This case study describes the clinical impact of moving to a single brand of glucose test strips. In 2013 the New Zealand public health system completed a move to procure test strips at a significant discount. The associated direct savings is estimated at around 40% of the total glucose strip budget. Half the local diabetes population undertake glucose monitoring using government-funded diabetes supplies. These patients no longer have a choice of brand of meters and strips. Although the majority of patients adapted well to this change, a small percentage did not. Also, some consumers expressed concerns about analytical performance of the new strips, when used in everyday life. A pragmatic postmarketing surveillance system, designed with consumer input, may help address these residual concerns.

Keywords

glucose monitoring, diabetes self management, health economics, organizational case studies, health technology assessment

Internationally, there is a move to reduce the costs to health care funders of glucose test strips.[1,2] This usually necessitates a change in, or restrictions around, strip provider(s). This may in turn require the consumer to change their meter/strip system. We describe a case study from New Zealand of the impact of such a change.

New Zealand is a remote country of over 4 million inhabitants, of whom around 220 000 have known diabetes and an estimated 10% of those with diabetes have type 1 diabetes. New Zealanders enjoy a relatively high standard of health, with the public health dollar funding the majority of health care consumables such as blood glucose monitoring test strips, thus strips are available at no or minimal cost to patients with diabetes. Over the past couple of years the publically funded health system has transitioned from offering 6 funded glucose meters manufactured by 4 international companies,[3] to a single supplier arrangement with 1 manufacturer supplying their range of meters and test strips through a local distributor.[4] The sole-supply tender was awarded to 1 of these 4 international companies; however prior to 2012 this company had only a small segment of the New Zealand meter/strip market. From March 1, 2013, patients wanting subsidized strips were only able to access these "new" strips (with occasional exceptions in special patient circumstances). The primary driver for this change is saving on publically funded strip purchase costs so that money can be more prudently spent elsewhere in health, for example on increasing access to publically funded insulin pumps.[2] The rationale for this local change therefore mirrors similar initiatives already underway in several other countries.[3,4]

A total of 116 000 new meters have currently been dispensed to patients. Although data from patients and health care providers about the New Zealand glucose meter changeover have yet to be collected in a systematic, scientifically rigorous format, there is sufficient anecdotal evidence, including evidence from posts on social media sites,[5,6] to start to piece together a picture of how this changeover went from the perspectives of both clinicians and patients. For the majority of patients the changeover was seen as a mild inconvenience or even of benefit, as it offered a chance to change from a meter that might be many years old, to one that was less bulky, was quicker to use, and required a lower volume of blood. However, for a minority of patients the change was problematic; it generated frustration, anger, and a loss of confidence in self-management skills. A few patients have elected to continue using their "old" meter and self-fund their test strips. What were the sources of these perceived problems?

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A Minority of Consumers Experienced Problems When Access Was Restricted to a Single Brand of Meter

Some problems with changeover to a single meter brand were easy to anticipate. Patients with poor eyesight or reduced dexterity often find that one meter system is easier to use than others and their preferred meter system may not be the "new" one. Also patients living in cooler parts of the country often prefer a meter with a functional temperature range that includes the ability to read at low temperatures, however the new meter system currently reads down to 10°C. Strip fill functionality varies between brands of strips.[7] Some patients have struggled with the technical requirements of the new system, often experiencing error messages. Less predictable problems that were encountered are described below.

A small number of patients reported intermittent highly variable test results despite being able to demonstrate good meter testing technique to their clinicians, suggesting intermittent suboptimal strip performance that was independent of strip batch number. Unfortunately the cause of this problem has proved elusive to standard clinical trouble shooting techniques. Another unforeseen problem related to the interpretation of paired, parallel testing using patients' "old" and "new" meter system. Many patients undertook parallel testing under their own initiative, often in response to adverse media coverage about the accuracy of their "new" meter. They frequently shared these findings with health professionals. One such observation was of a small positive systematic bias with the "new" meter compared to the "old" meter. This observation led to a formal comparison of the "new" meter with the "old" meter. This confirmed that there was an additive impact of a small negative bias from the "old" meter, together with a small positive bias from the "new" meter.[8]

Another unexpected observation which was disturbing to educators (or at least disturbing to these authors in their roles as clinicians and educators) was that many patients believed their "old" meter gave accurate ("true") results and any discrepancy between the "old" and "new" meter pointed to an inaccurate reading from the "new" meter. The perception that the new meter "read wrong" was psychologically very distressing for many patients. This psychological distress was only partly alleviated and in some cases even exacerbated, after explaining that neither meter system was 100% accurate or precise! The statistical concepts behind error of measurement seem not to be well understood by many. Also, cognitive biases such as anchoring effect,[9] were observed; patients believed that the familiar results from their "old" meter were somehow more "real" than those from the "new" meter. This finding was not confined to those with lower education attainment, a feature which is in keeping with the literature on numeric cognitive biases.[9] In our clinic we have therefore sometimes had difficulty building on prior "commonsense" knowledge around error of measurement, when explaining why glucose tests done on an identical blood sample but using 2 different meters, will usually give 2 different results. ("Doctor, you still haven't explained to me which of these 2 glucose test results from my 2 different brands of meter, is the correct one.")

Managing Meter/Strip Changeover

Multiple steps were put in place, both by the relevant government funding agency and by the meter distributor, to mitigate anticipated difficulties associated with this transition. These included supporting pharmacists, primary care teams, and diabetes consumer organizations at the front line of the meter changeover scheme.[10] Additional resources included workshops, a website presence, and a transitional supply scheme that allowed those patients struggling with the transition to obtain a short-term funded supply of their "old" meter test strips. Thus the resources required to manage this transition and also the additional indirect costs associated with the extra time and support these patients needed outside the government-funded support schemes, was not insubstantial.

Additional Hidden "Costs," Including Changing Over Meter Download Software Systems

The costs, both direct and indirect, of learning and adapting to a new meter download software system have also been difficult to quantify. In our own clinic, meter transition has meant a move away from an internally networked meter upload system, whereby patients coming in to the general diabetes clinic or antenatal diabetes clinic had a meter upload that could then be viewed anywhere within the hospital, to a non-networked and therefore clumsier information technology solution, resulting in disruption to clinic workflow.

An additional cost that is difficult to quantify is the psychological burden ("cost") the changeover placed on some patients and also indirectly, on their carers and health professionals.

Did Meter Changeover Lead to an Increase in Hypoglycemic Events?

Perhaps inevitably, anecdotal reports emerged linking meter changeover with hypoglycemic events and related adverse outcomes. The relationship (causal or otherwise) between changes in diabetes management and hypoglycemic events has historically been difficult to untangle. Diabetologists with long memories may remember the change from porcine to synthetic human insulin that occurred in the 1980s and 1990s. The United Kingdom in particular encountered problems of perceived causality between the changeover of insulin and an increase in hypoglycemic events.[11] This perception

did not seem to occur in countries that undertook a slower, managed changeover of insulin.[12]

Postmarketing Surveillance—What Do Consumers Want?

Postmarketing surveillance of FDA/EC approved/accredited glucose meters is approached differently in different countries. In New Zealand, the main objective of commissioned meter studies has been to build on international peer review publications when available and also on reports prepared for regulatory authorities, to ensure that newly introduced meters demonstrate no major systematic bias compared to venous plasma glucose. This related to a problem with systematic positive bias associated with the algorithm for converting the electrochemical signal to a glucose value, detected with 1 well-known brand of meter available in New Zealand around 6 years ago. This led to the local recall of over 12 000 meters. During the first 5 months of changeover (March to August 2013), 53 adverse events were documented by the authority that monitors devices in New Zealand,[10] a figure that is broadly comparable on a population basis to events registered with the FDA.

Do we know what consumers want from their postmarketing glucose meter surveillance system? Comments made directly to us and also those made by local patients in social media, reflect a desire for more pragmatically designed, "real-world" postmarketing surveillance studies. This local view mirrors comments made at recent international meetings. The Diabetes Technology Society, SKUP (Scandinavian Evaluation of Laboratory Equipment for Primary Health Care) and NOKLUS (Norwegian Quality Improvement of Primary Care Laboratories) are to be congratulated both for leading the way with these discussions and for developing validated real-world meter testing protocols.[13] Many of our patients and their significant others have however requested that postmarketing surveillance is even more firmly embedded in the real world. For example, how do we ensure that a substantial proportion of tests are within the critical glucose range of <80mg/dL without manipulating samples or using samples from nondiabetic participants? How do we design validation studies that allow for patient participation within their usual environment (home, work), rather than undertaking validation in an air-conditioned research clinic environment? How do we ensure that those patients participating in postmarketing surveillance studies represent those most likely to be at risk (both physically but also psychologically) from poorly performing meter/strip systems? Perhaps we need to canvas our consumers more widely about ideas for undertaking "real-world" yet scientifically valid meter studies, within a realistic budgetary envelope.

Most meter/strip manufacturing companies sell their products to multiple countries, thus the sharing of postmarketing information across national borders is commonplace. Do consumers have a role in surveillance that complements that of more structured scientific testing and regulatory monitoring? Our own experience outlined above would suggest yes, they do. Widespread use of social media will only increase the trend for consumers to swap their glucose meter stories. This will sometimes lead to early identification of problems with products, yet it also carries the potential for creating false alarms, in situations where there is in fact no objective problem with strip performance.

"Choice Is Good"—But Is Choice an Expensive Cultural Construct?

The switch to a sole supply arrangement "forced" change on patients who had previously been used to choice. The psychological impact of restricting choice has a cultural component, with some cultures perceiving a greater need for choice, than others.[14] The difficulties experienced in New Zealand around meter changeover may therefore be context dependent.[14] There are however likely to be sufficient cultural and clinical similarities between New Zealand and other developed countries, for some of the stories mentioned above to play out in a similar way elsewhere.

Conclusion

Our own country's recent experience suggests that transitioning from a scenario of consumers being able to choose from a modest range of glucose meters to restricted choice within a single brand is associated with many unintended consequences and indirect costs. Any proposed restriction in choice, especially if associated with an "enforced" meter changeover, needs to be managed in a way that avoids the changeover becoming a very expensive way of attempting to reduce health care costs.

Abbreviations

EC, European Commission; FDA, Food and Drug Administration; NOKLUS, Norwegian Quality Improvement of Primary Care Laboratories; SKUP, Scandinavian Evaluation of Laboratory Equipment for Primary Health Care.

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