

Post Market Review of Products Used in the Management of Diabetes

Stage 1

Submissions on the review of Blood Glucose Test Strips

Terms of Reference

- ***Describe the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) for people with type 2 diabetes;***

Response

Utilisation and patterns of use of SMBG for people with Type 2 diabetes appears to be highly variable.

From conversations with hundreds of patients in pharmacy settings across west and southern Sydney and the North Coast of NSW in the last 6 months, ^{Appendix 1} it is apparent many people with Type 2 diabetes, are confused and unclear as to what they should be doing to best manage their diabetes. This includes testing their blood glucose levels.

Although anecdotal, our observations are that those with Type 2 diabetes and on insulin are better informed and compliant with testing than those with Type 2 diabetes and not on insulin. Our assumption is that those on insulin may have attended a diabetes clinic for insulin initiation and have received more effective and intense training than possibly that being provided via General Practice (GP). We understand that very few Credentialed Diabetes Educators (CDE) work in GP. The lack of Medicare funding for the provision of private diabetes education services is one critical factor which may limit CDE's working in GP.

The confusion observed in pharmacy for the people with diabetes included;

- What Type of diabetes they have
- How often they should test their glucose levels
- Why they should test their glucose
- When & what they should be eating
- When they should test their glucose
- If exercise has any impact on managing their diabetes
- Who they should discuss their diabetes questions with

1. NDSS website November 2012

2. NDSS monthly statistics

3. Allen N et al Continuous glucose monitoring counselling improves physical activity behaviours of individuals with type 2 diabetes: A randomized clinical trial, Diabetes Res Clin Pract. 2008 June; 80(3): 371–379

- How old their glucose meter is
- How often they should check their glucose meter is functioning correctly

There are also be potential issues regarding National Diabetes Services Scheme (NDSS) distribution that contribute to compliance and education for people with diabetes. The NDSS “delivers diabetes-related products at subsidised prices and provides information and support services to people with diabetes”. For many years there was a limited number of “accredited” NDSS pharmacy who acted as “specialists” in diabetes in a postcode or area that delivered supplies and support to NDSS registrants. There are now approx 4,257 NDSS access points¹. The significant number of NDSS pharmacies may have diluted the “specialist” support provided via pharmacy.

It would seem that many pharmacies see little incremental financial benefit to supply NDSS products. In fact many feel that it is a cost burden to supply NDSS products.

The large number of NDSS outlets now in existence has the possible following effects;

1. Dilutes the number of people with diabetes attending each store and therefore the individual pharmacy experience in diabetes.
2. Creates competition within pharmacies to undercut on price and possible level of service provided to people with diabetes
3. Creates barriers to entry for new diabetes technologies and limits choice and access to alternative technologies which may enable improved utilisation and patterns of use. This is evident by the fact that in each category of products that are distributed via the NDSS, either 1 or two suppliers have *unusually high market shares*.
 - **Glucose test strips** two companies *control* over 90% market share
 - **Insulin pen needles**, 2 companies *control* over 99.5% market share
 - **Insulin pumps**, 1 company *control* over 75% market share².
4. Creates intense competition between suppliers and many suppliers now give away glucose meters for free in the hope that blood glucose test strip usage (and profit) will follow. The consequence is that many people with diabetes now have multiple glucose meters which may create confusion and uncertainty in glucose test results when using multiple blood glucose meters and attempting to compare different meters results. There must also be a question over the ability of a supplier to be able to provide the necessary training in the pharmacy environment required to ensure correct utilisation and patterns of use to achieve desired clinical outcomes. Suppliers during in pharmacy customer product training of a blood glucose meter do not (and should not) provide any clinical advice on; *when, how often or why* these people with diabetes need to test their blood sugar levels. Yet at the end of “training” these people leave the pharmacy with a new blood glucose meter with no clinical input on utilisation and patterns of use.

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5. Market dominance with few international suppliers, potentially prevents companies supplying their newer diabetes technologies for those Australians with diabetes. It is of interest that the second largest glucose meter company worldwide (the only Australian manufacturer) struggles to gain significant market share in Australia in the blood glucose test strip market.

Determine the clinical outcomes and benefits (e.g. HbA1C) of self-monitoring of blood glucose (SMBG) relative to HbA1C monitoring alone for people with type 2 diabetes not treated with insulin;

Response

Continuous Glucose Monitoring Systems (CGMS) may offer improved clinical outcomes and benefits as an adjunctive, diagnostic and educational tool to SMBG and or HbA1C.

The emergence of CGMS may prove to provide sustained clinical benefits via improved compliance and understanding of why and when people with Type 2 diabetes should measure blood glucose levels. Allen et al states” ***These data suggest that Personal Activity (PA) counselling interventions using CGMS feedback for individuals with type 2 diabetes may improve PA levels and reduce risk factors for diabetes-related complications***”³.

CGMS may be a useful adjunctive tool that can be used by clinicians to assist in educating people with diabetes to demonstrate the linkages between timing of testing, diet and exercise on both short (SMBG) and long term (HbA1C) glucose levels. There needs to be further local clinical trials to determine whether CGMS systems (including invasive and non invasive CGMS systems) can be a useful and cost effective adjunctive tool that enhances results already obtained from either SMBG or HbA1C.

While currently more expensive than SMBG, if used as diagnostic tool (***similar to how a Holter monitor is used to determine the continuous monitoring of the cardiovascular system***) CGMS may provide valuable diagnostic information about blood glucose levels over a period of say 24 hours up to several weeks ***prior to the recommendation to commence SMBG or prior to referral for HbA1C testing.*** This limited and defined use of CGMS may be more cost effective and improve clinical outcomes and compliance by providing additional diagnostic information to establish the correct utilisation and patterns for SMBG.

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- ***Consider the clinical criteria for eligibility for subsidised access to blood glucose test strips under the PBS and NDSS, accounting for clinical benefits offered through SMBG compared to regular HbA1C monitoring;***

Response

To overcome NDSS challenges with eligibility some pharmacies are requesting that people with diabetes obtain a PBS script (x 11 repeats) from their GP's for glucose test strips as this provides supplies to the customer and a PBS dispensing fee to the pharmacy.

Lack of adequate incentive to supply NDSS products for the pharmacy and those people without an NDSS card encourages this practice.

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Who are we

Bermaci Consulting is a consultancy that specialises in providing a range of services primarily to healthcare companies involved in marketing and or manufacturing medical technologies. It has provided services to clients in the diagnostic, pharmaceutical and medical devices markets. The primary consultant for Bermaci is John Douglas, B App Sc., Grad Dip Mkt., FFAICD and is the author of this submission.

The Douglas family name has been involved in the medical device industry since 1961. Robert James Douglas a plastics engineer pioneered the development and manufacturing of medical plastics and plastic blood transfusion bags in Australia. This technology was recognised worldwide and with funding assistance from the Hawke Federal Labor Government in the 1980's, a blood bag manufacturing factory utilising the Australian developed technology was built in Tianjian China.

John Douglas (Robert Douglas' son) has been involved in the diagnostic, pharmaceutical and medical devices area for over 25 years. He has pioneered the introduction of many new medical technologies onto the Australian market including diabetes technologies. Douglas has re entered the diabetes technologies market after a break of several years. This has given recent exposure and reflection on;

1. Changes in the blood glucose monitoring, insulin pump & insulin needle markets & technologies
2. Changes and challenges with the NDSS
3. Changes and challenges in diabetes reimbursement processes
4. Changes and challenges in the TGA regulatory processes
5. Changes and challenges in the delivery of product and service distribution processes
6. Changes and challenges for those with Type 1 & Type 2 diabetes

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Appendix 1

Suburbs of pharmacies where > 100 people with diabetes attended an “in store” glucose meter day during the period July 2012 – November 2012.

Thornleigh

St Mary’s

Merrylands

Toongabbie

Mount Druitt

Port Macquarie

Coffs Harbour

Lakemba

Hornsby

Parramatta

Carnes Hill

Bankstown

Maroubra

Panania

Cabramatta

Orange

Rosebery

Blacktown

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