The Pharmacy Guild of Australia

2 July 2013
Submission to the Review for Medicines Used in the Treatment of Type 2 Diabetes

1. Terms of Reference

The Terms of Reference for the Review are to:

1. Describe the utilisation and patterns of treatment of PBS listed drugs for Type 2 Diabetes Mellitus (T2DM), and compare these with PBS restrictions.
2. Consider if the utilisation of PBS listed drugs in current clinical practice represents expected cost effective use.
3. Consolidate the clinical trial evidence used to support PBS listings of diabetes medicines listed since 2002.
4. Collate and evaluate any additional clinical studies or meta-analyses for drugs currently PBS listed for T2DM that the Pharmaceutical Benefits Advisory Committee (PBAC) has not seen and that would inform their consideration.

2. Scope

Other Government programs and activities relating to diabetes will be considered in the context of the overarching evaluation of diabetes management to ensure a comprehensive approach to this review is achieved.

3. Background

The Pharmacy Guild of Australia (Guild) welcomes the opportunity to comment on the *Review for Medicines Used in the Treatment of Type 2 Diabetes* prepared by the Department of Health and Ageing (Department) as Stage 3 to the Post-Market Review of Products Used in the Management of Diabetes.

The Guild is the national peak pharmacy organisation representing community pharmacy. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services. The network of 5,200 community pharmacies operates in a highly regulated environment and employs 54,000 highly skilled staff (excluding proprietors) to provide the highest quality of care in delivering medicines and other related products and services. Within this community pharmacy network, 20% are located in rural and remote locations[1] where the rates of mortality due to diabetes are two to four times higher than rates in major cities.[2]

Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy[3] and is supported by the supply of medicines, advice and pharmacy support services through the community pharmacy sector. By law, every pharmacy must have a pharmacist on duty at all times during the hours of trade. Whenever a pharmacy is open, there is a pharmacist available for no-charge, routine health consultations without

the need for an appointment. In addition, many pharmacies have extended trading hours, including evenings, weekends and public holidays, providing Australians with easy access to a highly, trained and skilled health care professional at times when other providers are often unavailable.

Community pharmacy also maintains a high standard of patient care with the Quality Care Pharmacy Program (QCPP) which is recognised as the Australian Standard[4] for service provision within the community pharmacy sector. The QCPP is a quality assurance program aimed at raising the standards of pharmacy services, ensuring community pharmacies provide a uniform approach when delivering professional services and customer care. QCPP accreditation has been shown to support continuous improvement in the supply of medicines.[5]

As of 31 December 2012, approximately 98% of Australian community pharmacies were registered with QCPP and approximately 92% were accredited or in the process of becoming accredited.

In the 12 months to June 2012, community pharmacies provided approximately 12 million diabetes-related prescriptions[6] in addition to local screening, education and medication assistance services. In a recent published health survey, 94% of Australians reported using a pharmacy with 89% expressing satisfaction with the service, the highest of all the major health care providers.[7]

4. Comments

The Guild provides comment with general consideration of the scope of the review and the terms of reference for this particular stage.

Every year, the average Australian has about 22 recorded interactions with the health system, including four visits to a general practitioner (GP), 12 prescriptions and three visits to a specialist.[8] As people with diabetes visit their community pharmacy to fill their prescriptions as well as access other diabetes supplies (e.g. blood glucose monitoring products), it is likely that these people visit their pharmacy even more frequently than 12 times a year.

Diabetes is also associated with a number of serious and expensive co-morbidities including obstructive sleep apnoea, fatty liver leading to cirrhosis, and erectile dysfunction. Australian surveys show that 22-35% of adults with diabetes experience moderate to severe depressive symptoms, while 14-19% experience moderate to severe anxiety symptoms.[9]

5a) Diabetes Support through Community Pharmacy

Dispensing diabetes medicines

Dispensing is an integral component of medicine supply provided by community pharmacy. As a complete process, dispensing requires the professional and clinical review by a pharmacist to ensure a prescription is dispensed accurately according to the prescriber's intentions and consistent with the needs and safety of the consumer.

Counselling is an essential element of the dispensing process and ensures patients or their carers have sufficient information to enable an understanding of their medicines and the intended therapeutic effect, and to minimise the risk of adverse effects.[10]

Medicine Use Reviews

The MedsCheck and Diabetes MedsCheck services are funded by the Australian Government as part of the Fifth Community Pharmacy Agreement (Fifth Agreement).[11] While a MedsCheck service provides an in-pharmacy review of a consumer's medicines, focusing on education and self-management, a Diabetes MedsCheck has a greater focus on supporting a person's diabetes management and is targeted for people who are unable to gain timely access to existing diabetes education/health services in their community.

While the general aims of the MedsCheck services are to optimise a person's effective use of their medicines through improved understanding and adherence, the Diabetes MedsCheck also aims to improve a person's blood glucose monitoring and control in order to reduce the risk of developing complications associated with type 2 diabetes.

To be eligible for a Diabetes MedsCheck, a consumer must:

i. be a Medicare and/or Department of Veterans' Affairs (DVA) cardholder
ii. have not received a MedsCheck, Diabetes MedsCheck, Home Medicines Review (HMR) or Residential Medication Management Review (RMMR) in the last 12 months;
iii. be living at home in a community setting
iv. have recently been diagnosed with type 2 diabetes (in the last 12 months)

or

v. has less than ideally controlled type 2 diabetes and
vi. is unable to gain timely access to existing diabetes education/health services in their community

If a person with diabetes is not eligible for a Diabetes MedsCheck, they may still be eligible for a MedsCheck service for general QUM support and advice. In addition to the first three eligibility points above, a person is eligible for a MedsCheck if they take five or more prescription medicines or if they have had a recent significant medical event that may increase their risk of medicine misadventure by impacting their medication adherence or understanding.

Both MedsCheck services are conducted by a pharmacist within a community pharmacy setting and while not mandatory, it is recommended that with patient (or carer) consent, pharmacists provide the patient's GP with a summary of issues or recommendations.

Pharmacists are paid $60 for a MedsCheck service or $90 for a Diabetes MedsCheck service. There is no cost to the consumer for either service but there is a limit of one subsidised service per year.

The Guild draws attention to the National Diabetes Supply Scheme (NDSS) Head Agreement between the Department and Diabetes Australia which states that it is a requirement for a community pharmacy Access Point to be registered in the Diabetes MedsCheck Program.[12]

Pharmacy Practice Incentives

As part of the Fifth Agreement's Pharmacy Practice Incentive (PPI) Program[13], community pharmacies are eligible for modest incentive payments to encourage pharmacists to provide clinical support services to a specified quality standard for a range of priority areas, including:

- Primary Health Care – of which disease state management or screening/risk assessment for diabetes is an optional element
- Clinical Interventions – supporting the documentation of pharmacist intervention to manage identified QUM issues
- Working with Others – supporting interaction between pharmacists and other healthcare professionals for better patient health outcomes
- Dose Administration Aids (DAA) – supporting the provision of a DAA service
- Community Services Support – with registration as an NDSS Access Point as one of the optional elements for eligibility

Dose Administration Aids

DAA are devices designed to assist consumers to better manage their medicines, with the objective of avoiding medicine misadventure and associated hospitalisation. DAA services are particularly useful for people taking multiple medicines and who regularly mix them up or forget to take them.

As people get older, they are more likely to have diabetes as well as related diseases and conditions, particularly chronic kidney disease and cardio-vascular disease (CVD). Co-morbidities are most prevalent in people aged 65-74, although about 30-40% of Australians with co-morbidities are younger than age 65.[14]

People with a number of co-morbidities often have complex medicine regimens which can lead to adherence issues. Elderly people in particular are very vulnerable and are one group that can benefit from a DAA service. The use of DAA has shown improved adherence over 6 months from a baseline of 61% to 97%. Over the following 6 months, those continuing to use DAA showed a sustained 95% adherence while patients that stopped DAA use reduced to 69% adherence.[15]

DAA services are labour intensive, requiring significant professional oversight from the pharmacist. Community pharmacies have long been absorbing the costs in providing DAA services to their patients, mostly because of their professional and community responsibility and consideration of their valued patients who most need the service.

In 2008, the DVA introduced a subsidised DAA service for eligible veterans in which the community pharmacy receives weekly payment for the DAA service and payment to review the service every 6 months to ensure it remains appropriate. [16] This service builds on DVA's Quality Use of Medicines programs which include the Veterans' Medicines Advice and Therapeutics Education Services and aims to assist the veteran community to get the most out of their medicines and to reduce medicine mismanagement. Ongoing coordinated care is provided by the GP and pharmacist.

DAA is also a priority area for the PPI Program in which pharmacies are eligible for a modest incentive payment to provide a more standardised DAA service within an auditable quality assurance framework. At the discretion of the pharmacist, consumers continue to contribute a co-payment for the service but generally, the incentive and any patient contribution covers only a fraction of the costs involved in providing the service.

National Diabetes Supply Scheme

The NDSS aims to ensure people have timely, reliable and affordable access to the supplies and services they require to effectively self-manage their diabetes.[17] This is largely achieved through a nation-wide network of Access Points from where NDSS registrants can purchase significantly discounted supplies. Diabetes Australia estimates that the NDSS covers 80%–90% of people with diagnosed diabetes.

There are currently 4,050 Access Points across Australia, the majority of which are community pharmacies.[18] As of January 2012, a total of 1,074, 368 people with diabetes were registered on the NDSS of which 738,395 were classified with T2DM. Within the 6 months from July to December 2011, over 2.6 million products were supplied to registrants.

However, the Guild highlights to the Review that Access Points under the NDSS are mandated to provide unremunerated services that 'extend(s) beyond just being a shopfront for NDSS products' including to 'provide registrants with information on diabetes by a person/s engaged or employed by the Access Point who is capable of providing an informed response to registrant questions[19]".

A 2011 analysis[20] estimated that based on pharmacy cost and income trends, the financial impact on community pharmacy Access Points is an average annual loss of $7,481. Despite this, community pharmacies have elected to be involved in the NDSS due to a high level of commitment in providing a comprehensive diabetes service to the community as the NDSS is the only subsidised source of a full range of diabetes-related products and community pharmacy is the most consumer-friendly access point for the majority of NDSS registrants. However, with the impact of the PBS reforms on community pharmacy and particularly price disclosure, there is limited capacity to continue cross-subsidising such services and the sustainability of this model will need to be reconsidered.

Co-morbidities and minor ailments

If not well managed, diabetes can have adverse effects on almost every organ of the body. People with diabetes experience increased rates of heart attacks, strokes, eye damage and blindness, end-stage renal disease, limb amputations and other complications. More than half of people diagnosed with diabetes in 2003 had a disability, including self-care and mobility. The more than 1 million Australians currently diagnosed with diabetes face daily self-management, blood glucose testing, and constant attention to nutrition and physical activity.[21]

In addition to supplying first aid, patient and mobility aids, foot care and eye care products along with professional information and advice, many community pharmacies provide services such as blood pressure and/or cholesterol monitoring and/or weight loss support. While many of these services have in the past been ad hoc and informal, the development of software platforms such as GuildCare[22] is providing pharmacists with a more structured format to delivering these services.

Know your numbers

'Know your numbers' is a campaign that has been developed to raise community awareness and detection of cardiovascular disease and type 2 diabetes. Know your numbers promotes the importance of regular blood pressure and type 2 diabetes risk assessment checks through opportunistic health checks in community pharmacy and other community settings.[23]

In 2012, the NSW Government contracted the National Stroke Foundation and the Pharmacy Guild of Australia (NSW) to operate the 'Pharmacy Health Checks: Know Your Numbers' program as a four-year pilot. Available from 500 pharmacies in NSW, the health checks are free, do not require an appointment and are delivered to a specified quality assurance standard. The pharmacist conducts a blood pressure test and assists the consumer to complete an AUSDRISK survey of risk factors. Those identified at risk are

provided lifestyle advice by the pharmacist, referred to a lifestyle modification program or referred to a GP.

While 'Know your numbers' has generally been taken up for short periods each year in Queensland and Victoria, the NSW program recognises that community pharmacy cannot be expected nor has the capacity to continually provide such professional services for free. With the support of the NSW Government, participating pharmacies are paid an annual incentive fee of $1,000 for meeting program targets. As of 13 May 2013, there have been 58,975 health checks of which 34% had high blood pressure or were assessed as being at a high risk of developing type 2 diabetes within five years.[24] It is expected over 385,000 free health checks will be performed over the life of the program.[25]

The success of the program shows that community pharmacies are willing and able to actively engage in remunerated professional services such as the health checks program in NSW, and have a role to play in the delivery of primary and preventative health services to the community.

Medscreen

Medscreen is an adherence program that is conducted as part of the GuildCare platform for a number of medicines including Metformin. As part of the service, pharmacists review a patient's adherence (measured by a Medsindex score[26] out of 100) and looks at issues that may be impacting the quality use of the medicine. Pharmacies providing Medscreen metformin services are eligible for an incentive payment as part of the PPI program. GuildCare has recently implemented Medscreen support services for some other diabetes medicines, including gliclazide, glimepiride and exenatide.

5b) Issues and Recommendations

Continuity of supply

In late 2011, there was a supply issue with extended-release metformin products. Prescribers and pharmacists were advised in October 2011 about supply shortages for Diabex® XR 1000 and advised to use the extended-release 500mg (XR-500) products as an alternative. This situation created a number of issues for prescribers, pharmacists and consumers:

- While the XR-500 products had double the quantity (120 units per pack compared to 60 units per pack of the Diabex XR 1000), consumers had to take twice as many tablets for the same dose. This was problematic for people with swallowing difficulties and often added to an already complex dosing regimen. It also impacted preparation of DAA which required the packing of twice as many metformin tablets into an already confined receptacle.
- Pharmacists were faced with an increased workload when people presented prescriptions or repeats for Diabex XR 1000. Pharmacists cannot legally supply nor claim for a different strength product when a prescription states a specific strength. This required the pharmacist contacting prescribers in order to advise of the supply issue and arrange a new prescription for the XR-500 product in the interim.

  In the event that patients presented to the pharmacy when their doctor was unavailable, pharmacists were put into the insidious position of not being able to legally supply a medicine because they did not have an authority to change or supply. In these instances, patients had to attend either another prescriber or the local emergency department in order to get a replacement prescription.

- Doctors were faced with calls from patients and pharmacists advising of the supply issue and requesting new prescriptions for the XR-500 product. If a patient's regular doctor could not be contacted, the patient had to visit another prescriber with additional costs to the health system and patient.
- As the supply situation continued for Diabex XR 1000, supplies of XR-500 products were impacted and there were often delays. This added to the frustration for everyone as prescribers had to review patients to prescribe other forms of metformin and pharmacists were again unable to maintain regular supply of an essential medicine for their patients. Reports at the time indicated there were more than 112,000 prescriptions in January 2012 for the three available XR-500 products.[27]
- Although in no way responsible for the supply issue, pharmacists received the brunt of anger and frustration from consumers and prescribers. This also had a negative impact on the trust and professional relationship pharmacists had with their patients and local prescribers.

Recommendation:

i. There needs to be better supply guarantees from manufacturers for medicines listed on the PBS, particularly when there is only one variant available for a particular form or strength or when one manufacturer is responsible for all available listed variants.

ii. In the event of an impending or actual supply shortage, there needs to be better communication with the prescribing and pharmacy sectors with resources to assist in informing patients. Information should be publicly available from the manufacturer's website with details of the supply issue and expected resolution dates. This will enable pharmacists in particular to direct prescribers and/or consumers to the relevant information.

The Department should also actively monitor any situation with supply issues and ensure that the information available from the manufacturer is current. Manufacturers should have contingency plans, including communication plans, enforced by the Department if resolution dates are further delayed.

Prescribing issues

With the introduction of modified release formulations for diabetes medicines, the Guild has received reports of prescriptions for 'once daily' therapy written with 'twice daily' instructions. This impacts the workflow of both the pharmacist and prescriber as the pharmacist must contact the prescriber to clarify intentions. If the patient is presenting to the pharmacy after their prescriber has closed, the patient's treatment can be delayed as the pharmacist is unable to confirm the prescriber's intention.

The Guild also notes that while the guidelines for GPs[28] advises that non-adherence is common and may be a barrier to achieving treatment targets and for doctors to consider simplifying treatment schedules and limiting the number of medications and medication taking occasions, it only recommends to review medication adherence as part of the annual cycle of care. Adherence should always be considered when treatment goals are not being achieved and always reviewed before increasing the dose or adding to the medicine regimen. Assessing and supporting medication adherence before adding to a person's medicine regimen can improve patient health outcomes and contribute to containing health costs for the Government and the consumer by cost-effectively maximising the quality use of medicines.

Recommendation:

Pharmacists should be better utilised and compensated for supporting measures to improve prescribing practices. This could involve:

i. Introducing greater incentives to encourage pharmacists to extend their roles through greater clinical interaction with the prescriber. This concept has been introduced as part of the PPI Program in the Fifth Agreement through the 'Clinical Interventions' and 'Working with Others' priority areas.29 However, as it is currently funded, it can do no more than raise awareness of the need for collaboration. Meaningful practice change would require resourcing pharmacy more appropriately.

ii. Developing the MedsCheck/Diabetes MedsCheck services so that pharmacists have a greater capacity to follow up on adherence issues for at-risk patients, enabling prescribers to better utilise pharmacist support and advice.

Adherence Issues

A recent report[30] from the USA about medication adherence identified the following six key predictors of medication adherence, in order of magnitude:

i. patient's personal connection with a pharmacist or pharmacy staff
ii. how easy it is for them to afford their medications
iii. the level of continuity they have in their health care
iv. how important patients feel it is to take their medication exactly as prescribed
v. how well informed they feel about their health
vi. the extent to which their medication causes unpleasant side effects

A 2013 research compendium from the USA[31] identified research published in 2011 which quantified the health system savings from improved adherence for patients with congestive heart failure, high blood pressure, diabetes and high cholesterol. Specifically, patients with diabetes with good adherence to their medicines saved the USA health system $3,756 per year as a result of fewer emergency department visits and fewer in-patient hospital days.

Patients are adherent to approximately 50% of their prescribed medicines, which decreases when multiple, chronic conditions are involved.[32] This may be further complicated when medication costs also create a barrier to access. A 2009 report indicated that 9% of Australian people delayed having a prescription filled because of cost.[33] Poor adherence can result in avoidable hospitalisations and has been shown to affect a person's quality and length of life.[34]

As previously stated under 'Prescribing issues', adherence should always be considered when treatment goals are not being achieved and always reviewed before increasing the dose or adding to the medicine regimen.

The Diabetes Medication Adherence Service (DMAS)[35] was trialled as a pilot in the Fourth Community Pharmacy Agreement and demonstrated the effectiveness of community pharmacy in supporting diabetes self-management and medication adherence for people with uncontrolled type 2 diabetes. DMAS involved specially trained and credentialed pharmacists conducting a series of patient consultations over a 6 month period. The aim of the service was to assist patient self-management and improve the quality use of medicines for people with diabetes through enhanced community pharmacy intervention. The DMAS pharmacist also provided lifestyle advice and support and considered other health issues for the patient such as blood pressure and weight.

An independent evaluation[36] was undertaken which reported:

- a decrease in mean blood glucose level from 9.48 mmol/L to 8.64 mmol/L
- a decrease in mean BMI from 33.1 to 32.9
- a decrease in overall mean Systolic blood pressure by 6.00 mmHg and Diastolic by 4.3 mmHg
- a decrease across all forms of identified medicine management problems, particularly adherence issues
- improved exercise in 41% of patients
- an increase in alcohol free days for 23% of patients, with 14% of patients reducing the average number of alcoholic drinks consumed

Recommendations:

i. Improve access to DAA services for at-risk patient groups.

   - PBS subsidised DAA service – implement a PBS subsidised DAA service similar to the DVA DAA scheme targeted at patients most at risk of poor adherence. As with the DVA scheme, doctors could prescribe the DAA service and pharmacists would conduct a 6-monthly review and report back to the doctor to prescribe continuation of the service. A subsidised service may have strict patient eligibility criteria such as age and co-morbidities (e.g. diabetes, CVD, dementia or combination of).
   - Under the *Living Longer Living Better* Aged Care Reforms, the intent is for all four levels of Home Care Packages to be designed to assist people to remain living at home for as long as possible and enable consumers to have choice and flexibility in the way that care and support is provided at home. One proposal is for people with any package level to have access to nursing and allied health services.[37]

     While not diabetes specific, this means that elderly patients with chronic health conditions could have greater access to non-subsidised pharmacy services such as DAA services. It is essential that Approved Providers of these packages are aware of the service options available so that they can appropriately assess their patients and make relevant recommendations.

     The Guild would be pleased to work with the Department and other relevant stakeholders to develop a resource for reference by approved providers or care co-ordinators with information about services available through community pharmacy and whether they are Government subsidised or private.

ii. Implement a structured self-monitoring of blood glucose (SMBG) program through community pharmacy. One such model is depicted in Appendix A, where a MedsCheck service becomes the entry point into a more structured SMBG program that allows for scheduled reviews of a developed action plan, and careful monitoring of test strip utilisation over a twelve month period. It would encompass all of the components recommended in the International Diabetes Federations (IDF) Guidelines[38], recent research related to the effectiveness of SMBG and testing quality and interpretation, rather than testing frequency, as well as the previously researched and piloted DMAS.

iii. Where affordability is an issue for individuals, pharmacists may be able to assist by liaising with the prescriber to develop a more affordable medicine regimen.

However, such services extend beyond conventional dispensing support and pharmacists need to be appropriately recompensed for their time and service.

While services such as the Diabetes MedsCheck provide such opportunities, there is limited access with strict patient eligibility criteria and a limit of one subsidised service per year. A more structured support service such as DMAS provides greater scope for ongoing review and support by the pharmacist.

If affordability is a broader issue for patients with diabetes, consideration may be given to general policy changes such as facilitating access to the PBS safety net scheme to lower cost barriers.

Use of a regular preferred pharmacy

Acknowledging consumers have the right to have prescriptions filled at the pharmacy of their choice and that the use of generic medicines can save money for consumers as well as the public health system, attending different pharmacies can impact a person's medication adherence and ultimately diabetes control and health outcomes.

The USA research compendium's review of adherence studies[39] identified that in the USA, medications for high blood pressure and diabetes saw primary non-adherence rates in excess of 25%. Recommendations from the studies included the creation of a centralised 'Pharmacy Home' where a patient's pharmacy care is synchronised and managed at a single pharmacy so that a single health care professional has a full view of the patient's pharmacy care needs.

Also from the USA, a separate medication adherence report[40] identified a person's 'sense of connectedness' with their pharmacist or pharmacy staff as the single strongest individual predictor for prescription medication adherence. Breaking this down further, only 36% of patients who obtained their medication by mail reported a personal connection with their medication provider compared to 89% who used their neighbourhood pharmacy.

In addition to sacrificing the 'sense of connectedness' in which the pharmacist has an understanding of their patient, their needs and level of understanding and self-management, frequently changing pharmacies can result in different brands being supplied which can be confusing for some at-risk patients.

Several diabetes medicines listed on the PBS are available as a number of different brands. As an example, depending on the strength prescribed, there are up to 14 brands of metformin available, up to 5 brands of gliclazide, 8 brands of glimepiride and 12 brands of pioglitazone.

It is not feasible for pharmacies to stock the full range of brands for every strength and every form of PBS medicine. They usually stock a small range of brands for the different strengths and forms. This means however that patients presenting to different pharmacies may be supplied different brands of medicine each time. Patients who should remain on a consistent branded product for safety and adherence reasons should be encouraged to select and attend one preferred pharmacy where possible. This establishes a trusting relationship which not only promotes consistent product supply but better enables their regular pharmacist to routinely monitor their diabetes management and address any identified issues.

Recommendation:

The Guild would like to see consumers with chronic health conditions educated and encouraged to select and use one preferred pharmacy so they can develop an ongoing professional relationship with the pharmacist to better support them in managing their health condition. It would also promote a sense of connectedness for the patient with their preferred pharmacist and pharmacy staff, facilitating greater medication adherence and ultimately glucose control and health outcomes.

Team Care coordination

The International Diabetes Federations Guidelines[41] emphasise the need for strong collaboration between patients and their healthcare team in reviewing, interpreting, and appropriately acting upon the data obtained through structured diabetes care programs.

Although pharmacists are the most accessible and most visited primary health care professional, their involvement in formal team care health arrangements is often limited. This may be because other health care professional groups are unaware of the scope of a pharmacist's practice or the types of services available through pharmacy.

Even though the prescribing-dispensing process provides for more interaction between doctors and pharmacists, there is little formalised collaboration outside of this. This is demonstrated by the Guidelines for Type 2 Diabetes Management in General Practice[42] which identifies pharmacists as providing 'useful advice on medication usage and potential problems' and having 'skills in patient care and dosage aids which enhance patient compliance and understanding'. However the only pharmacy service about which these Guidelines advise is 'a formal Home Medicines Review (HMR) arranged by general practitioners for the assessment of a person's understanding of their medicines and devices and how well these are being used'. There is no mention about the MedsCheck or DAA services and nothing encouraging greater collaboration between doctors and pharmacists.

Recommendation:

Acknowledging the role of Medicare Locals in encouraging a culture of inter-professional learning and supporting multidisciplinary teams and practice improvement, more work needs to be done at both a national and local level to promote multi-disciplinary team care. Where the development or review of practice guidelines are funded by the Australian Government, this should be done in the context of patient centredness. Rather than developing guidelines for a particular provider group, general primary care guidelines could be developed with applications to the full spectrum of healthcare providers. The Guild would like to see such guidelines identifying team care arrangements utilising community pharmacists for QUM and medicine adherence support services for at-risk patients.

Along with developing relevant guidelines, it is essential that all providers are adequately recompensed for their care and coordination and the development of any team care service arrangements should reflect this.

Prevention and Early Intervention

The statistics about diabetes are staggering. It is estimated to affect in excess of 1.5 million Australians with 275 more people being diagnosed with type 2 diabetes every day. The number of Australians diagnosed with diabetes is expected to grow to 3.5 million by 2033 with estimated costs to the health system of up to $6.57 billion a year. In addition,

the complications of diabetes can increase the costs of managing the disease by as much as 12 times.[43]

With such figures, it is sensible to prioritise prevention and early intervention as a cost-effective management strategy. An estimated 2.45 million Australians have pre-diabetes[44]. Early detection is important as diabetes can remain asymptomatic for many years which may result in significant diabetes-related complications becoming established before diagnosis[45]. Further supporting the case for early detection is irrefutable evidence of available, cost effective interventions for preventing and controlling type 2 diabetes. Well-designed randomised controlled trials (RCT) have shown that diabetes related complications can be prevented or minimised in people with type 2 diabetes by improving metabolic control[46].

A consequence of screening for undiagnosed type 2 diabetes is the detection of people with pre-diabetes. RCTs have shown that progression to type 2 diabetes can be prevented or delayed by lifestyle changes and pharmacotherapy[47].

The two trials[48,49] that used intensive individualised diet and exercise interventions showed a 58% reduction in the incidence of diabetes while pharmacotherapies such as metformin[50], acarbose and orlistat[51], and rosiglitazone[52] have shown 25-60% reductions in the incidence of diabetes.

Overall, these findings highlight the need for more effective screening of the general population to facilitate increased risk identification and earlier interventions to prevent the development of diabetes and its complications. Of the three approaches to screening in the general community (opportunistic, population-based, and selective-screening), opportunistic is considered to be the most efficient and effective[53].

Opportunistic risk identification involves screening individuals during routine encounters with the health care system[54]. Although various health care settings have been trialled, no single setting can capture the entire 'at risk' population. However, community pharmacies are ideally placed and pharmacists well trained and skilled to assist in the detection, education and referral of individuals at risk of diabetes[55]. Community pharmacists are highly accessible, widely available and in frequent contact with the public. Individuals who are healthy and unwell visit community pharmacies, providing an opportunity to engage people along the health spectrum and hard-to-reach populations who do not utilise other health services, of increasing importance given workforce shortages, budgetary constraints and changing population demographics.

Recommendation:

Consideration is given to implementing a remunerated pre-diabetes screening program in community pharmacy based on research conducted in the Pharmacy Diabetes Care Program commissioned under the Third Community Pharmacy Agreement[56].

The program could involve three-steps that align with evidence-based, best practice guidelines[57] developed by the National Health and Medical Research Council (NHMRC):

- risk assessment using a validated tool (AUSDRISK)[58]
- point of care (POC) testing using capillary blood in line with professional standards and
- review of and response to results in line with recommendations within NHMRC guidelines

The model presented in Appendix A demonstrates a community pharmacy pre-diabetes screening service that complements a SMBG service for people diagnosed with type 2 diabetes.

Impact of Price Disclosure

A recent Report[59] from Medicines Australia indicates that PBS reforms are delivering savings of nearly $2.7 billion by the end of the 2012-13 period and $17.8 billion by the 2017-18 period.

Price disclosure has already reduced the PBS price of several diabetes drugs. Cumulative reductions (up to and including the announced 1 August 2013 reductions) include 29.6% for metformin, 35.9% for glimepiride and 29.1% for pioglitazone. Significant reductions have also flowed on to some single-brand combination products. These price reductions, driven by market competition in the off-patent market, are ensuring that the utilisation of PBS listed drugs in current clinical practice continue to represent cost effective use.

While the Guild strongly supports the objectives of price disclosure, the Medicines Australia Report, which follows reports of significant reductions in the estimates of future pharmaceutical benefits expenditure in the 2013 Federal Budget, demonstrates the need to fully understand its impact on community pharmacy. Until now, community pharmacies have largely been able to remain viable despite the major savings that governments have demanded in Community Pharmacy Agreements and under a range of other pressures through the trading terms they receive after PBS medicines come off patent.

However, as price disclosure eliminates these trading terms, there is a real risk that further funding cuts could undermine the viability of Australia's highly trusted community pharmacy network, as evidenced by the record number of pharmacy insolvencies since this policy has been implemented. While the economic health of many pharmacies flounders, there remains an expectation from consumers, Government and the profession itself for greater service delivery. There are expectations of more pharmacists delivering professional services, more pharmacists in the front-of-shop, more pharmacist time spent with patients, more collaboration with other health care providers and more training. However, outside of Fifth Agreement programs, there are few other funding incentives to deliver on these expectations. As an example, even with the NDSS, community pharmacy is not remunerated and yet is expected to provide diabetes support above and beyond simple product supply. The sustainability of community pharmacy as a non-remunerated NDSS Access Point will need to be reconsidered as the capacity for cross-subsidising such services diminish.

Unless Government is prepared to re-invest in community pharmacy with some of the savings from PBS reforms, consumers may be faced with greater costs for the additional pharmacy services and/or reduced access to services. Neither is an acceptable outcome to the Guild. We value the trust and respect the community has for community pharmacy and we don't want this jeopardised. Nor do we want to see inequities of access favouring those with the means to pay for health care.

Recommendations:

With the ever-increasing numbers of Australians being affected by diabetes or pre-diabetes, the Guild recommends reinvesting back into community pharmacy some of the savings to the PBS from price disclosure, including in the form of structured pharmacy diabetes services. This would not only contribute to better managing the burden that

diabetes is placing on the health system, including the PBS, but also assist in improving community pharmacy's longer term viability, enabling it to continue servicing the health needs of Australians.

5. Discussion

In current practice, community pharmacists typically contact the prescriber on issues relating to legal aspects of prescribing, clarification of items and safety issues such as incorrect dosing or medication interactions. The introduction of incentives such as those offered under the Fifth Agreement's PPI Program is encouraging pharmacists to extend their roles through more clinical interventions with prescribers. However, there are a number of variables that influence the uptake and success of clinical interventions, including:

i. Workload – there are no controls as to when a patient presents a prescription at a pharmacy. Typically, at busier times, pharmacists may be less likely to perform more complex interventions and will focus on dispensing activities such as review of legal and safety elements.
ii. Duty pharmacist – it has been shown that the level of clinical intervention varies according to the dispensing pharmacist's experience, training and knowledge.
iii. Prescriber attitude – while a pharmacist may highlight a prescribing anomaly with the prescriber, prescription changes are dependent on the prescriber accepting the pharmacist's advice and/or recommendation. This is largely dependent on the prescriber's experience, training and knowledge as well as inter-professional relationship with the pharmacist.
iv. Pharmacist-prescriber relationship – except for legal, clarification or safety issues, many pharmacists are often reticent to discuss changing prescribing patterns with a prescriber with whom they do not have a close working relationship.
v. Incentive amount – while they have high uptake and have effected some change, particularly in the level of documentation of interventions and other pharmacist activities, current PPI incentives are modest, particularly when compared to those provided to general practice[60] to implement services and facilitate significant practice change and greater resourcing.

Pharmacists that have been specifically trained, and in some instances credentialed for specific services (e.g. HMR, DMAS), are often better equipped and experienced to discuss collaborative care arrangements for specific patients as well as more general prescribing pattern recommendations. We need to enhance the skills of all pharmacists to more effectively participate in collaborative models of care and improve the awareness of other health care professionals of what community pharmacists can contribute.

There have been a number of studies in Australia and overseas which have shown that pharmacist involvement as an active member of the health care team leads to improved patient health care.[61,62] The Guild maintains that it is essential to include the community pharmacist as an active team member and would encourage arrangements that facilitate involvement of community pharmacists as part of a patient's multi-disciplinary health support team.

Along with dispensing medicines for a person with type 2 diabetes, the supply of NDSS products and other therapeutic products and support services uniquely positions community pharmacy as the most frequently visited health care destination. Together with the ready accessibility to a pharmacist for information and advice, there is an

opportunity for Government and other interested parties to capitalise on the frequency of visits and accessibility to a health care professional to better utilise community pharmacy with prevention and early intervention of diabetes as well as providing ongoing professional management support for people with diabetes and associated co-morbidities.

While there has been an investment in the foundation for a structured, multi-layered and quality integrated diabetes program within community pharmacy, the Guild now calls upon the Australian Government to re-invest some of the savings to the PBS from price disclosure back into the community pharmacy sector. Building on this past investment and the established infrastructure of community pharmacy, the Government can foster a new model of service that provides for a structured service that utilises community pharmacists as part of the multi-disciplinary health care team. Such a service, when implemented in conjunction with Diabetes MedsCheck, DAA services and other pharmacy QUM services not only has the potential to improve the future health outcomes of people with type 2 diabetes in a cost effective way but can significantly contribute to the increased health costs expected over the coming years to manage the ever increasing number of Australians with diabetes.

Any structured diabetes program through community pharmacy would also be enhanced, particularly for rural and remote regions, if the pharmacy was viewed as an 'other health care facility' in which a patient could access telehealth and engage in a video conference with a specialist at another location[63], thus ensuring that there is access to a 'team' of health professionals.

6. Conclusion

A person with diabetes already recognises their local community pharmacy as a diabetes health destination, given that 98% of NDSS Access Points are community pharmacies. The Guild has highlighted a number of options which could capitalise on this recognition and the accessibility to utilise the skills and expertise of community pharmacists to better provide for Australians with type 2 diabetes. This in turn may reduce distorted PBS growth in the future from ever-increasing demand for subsidised diabetes medicines.

A structured and adequately subsidised diabetes service through community pharmacy is essential, given there is one Australian diagnosed with diabetes every 5 minutes[64]. This is particularly important for Australians living in rural and remote locations where the lack of diabetes support services is compounded by the unavailability of other healthcare professions due to geographic distribution or workforce shortages.

7. Summary of Recommendations

i. There needs to be better supply guarantees from manufacturers for medicines listed on the PBS, particularly when there is only one variant available for a particular form or strength or when one manufacturer is responsible for all available listed variants.

ii. In the event of an impending or actual supply shortage, there needs to be better communication with the prescribing and pharmacy sectors with resources to assist in informing patients. Information should be publicly available from the manufacturer's website with details of the supply issue and expected resolution dates. This will enable pharmacists in particular to direct prescribers and/or consumers to the relevant information.

   The Department should also actively monitor any situation with supply issues and ensure that the information available from the manufacturer is current. Manufacturers should have contingency plans, including communication plans, enforced by the Department if resolution dates are further delayed.

iii. Pharmacists should be better utilised and compensated for supporting measures to improve prescribing practices. This could involve:

   - Introducing greater incentives to encourage pharmacists to extend their roles through greater clinical interaction with the prescriber. This concept has been introduced as part of the PPI Program in the Fifth Agreement through the 'Clinical Interventions' and 'Working with Others' priority areas.[65] However, as it is currently funded, it can do no more than raise awareness of the need for collaboration. Meaningful practice change would require resourcing pharmacy more appropriately.
   - Developing the MedsCheck/Diabetes MedsCheck services so that pharmacists have a greater capacity to follow up on adherence issues for at-risk patients, enabling prescribers to better utilise pharmacist support and advice.

iv. Improve access to DAA services for at-risk patient groups.

   - PBS subsidised DAA service – implement a PBS subsidised DAA service similar to the DVA DAA scheme targeted at patients most at risk of poor adherence. As with the DVA scheme, doctors could prescribe the DAA service and pharmacists would conduct a 6-monthly review and report back to the doctor to prescribe continuation of the service. A subsidised service may have strict patient eligibility criteria such as age and co-morbidities (e.g. diabetes, CVD, dementia or combination of).
   - Under the *Living Longer Living Better* Aged Care Reforms, the intent is for all four levels of Home Care Packages to be designed to assist people to remain living at home for as long as possible and enable consumers to have choice and flexibility in the way that care and support is provided at home. One proposal is for people with any package level to have access to nursing and allied health services.[66]

     While not diabetes specific, this means that elderly patients with chronic health conditions could have greater access to non-subsidised pharmacy services such as DAA services. It is essential that Approved Providers of

these packages are aware of the service options available so that they can appropriately assess their patients and make relevant recommendations.

The Guild would be pleased to work with the Department and other relevant stakeholders to develop a resource for reference by approved providers or care co-ordinators with information about services available through community pharmacy and whether they are Government subsidised or private.

v. Implement a structured self-monitoring of blood glucose (SMBG) program through community pharmacy. One such model is depicted in Appendix A, where a MedsCheck service becomes the entry point into a more structured SMBG program that allows for scheduled reviews of a developed action plan, and careful monitoring of test strip utilisation over a twelve month period. It would encompass all of the components recommended in the International Diabetes Federations (IDF) Guidelines , recent research related to the effectiveness of SMBG and testing quality and interpretation, rather than testing frequency, as well as the previously researched and piloted DMAS.

vi. Where affordability is an issue for individuals, pharmacists may be able to assist by liaising with the prescriber to develop a more affordable medicine regimen. However, such services extend beyond conventional dispensing support and pharmacists need to be appropriately recompensed for their time and service.

While services such as the Diabetes MedsCheck provide such opportunities, there is limited access with strict patient eligibility criteria and a limit of one consultation per year. A more structured support service such as DMAS provides greater scope for ongoing review and support by the pharmacist.

If affordability is a broader issue for patients with diabetes, consideration may be given to general policy changes such as facilitating access to the PBS safety net scheme to lower cost barriers.

vii. The Guild would like to see consumers with chronic health conditions educated and encouraged to select and use one preferred pharmacy so they can develop an ongoing professional relationship with the pharmacist to better support them in managing their health condition. It would also promote a sense of connectedness for the patient with their preferred pharmacist and pharmacy staff, facilitating greater medication adherence and ultimately glucose control and health outcomes.

viii. Acknowledging the role of Medicare Locals in encouraging a culture of inter-professional learning and supporting multidisciplinary teams and practice improvement, more work needs to be done at both a national and local level to promote multi-disciplinary team care. Where the development or review of practice guidelines are funded by the Australian Government, this should be done in the context of patient centredness. Rather than developing guidelines for a particular provider group, general primary care guidelines could be developed with applications to the full spectrum of healthcare providers. The Guild would like to see such guidelines identifying team care arrangements utilising community pharmacists for QUM and medicine adherence support services for at-risk patients.

Along with developing relevant guidelines, it is essential that all providers are adequately recompensed for their care and coordination and the development of any team care service arrangements should reflect this.

ix. Consideration is given to implementing a remunerated pre-diabetes screening program in community pharmacy based on research conducted in the Pharmacy Diabetes Care Program commissioned under the Third Community Pharmacy Agreement[67].

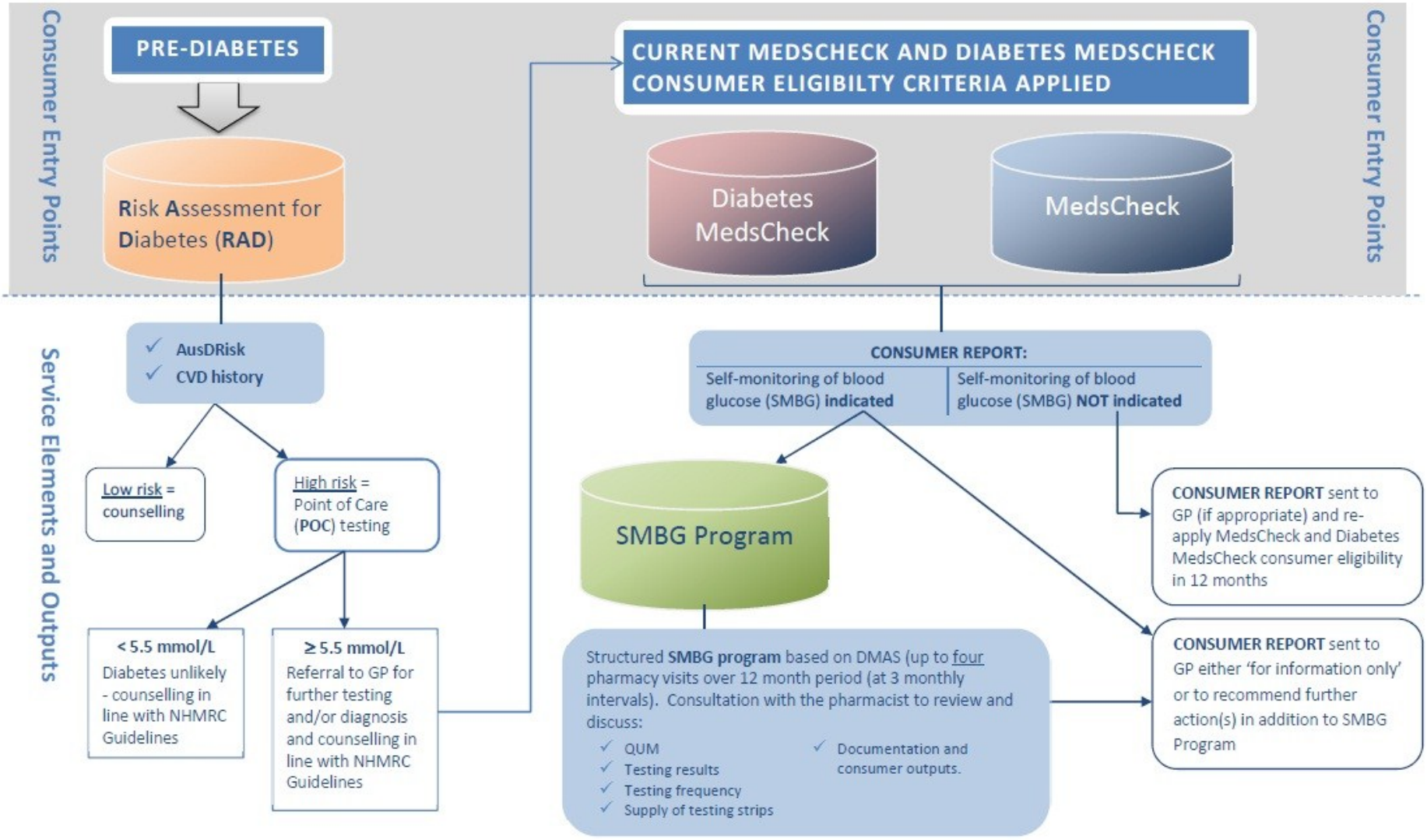
The program could involve three-steps that align with evidence-based, best practice guidelines[68] developed by the National Health and Medical Research Council (NHMRC):

- risk assessment using a validated tool (AUSDRISK)[69]
- point of care (POC) testing using capillary blood in line with professional standards and
- review of and response to results in line with recommendations within NHMRC guidelines

The model presented in Appendix A demonstrates a pre-diabetes screening service that could be implemented in community pharmacy and how it could align with a SMBG service for people diagnosed with type 2 diabetes.

x. With the ever-increasing numbers of Australians being affected by diabetes or pre-diabetes, the Guild recommends reinvesting back into community pharmacy some of the savings to the PBS from price disclosure, including in the form of structured pharmacy diabetes services. This would not only contribute to better managing the burden that diabetes is placing on the health system, including the PBS, but also assist in improving community pharmacy's longer term viability, enabling it to continue servicing the health needs of Australians.

Appendix A – Pre-Diabetes Screening & Self-Monitoring Blood Glucose Service Model



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