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The Secretary,
The House of Representatives Standing Committee on Health,
PO Box 6021,
Parliament House,
Canberra ACT 2600

Wednesday, 8 July 2015

Dear Sir / Madam,

A more rational, targeted and cost effective strategy for the prevention and management of cardiovascular disease in primary health care

Thank you for your invitation for me to lodge a submission for the Inquiry into Chronic Disease Prevention and Management in Primary Health Care. My submission is for a more rational, targeted and cost effective strategy for the prevention and management in primary health care of cardiovascular disease (CVD), the foremost burden of disease in Australia (1). Not only is CVD the greatest contributor to mortality, morbidity and expenditure in Australia, it is also significantly more prevalent in Australians with lower socioeconomic status, Indigenous Australians and those living in rural and regional areas, therefore contributing substantially to health inequalities (2). Most of this submission seeks to shift primary preventive activities away from the established individual risk factor management to a more holistic absolute risk approach. Also there is an urgent need to addresses a much ignored and poorly managed type of CVD namely peripheral arterial disease (PAD).

Why take an absolute risk rather than individual risk factor approach? An absolute risk approach best identifies who has covert CVD and therefore who is most likely to benefit from drug therapy. Absolute risk looks at the probability of a CVD event over a 5 year period. This approach looks at the whole person and all their major determinants of risk rather than individual risk factors that a person might have (e.g. isolated elevated blood pressure or cholesterol). Drug therapy is best given to those with high absolute CVD risk irrespective of individual risk factor levels because, being at the highest stroke and heart attack risk, they will have more events avoided and therefore have a lower number needed to treat to gain benefit. This approach also avoids CVD risk remaining unrecognised in the setting of other diseases. For example in diabetes management of the condition as high blood sugar (something that does not contribute substantially to CVD risk) may lead to neglect of the management of risk factors that do (e.g. high blood pressure and cholesterol) in a disease that has a whole of life CVD event rate of 60-70%.

In summary the absolute risk strategy:

- Recognises that blood pressure and lipid levels represent a continuum of risk;
- Is more cost effective;
- Avoids medicalisation of the low risk population and identifies those most likely to have covert CVD, avoiding costly additional investigations;
- Allows drugs to be initiated at a level above the ideal rather than an arbitrary cut point and;

• Ensures that attention is paid to CVD risk which otherwise might be subsumed within a particular chronic disease management strategy (e.g. diabetes).

Peripheral arterial disease (PAD) is a manifestation of systemic atherosclerosis. It affects 10–15% of the general population, and is often asymptomatic; leading to under-diagnosis and under-treatment (3). Australians with this condition are at the greatest risk of heart attack or stroke and paradoxically undertreated (4, 5). Atherosclerotic risk factors are often not intensively managed in PAD patients and can be a neglected component of CVD in primary care.

Addressing your Terms of Reference

1. Examples of best practice in chronic disease prevention and management, both in Australia and internationally

As previously outlined, the recommendation to initiate drug therapy for the primary prevention of CVD in a number of countries, including Australia, is now based on calculated absolute risk of subsequent CVD events rather than the previous recommendation related to individual risk factor thresholds (6-8). A recent meta-analysis of individual patient data from trials of blood pressure lowering medication provides compelling evidence for the rationale of an absolute risk based approach for the management of elevated blood pressure (9). Such an approach largely abandons the use of a simple cut point such as a systolic blood pressure ≥140 mmHg to calculate the individual's absolute risk score, a composite of a number of risk factors, and treat based on the absolute risk irrespective of individual risk factor measures. Clinicians have a number of concerns about moving to this approach, such as the long established epidemiological evidence of elevated blood pressure being associated with major adverse cardiovascular events, and the clinical trial evidence of reduction of these events with blood pressure lowering pharmacotherapy. However, the same data can be used to demonstrate that the reduction in CVD events do not depend on the blood pressure being above or below any threshold, and the likely benefit (absolute risk reduction) of drug therapy is determined by the absolute risk of an individual (9).

2. Opportunities for the Medicare payment system to reward and encourage best practice and quality improvement in chronic disease prevention and management

The Department of Health has a number of programs promoting healthy lifestyles such as 'Healthy Weight' and 'Healthy Spaces and Place' but no specific programs promoting awareness of absolute CVD risk and its management. Medicare Benefit Schedule (MBS) proformas for health assessments in ATSI adults still use an individual risk approach and do not include any absolute CVD risk assessment. Both these situations could be addressed.

Peripheral arterial disease (PAD) as previously outlined is often unrecognised and under-treated. A barrier to its recognition (i.e. diagnosis) is the need to acquire and train on special equipment to be able to diagnose it with a measure called the Ankle Brachial Index (ABI). Australian research has shown that existing newer blood pressure measuring devices can reliably screen for ABI without the need for expensive equipment or training (10). Hence I would recommend a Medicare payment for determination of ABI not based on the current requirement for a print out to incentivise GPs to identify this condition (11).

3. Opportunities for the Primary Health Networks to coordinate and support chronic disease prevention and management in primary health care

Primary Health Networks (PHNs) are potentially an important enabler of implementation through the delivery of training, facilitating data collection through tools such as the PenCAT software,

through the use of local champions in a range of primary care providers and through the new 'Health Pathways' projects that provide GPs with locally-relevant protocols and referral pathways via a web-based portal. The National Heart Foundation is working in partnership with Medicare Locals/PHNs to try and use these mechanisms to increase the use of absolute CVD approach to primary prevention. PHNs can also have a large role in addressing barriers contributing to the evidence-practice gap such as: persistent individual risk-based prescribing patterns amongst GPs; time constraints in primary care; inconsistencies and limited coordination between primary care providers; lack of community awareness about absolute CVD risk and low health literacy; and lack of a coordinated and systematic approach to implementation.

There have been recent education programs supporting the NVDPA guidelines, e.g. Australian Atherosclerosis Society – High Blood Pressure Research Council of Australia Joint GP Masterclass and the National Prescribing Service Medicinewise program. It has been feedback from these education sessions and other evidence (e.g. Bonner C, et al. (12)) that has identified the need to provide robust evidence to address scepticism. There have been recent practical reductions in barriers to use, e.g. Medical Director, the dominant clinical software in general practice, now has the Australian Risk calculator embedded within and automatically populated with risk factor variables. What is required is to get GPs to push the button to activate it at the appropriate time for clinical decision making.

4. The role of private health insurers in chronic disease prevention and management

Private health insurance is currently not permitted to operate in the general practice environment. It could be argued if they were then more money would be available for evidence based prevention and management as they are not wont to spend money inefficiently.

5. The role of State and Territory Governments in chronic disease prevention and management

There have been to moves to integrate care between primary and acute care especially in relation to CVD secondary prevention (secondary prevention populations being at very high risk of subsequent CVD events and therefore recidivism in the state hospitals).

6. Innovative models which incentivise access, quality and efficiency in chronic disease prevention and management.

The absolute risk approach to the primary prevention and management of CVD has been endorsed by all relevant peak bodies (National Heart Foundation of Australia, National Stroke Foundation, Kidney Health Australia and Diabetes Australia) through collaborative work in the National Vascular Disease Prevention Alliance in recognition of this disease being a common end point for these groups' respective disease processes. This work has led to the production of a common 'non-competitive' clinical management guideline (6). This approach has also been accepted by the National Health and Medical Research Foundation (NHMRC) through their 'case for action' process and endorsed guidelines (13).

Elevated blood pressure (BP) is the longest established CVD risk factor and therefore a test case for change in approach from management of an individual risk factor to an absolute risk approach. Achieving optimal control of BP is an identified evidence-practice gap (14). In August 2014, the Lancet published a meta-analysis of individual patient data from 11 trials of 51,917 participants with risk algorithms dividing them into 5-year absolute CVD risk categories of <11%, 11-15%, 15-21% and >21%. They found that treating 1000 patients in each group with BP-lowering medication for 5 years would prevent 14 (95%CI 8-21), 20 (8-31), 24 (8-40) and 38(16-61) CVD events, respectively (P=0.04 for trend) (9). In other words, by identifying 1000 patients with an absolute

CVD risk of >21% and lowering their BP, 38 heart attacks and/or strokes would be prevented over 5 years. On the other hand, identifying 1000 patients with an absolute CVD risk <11% and treating their BP would prevent 14 CVD events over 5 years. With estimates that more than 60% of Australians have three or more modifiable CVD risk factors, this approach is likely to prevent a substantial number of CVD events across the population. The authors recommend that 'a blood-pressure lowering treatment should target those at greatest cardiovascular risk, not just those with the highest BP level. A risk-based approach is likely to be more cost-effective than a blood-pressure-based approach, and could simultaneously reduce the numbers of patients needing treatment, and control drug costs, while increasing the numbers of averted strokes and heart attacks.' Most elevated BP is managed in general practice and it is the commonest condition managed there, accounting for 9 out of every 100 consultations (15).

This latest evidence builds on earlier work, from an individual patient meta-analysis of more than 135,000 patients showing that an absolute CVD risk approach to statin use to lower LDL cholesterol also increased the number of CVD events averted. For example, if 1000 patients with a 5-year CVD risk of 20-30% have their LDL cholesterol levels reduced by 1 mmol/l then 20 vascular deaths will be avoided and 61 major vascular events avoided over 5 years (16).

A 2015 study published in Hypertension also provides support for the value of the absolute risk approach in patients with type 2 diabetes (17). It found that a multivariable treatment algorithm can identify those individuals who benefit most from blood pressure–lowering therapy in terms of absolute risk reduction of major adverse cardiovascular events and may be used to guide treatment decisions in individual patients with diabetes.

Economic benefits of the absolute CVD risk approach to primary prevention

One Australian cost-effectiveness study has estimated that appropriate prescription of BP-lowering medication and statins using the absolute risk approach would save $5.4 billion for the Australian Government over the lifetime of population aged 35-84 years in 2008. This could increase to $7.1 billion if statin prices were matched to New Zealand rates (18).

Furthermore, although an absolute CVD risk approach is potentially more than twice as effective in reducing death from CVD than treating people with a single risk factor approach (16) several Australian studies have identified that patients are missing out on appropriate evidence-based treatments. Data from 2618 consecutive adult patients presenting to 99 GPs in 2009 found that only 23% of patients with high absolute CVD risk had been prescribed both antihypertensive medication and a statin (19). Even patients who had a history of CVD (secondary prevention) had been prescribed these recommended treatments in 53% of cases in one study (19) and 50% in another (20). A recent analysis of a random sample of concession card-holders found these results have not improved and that only 42% of high coronary risk patients had been prescribed a lipid-lowering drug between 2006 and 2013 (21). The gap is similar amongst Indigenous Australians suggesting that deficiencies across the health system are to blame.

The Practice Incentive Program (PIP) encourages quality improvement and better health outcomes for patients. The program currently includes payments for activities related to diabetes, immunisation, asthma and others but not for absolute CVD assessment and management. This could be addressed.

The Pharmaceutical Benefits Scheme (PBS) criteria for prescribing statins also continue to use an individual risk approach and are not consistent with current NHMRC-endorsed guidelines. This is a problem because many patients with high absolute CVD risk are from lower socioeconomic status and would be possibly have difficulty paying full price for statin therapy although many are available now in generic form. For example, 30% of high absolute CVD risk indigenous patients in

one study would not qualify for statin subsidies under current PBS criteria (13). At a NHMRC Translational Faculty meeting changes to the PBS criteria for lipid lowering drugs was endorsed as the single most important change needed to embed an absolute risk approach to CVD prevention and management in clinical practice. Current PBS criteria for the use of statins are found at http://www.pbs.gov.au/info/healthpro/explanatory-notes/gs-lipid-lowering-drugs .

The prescribing criteria for lipid lowering medications were revised in 2006 to attempt to bring the prescribing criteria more in line with an absolute risk approach, with the criteria at that time being for levels approximately equivalent to an absolute risk of ≥ 15% over 5 years. The PBAC has stated publicly that it favours an absolute risk approach to the prescribing of lipid lowering therapy (22). Although the PBAC was aware of the publication of the NVDPA guidelines, this is not sufficient for the PBAC to review the prescribing criteria and in general the PBAC cannot act without a request from either a sponsor or the Minister.

There are 8 high risk criteria which can be met and, if these are not met, a further complex 7 post-dietary qualifying criteria each with differing age and/or total cholesterol or cholesterol fraction or triglyceride treatment thresholds. Such complexity spawns confusion, non-compliance and inefficiencies of prescribing practice (23). If cholesterol lowering medication for primary prevention was based simply on absolute risk alone this would make GPs make such calculations, simplify the process, and ensure that those most likely to benefit from statins are the ones that receive them. The two drugs with the highest cost to government in financial year 2013-14 were rosuvastatin ($287.9million) and atorvastatin ($279.2 million) both statins http://www.pbs.gov.au/statistics/2013-2014-files/expenditure-and-prescriptions-12-months-to-30-june-2014.pdf .

7. Best practice of Multidisciplinary teams chronic disease management in primary health care and Hospitals

Absolute risk estimation is becoming an automated process so little need for additional staff although would make the utilisation of health workers in a more efficient and equitable manner as intervention would be directed at those most likely to benefit from it.

8. Models of chronic disease prevention and management in primary health care which improve outcomes for high end frequent users of medical and health services

Over 90% of Australian adults have at least one modifiable CVD risk factor, while 64% have three or more (6). It is therefore critical that we optimise the prevention of CVD in people with potentially modifiable risk factors for the disease that this is just not based on individual risk factors alone or we will ‘medicalise’ the vast majority of the Australian population. As it is ‘hypertension’ is the commonest problem managed in general practice (15).

Thank you for consideration of this submission which has broad peak body support and requires a simple redirection of priorities.

Yours sincerely

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