



GSK comments on the Men's Health Initiative

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Introduction

GlaxoSmithKline (GSK) commends the Government on its initiative to draft Australia's first Men's Health Policy and welcomes the opportunity to provide feedback and input. It is well documented that life expectancy for men is approximately 5 years lower than that for females. Although, this has been improving over the past 20 years, there are still considerable challenges facing men and their health, in particular risk factors relating to chronic illnesses which remain higher in the male population¹.

GSK heritage companies have operated in Australia since 1886. We have two operating groups – GSK Pharmaceuticals, based in Boronia, VIC and GSK Consumer Healthcare, based in Ermington, NSW. We employ approximately 2000 people across Australia. GSK is one of the leading suppliers of medicines and vaccines to the Pharmaceutical Benefits Scheme and the National Immunisation Program, providing treatments for conditions such as asthma, diabetes, HIV/AIDS, infections, cancer, weight loss, smoking cessation and prostate health as well as a wide range of vaccines to prevent childhood illnesses.

This submission is being made on behalf of GSK's Pharmaceuticals and Consumer Health divisions and will consider some of the challenges and opportunities facing Men's Health. It will also focus on the importance of awareness and early intervention of some of the main risk factors and health issues affecting men, including some specific therapy areas – diabetes, obesity, tobacco use and prostate health.

Men's Health

The top five leading causes of chronic diseases in men are smoking, lack of exercise, poor diet, alcohol misuse and obesity. All these risk factors are largely preventable, yet despite this the prevalence of many of these risk factors has increased over the last two decades².

Both men and women have different health needs and thus, in line with the World Health Organisation (WHO) Madrid Statement, specific policies for each are recommended in order to address their gender-based health requirements. Specific policies also assist in addressing the changing health issues faced by men over their life course. Attention needs to be given to managing health problems in different stages of a man's life. Over 40% of men aged over 40 years have health problems relating to heart disease, metabolic disease, lung disease and prostate health. This increases to over 60% as men approach 70 years of age. Greater focus is needed on early diagnosis of these conditions thereby allowing the health sector to prevent and target them more effectively. A policy which focuses on prevention and appropriate treatment coupled with targeted action plans would prove a step in the right direction to improve the health of Australian men.

There is a gap in our understanding of how men deal with their personal risk factors and rationale for how and why they make or don't make changes to address those risk factors. Many men feel that health related behaviour is foreign and they are not expected to discuss their illnesses or health to the same extent as women. In a study evaluating the impact of early detection of prostatic cancer, George and colleagues commented that "even though urinary symptoms interfered with their activities of daily living this was still not seen as a sufficient reason to consult a doctor". Men's acceptance of symptoms despite the anxiety they experience related to these is an alarming phenomenon³. This may be because men consider themselves to be invulnerable in terms of illness or perhaps due to their perceived sense of role in society or masculinity makes it difficult for them to seek help regardless of the health consequences⁴. More alarming is that men believe that they should 'tough out' illnesses rather than admit 'weaknesses'. They also think they would be 'wasting the doctor's time' with their problems⁵.

A UK study illustrated that men do recognise the value of early detection of disease and see information as an intrinsic part of feeling empowered. They want professionals to clearly explain the rationale behind the processes and investigations being undertaken. However, they saw their General Practitioners (GP) as 'reactive' rather than 'proactive' when it came to discussing men's health issues⁶.

Establishing a good rapport between men and their healthcare professionals is therefore a particularly critical first step for developing effective communication channels that will ultimately help to improve their health outcomes. In addition, having clear and robust education campaigns for both community

and health professionals could help build greater awareness and assist in ensuring men have access to advice which assist them in changing the behaviours necessary to improve health outcomes. Any approach taken with men's health needs to integrate with the existing programs and initiatives which are working.

Another path worth consideration is the establishment of more male specific healthcare centres and provision points. Several clinics exist which deal primarily with female health but fewer provide specific support for men's health. Easier access to male friendly GP clinics which provide a 'safe' environment for men to openly discuss any concerns or issues that men have may prove valuable in addressing men's health needs.

The Government has launched several initiatives to address lifestyle risk factors for chronic diseases. One such initiative is the 'Lifescrpts' program. Lifescrpts allows doctors to tailor programs to patient needs⁷. A way forward may be to integrate such programs with specific men's health issues targeting risk factors faced in different stages of life. A US based study found that targeted workplace programs were helpful in raising awareness of risk factors. In this study positive steps had been taken to improve 60% of risk factors. Actions included visits to the GP for health screens and lifestyle modifications⁸. Such targeted programs may be useful in the workplace to raise awareness of issues such as diabetes, smoking, prostate health, and lifestyle risk factors

Men's health week (15-21 June) is another valuable forum to raise awareness of issues and challenges facing men's health. These forums are a good opportunity for Government, community and the private sector to work together to raise awareness to men's health and the importance of preventing and managing risk factors.

However, it is critical that these, and other related, programs are continuously evaluated to ensure the initiatives are improving health of men and delivering value to our healthcare professionals.

Diabetes

Type 2 diabetes (T2D) accounts for 92% of all diabetes cases in Australia. The prevalence of this disease increases with age with over 22% of people over 75 years of age having T2D. Diabetes, largely a preventable condition, poses long term complications including renal diseases, blindness, cardiovascular disease, infections and depression⁹.

Research shows that almost 50% of people with T2D are not at their blood glucose target¹⁰. Blood glucose levels are measured in millimoles per litre of blood (mmol/L). The normal range for blood glucose is 4-6 mmol/L. A landmark UK based study demonstrated that 50% of patients had a diabetes-related complication at diagnosis suggesting that patients are presenting at a later stage of disease¹¹. Staggeringly almost 1 in 4 Australians over 25 years of age have either diabetes or elevated blood sugar that is close to the range recognised for diabetes. This condition, known as pre-diabetes¹², does indicate a higher likelihood of an individual developing diabetes in the future.

GSK would like to recognise the Council of Australian Governments' initiative which targets patients aged 40-49 years of age at high risk of diabetes. Recognition is also due to the Victorian Government for initiating the 'Life!-Taking action on Diabetes' program, an important part of the 'Go for your Life' strategy which has been developed to support Victorians over 50 years of age and Aboriginal and Torres Strait Islander people of all ages to prevent T2D¹³.

Significant work has been undertaken by groups such as Diabetes Australia on initiatives to raise awareness of diabetes and implications of uncontrolled disease. The 'waist measurement' campaign launched in 2008 increased visibility of the disease and also provided patients with a simple tool – a tape measure – to gauge one of their risk factors. The Government's more recent 'measure up' campaign represents a further initiative to highlight awareness of risk factors leading to diabetes. The role of patient groups, Government and private industry all working together to support such initiatives should be further explored in order to maximise the impact and reach and ensure that all such initiatives work synergistically together.

It should be noted, however, that, for many patients, healthy dietary habits, being active and a healthy weight are not sufficient to control blood sugar levels. For these patients, medications and other interventions are available to doctors and their patients to control T2D. One key challenge involved here however is improving patients' knowledge of their oral diabetes medication. In a survey

conducted by Brown *et al*, only 35% of patients recall receiving advice about their medication, 15% of patients know how their medication works and only 10-15% knew the side effect profile of their medicines¹⁴.

Two key factors help patients use their medicines appropriately and consistently: a mutual exchange of information between a patient and their healthcare professional, and an acceptance by the patient of the need to change behaviours and lifestyle. Another key issue is the patient presenting to a doctor early in their disease. Currently, many Australians with diabetes remain undiagnosed and many who have been diagnosed have not achieved their target blood glucose levels. Most patients presenting to their doctor with diabetes will have already lost 50% of their pancreatic beta cell function, the cells which produce insulin necessary to maintain normal blood sugar levels¹⁵. Considering that 1 in 4 Australians over 25 have pre-diabetes, diagnosing this earlier and accessing treatment are key to ensuring better health outcomes for patients.

GSK recognises that diabetes is one of the top seven national health priorities for the Government and, while several innovative policies to prevent and manage this disease have been developed and implemented, further consideration may need to be given to the execution and evaluation of these strategies particularly at the primary care interface.

Obesity

Obesity is another largely avoidable condition of which the prevalence has grown over the last 10 years, with being overweight or obese recently overtaking tobacco smoking as the leading risk factor for premature death and disease in Australia¹⁶. This issue particularly affects men with a 2004 Victorian survey revealing that men are more likely to be overweight than women regardless of their age. In the period 1999 to 2000, the proportion of overweight men increased from 47% to 66% whilst the percentage of overweight women has increased from 27% to 47%¹⁷.

Excess body weight is associated with a range of health problems including cardiovascular disease, T2D, sleep apnoea, osteoarthritis, psychological disorders and social problems. Being overweight or obese also leads to decreased life expectancy and reduced quality of life. Research from the US suggests that, whilst most people report having a primary care doctor (87%) and also report seeing a doctor at least annually (92%), only 30% of those who self-identify as being overweight would see a doctor to help them lose weight¹⁸.

The Government has introduced various initiatives to assist people control their weight and undertake behavioural changes relating to weight loss and active lifestyles. However, many people find the necessary behavioural changes challenging. Accompanying appropriate support and balanced communication with effective medicines can both educate and empower individuals to reshape their own behaviour whilst delivering more positive health outcomes. As such, a third pillar recognizing that appropriate and effective pharmacological adjuncts can assist people, particularly those finding it hard to adapt their behaviour, should be considered in addition to exercise and diet.

Orlistat, known as 'alliTM', is a weight control medicine which is available in Europe and the USA and for which GSK is currently seeking registration in Australia. This medicine has been clinically proven to help people lose 50% more weight than dieting alone by preventing about 25% of the fat from food consumed being absorbed by the body. The use of alli is supported by the 'alli program'¹⁹ which aims to educate people about the benefits of adhering to a reduced calorie, lower-fat diet and to implement lifestyle changes to help sustain a healthy weight. Medicines like alli with a well established and clinically proven safety and efficacy profile when available over the counter can play a role in Australia's broader strategy to address men's weight issues.

Education however plays a vital role in any long term weight reduction program. Raising awareness that there is no 'magic bullet' and that long-term weight loss will only be achieved if changes in dietary habits and physical activities are adopted is vital. GSK fully supports and seeks to ensure that any pharmacological therapy is implemented alongside appropriate education around dietary habits and the importance of physical activity.

Smoking Cessation

In 1980, over 40% of Australian men aged over 18 smoked – today this figure has dropped to 18%²⁰. While overall smoking rates have been decreasing, these have not fallen evenly across the population with certain populations still smoking disproportionately, in particular indigenous males. In 2003, approximately 8% of the total burden of disease and injury in Australia was caused by tobacco use with COPD, ischaemic heart disease and lung cancer accounting for more than three quarters of this. Smoking contributes to more hospitalisations than alcohol and illicit drugs, creating substantial costs within the health system. In 2001-02, smoking was responsible for almost 300,000 hospitalisations resulting in nearly 1.5 million hospital bed days and \$700 million in costs²¹. Additionally the social costs of tobacco (productivity, healthcare and resources) use in Australia were an estimated to be \$21.1 billion, about 2.3% of the gross domestic product²².

The disease and deaths related to smoking are largely preventable and, while health benefits of smoking cessation are real, the benefits will most likely not be realised for several years due to the lag time between initiation of smoking and onset of disease²³. It is therefore imperative that more needs to be done to help Australia reach its target of reducing the prevalence of smoking to 9% by 2020.

Public health campaigns have had a significant impact on smoking rates in Australia. In 2006, the National Drugs and Poisons Scheduling Committee, in coordination with the National Tobacco Strategy, made nicotine replacement therapy (NRT) available as an over-the-counter medicine purchasable in pharmacies, grocery outlets and convenience stores thus improving smokers' access these therapies. This, along with public health campaigns, has led to improvements in smoking cessations rates in Australia²⁴.

Over the years, new and potentially more effective ways of using various NRT regimes have emerged. For example, the combined uses of patches and oral dose forms, such as gum or lozenges have been shown to be more effective than standard mono-therapy. In addition, the use of NRT even in those who continue to smoke has been shown to help reduce cigarette consumption and encourage people to ultimately quit. In the case of patches, pre-cessation use has been shown to help deliver increased quit rates. Appropriate use and availability of NRT should continue to be encouraged as part of the broader agenda to assist patients stop smoking and to ensure that smoking ceases to be the significant public health problem, especially for Australian males, that it is today.

Finally, increased investment in government funded quit advertising has been recommended by the National Preventative Health Taskforce²⁵ and could help to continue growing and delivering benefits. In order to assist in targeting any additional investment, GSK would be happy to share the consumer and patient insights we have and other relevant information.

Prostate Health

A direct association exists between men's reproductive health disorders and age. This would suggest that more men are likely to seek help in the future as these issues become more prominent with the ageing of the male population²⁶.

Governments have undertaken several initiatives in this area, specifically in relation to prostate cancer. Although early screening of this disease is a personal choice, men with a family history of prostate cancer should be encouraged to invest in early screening to avoid complications and protect their health. Prostate conditions experienced by men are not limited to cancer however. Other debilitating conditions include Benign Prostatic Hyperplasia (BPH) and Prostatitis. BPH is the most common form of prostate disease - the enlargement of the prostate gland. It is a progressive disease characterised by lower urinary tract symptoms, which can have significant impact on a man's quality of life and, if left untreated, can lead to complications of the bladder and kidney which can create the need for surgery. BPH is an area of unmet need for men's health, affecting more than 50% of men over the age of 60 and 90% of men over the age of 70²⁷.

Research shows that initial diagnosis of BPH can be delayed as many patients go through a 'denial phase' before presentation. This is primarily driven by feelings of embarrassment and uncertainty. BPH has, however, a significant impact on quality of life for both the patient and their partner. Despite

this, there is a high tolerance of symptoms of the condition because patients may be too embarrassed to discuss it. The highest areas of impact are: sleep deprivation for the patient and partner, sexual function and pride²⁸.

Men with BPH symptoms show an even greater impairment of health than those with chronic illnesses, such as gout, hypertension, angina or diabetes. Understandably most men are concerned about the progression of this disease, in particular the risk of surgery, worsening of symptoms and the impact on their sex life and relationship with their spouse²⁹.

As long as the symptoms of BPH are taken care of however, men are open to a treatment that limits progression of disease. This is particularly true as men are intent on avoiding surgery where possible. A US survey of men over 50 years of age reported that 25% had moderate to severe symptoms of BPH. Despite this, less than 50% of men with symptoms are diagnosed with BPH and less than 30% are treated with medicines^{30,31}.

Interestingly in Australia, many more surgical interventions are related to BPH than for malignant growths. Of the 21,110 transurethral prostatectomies performed in 2004-05, more than 2/3 were for a primary diagnosis of BPH. Although successful, these procedures can result in complications which can have profound impact on an individual and their partners' wellbeing, such as erectile dysfunction and incontinence. In some cases, there is also a need for follow-up surgery³². Incidentally research also shows that surgery rates in Australia are amongst some of the highest in comparison to other countries³³.

The likelihood of BPH progression leading to acute urinary retention and BPH related surgery increases as the prostate increases in size. Data shows that therapies such as 5 alpha reductase inhibitors in combination with alpha-blockers result in reduced rates of BPH surgery by 67% and risk of acute urinary retention by 75% compared to no therapy or alpha-blockers alone³⁴. This is because 5 alpha reductase inhibitors halt the underlying disease process and reduces prostate size which improves BPH symptoms thus reducing risk of surgery³⁵.

Currently there are no pharmacological agents listed on the Pharmaceutical Benefits Scheme, specifically, for BPH in Australia. This may have implications on treatment options for patients as it is likely to impact both the prescribing of such medicines and patients' compliance due to cost of medicines.

GSK would encourage the Government, within the context of the work they are undertaking on men's health, to enhance the emphasis on men's reproductive health and the early diagnosis of conditions such as BPH. Andrology Australia has also been working to highlight the challenges, issues and solutions facing male reproductive health and aging and their work highlights the importance of having a body which continues to raise awareness of men's reproductive health in the general and medical communities.

Conclusion

As highlighted in the areas featured above, delivering a focus on prevention and appropriate treatment coupled with targeted action plans would prove a step in the right direction to improve the health of Australian men. Both in these areas and more broadly, the barriers that men experience in accessing health services need to be reduced and support needs to be provided to ensure that healthcare providers are comfortable and well equipped to consult effectively regarding a range of conditions, including prostate health, diabetes, obesity and smoking cessation. These issues need to be tackled by healthcare providers, the private sector and the broader community working together to make sure that the discomfort men feel when they engage with their physician is minimised³⁶. While several policies have been developed, consideration should also be given to evaluating existing policies and programs to better understand the uptake of initiatives, increase our understanding of successful practices and to avoid any duplication.

With over 40% of men aged over 40 years experiencing health problems relating to heart disease, metabolic disease, lung disease and prostate health, delivering access to early detection, effective support, communication and access to appropriate therapies are key to ensuring best outcomes for our male population.

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