

USED OF EPIDEMIOLOGICAL EVIDENCE FOR POLICY DEVELOPMENT

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ABSTRACT

Background: Epidemiological studies are used to determine the magnitude of health problems, to define their distribution and associated factors and to measure health outcomes of risk factors or behaviours, or even intentional interventions. The capability to generate evidence makes epidemiology a possible useful tool for well-informed policy making. This article aims to explore the use of epidemiology in health policy development.

Materials and Methods: Manual and computerised search was conducted using various electronic and public domain databases. Articles, reports, and publications pertaining to the use of epidemiology in policy development globally and in Malaysia were gathered, screened, and analysed focusing on the Malaysian HPV vaccination policy and the Australian tobacco policy.

Result: Two categories of health policies were identified; allocative and regulatory. Malaysian HPV vaccination policy is an example of allocative policy in which the population at risk are provided with the vaccine based on the epidemiological evidence of high prevalence and incidence of cervical cancer in Malaysian females, high mortality and morbidity burden, and high vaccine efficacy and cost-effectiveness. On the other hand, the Australian plain tobacco packaging policy is an example of the regulatory policy, in which a directive is set to influence the behaviours and actions of public in order to ensure the population health interest and prevent harm. Epidemiology in this aspect has provided tremendous evidence on the adverse effects of smoking, where it is found to be responsible for the largest burden of disease among Australian of all ages in the country. In response, plain packaging policy was enacted to reduce the misleading marketing of tobacco products in favour of the public health.

Conclusion: Although epidemiological evidence is essential in continuous evidence-based health policy development, there are some challenges in translating the evidence into policies. Therefore, epidemiologists' contribution in presenting relevant epidemiological evidence in a more systematic, effective and understandable form for the decision makers is vital in the course of health policy development.

Keywords: Epidemiology, health policies, tobacco, HPV vaccination

1.0 INTRODUCTION

The importance of epidemiology in public health has been strong since the mid-1800s. Since the success of tracing the source of cholera outbreak in London in 1854 by John Snow, currently regarded as one of the fathers of modern epidemiology, the application of evidence-based information in public health decisions has become ever more established. Last (2004) defined Epidemiology as ‘a science that studies the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems’. Data on the needs for health care of the population are vital to be provided to relevant parties for necessary actions to be taken, thus epidemiological studies play a critical role in projecting size and defining geographic dimensions of afflicted populations, measuring short- and long-term health outcomes, granting evidence to determine causal association between risks and the health outcomes and assessing burden of disease, particularly with respect to chronic diseases. Epidemiologists have a variety of “tools” at their disposal that can be of assistance during policy development process. Examples of epidemiological tools that can be applied are public health surveillance, risk assessment, local needs assessment, economic evaluation, expert panels review, systematic reviews, meta-analysis and weight-of-evidence synthesis.

Health is an important freedom that is essential for our wellbeing as well as our normal functions as human beings. Some factors that influence health are best to be pursued collectively, in which, government interventions are utmost needed. Development of policies is not an alien issue in healthcare, in fact, in the current era, health care systems and services without any political involvement are not sustainable. Policy is a statement that emphasises on content, process, and power, however it is not limited and bound by any time frame. There are several types of policies, namely substantive policy and administration policy; vertical and horizontal policy (Smith, 2003); reactive and proactive policy and current and future policy (Development Associates Link International [DALI] Inc. Follow, 2010).

A public policy is an intended and customarily a deliberate resolution that provides guidance to address any selected public affairs. Forty-five years ago, Thomas Dye defined ‘public policy’ as “anything a government chooses to do or not to do” (Whittington, 1972). In spite of the fact that Dye over simplified the term, his definition captured the broad extent of the topic. In line to the purpose of this study, the policy that will be focused on is the health policy. Health policy was defined by Lee and Mills in 1982 as ‘authoritative statements of intent, probably adopted by governments on behalf of the public, with the aim of altering for the better health and welfare of the population’. In a more understanding manner, the World Health Organisation (WHO) states health policy as decisions, plans, and actions that are undertaken to achieve specific health care goals within a society (World Health Organisation [WHO], 2017). It is about the planning and improvising of health care system and the actions taken at a political level to provide, sustain and improve the health of the population. Four important components of health policy framework are content, context, process and actors or stakeholders, all which contribute significantly in the development of a health policy.

The steps of policymaking vary based on different schools of thought, however the policymaking process proposed by Althaus, Bridgman, and Davis (2015), in the Australian Policy Handbook, is being selected as the reference for this study. There are eight steps in total, namely; 1) issue or problem identification, 2) analysis and policy formulation, 3) policy

instrument development, 4) consultation, 5) coordination, 6) decision, 7) implementation and 8) evaluation. These eight steps can be categorised into three different phases, the first phase being policy formulation phase, followed by policy implementation and policy evaluation phase. The contribution of epidemiology is the greatest in the first and third phase of policymaking process. Agenda setting, situational analysis and policy objectives setting are among the initial steps in policy formulation phase which demand evidence-based (epidemiological) inputs. Likewise, epidemiological tools such as economic evaluation, mortality, morbidity and burden of disease data contribute tremendously during policy process evaluation as well as policy outcome and impact evaluation phase. In addition to the usual indicators of impact analysis, epidemiology can contribute to the improvement and application of new methodologies, such as the development of scenarios that help the decision-making process by projecting the possible consequences of adopting different courses of action. The ability to model complex scenarios has developed rapidly, providing increasingly reliable and valid projections. Evidence-based guided policymaking process is a continuous process, in which researchers keep on providing new epidemiological input, to be of help to the policymakers in deciding whether to continue, improve, expand or terminate a policy.

Gazing back into the history of the rise of modern epidemiology, John Snow had intelligently demonstrated how to use epidemiological tools in tracing the source of 1854 London cholera outbreak by illustrating the location of a water pump and the clusters of the cholera cases on a map. This discovery eventually steered political involvement and led to the removal of the handle of a water pump on Broad Street, which successfully eased the cholera outbreak. This is just one simple example of the importance of evidence-based information in public health decision making. Numerous other examples of achievements of epidemiological studies applications in policymaking include the establishment of tobacco smoking as a cause of lung cancer and other diseases (Doll & Hill, 1954); the identification of powerful and remediable causes of cancer, such as asbestos exposure (Lemen, Dement, & Wagoner, 1980) and the teratogenic effects of thalidomide (McBride, Vardy, & French, 1982).

All various forms of health policies fit into two basic categories – allocative and regulatory. Allocative category is the combination of distributive and redistributive policies while the regulatory category can be subdivided into competitive and protective regulatory policies (Birkland, 2001, Longest, 2010, Shi, 2013). Allocative policies are designed to provide net benefits to some distinct group or class of individuals or organisations at the expense of others to ensure that public objectives are met (Longest, 2010). In allocative policies, policymakers seek to alter demand for or supply of particular products and services or to guarantee access to products and services for certain people. A good example of allocative type of policy is the Human Papilloma Virus (HPV) vaccination policy in Malaysia in which girls at the age of 13 are given free HPV vaccines after obtaining consent from their parents or guardians to protect them against two types of HPV, which are known to be responsible for approximately 70% of cervical cancer cases. Meanwhile, regulatory policies are designed to influence the actions, behaviours and decisions of others by directive to ensure that public objectives are met (Longest, 2010). Australian Tobacco Policy is an example of regulatory policy which aims to improve the health of all Australians by eliminating or reducing their exposure to tobacco in all its forms.

Policymaking is one of the fundamental activity of governments. It is through the public

polycymaking process that governments establish the framework within which all citizens must function; and it is the process via which governments decide which societal goals to pursue and how to best pursue them (Young, 2014). It is an undeniable statement to mention that epidemiology is the basis for all thorough and reasonable health policies. Therefore, this report is aimed to describe the use of epidemiology in health policy development.

2.0 MATERIALS AND METHODS

The research team conducted a manual search of articles, reports, journals and related publications by various sources such as the Ministry of Health Malaysia (MOH), academic institutions and international organisations pertaining to the use of epidemiology in policy development globally and in Malaysia. In the initial phase, the available literatures were accessed on 13th and 14th February 2017 from three electronic databases – Pubmed, PMC, and PLoS and public domain databases – Google and Google Scholar. Subsequently, more articles and reports were identified by combing through the references from the relevant literatures. The search keywords include; ‘use of epidemiology’, ‘policy development’, ‘allocative policy’, ‘regulatory policy’, ‘tobacco policy’ and ‘HPV vaccination policy’. The search was focused on Australian Tobacco Policy and Malaysian HPV vaccination policy to illustrate the use of epidemiology in regulatory and allocative type of policies respectively.

3.0 RESULTS

This section will describe the use of epidemiology in the formulation, implementation and evaluation phase of allocative policy and regulatory health policy development.

3.1 HPV vaccination policy in Malaysia

Human Papillomavirus (HPV) vaccination policy is a good example to illustrate how epidemiological tools are applied in allocative health policy development. Epidemiological studies have provided valuable data on the prevalence, incidence, mortality and morbidity of cervical cancer, the magnitude and burden of the disease and the link between HPV infection and the progression to developing cervical cancer.

Globally, in 2012, cervical cancer was ranked as the fourth most common cancer in women with an estimated 530,000 new cases in 2012 alone (Bruni et al., 2015). On top of that, cervical cancer has caused an estimated of more than 270,000 deaths worldwide, annually, in which more than 85% of these death occurred in the less developed regions (Bruni et al., 2015). Various epidemiological studies have also shown that HPV is the most common viral infection of the reproductive tract, and persistent infection with specific types of HPV may lead to precancerous cervical lesions. If left untreated, these precancerous cervical lesions may progress to become cancerous. Although there are at least 13 known cancer causing HPV genotypes, out of more than 100 known HPV genotypes, the two most common "high-risk" genotypes that are of concern are HPV 16 and 18. Both of these genotypes are known to have caused approximately 70% of all cervical cancers (WHO, 2014).

Vaccination against HPV infection offers a promising additional component to the current practice of regular cervical screening for early detection and treatment of precancerous cervical lesions. Cost-effectiveness models in low- and middle-income countries suggest that a combination of HPV vaccination and cervical screening once to three times per lifetime is cost-effective for cervical cancer prevention (Goldie et al., 2006). There are currently three HPV vaccines that have been approved by the U.S. Food and Drug Administration to protect women against both HPV 16 and 18; Cervarix, Gardasil, and Gardasil 9. Clinical trial results have shown that all the three vaccines are safe and effective in preventing infection with HPV 16 and 18, as well as offering some cross-protection against other less common HPV genotypes which can also cause cervical cancer. Gardasil, in addition, protects against HPV 6 and 11 which can cause anogenital warts. These vaccines work best if administered prior to exposure to HPV, therefore they are preferably to be administered before first sexual activity.

Following WHO recommendations to introduce HPV vaccines into the Malaysian National Immunisation Programme (NIP), Ministry of Health Malaysia (MOH) reviewed various related local epidemiological data such as and not limited to the prevalence of cervical cancer and HPV-related disease in Malaysia, burden of the disease, vaccine safety, and cost-effectiveness of HPV vaccination in Malaysia.

National Cancer Registry Report 2007 showed that cervical cancer ranked the third most common cancer among Malaysian women with an age-specific incidence rate of 7.8 per 100,000 women (95% CI: 7.3, 8.4). Among these cervical cancer cases, almost half were diagnosed at late stages with 26% and 19% being diagnosed at stage 3 and stage 4 respectively (Zainal & Nor Saleha, 2011). Global Cancer Statistics 2012 reported that the age-standardised mortality rate of cervical cancer in Malaysia was 4.7 per 100,000 women per year (Bruni et al., 2015). The study on distribution of HPV genotypes in Malaysia by local researchers was not recent and limited with small sample size, which was based on 29 cases of invasive squamous cell carcinoma between year 1991 to 1992 and 43 cases between year 1995 to 2000 (Cheah, Looi, & Sivanesaratnam, 2011). The result of the study showed that HPV 16 and 18 contributed to 85% of the HPV associated cervical cancers in Malaysian (Cheah et al., 2011). Another set of data came from WHO/ICO Information Centre on HPV and cervical cancer which was developed by World Health Organisation and the Catalan Institute of Oncology to assess the global as well as country burden of disease (Castellsague et al., 2007). Based on data from South-Eastern Asia where Malaysia belongs to, it was estimated about 6.2% of women in general population to have HPV infection at a given time, with 71.8% of invasive cervical cancers are caused by HPV 16 or 18 (Castellsague et al., 2007).

A cost-effectiveness study of HPV vaccination in Malaysia reported that HPV vaccine increased life expectancy by 13.04 years (Ezat & Aljunid, 2010). Meanwhile, the average Quality Adjusted Life Years saved (QALYs) is 24.4 among vaccinated group as compared to only 6.29 among unvaccinated group (Ezat & Aljunid, 2010). In another study on potential costs and consequences of HPV vaccination, it was estimated that vaccination with bivalent vaccines will be able to prevent 4,199 cervical cancer cases per year, thus averting RM45.4 million in annual HPV-related treatment costs (Aljunid, Zafar, Saperi, & Amrizal, 2010).

After gathering enough epidemiological evidence, MOH submitted the proposal of the HPV vaccination policy to the National Committee on Immunisation Policy and Practices (NCIPP) for review before it was brought to Cabinet Meeting. In 2010, the proposal became a policy with strong financial support from the government. HPV vaccine was incorporated into the Malaysian Expanded Programme on Immunisation (EPI) for nationwide implementation (Lim, 2014). As with other vaccines under the NIP, the HPV vaccines are administered for free to all girls aged 13 years with consent from parents (Buang & Jahis, 2016). The HPV vaccines are mainly delivered by MOH through an on-going school-based programme while for those out-of-school girls aged 13 years, the vaccines are to be administered at the health facilities. The public acceptance and coverage of HPV vaccination in Malaysia were good with 95.9% and 98.4% respectively in 2010, increased to 98.5% and 99.6% respectively in 2014 (Buang & Jahis, 2016).

3.2 Australian Tobacco Policy

In general, tobacco control relies on implementation of comprehensive multisectoral measures that work together in a complementary way. In Article 4.4 of WHO Framework Convention on Tobacco Control (WHO FCTC), multisectoral measures, responses and collaboration at national, regional and international levels to reduce consumption of all tobacco products are recognised as comprehensive strategies to prevent the incidence of diseases, premature disability and mortality related to tobacco consumption and exposure to tobacco smoke. One of the provisions aimed at reducing demand of tobacco is in Article 11 (packaging and labelling of tobacco products) and Article 13 (tobacco advertising, promotion and sponsorship) in WHO FCTC. In late 2012, Australia became the first nation to implement plain packaging of tobacco products through the Tobacco Plain Packaging Act of 2011. Tobacco policy in Australia is a good example to illustrate how epidemiological evidence is applied during a regulatory health policy development.

The contribution of tobacco into the total burden of disease and injury in Australia in 2003 was approximately 7.8%, with lung cancer, chronic obstructive pulmonary disease and ischaemic heart disease accounting for beyond three-quarters of this burden. Of the 14 risk factors examined, tobacco was responsible for the largest amount of burden across all ages especially in males due to the higher prevalence of smoking 20 to 30 years ago in Australian males compared to females (Begg et al, 2007). Each year, tobacco related products murder an estimated 15,000 Australians and prices Australia \$31.5 billion in social (including health) and economic costs (Collins & Lapsley, 2008).

The rationale for implementing plain packaging are linked to a body of empirical evidence concerning the effects of the measure. Studies have demonstrated that smokers found plain tobacco packaging as less attractive (Zacher et al, 2014). In view of high prevalence of smoking among young group, age 20 to 30 years, the tobacco plain packaging strategy was set out in the Tobacco Plain Packaging Act 2011 as to improve public health by discouraging people from using tobacco products, encouraging people to give up using tobacco products, discouraging relapse of tobacco use and reducing exposure to tobacco smoke (Begg et al, 2007; Australian Institute of Health and Welfare, 2014). Plain packaging is able to reduce elements of the appeal of tobacco products, by reducing their attractiveness, liking, prestige, stylishness, quality, satisfaction and taste (Wakefield, Germain & Durkin, 2008).

The introduction of plain packaging can limit tobacco branding and reduce misleading messages to the consumers with respect to health consequences of consuming different tobacco products. “Mild” and “light” stamp on top of the tobacco brand name mislead the consumers into perceiving that the products are less harmful to health than other regular brand variants, in which it is not actually the case (Durkin et al, 2015). In Australia, a national cross-sectional survey found that plain packaging has already reduced consumer misperceptions of harm. From the survey, 69.8% of adult smokers believed that tobacco brands do not differ in harmfulness compared to 65.7% before the implementation of plain packaging a year earlier (Wakefield et al, 2015).

Plain packaging policy has also been reported to increase the effectiveness of health warnings. Experimental studies suggest plain packaging makes health warnings more salient with warnings being better recalled and considered more serious and believable (Goldberg, Liefeld, Madill, & Vredenburg, 1999). On top of that, the effects of health warnings have been found to increase with their size (Borland, Savvas, Sharkie & Moore, 2013). Previously, branding on tobacco packaging distracts the health warnings and reduce the ability of warnings to be effectively conveyed to consumers for discouraging tobacco consumption. Australia updated and introduced new health warnings and increase the size of graphic health warnings on tobacco products at the same time plain packaging was introduced. The selection of the colour for Australian plain tobacco packs and the exact content, size and placement of the enlarged health warnings graphics on the tobacco packs were determined after a series of experimental and qualitative studies to test which pack colour consumers found least appealing, and the nature and format of graphic health warning on plain packs that were most salient, relevant and believable (Gfk Blue Moon, 2011).

Post implementation evaluation on tobacco plain packaging was conducted by the Australian government in late 2016, four years after the policy implementation. The report stated that plain packaging had significantly reduced the average smoking prevalence among Australian aged 14 years and above by 0.55%. The report predicted that without the 2012 packaging changes, average smoking prevalence among the group in the post-implementation period would have been 17.77% as opposed to 17.21% with the packaging changes (Chipty, 2016). Another survey, the National Drug Strategy Household Survey (NDSHS) 2013 in Australia reported that daily smoking prevalence among Australians aged 14 years and above has fallen significantly from 15.1% in 2010 to 12.8% in 2013 after the implementation of plain packaging policy. The NDSHS 2013 included a period of 12 months of tobacco plain packaging being in effect. Another significant finding of NDSHS 2013 was the proportion of people that never smoke had risen from 58% in 2010 to 60% in 2013.

Major health impacts of the plain packaging changes such as reduction in tobacco-related diseases, premature disability and mortality will be more apparent in years to come as behavioural changes in tobacco smoking initiation, cessation and relapse are only affecting the subset of current and future smokers. Thus, continuous evaluation of the policy is essential to provide epidemiological evidence in deciding whether the policy has met its objectives.

4.0 DISCUSSION

While understanding the importance of epidemiological evidence in policymaking, it is important to highlight the issues and challenges in applying this evidence at the different stages of health policy development.

In Kingdon's model of policy formulation, there are three "streams", namely problem, policy solution and political streams. The three streams need to come together and meet at a point for a policy to move forward (Kingdon, 1986). Epidemiology has different application in each of the stream in Kingdon's model. In problem stream, epidemiology plays a crucial role with its main strength in defining a health problem, from distribution of disease and its associated risk factors, to burden of diseases and health economic studies that are closely related to a country's development. In policy solution stream, epidemiology through study of disease causation pathway and identification of risk factors, will be able to recommend the potential policies to solve the health problem. Finally, politics and public opinion from various stakeholders also influence policy development, which is described in the last stream, the political stream. The reporting of new findings from epidemiological studies relating to diseases through various channels such as mass media and journal publications is a good platform to highlight the magnitude of certain health problems to the public. When the public is concerned about these health problems, the issues will then become the focus of political attention. Without strong political will, problem and policy solution alone will fail to push for new policy development, policy improvement or policy expansion. Epidemiology is unquestionably important in defining evidence-based problem, supporting policy formulation (Davis, Peterson, Bandiera, Carter-Pokras, & Brownson, 2012) and convincing political decision-making through effective communication.

In defining health problems through epidemiology, the issues and challenges may vary across countries and regions. The paucity of studies or health information in particular population or geographical areas is a barrier in policymaking. In the case of vaccines, vaccine epidemiology plays an important role in reducing morbidity and mortality from vaccine-preventable diseases. However, in many low- and middle-income countries, there are limited training opportunities on vaccine epidemiology (Lahariya, 2016). Lacking of local epidemiological data on important aspects required for the development of immunisation policy is one of the most important challenges for policymakers. Looking into data from surveys conducted in mid 1990s on sexual debut among Malaysian adolescents, the age at first intercourse varies between surveys, ranging from nine to 24 years (National Population and Family Development Board [NPFDB], 1998; Chiam, 1995). The trend in sexual and reproductive behaviours among adolescents may have changed over the 15 years from the time of the survey and the introduction of the HPV vaccination programme in 2010, contributed by the availability and advancement in information and communication technologies. As the issue on reproductive health and sexuality is still considered a sensitive topic in Malaysian culture, the adolescents are not known to discuss these health issues openly, thus, to obtain a representative local data on the age of sexual debut is a big challenge (NPFDB, 1998).

Globalisation has led to another challenge in the use of epidemiology in policy development. Epidemiologist, researchers and policymakers are required to think, decide and initiate quick actions to keep up with the rapidly evolving health issues and changing of disease patterns. Epidemiological evidence needs to be made available and timely for policy development,

especially when specific health issues are of public concern and gaining political attention. Unfortunately, some of the epidemiological studies require years of observation before a conclusive evidence can be reported. A better communication between epidemiologists and policymakers regarding policy directions will help to tailor future researches in accordance to policymakers' needs, avoiding mismatches between the time taken for knowledge production and the needs of practical actions. While this allow epidemiologists to bridge information gaps on health problems of different population groups in terms of its magnitude, distribution patterns, inequalities issues, temporal trends and other issues, it also increases the practicality of the epidemiological evidence in policy development.

As illustrated in the above examples, challenges in using epidemiological tools in identifying health problems during the initial stage of health policy developments include lack of expertise to conduct high quality study, lack of equipment and tool, non-conducive health system for study and financial constraint. This is especially true in many low and middle income countries. Without local data to represent the magnitude of health problems, less likely the problems will be pushed into political arena. To overcome this, WHO and various international agencies have been actively offering training, technical assistance as well as financial support in conducting epidemiological research in these countries. The training of epidemiologists should include application of epidemiological evidence in policy development as epidemiologists have been found to pay less attention in identifying cost-effective and efficacious policy interventions (Carter-pokras et al., 2013). The aspects on evaluation and dissemination of findings must be emphasised and planned from the beginning of the policy planning process.

Once the health problems are defined with potential policy solutions identified, the last but not least challenge will be to push the issue into becoming a political agenda so that the policy will be adopted. One of the ongoing and never ending issue is on tobacco control and prevention. While recognising tobacco use as a significant risk factor in premature deaths and many non-communicable diseases, the implementation of total ban of tobacco policy remains a major challenge due to lack of political will. Big tobacco companies have been successful in lobbying the political arena for decades and besides that, many countries still rely on the tobacco tax as one of their main revenue. FCTF and tobacco control strategies under global leadership of WHO have managed to get more political commitment globally in curbing the tobacco endemic with the tobacco control policies.

5.0 CONCLUSION

The use of epidemiological evidence in policy development is vital as illustrated in the two case studies on main health areas. Globalisation, lack of resources and expertise and poor political interest are some of issues and challenges in translating epidemiology into policy. Epidemiologists can play a bigger role by not just analysing data to define health problems and present the data in a form that is comprehensible to the people outside the field, but to work closely with policymakers to support potential policies to solve the health problems. It is foreseeable that in the era of genomics, big data, technological advancement and constrain resources, the need and use of epidemiology in policy development (formulation, implementation and evaluation) is inevitably important in the future.

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Declaration

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Authors' contribution

Author 1: information gathering, preparation and editing of manuscript
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Author 7: information gathering, preparation and editing of manuscript
Author 8: information gathering, preparation and editing of manuscript
Author 9: information gathering, preparation and editing of manuscript
Author 10: review of manuscript and editing

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