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Drugs, sex, money and power: An HPV vaccine case study

Marion Haas[a,*], Toni Ashton[b], Kerstin Blum[c], Terkel Christiansen[d], Elena Conis[e], Luca Crivelli[f], Meng Kin Lim[g], Melanie Lisac[c], Margaret MacAdam[h], Sophia Schlette[c]

[a] Centre for Health Economics Research & Evaluation (CHERE), University of Technology Sydney, Level 4, 645 Harris St, Ultimo NSW 2007, Australia
[b] Centre for Health Services Research and Policy, University of Auckland, New Zealand
[c] Bertelsmann Foundation, Guetersloh, Germany
[d] Department of Public Health, University of Southern Denmark, Odense, Denmark
[e] Department of Anthropology, History and Social Medicine, University of California, San Francisco, USA
[f] Institute of Microeconomics and Public Economics (MecoP), University of Lugano, Switzerland
[g] Yong Loo Lin School of Medicine, National University of Singapore, Singapore
[h] Canadian Policy Research Networks, Canada

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ABSTRACT

In this paper we compare the experiences of seven industrialized countries in considering approval and introduction of the world's first cervical cancer-preventing vaccine. Based on case studies, articles from public agencies, professional journals and newspapers we analyse the public debate about the vaccine, examine positions of stakeholder groups and their influence on the course and outcome of this policy process. The analysis shows that the countries considered here approved the vaccine and established related immunization programs exceptionally quickly even though there still exist many uncertainties as to the vaccine's long-term effectiveness, cost-effectiveness and safety. Some countries even bypassed established decision-making processes. The voice of special interest groups has been prominent in all countries, drawing on societal values and fears of the public. Even though positions differed among countries, all seven decided to publicly fund the vaccine, illustrating a widespread convergence of interests. It is important that decision-makers adhere to transparent and robust guidelines in making funding decisions in the future to avoid capture by vested interests and potentially negative effects on access and equity.

1. Introduction

"It took 15 years for Gardasil to make a national hero of its creator, Ian Frazer. But it took just three days for the world's first cancer-preventing vaccine to make a national dill of federal Health Minister Tony Abbott. [...] John Howard, alert as ever to the public mood, delivered sparkling prime ministerial endorsement to Gardasil along with a clear direction to Minister Abbott that the immunisation program should proceed. And pronto." [1].

"[T]he public, as well as policy-makers, must be provided with sound and comprehensive multidisciplinary evidence for vaccination as well as unbiased data about the potential benefits and harms expected from widespread immunization with the HPV vaccine, and all this information must come *before* governments allocate huge sums of already limited health care dollars to such programs. Individual girls and women, as well as policy-makers, can only make truly informed decisions about vaccinations when they have all the evidence. At this point in time, there are more questions than answers." [2, p. 16].

In this paper, we analyse and compare the experiences of seven countries (Australia, Canada, Denmark, Germany, New Zealand, Switzerland and the U.S.) in considering

* Corresponding author. Tel.: +61 0 2 9514 4721; fax: +61 0 2 9514 4730.
E-mail address: marion.haas@chere.uts.edu.au (M. Haas).

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the world's first cervical cancer-preventing vaccine and making a decision about its introduction and/or funding. The above quotations nicely illustrate two characteristics of this process. First, on the whole, the countries considered here approved the HPV vaccine and related programs with marked haste, some circumventing established channels and procedures in the process. Second, public debates ensued in many countries, fuelled by uncertainties about the duration of the vaccine's efficacy and the precise nature of the link between HPV and cervical cancer. Because vaccine programs are still new, the rate of the HPV vaccine's uptake—and its impact on routine Pap test utilization—remains largely to be determined. With respect to the establishment of such programs, however, our analysis suggests that countries with different decision-making processes can arrive at a similar decision about the value of a health policy or program, a pattern that reflects the influence of a particularly strong and ubiquitous set of political pressures at work.

2. Materials and methods

The International Network Health Policy and Reform[1] convenes experts from 20 countries to report on and compare health policy processes from around the industrialized world. In 2007, several countries in the Network reported on the introduction of a human papillomavirus (HPV) vaccine for the prevention of cervical cancer. The almost simultaneous consideration and adoption of this particular policy issue in several countries provides a unique opportunity to compare in detail the relevant policy processes and outcomes. Here we use Network member case studies [3–8] from six of the seven countries mentioned above as well as publications by public agencies, in journals and newspapers to examine the debate about the vaccine and the actors who influenced the debate and its outcome. For Denmark we only employed the latter resources [9–14].

3. Human Papillomavirus and the development of a vaccine

Worldwide, cervical cancer is the second most common cancer among women [15]; nearly half a million women are diagnosed with and more than 270,000 die of the disease each year [16]. Of the more than 100 HPV strains that infect humans, more than 20 are linked to cervical cancer [17]. Cervical cancer is a rare outcome of a fairly common infection with HPV; in the majority of cases HPV infections are transient and asymptomatic [18,19].

Nonetheless, the establishment of a viral cause of cervical cancer paved the way for the development of a vaccine with the potential to prevent this cancer [17,20]. In 1991, investigators at the University of Queensland found a way to form non-infectious virus-like particles (VLPs) that strongly activated the immune system. In 1993, a laboratory at the U.S. National Cancer Institute generated the VLPs that formed the basis for the HPV16 component of the first cervical cancer vaccine, Gardasil, which was jointly developed by Sanofi-Pasteur and Merck. Later, GlaxoSmithKline developed its own cervical cancer vaccine, Cervarix.

Both Gardasil and Cervarix target HPV types 16 and 18, which together cause more than 70% of all cervical cancers [21]. (Neither vaccine prevents 100% of cervical cancers.) Gardasil also targets HPV types 6 and 11, which cause genital warts. Three doses of the vaccine are required (at 0, 1 and 6 months), and the duration of protection appears to be at least 5 years. As HPV is easily transmitted and most infections occur soon after a woman first becomes sexually active, the vaccines are most effective if administered prior to the commencement of sexual activity. Widespread use of the vaccines is expected to reduce the incidence of cervical cancer; however, women who receive the vaccine will continue to need regular Pap screening because neither vaccine protects against all oncogenic HPV types and because the duration of protection remains uncertain [22]. The European Commission also recommends that authorities carry out population-wide, quality assured cervical screening by Pap smear (according to the EU guidelines) before introducing HPV vaccination into the population [3].

4. Comparing and contrasting the approval process

In all seven countries considered here, the vaccine was approved for use in 2006 and made available to women as a three-dose schedule for between 292 PPP-$ and 527 PPP-$[2] (see also Table 1). Although there was debate in the scientific community about issues of safety and efficacy in connection with the approval process, the public debate, which is the subject of this paper, occurred during and after policy processes concerned with developing or implementing subsidized vaccination programs were commenced.

In Canada, Gardasil was approved for use in the summer of 2006. Following advice from Canada's National Advisory Committee on Immunization that the vaccine's high cost was preventing its adoption, the Canadian government approved CAN$300m (248m PPP-$) in new funding to the provinces to provide free vaccination to girls aged 9–13 [8]. By June 2008, five provinces had adopted a free vaccination program, and all ten provinces have now approved voluntary school-based programs. Implementation of the vaccination program has been accompanied by media and professional articles questioning the wisdom of the free vaccination program in light of ongoing concerns about the vaccine's necessity [23]. It has also been reported that this is the most expensive vaccination program ever introduced in Canada [24].

[1] Since 2002 the International Network Health Policy and Reform has brought together health policy experts from around the world to report on current health reform issues and health policy developments in their countries. In two survey rounds per year, Network members report up to five health policy issues using a questionnaire aimed at describing and analysing the dynamics or the processes of the policy or policy proposal under review. Although members are experts in policy research, their reports are based on expert assessment, not the results of structured research. All reports are available on the Network's website www.healthpolicymonitor.org.

[2] In this paper, all costs were converted using 2007 OECD purchasing power parities (see http://www.oecd.org/dataoecd/61/56/39653523.xls).