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The Australian funding debate on quadrivalent HPV vaccine: A case study for the national pharmaceutical policy

Elizabeth Ellen Roughead*, Andrew L. Gilbert, Agnes I. Vitry

Quality Use of Medicines and Pharmacy Practice Research Centre, Sansom Institute, University of South Australia, GPO Box 2471, Adelaide, SA 5001, Australia

Abstract

Objectives: To analyse the media and political reactions to the initial decision of the Pharmaceutical Benefits Advisory Committee (PBAC) to reject funding of the quadrivalent human papilloma virus (HPV) vaccine in Australia.
Methods: A case study, informed by media reports and government documents, was utilised to examine the reactions of key stakeholders; PBAC, consumers, consumer organisations, pharmaceutical industry, politicians, health professionals and the media to the initial decision to reject funding of HPV vaccine.
Results: The initial decision to reject funding of the HPV vaccine led to unprecedented public response with over 300 newspaper articles and calls by consumers, health professionals and politicians to intervene in the decision making process. Misunderstanding of the decision making process, particularly cost-effectiveness assessments, the need for an independent process, the legislated inability of a timely and transparent response from policy makers and the lack of a risk mitigation strategy all played a role in the public outcry.
Conclusions: Despite 15 years of implementation of cost-effectiveness assessments there is still a need for improving stakeholder understanding of the decision making process and for timely transfer of complete information. Risk mitigation strategies should be considered as part of the communication plan for all decisions.

Keywords: Papillomavirus vaccines; Insurance; Health; Reimbursement; Cost–benefit analysis; Resource allocation; Public debate

1. Introduction

Australia has a well established, independent process for determining which medicines will be subsidised under its national Pharmaceutical Benefits Scheme (PBS) [1,2]. Decisions to list a medicine on the PBS are based on recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC) to the Minister of Health. PBAC is an independent statutory committee, which is required by legislation to consider comparative efficacy, safety and cost-effectiveness of a product before making its recommendations. Medicines may be recommended on either a cost-minimisation basis (i.e. equivalent to existing listed medicines) or a cost-effectiveness basis. Under this process, it is not uncommon for the PBAC

* Corresponding author. Tel.: +61 8 8302 1238; fax: +61 8 8302 1087.
E-mail address: libby.roughead@unisa.edu.au (E.E. Roughead).

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to reject submissions of new medicines. In 2006, 35 (47%) of the 75 major submissions the PBAC reviewed were rejected [3]. The ability of the PBAC to function independently in making decisions about medicines subsidy is critical to ensuring equitable access to necessary medicines, which in turn is critical to supporting Australia's system of universal health care [4].

Health technology assessments are now used by many countries including the UK, Canada, France, Norway, Sweden, as well as agencies in the USA. Australia was one of the first countries to institute mandatory cost-effectiveness assessments for pharmaceuticals, beginning in 1993, after trialling the process since 1990. Despite its long history, there is still some vulnerability in Australia's process. In this paper we present a case study of the events that unfolded with the initial decision to reject funding of the quadrivalent HPV vaccine (Gardasil®) viewed within the conceptual framework of Australia's National Medicines Policy. The decision caused considerable public and political debate and outrage which could have potentially threatened the whole PBS. The issues highlighted in the case study are likely to be pertinent to all countries implementing health technology assessments.

2. Methods

2.1. Data sources

To inform this case study, Australian media reports that mentioned Gardasil® and which were indexed in Newsbank database from December 2004 until 31 December 2006 were extracted (523 articles). This included all major Australian newspapers, including the Sydney Morning Herald, Daily Telegraph and the Age, but excluding the Perth major paper, the West Australian. We sourced fact sheets, media releases and transcripts of interviews conducted by journalists and the Public Summary Document of the Pharmaceutical Benefits Advisory Committee decision from the Australian Government Department of Health and Ageing website. We analysed this case study within the context of Australia's National Medicines Policy and one of its major objectives, of providing equitable access to necessary medicines at a cost the individual and community can afford.

3. Results

3.1. Case study

Initial development of the HPV vaccine was undertaken by Drs Zhou and Frazer (University of Queensland, Australia) in the 1980s with grants from government and charitable organisations [5]. In 1989, the University entered into a collaborative agreement with the then Australian company, CSL Ltd., which was privatised in 1994. In 1995, CSL Ltd. entered into a collaborative agreement with Merck Ltd. to further product development.

By December 2004, the first reports of the HPV vaccine appeared in the Australian press and in April 2005, the blockbuster potential was first mentioned: "It's the world's biggest vaccine" [6]. By May 2005, the results of a phase II clinical trial were reported: "Vaccine will save women" [7] and in October 2005, press articles, reported the results from a phase III clinical trial: "Medical miracles Aussie doctors unveil cervical cancer lifesaver" [8] "Cervical cancer vaccine Nobel prize-winning stuff" [9]. Press continued in December 2005 with the announcement of the application for approval to the USA Food and Drug Administration and the Australian Therapeutic Goods Administration.

On Australia Day, the 26th of January 2006, the Australian of the Year was awarded to Ian Frazer, for his role in developing the vaccine, by the Australian Prime Minister. At the time it was reported "the Prime Minister said he would discuss with federal Health Minister Tony Abbott making the vaccine . . . available to young women across Australia" [10].

In June 2006, the regulatory approval of Gardasil® in Australia and the planned submission to the PBAC were first reported: "CSL said that in November it will put to the Government a plan to vaccinate all girls at the end of primary school - aged 11 and 12 - with a "catch-up" program for high-school girls [11]." Support for the vaccine was also observed from politicians: "South Australian Health Minister John Hill . . . pledged his full support to the plan [school immunisation] [12]". "Acting Premier Anna Bligh said . . . Queensland would consider jointly funding a national plan . . ." [13]. 'Democrats leader Senator Lyn Allison issued a statement urging the government to proceed as quickly as possible. . .' [14].