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A Report of the CSIS Global Health Policy Center

APRIL 2015

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HPV Vaccination in Japan

The Continuing Debate and Global Impacts

Rose Wilson, Pauline Paterson, Jeremy Chiu, William Schulz, Heidi Larson¹

Introduction

In June 2013, the Japanese Ministry of Health, Labour, and Welfare (MHLW) suspended its active recommendation of the human papillomavirus (HPV) vaccination after a small number of highly publicized alleged adverse events stoked public fears about the vaccine's safety.² While the MHLW continues to provide the HPV vaccination for those who request it through the National Immunization Programme (NIP), as of mid-April, the suspension of the HPV vaccination recommendation continues.

Since the release of our CSIS report *The HPV Vaccination in Japan: Issues and Options*³ in May 2014, anti-vaccine groups have strengthened their control of the narrative surrounding the HPV vaccine, intensified their activities, and continued to capture media and public attention. The medical community has split as prominent personalities have come forward to support claims of adverse effects linked to the HPV vaccine even in the absence of any evidence of association. Countermeasures by the MHLW, medical professional groups, and others have been comparatively weak and, it appears, ineffectual. It remains unclear how and when this increasingly complicated and difficult situation will be resolved.

In this paper, we outline major events with regards to the HPV vaccine controversy in Japan since May 2014, highlighting long-term implications of the rapid drop in vaccination coverage and recommending how to best move forward. There are also two addendums that explore global perspectives on the current situation in Japan and examine examples of how other countries have dealt with concerns and opposition to the HPV vaccine.

¹ Rose Wilson is a graduate student, Pauline Paterson a research fellow, Jeremy Chiu a research intern, William Schulz a researcher, and Heidi Larson a senior lecturer in the Department of Infectious Disease Epidemiology at the London School of Hygiene & Tropical Medicine in London, England.

² Heidi Larson et al., "Tracking the global spread of vaccine sentiments: The global response to Japan's suspension of its HPV vaccine recommendation," *Human Vaccines & Immunotherapeutics* 9, no. 10 (2014): 1–8.

³ Rose Wilson, Pauline Paterson, and Heidi Larson, *The HPV Vaccination in Japan: Issues and Options* (Washington, DC: CSIS, May 2014), http://csis.org/files/publication/140514_Wilson_HPVVaccination_Web.pdf.

Update on Japan's HPV Situation since June 2014

Medical Schism

The safety of the HPV vaccine remains a subject of intense controversy and debate in Japan, despite global scientific evidence pointing to the vaccine's safety. Conflicting views have proliferated within the medical profession in Japan, as a growing number of physicians have spoken publicly in support of claims that the HPV vaccine may lead to adverse events. In 2013, Sotaro Sato, a Japanese internist and cardiologist, was widely quoted on anti-vaccine sites, reporting on the side effects perceived to be caused by the HPV vaccine.⁴ In 2014 Kusuki Nishioka, a professor of medicine and director and chairman of the Institute of Medical Science, Tokyo Medical University, emerged as a new "expert" claiming a causal link between the HPV vaccine and pain symptoms experienced by young women. Nishioka spoke at an international rheumatology conference in Moscow on June 5, 2014, with a presentation titled "HPV Vaccination Associated with Neuropathic Syndrome (HANS): A novel disease entity associated with HPV Vaccination."⁵

The Danish website HPV Vaccine Info reported that Nishioka subsequently presented at a symposium at Tokyo Medical University on July 27, 2014, titled "What we found in the HPV scandal—The problem of medical ethics and education."⁶ The conference aimed to "consider the actualities and issues of pharmacovigilance in Japan through the scourge of HPV (cervical cancer) vaccine injuries." Cohosts included Medwatcher Japan (a nongovernmental organization, NGO, that monitors and seeks to prevent drug-induced "disasters") and *The Informed Prescriber* (a magazine published by a nonprofit drug treatment study group),⁷ with support from the Japanese Society for Pharmacoepidemiology Task Force and DIPEX-Japan (a discussion forum for diseases, diagnoses, and side effects).⁸

In October 2014, other academics became involved in the controversy with the publication of an article by Tomoaki Kinoshita et al. that concluded, "Immunization with HPV vaccines may secondarily induce sympathetically mediated disorders, including CRPS-I [chronic regional pain syndrome type 1], OH [orthostatic hypotension] and POTS [postural orthostatic tachycardia syndrome]." The article went on to emphasize that these "disorders have not been reported in foreign cohort studies of human HPV vaccines and it thus

⁴ "SaneVax Reports on Japan's Struggle with HPV Vaccination Injuries," *Age of Autism*, August 26, 2013, <http://www.ageofautism.com/2013/08/sanevax-reports-on-japans-struggle-with-hpv-vaccination-injuries.html>.

⁵ Forum of the University Science, "Program," June 5, 2014, <http://forum-uniscience.ru/en/programma/june-5-2014/>.

⁶ "Japansk organisation afslører interessekonflikter," *HPV Vaccine Info*, August 7, 2014, <http://hpv-vaccine-info.org/japansk-organisation-afslorer-interessekonflikter/>.

⁷ Yakugai Ombudsperson "Medwatcher Japan," Symposium: Consideration of pharmacovigilance—Lessons learned from the adverse effect of HPV vaccination," July 27, 2014, <http://www.yakugai.gr.jp/en/topics/topic.php?id=873>.

⁸ Database of Independent Patient Experience, "DIPEX Japan," 2015, <http://www.dipex-j.org/>.

remains unclear why Japanese girls are more frequently involved. It is unlikely that the Japanese environment plays a role in the pathogenesis of this disorder.”⁹

The authors called for further research on the alleged HPV vaccine side effects, reinforcing public concerns. On December 10, 2014, Nishioka presented at a symposium held by the Japan Medical Association and the Japanese Association of Medical Sciences, arguing that the HPV vaccine should be promoted only after issues regarding the vaccine’s safety are firmly settled. This evolving schism within the medical community has continued, with many other medical professionals openly supporting HPV vaccine uptake (such as Ryo Konno, Japanese Expert Board for the Eradication of Cervical Cancer). On March 30, 2015, over 200 medical professionals also took action by signing a statement requesting Japanese media to have balanced coverage on HPV vaccination. More than 250 members of the Japan Pediatric Society have called upon the government to reinstitute an active recommendation for HPV vaccination.

MHLW Response

In January 2014, a panel of experts within the MHLW ruled out the possibility that changes within the immune system or central nervous system caused adverse events following HPV vaccination.¹⁰ Subsequently, on September 16, 2014, the online newspaper *Asahi Shimbun* reported that following the MHLW statements, Kusuki Nishioka and six other medical experts had studied the cases of 2,500 women who complained about health problems after receiving the HPV vaccine. Directly contradicting the MHLW, Nishioka and others announced at a news conference in Nagano on September 13, 2014, that the side effects are caused by a dysfunction within the central nervous system.¹¹

According to the *Asahi Shimbun* and the Japan News Network,¹² the MHLW planned to follow up on the approximately 2,500 reported cases of HPV-related side effects and set up a system to treat 176 young women who complained about widespread pain and mobility disorders that supposedly resulted from the vaccine. While the MHLW’s plan to treat women suffering from pain and mobility disorders may be interpreted as a positive gesture to appease an anxious public, it risks misinterpretation as an admission that the vaccine did in fact cause adverse effects.

⁹ Tomoaki Kinoshita et al., “Peripheral sympathetic nerve dysfunction in adolescent Japanese girls following immunization with the human papillomavirus vaccine,” *Internal Medicine* 53, no. 13 (2014): 2185–200.

¹⁰ Yakugai Ombudsperson “Medwatcher Japan,” “Regarding the MHLW councils on cervical cancer vaccines (HPV vaccines) held on January 20th, 2014,” January 22, 2014, <http://www.yakugai.gr.jp/en/topics/topic.php?id=856>.

¹¹ Tomoko Saito, “Researchers: Cervical cancer vaccination linked to symptoms affecting nervous system,” *Asahi Shimbun*, September 16, 2014, http://ajw.asahi.com/article/behind_news/social_affairs/AJ201409160043.

¹² “子宮頸がんワクチンで副反応、製薬会社2社に救済求める,” Japan News Network, 2015.

Impacts on the Public

Over the last year, controversy within the Japanese medical and political arenas over the HPV vaccine has touched the public at large. Through social media and highly publicized events, anti-vaccine groups have gained control of the narrative surrounding the HPV vaccine. The reported adverse events following immunization (AEFI) are now established “facts” in the eyes of the media and members of the public exposed to unscientific, sensationalist reporting.

Throughout 2013 and 2014, YouTube videos depicting Japanese girls suffering from seizures and walking disturbances were common on Japanese social media sites. The Japan National Cervical Cancer Vaccine Victim Liaison Committee also posted a disturbing YouTube video on its website on November 25, 2014, depicting a Colombian teenage girl suffering from walking disturbances.¹³

The Japan National Cervical Cancer Vaccine Victim Liaison Committee has also staged public demonstrations. On March 31, 2015, a protest was held outside MSD (Merck Group) and GlaxoSmithKline headquarters in Tokyo, at which the Japan National Cervical Cancer Vaccine Victim Liaison Committee submitted its demands to the two companies, calling for a halt to HPV vaccination and compensation to be paid to “victims.” The protests were broadcast live on TV and online by most major news channels, including Nippon Network News,¹⁴ All-Nippon News Network,¹⁵ and Fuji News Network.¹⁶ The anti-vaccination group held a press conference and then moved to the MHLW, where the members again submitted their demands. Finally, they spoke to an audience with elected officials. These events were planned well in advance and advertised through individual blogs and social media sites.¹⁷

¹³ “全世界で被害が出ています!!,” National Cervical Cancer Vaccine Victim Liaison Committee, November 25, 2014, <http://hpvv-danger.jp/archives/653>.

¹⁴ “中高生ら 子宮頸がんワクチンの被害訴え,” Nippon Network News, 2015.

¹⁵ “「子宮頸がんワクチン」副作用”被害で2500件報告,” All-Nippon News Network, 2015.

¹⁶ “「子宮頸がんワクチン被害者団体、製薬会社に初めて要求書提出,” Fuji News Network, 2015.

¹⁷ “みかりんのささやき～子宮頸がんワクチン被害のブログ～,” Ameba, March 30, 2015, <http://ameblo.jp/3fujiko/entry-12007957544.html>.

ツイート 9

シェア 103



National Cervical Cancer Vaccine Victim Liaison Committee: Teenage women and parents complain about side effects after receiving cervical cancer vaccine.

On April 25, 2015, the National Cervical Cancer Vaccine Victim Liaison Committee will hold a national meeting titled “Vaccine Talk 2015” in the Chiyoda ward of Tokyo. The gathering will focus on expanding its network of support for “victims” of the HPV vaccine. Invited speakers include professors from the University School of Medicine, members of the Saku Health and Welfare Office, and members of the editorial boards of online newspapers.¹⁸ See Table 1 for a timeline of major events relating to the HPV vaccine in Japan.

¹⁸ “2015ワクチントーク全国集会開催のお知らせとプライベート・コメントの募集(しめきりは3月29日です,) ConsumerNet.Jp, February 13, 2015, <http://consumernet.jp/?p=1659>.

Table 1: Major Events in Japan Related to the HPV Vaccine (2009–2015)

<p>March 2010 After HPV vaccination, three girls complain of complex regional pain syndrome (CRPS) and nine from chronic pain.</p>	<p>April 2010 126 of 1,747 local governments were providing funding for the HPV vaccine.</p>	<p>October 2010 Central and all local governments launch a temporary funding program.</p>
<p>March 8, 2013 <i>Asahi</i> newspaper press report of 50 girls suffering from CRPS and 100 absent from school after receiving HPV vaccine.</p>	<p>March 10, 2013 Adverse events reported on TV news.</p>	<p>March 25, 2013 Press conference by “victim” group showing videos of girls suffering from walking disturbances and seizures, which was also posted on YouTube.</p>
<p>April 1, 2013 HPV vaccine included in National Immunization Program (NIP). Optional and given for free.</p>	<p>April 13, 2013 Suginami local government announces its annual budget compensation for parents claiming their daughters had suspected CRPS following HPV vaccination. Case reported at local assembly meeting.</p>	<p>May 19, 2013 Another press conference by “victim” group.</p>
<p>June 13, 2013 World Health Organization (WHO) Global Advisory Committee on Vaccine Safety report released stating HPV vaccine is safe. Not reported in Japanese media.</p>	<p>June 14, 2013 Second joint meeting of Vaccine Adverse Reactions Review Committee (VARRC). MHLW decided to temporarily suspend recommendation of HPV vaccine.</p>	<p>October 2014 National Cervical Cancer Vaccine Victim Liaison Committee opens branch in Osaka.</p>
<p>December 10, 2014 Symposium held by Japan Medical Association and Japanese Association of Medical Sciences. Concludes that HPV vaccines should be promoted only after issues regarding vaccine safety are settled.</p>	<p>March 31, 2015 Anti-vaccination groups hold protest outside MSD and GSK, which is broadcast live on TV and online news channels. They then hold press conference and visit MHLW to submit their demands.</p>	<p>April 25, 2015 National Vaccine Talk in Tokyo Chiyoda ward organized by anti-vaccination groups. Theme is cervical cancer vaccine victims and reports of adverse events, with aim of expanding network of support for “victims.”</p>

Implications of Policy Choices

Eroded Public Trust

The MHLW’s suspension of active recommendation of HPV vaccination in Japan has negatively impacted public trust in the vaccine. The lack of information regarding the reported AEFI, combined with the lack of a clear decision by the Japanese government to reinstate active promotion of HPV vaccination, created an information void. Anti-

vaccination individuals subsequently filled this void, allowing rumors to proliferate and spread.

Other MHLW actions have fueled public skepticism, aggravated anti-HPV vaccine sentiment, and amplified fears of AEFI. When a local government authority agreed to provide compensation, anti-vaccine activists saw this as an admission of guilt and confirmation of a causal link between the vaccine and pain symptoms. By early 2015, the cumulative impact was a drop in HPV vaccine uptake from over 70 percent to under 5 percent for adolescent girls.¹⁹

The trigger for increased media coverage in Japan was the publicity gained by anti-vaccination groups, one of which is headed by politician Toshie Ikeda, who is highly active on Facebook and Twitter and an influential leader in the narrative on anti-vaccine sentiment.²⁰ Anti-vaccination groups continue to grow: on October 4, 2014, the *Japan Times* reported that the National Cervical Cancer Vaccine Victim Liaison Committee, which currently has 287 members and operates six branches across the country, including Hokkaido and Kumamoto, was poised to open a new branch in Osaka.

In Japan, the absence of an effective media watchdog and relatively lax libel laws mean that newspapers, news programs, social networks, and victim support groups can freely publish—with little if any accountability—unverified stories and videos of girls who claim to suffer from adverse events following HPV vaccination.²¹

The Cost of Not Recommending the HPV Vaccine

Japan's suspension of proactive recommendation of the HPV vaccine continues to baffle the global scientific community.²² The long-term costs of not recommending the HPV vaccine are considerable, but the impact in terms of cervical cancer deaths and morbidity may not be seen for decades. It has been suggested that the number of cervical cancer cases could be reduced by 73 percent if all 12-year-old girls in Japan were vaccinated.²³

Not actively promoting HPV vaccination is putting the Japanese population at long-term unnecessary risk. It is estimated that 67.1 percent of cervical cancers in Japan are related to HPV types 16 and 18.²⁴ Cervical cancer is the second-most-common female cancer in

¹⁹ "Suspension of Government Support for the HPV Vaccine," BBC, February 8 2015, <http://www.bbc.co.uk/programmes/p02ht8wt>.

²⁰ Wilson, Paterson, and Larson, *The HPV Vaccination in Japan: Issues and Options*.

²¹ *Ibid.*

²² Stuart Gilmour et al., "HPV Vaccination Programme in Japan," *The Lancet* 382 (2013): 768; Norma Erikson, "Japan and the HPV Vaccine Controversy," SaneVax Inc., April 8, 2014, <http://sanevax.org/japan-hpv-vaccine-controversy/>.

²³ Ryo Konno et al., "Cervical Cancer Working Group Report," *Japanese Journal of Clinical Oncology* 40 (2010) Supplement 1: i44–i50.

²⁴ *Ibid.*

women aged 15 to 44 years in Japan,²⁵ and the rate of Pap tests is low, at around 25.4 percent.²⁶ Oropharyngeal cancers are on the rise,²⁷ and over the past 10 years, and nearly 6,000 cases of genital warts have been reported annually on average.²⁸ Not actively promoting HPV vaccination, and the associated media hype surrounding vaccine side effects, has the additional risk of reducing uptake of other essential immunizations.

Recommendations

1. Reinstate an active government recommendation of HPV vaccination. To dispel fear and misinformation, it is first essential that high-level Japanese political leadership restores an active recommendation for HPV vaccination. This should be supported by evidence including statistics on the vaccine's safety and successful implementation and high uptake rates of the vaccine in other countries. This process should entail continuous and open engagement with the media and key stakeholders such as the MHLW. Where possible, documenting the public health impacts of the suspended recommendation through monitoring HPV infection rates and cervical cancer will also be an important advocacy tool. A cancer registration and surveillance system to collect morbidity and mortality data has also been recommended to monitor the positive success and impacts of HPV vaccination uptake.²⁹

2. Support Japanese production of the HPV vaccine. Takeda Pharmaceutical Company (the largest pharmaceutical company in Asia) has announced that it transferred its license agreement with the Japan Health Sciences Foundation for worldwide patent rights of an HPV vaccine to the Chemo-Sero-Therapeutic Research Institute (Kaketsuken) in Japan on March 10, 2015.³⁰ An efficacious Japanese-manufactured HPV vaccine could increase trust in the vaccine.

3. Listen more carefully to the public at large. Politicians and those within the MHLW are well advised to more carefully listen to the public. Many within the scientific community have suggested that AEFI following HPV vaccination are psychogenic.³¹

²⁵ HPV Information Centre, "Human Papillomavirus and Related Diseases Report: Japan," March 20, 2015, <http://www.hpvcentre.net/statistics/reports/JPN.pdf>.

²⁶ Takahiro Tabuchi et al., "Does Removal of Out-of-pocket Costs for Cervical and Breast Cancer Screening Work? A Quasi-experimental Study to Evaluate the Impact on Attendance, Attendance Inequality and Average Cost per Uptake of a Japanese Government Intervention," *International Journal of Cancer* 133, no. 4 (2013): 972–83.

²⁷ D. Forman et al., "Global Burden of Human Papillomavirus and Related Diseases," *Vaccine* 30 (2012) Supplement 5: F12–23.

²⁸ Hirokazu Yoshikawa et al., "Efficacy of Quadrivalent Human Papillomavirus (types 6, 11, 16 and 18) Vaccine (GARDASIL) in Japanese Women Aged 18–26 Years," *Cancer Science* 104, no. 4 (2013): 465–72.

²⁹ Heidi J. Larson, Pauline Brocard, and Geoffrey Garnett, "The India HPV-Vaccine Suspension," *The Lancet* 376 (2010): 572–73.

³⁰ "Takeda Announces Transfer of License Agreement for Human Papillomavirus (HPV) Vaccine to Kaketsuken," PipelineReview.com (La Merie Publishing), March 10, 2015, <http://pipelinereview.com/index.php/2015031057121/More-News/Takeda-Announces-Transfer-of-License-Agreement-for-Human-Papillomavirus-HPV-Vaccine-to-Kaketsuken.html>.

³¹ J. Paul Buttery et al., "Mass Psychogenic Response to Human Papillomavirus Vaccination," *Medical Journal of Australia* 189, no. 5 (2008): 261–62.

Members of the public may perceive this label (and the term “mass hysteria”) as patronizing and dismissive of real concerns and actual physical suffering.³²

In cases of mass psychogenic illness following immunization, a crisis of confidence can erupt around a vaccine and manifest itself in frightening physical symptoms. Claims of psychogenic adverse reactions should not be ignored or dismissed as specious; shutting out dissenters only creates fodder for less-informed groups, as anti-vaccine sentiment, misinformation, and possibly even psychogenic adverse reactions themselves can spread over the Internet and social media worldwide.

4. De-stigmatize HPV. Perception of disease risk has a large influence on vaccine acceptance. In some cases, cultural and social mores, such as those pertaining to sexual behavior, influence vaccine acceptance. In the case of HPV vaccination, social beliefs about sexual behavior may overshadow appreciation of the true health risks of the virus.³³ HPV transmission does occur mainly through skin-to-skin mucosa contact during sex, but there is some evidence to suggest that HPV can be transmitted through nonsexual contact.³⁴ This fact, as well as education surrounding the other cancers that HPV can cause, could be used in promotional materials to alleviate stigma surrounding the vaccine.

Conclusion

In the past year, the situation in Japan vis-à-vis HPV vaccine policy has become far more complicated and difficult to unwind. Anti-vaccine interests have strengthened their control over messaging and the media airwaves, intensified political pressures, and contributed to further erosion of public trust and confidence. An emerging group of scientists and medical researchers are joining the anti-HPV vaccine camp, claiming a causal link between the HPV vaccine and pain syndrome without evidence to support their assertions. Serious spillover effects persist, both within Japan itself and in other countries where there is active debate over the scientific merits of the vaccine. Ineffective action and a conspicuous lack of high-level political leadership from the Japanese government only invites more, not less, intense action by anti-vaccine interests. The acute problem seen in Japan is rooted in society and politics and will require political leadership by senior members of the current administration, particularly within the context of Prime Minister Abe’s “womenomics” initiative. Leadership, science, and sustained public health efforts will all be essential in finding a lasting resolution.

³² C. John Clements, “Mass Psychogenic Illness after Vaccination,” *Drug Safety* 26, no. 9 (2003): 599–604.

³³ Heidi J. Larson, “Commentary: The uptake of human papillomavirus vaccination: The power of belief,” *International Journal of Epidemiology* 42, no. 3 (2013): 908–10.

³⁴ Eric J. Ryndock and Craig Meyers, “A risk for non-sexual transmission of human papillomavirus?,” *Expert Review of Anti-infective Therapy* 12, no. 10 (2014): 1165–70.

Addendum 1: Update of International Perception of the HPV Controversy in Japan

Anti-HPV-vaccination groups worldwide have applauded the MHLW’s decision to suspend the recommendation of the HPV vaccination, as concerns surrounding the vaccine’s safety have surfaced in many countries. This addendum focuses on how other countries have been influenced by the situation in Japan.

Denmark



A documentary titled “De Vaccinerede Piger” (“The Vaccinated Girls”) was televised in Denmark in March 2015. In the documentary, several Japanese doctors relayed fears that the HPV vaccine causes severe side effects.³⁵ The film focused on statements from Kusuki Nishioka, who claimed that Japan suspended its HPV recommendation in response to these adverse effects. The documentary featured the stories of 47 Japanese girls who believed they became ill after receiving the HPV vaccine.

Danish support for Japan’s suspension of its HPV vaccine recommendation could have dangerous consequences for vaccine uptake in Denmark. According to Zeraiq et al., who studied attitudes

and knowledge toward HPV vaccination among Arab mothers and their daughters in Denmark, there is already a vaccination knowledge gap between generations.^{36, 37}

Anti-vaccination websites such as SaneVax have been quick to republish such stories. SaneVax (which originated in the United States) published a letter from parents in Denmark

³⁵ Nicolaj Albrectsen, Michael Bech, and Signe Daugbjerg, “Piger bliver syge: I Japan anbefaler de ikke længere HPV-vaccinen,” TV2, March 27, 2015, <http://nyhederne.tv2.dk/samfund/2015-03-27-piger-bliver-syge-i-japan-anbefaler-de-ikke-laengere-hpv-vaccinen>.

³⁶ Lina Zeraiq, Dorthe Nielsen, and Morten Sodemann, “Attitudes towards human papillomavirus vaccination among Arab ethnic minority in Denmark: A qualitative study,” *Scandinavian Journal of Public Health*, March 9, 2015 [E-pub ahead of print].

³⁷ They found that mothers turned to Arabic television channels as a source of health information, whereas daughters used the Internet and Western television channels, and that mothers who do not speak Danish learn about the HPV vaccine from their daughters. If their daughters watch a documentary such as “De Vaccinerede Piger,” it is likely that the information would be passed on to their mothers. Due to language barriers, many mothers are unable to read information provided by the Ministry of Health, and a very unbalanced view of the vaccine is formed from readily available anti-vaccine media. These sentiments can be exacerbated by the mothers’ social networks, which largely comprise other Arabic-speaking mothers and often have a fear-inducing impact on the mothers’ perception of the HPV vaccine. This is especially worrying as the study also found that a key motivator for the daughters’ acceptance of the vaccine stemmed from their mothers’ approval.

that refers to Japan's suspension of its HPV vaccine recommendation; India's prohibition of the vaccine following deaths in clinical studies, as well as a potential lawsuit brought against Merck; 1,200 health professionals in France refusing to vaccinate against HPV; and France and Spain initiating action against the manufacturer.³⁸ According to SaneVax, the letter will be sent to the Danish Parliament, Danish health authorities, and the Danish press; shared with the international press in United States, England, France, Spain, India, and Japan; circulated in various medical magazines; and posted to Facebook.

Despite pressure from anti-vaccination groups, the Danish Health and Medicines Authority (DHMA) has been monitoring and evaluating reports of suspected adverse reactions associated with the HPV vaccination since its introduction in 2009,³⁹ and in September 2014 the DHMA stated, "[T]he Danish Health and Medicines Authority still assesses that the benefits of the HPV vaccine outweigh the possible risks."⁴⁰ Vaccination uptake remains high for girls, at around 70 percent.⁴¹

New Zealand

New Zealand approved the use of HPV vaccination for both females and males in 2006⁴² and provides it for free to girls under the age of 20, mainly through a school-based vaccination program.⁴³

Coverage is currently low for girls at 52.6 percent for all three doses.⁴⁴ One of the reasons for this is a fear among parents that giving adolescents the vaccine could encourage sexual debut at a young age.⁴⁵ The group Family First NZ claims that parents in New Zealand are rightly rejecting the pressure to have their children vaccinated against a "consequence of behavior," not an infectious disease. The group cites various sources of incidence data on HPV AEFI, namely reports by the Centers for Disease Control and Prevention (CDC) and BMJ. Family First NZ cited Japan's decision to suspend its HPV vaccine recommendation in

³⁸ SaneVax, "The HPV Vaccine Scandal in Denmark," August 17, 2014, <http://sanevax.org/hpv-vaccine-scandal-in-denmark/>.

³⁹ Danish Health and Medicines Authority, "Danish Pharmacovigilance Update, May 2014," volume 5, July 14, 2014, <https://sundhedsstyrelsen.dk/en/news/2014/danish-pharmacovigilance-update-may-2014>.

⁴⁰ Danish Health and Medicines Authority, "Danish Pharmacovigilance Update, September 2014," volume 5, October 17, 2014, <http://sundhedsstyrelsen.dk/en/news/2014/danish-pharmacovigilance-update,-september-2014>.

⁴¹ Zeraiq, Nielsen, and Sodemann, "Attitudes towards human papillomavirus vaccination among Arab ethnic minority in Denmark."

⁴² The New Zealand HPV Project, "About HPV Vaccine," <http://www.hpv.org.nz/hpv-vaccine/about-hpv-vaccine>.

⁴³ Ministry of Health NZ, "HPV immunisation programme," <http://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/hpv-immunisation-programme>.

⁴⁴ Ministry of Health NZ, "HPV Immunisation Coverage by Ethnicity, Vaccination and Eligible Birth Cohort—All DHBs [District health boards]," March 7, 2014, http://www.health.govt.nz/system/files/documents/pages/hpv_immunisation_coverage_by_ethnicity_vaccination_and_eligible_birth_cohort-feb2014.pdf.

⁴⁵ "Herald on Sunday editorial: Why do Pakeha spurn HPV vaccine?," *The New Zealand Herald*, March 15, 2015, http://www.nzherald.co.nz/opinion/news/article.cfm?c_id=466&objectid=11417400.

2013 and mentioned Sataro Sato, the Japanese internist and cardiologist who dominated the Japanese scientific narrative in the media in 2013 and 2014.⁴⁶

Colombia

Japanese online discussions have referred to a cluster of reported adverse events following HPV immunization in Colombia as proof of other AEFIs.

Colombia has provided the HPV vaccine for free since September 2012. Although some religious groups feared that the vaccine would cause promiscuity, by 2013 average uptake had reached around 70–80 percent for adolescent girls.

However, on May 28, 2014, the first suspected AEFI was reported in the small town of El Carmen de Bolívar. By June 3, 2014, more girls had reported side effects from the vaccine⁴⁷ that were remarkably similar to the symptoms reported in Japan, including weakness in the legs and fainting. This was widely reported by major Colombian news outlets^{48, 49} and an increase in reported side effects followed. However, very few cases of AEFI were reported during the school holiday, from mid-June to mid-July.

In August 2014, the government paid for the affected girls to receive specialized treatment. Reports peaked at the end of August when the governor of El Carmen de Bolívar met with officials from the National Institutes of Health (NIH) and a member of Parliament in El Carmen de Bolívar. Forty-five AEFI were reported in one day, with lawyers encouraging “victims” to bring their cases forward.

NIH carried out a thorough investigation,⁵⁰ considering claims that lead poisoning or even the use of Ouija boards had caused the symptoms. They surveyed around 400 girls who had reported symptoms but had not visited a doctor, finding that 20 percent of girls had not been vaccinated in the first place. There was no direct or indirect evidence linking the vaccine and the reported symptoms, and most girls were discharged from the hospital within an hour and without any abnormal findings.⁵¹ However, when the president sought to alleviate concerns by dismissing the reported AEFI as a “phenomenon of collective

⁴⁶ Family First NZ, “Parents Right to Question HPV Vaccine,” March 15, 2015, <https://www.familyfirst.org.nz/2015/03/parents-right-to-question-hpv-vaccine/>.

⁴⁷ Paula Carrillo, “Mystery illness plagues girls in Colombia,” Agence France-Presse, September 18, 2014, <http://news.yahoo.com/mystery-illness-plagues-girls-colombia-052825963.html>.

⁴⁸ Benjamin Radford, “Colombian Girls Blame Vaccine for Mysterious Symptoms,” *Discovery News*, September 24, 2014, <http://news.discovery.com/human/psychology/colombian-girls-blame-vaccine-for-mysterious-symptoms-140924.htm>.

⁴⁹ “Hundreds of teenage girls in Colombia struck by mystery illness,” Associated Press, August 27, 2014, <http://globalnews.ca/news/1530883/hundreds-of-teenage-girls-in-colombia-struck-by-mystery-illness/>.

⁵⁰ Christoffer Frendesen, “Government investigates mystery illness affecting teen girls in Colombia’s north,” *Columbia Reports*, August 28, 2014, <http://colombiareports.co/hospitalization-200-girls-northern-colombia-teenage-generates-concern-vaccine/>.

⁵¹ MinSalud, “Vacuna contra VPH no tiene relación con casos de niñas de Carmen de Bolívar,” Press bulletin No. 234, August 28, 2014, <http://www.minsalud.gov.co/Paginas/Vacuna-contr-VPH-no-tiene-relaci%C3%B3n-con-casos-de-ni%C3%B1as-de-Carmen-de-Bol%C3%ADvar.aspx>.

suggestion,” this stirred charges that the government was disregarding the “victims” experiences.⁵² Forty sufferers took to social media, posting videos of their symptoms, sparking a media sensation⁵³ and leading to a string of public protests.⁵⁴

Colombian and Japanese anti-vaccine groups have used social media in similar ways. Very recently, the Colombian government provided Internet access, cheap laptops, and tablets to smaller towns; most young people have subsequently been able to access Facebook and YouTube, where anti-vaccination content is abundant. Through these new modes of communication, transmission of information has changed, with children watching these videos online and then relaying the information to their parents.⁵⁵

News of these events has quickly spread around the world (Figure 1). On February 27, 2015, the National Cervical Cancer Vaccine Victim Liaison Committee (an anti-HPV-vaccination group in Japan) posted an article on its Facebook page referring to the situation in Colombia. The article includes a quote from Yehuda Shoenfeld, an autoimmune disease expert at the University of Tel Aviv, stating that he considered it improbable that the symptoms experienced by girls are psychological. Shoenfeld also mentioned that “thousands” of women were similarly affected by the vaccine in the United States.⁵⁶

Due to these events, as of April 2015, vaccine coverage in Colombia has fallen from around 80 percent to 20 percent among girls.⁵⁷ However, reported cases of AEFI from El Carmen de Bolívar have greatly decreased, the national vaccine recommendation has not been withdrawn, and the vaccine continues to be part of the National Immunization Program (NIP).⁵⁸

The reduction in reported AEFI could be due to a number of factors. First, Colombian news coverage has recently been dominated by an outbreak of Chikungunya, diverting attention away from the HPV controversy and possibly reducing the social stimulus that drives mass psychogenic illness.⁵⁹ Second, unlike the case in Japan, the Colombian government (which

⁵² Gabrielle Mentjox, “‘Mass hysteria’ probable cause of mystery illness in 100s of Colombia schoolgirls: President Santos,” *Columbia Reports*, September 1, 2014, <http://colombiareports.co/mass-hysteria-probable-cause-mystery-illness-100s-colombia-schoolgirls-president-santos/>.

⁵³ Heidi Larson and Will Schulz, “The State of Vaccine Confidence 2015,” London School of Hygiene and Tropical Medicine: The Vaccine Confidence Project, <http://www.vaccineconfidence.org/The-State-of-Vaccine-Confidence-2015.pdf>.

⁵⁴ Benjamin Radford, “Colombian Girls Blame Vaccine for Mysterious Symptoms,” *Discovery News*, September 24 2014, <http://news.discovery.com/human/psychology/colombian-girls-blame-vaccine-for-mysterious-symptoms-140924.htm>.

⁵⁵ Leonardo Arregoces, London School of Hygiene and Tropical Medicine, e-mail communication, April 9, 2015.

⁵⁶ Miguel Jara, “Los daños de la vacuna del papiloma humano NO son sólo psicológicos,” February 22, 2015, <http://www.migueljara.com/2015/02/22/los-danos-de-la-vacuna-del-papiloma-humano-no-son-solo-psicologicos/>.

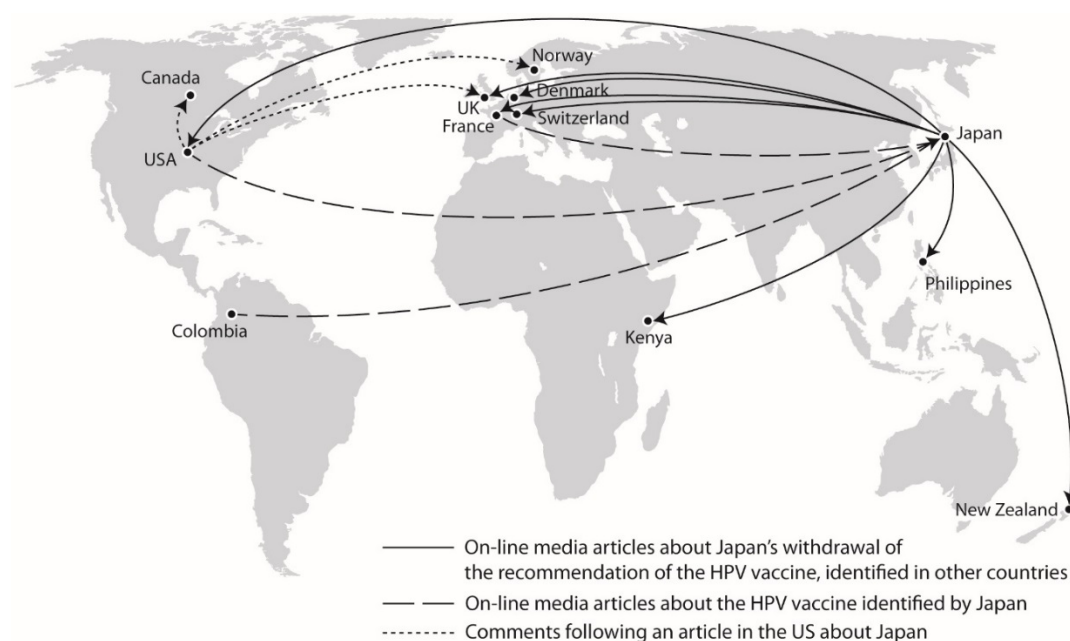
⁵⁷ “Caso de niñas del Carmen de Bolívar desplomó vacunación contra el VPH,” *El Tiempo*, February 14, 2015, <http://www.eltiempo.com/estilo-de-vida/salud/vacuna-contra-el-papiloma-humano-cayo-58-puntos-porcentuales/15246061>.

⁵⁸ MinSalud, “Programa Ampliado de Inmunizaciones (PAI),” <http://www.minsalud.gov.co/salud/publica/Vacunacion/Paginas/pai.aspx>.

⁵⁹ “Chikungunya infections spread to Colombia,” BBC, September 11, 2014, <http://www.bbc.co.uk/news/world-latin-america-29169337>.

most Colombians trust) and particularly the Ministry of Health are firmly confident in the safety and efficacy of the HPV vaccine.⁶⁰ Third, various scientific societies locally and globally supported the government, actively reminding the public of the dangers of cervical cancer.⁶¹ Finally, the Catholic church supports vaccination, which proved crucial in convincing Colombia’s Catholic populace of the HPV vaccine’s safety. One priest encouraged a dialogue between angry parents and the Ministry of Health, which helped parents accept that there was no likely link between the vaccine and AEFI.⁶²

Figure 1. Map showing global transmission of: 1) Information about other countries’ HPV situation reported in the Japanese media; and 2) reporting and discussion on the Japanese suspension of the HPV vaccine recommendation outside of Japan (January 2014–April 2015)



Source: Heidi J. Larson et al., “Tracking the global spread of vaccine sentiments: The global response to Japan’s suspension of its HPV vaccine recommendation,” *Human Vaccines & Immunotherapeutics* 9, no. 10 (2014): 1–8.

⁶⁰ Larson and Schulz, “The State of Vaccine Confidence 2015.”

⁶¹ MinSalud, “Vacuna contra VPH no tiene relación con casos de niñas de Carmen de Bolívar,” Press bulletin No. 234, 2014, <http://www.minsalud.gov.co/Paginas/Vacuna-contra-VPH-no-tiene-relaci%C3%B3n-con-casos-de-ni%C3%B1as-de-Carmen-de-Bol%C3%ADvar.aspx>.

⁶² Leonardo Arregoces, London School of Hygiene and Tropical Medicine, e-mail communication, April 9, 2015.

Addendum 2: Country Case Studies of Relevant HPV Vaccination Events

Other countries have also experienced low uptake of the HPV vaccine. This addendum explores the reasons contributing to low uptake and how each country has endeavored to address the situation.

France

In 2013, contradictory reports were released regarding a young woman's complaint about an AEFI in response to the HPV vaccine.⁶³ In September 2014, Henri Joyeux, an oncology and surgery specialist from the Faculty of Medicine, Montpellier, published cautionary statements regarding an authorization from the Haut Conseil de la Santé Publique (High Counsel of Public Health) to administer Gardasil® to girls aged nine and above⁶⁴ compared to the previous established age of 11.^{65, 66} Joyeux started an online petition with the Institut pour la Protection de la Santé Naturelle (IPSN) on September 15, 2014, calling for a stop to school-based HPV vaccination.⁶⁷ As of April 1, 2014, the petition had received 374,093 signatures. Letters bearing the signatures, many of which came from outside of France, were sent to the French president, Ministry of Health, and Ministry of Education on October 9, 2014.⁶⁸

Again, the anti-vaccination site SaneVax has been quick to misreport the situation, stating that 1,200 French health professionals are refusing to vaccinate; that the domestic manufacturer of the vaccine had threatened to withdraw its production from the country if aluminium in vaccines is prohibited; that doctors from La Réunion (a French island in the Indian Ocean) have requested a commission to investigate the HPV vaccine and to stop vaccination until the results are available; and that France and Spain have taken legal

⁶³ Laetitia Clavreul and Emeline Cazi, "Des experts font le lien entre Gardasil et sclérose en plaques," *Le Monde*, November 24, 2013, http://www.lemonde.fr/sante/article/2013/11/24/premiere-plainte-contre-levaccin-anticancer-gardasil_3519409_1651302.html; "Santé: Le Vaccine Gardasil Bientôt Visé par Trios Nouvelle Plaintes," *Le Parisien*, November 24, 2013, <http://www.leparisien.fr/laparisienne/sante/sante-le-gardasil-au-coeur-d-une-plainte-24-11-2013-3344849.php>; Sanofi Pasteur MSD, "Sanofi Pasteur MSD Rejects Opinion of Regional French Compensation Group in Gardasil Vaccination Claim," Sanofi Pasteur MSD media statement, November 25, 2013, https://www.spmsd.co.uk/upload/public/Files/10/Final%20SPMSD%20Media%20Statement_Gardasil%20FR.pdf.

⁶⁴ Breizh-info.com, "Papillomavirus (HPV): Le professeur Henri Joyeux sonne l'alarme," September 9, 2014, <http://www.breizh-info.com/16822/sante/papillomavirus-hpv-professeur-henri-joyeux-sonne-lalarme/>.

⁶⁵ Haut Conseil de la Santé Publique, "Infections à HPV: Nouveau schéma vaccinal du vaccin Gardasil®," March 28, 2014, <http://www.hcsp.fr/Explore.cgi/avisrapportsdomaine?clefr=416>.

⁶⁶ Haut Conseil de la Santé Publique, "Vaccination contre les infections à papillomavirus humains. Données actualisées," July 10, 2014, <http://www.hcsp.fr/Explore.cgi/avisrapportsdomaine?clefr=454>.

⁶⁷ Institut pour la Protection de la Santé Naturelle, "NON à la vaccination massive des enfants contre les papillomavirus," September 25, 2014, <http://www.ipsn.eu/actualites/non-a-la-vaccination-massive-des-enfants-contre-les-papillomavirus/>.

⁶⁸ Institut pour la Protection de la Santé Naturelle, "Vaccins HPV, les autorités réagissent...," November 19, 2014, <http://www.ipsn.eu/actualites/vaccins-hpv-les-autorites-reagissent/>.

action against the manufacturer. However, the HPV vaccine continues to be administered under the NIP and a national recommendation for vaccination stands.

United States

On July 30, 2014, a 12-year-old girl died in Wisconsin, just hours after receiving an HPV vaccine.^{69, 70} There was no official government statement regarding the incident until October 22, 2014, when local media reported the medical examiner's findings that the death was unrelated to the HPV vaccine.⁷¹ Over the following months, other groups moved to build a narrative and fill the void of public information: news of the event began to spread across the country, to the United Kingdom, and to other anti-vaccination communities.^{72, 73, 74, 75, 76, 77}

After the government statement was issued, many media outlets (with the notable exception of anti-vaccination websites) updated their previous reports to publish the findings and reduce speculation.⁷⁸ On December 10, 2014, the Food and Drug Administration (FDA) approved Gardasil®-9, a new 9-valent HPV vaccine that covers the existing quadrivalent Gardasil® panel of HPV 6, 11, 16, 18, with the addition of other high-risk (oncogenic) HPV subtypes, namely HPV 31, 33, 45, 52, and 58.^{79, 80, 81}

⁶⁹ Myra Sanchick and Ashley Sears, “‘The only thing different about that day was that shot’: Did a trip to the doctor kill a healthy 12-year-old girl?,” Fox 6 Now, August 7, 2014, <http://fox6now.com/2014/08/07/the-only-thing-different-about-that-day-was-that-shot-did-a-trip-to-the-doctor-kill-a-healthy-12-year-old-girl/>.

⁷⁰ Mark Johnson, “A day that started with a routine doctor visit ends in girl’s death,” *Journal Sentinel*, August 7, 2014, <http://www.jsonline.com/news/health/for-girl-a-day-that-started-with-a-routine-doctors-visit-ended-in-her-death-b99326702z1-270410121.html>.

⁷¹ Karen Herzog, “Medical examiner: Girl’s death not caused by HPV vaccination,” *Journal Sentinel*, October 22, 2014, <http://www.jsonline.com/news/health/medical-examiner-girls-death-not-caused-by-routine-vaccination-b99376029z1-280058462.html>.

⁷² Jessica Jerreat, “‘Did the HPV vaccine kill my daughter’: Mother demands answers after healthy and active daughter, 12, collapses and dies after getting vaccine,” *Daily Mail*, August 8, 2014, <http://www.dailymail.co.uk/news/article-2720333/Did-HPV-vaccine-kill-daughter-Mother-demands-answers-healthy-active-daughter-12-collapses-dies-getting-vaccine.html>.

⁷³ Deborah Hastings, “Wisconsin mom: ‘Did HPV vaccine kill my 12-year-old daughter?’,” *New York Daily News*, August 8, 2014, <http://www.nydailynews.com/news/national/wisc-mom-hpv-vaccine-killed-12-year-old-girl-article-1.1897850>.

⁷⁴ “Family: 12-Year-Old Daughter Died Hours after Getting HPV Vaccine,” CBS Atlanta, August 12, 2014, <http://atlanta.cbslocal.com/2014/08/12/family-12-year-old-daughter-died-hours-after-getting-hpv-vaccine/>.

⁷⁵ Health Impact News, “Gardasil Vaccine: One More Girl Dead,” August 11, 2014, <http://healthimpactnews.com/2014/gardasil-vaccine-one-more-girl-dead/>.

⁷⁶ SaneVax, “Gardasil Vaccine: One more girl dead,” August 17, 2014, <http://sanevax.org/gardasil-vaccine-one-girl-dead/>.

⁷⁷ “Healthy 12-Year-Old-Girl Dies after Injected with HPV Vaccine,” *Inquisitr News*, September 28, 2014, <http://www.inquisitr.com/1504519/healthy-12-year-old-girl-dies-after-injected-with-hpv-vaccine/>.

⁷⁸ Myra Sanchick, “Medical Examiner: HPV vaccine did not cause death of 12-year-old Waukesha girl,” Fox 6 Now, October 22, 2014, <http://fox6now.com/2014/10/22/medical-examiner-hpv-vaccine-did-not-cause-death-of-12-year-old-waukesha-girl/>.

⁷⁹ Merck, “FDA Approves Merck’s HPV Vaccine, GARDASIL®9, to Prevent Cancers and Other Diseases Caused by Nine HPV types—Including Types That Cause about 90% of Cervical Cancer Cases,” December 11, 2014, <http://www.mercknewsroom.com/news-release/prescription-medicine-news/fda-approves-mercks-hpv-vaccine-gardasil9-prevent-cancers-an>.

⁸⁰ Elmar A. Joura et al., “A 9-Valent HPV Vaccine against Infection and Intraepithelial Neoplasia in Women,” *New England Journal of Medicine* 372 (2015): 711–23.

India

In April 2010, the Indian government suspended a national HPV vaccination demonstration project due to pressure from advocacy groups. Public concerns centered around the target population, relevance, safety, cost-effectiveness of the vaccine, as well as distrust of the pharmaceutical industry.⁸² Suspension of the demonstration project generated controversy, petitions, parliamentary investigations, recommendations and reports,⁸³ and ongoing Supreme Court hearings.^{84, 85, 86} The Parliamentary Standing Committee even asked the government to take up the matter with other countries where PATH (Program for Appropriate Technology in Health) had assisted in similar demonstration projects, including Uganda, Vietnam, and Peru.

The private health sector has provided the HPV vaccine since mid-2010. In early 2015, the National Immunization Technical Advisory Group (NITAG) was invited to evaluate the safety and efficacy of the vaccine for its introduction into the Indian NIP. However, the earliest projected implementation will be in 2016.⁸⁷

United Kingdom

Following reports of a young girl's death after receiving an HPV vaccination, the UK government opened an investigation and issued a response within 24 hours, clarifying that the vaccine had not caused the girl's death.⁸⁸

Since 2013, there have been calls to expand HPV vaccination to boys.^{89, 90} In November 2014, the Joint Commission on Vaccination and Immunization resolved that it would be more

⁸¹ National Cancer Institute, "Gardasil 9 Vaccine Protects against Additional HPV Types," March 2, 2015, <http://www.cancer.gov/clinicaltrials/results/summary/2015/gardasil9-0215>.

⁸² Larson, Brocard, and Garnett, "The India HPV-Vaccine Suspension," 572–73.

⁸³ Department-Related Parliamentary Standing Committee on Health And Family Welfare, "Seventy Second Report Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by Path in India," Parliament of India Rajya Sabha, August 30, 2013, <http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/72.pdf> and <https://www.pharmamedtechbi.com/~media/Supporting%20Documents/Pharmasia%20News/2013/September/HPV%20Vaccines%20Parliamentary%20Report%20%20Aug%2031%202013.pdf>.

⁸⁴ "Supreme Court asks Centre to respond on clinical trial of vaccines," *The Economic Times*, January 13, 2015, http://articles.economictimes.indiatimes.com/2015-01-13/news/58024587_1_gardasil-and-cervarix-vaccines-justices-dipak-misra.

⁸⁵ Teena Thacker, "Government orders HPV vaccine study," *The Asian Age*, February 25, 2015, <http://www.asianage.com/india/government-orders-hpv-vaccine-study-751>.

⁸⁶ "Court glare on 'harmful, costly' vaccines—Rs 15 or Rs 525? Notices to govt after petitions allege favour to private players," *The Telegraph India*, September 2, 2013, http://www.telegraphindia.com/1130903/jsp/nation/story_17305212.jsp#.VR0sifnF98F.

⁸⁷ Thacker, "Government orders HPV vaccine study."

⁸⁸ World Health Organization, "Case Study C: How a Potential HPV Vaccination Crisis Was Averted," <http://vaccine-safety-training.org/c-resources.html>.

⁸⁹ James Meikle, "HPV vaccine could be given to boys as well as girls in UK," *The Guardian*, November 28, 2013, <http://www.theguardian.com/society/2013/nov/28/hpv-vaccine-boys-girls-cancer-uk>.

⁹⁰ "HPV vaccine: should boys get it too?," *The Telegraph* (London), March 12, 2015, <http://www.telegraph.co.uk/men/active/mens-health/11467138/HPV-vaccine-should-boys-get-it-too.html>.

advisable to vaccinate men who have sex with men,⁹¹ and the population-wide vaccination of boys has been subsequently postponed until 2017.^{92, 93, 94} This postponement has sparked increased discussion in the local media, with an emphasis on criticizing government officials on budgeting and votes.^{95, 96}

Australia

In Australia, positive and transparent information about the HPV vaccine was strengthened following adverse events experienced by several dozen Melbourne schoolgirls. The state government established a new service, Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) in April 2007⁵⁴ and the vaccine was not suspended. On September 2, 2014, Harrison et al. published that the large decrease in genital warts in Australian women of vaccine-eligible age highlights the success of the National HPV Vaccination program.⁹⁷ The publication received wide media attention both within Australia and globally.^{98, 99, 100} A separate paper by M. A. Smith of the Cancer Screening Group cited trends in HPV vaccination in Australia, concluding that “Australia has implemented a successful and equitable vaccination program against HPV.”¹⁰¹

In response to the successful vaccination program, there have been reports that Australia is planning to shift to primary HPV testing from Pap tests next year, as mentioned by Karen Canfell, chairman of Cancer Council Australia’s Cancer Screening Committee.⁹⁷

⁹¹ Laura Donnelly, “Gay men to be offered HPV jab under new guidelines,” *The Telegraph* (London), November 12, 2014, <http://www.telegraph.co.uk/news/health/news/11226126/Gay-men-to-be-offered-HPV-jab-under-new-guidelines-to-Government.html>.

⁹² Joint Committee on Vaccination and Immunisation, “Minute of the meeting on 4 February 2015,” <https://app.box.com/s/iddfb4ppwkmjtusir2tc/1/2199012147/27417264008/1>.

⁹³ “UK postpones HPV vaccine for males,” *Washington Blade*, March 20, 2015, <http://www.washingtonblade.com/2015/03/20/uk-postpones-hpv-vaccine-for-males/>.

⁹⁴ UK Parliament, “Human Papillomavirus: Vaccination: Written question—225307: To ask the Secretary of State for Health, when he expects his Department to be in a position to make a decision on HPV vaccination for adolescent boys,” March 4, 2015, <http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2015-02-25/225307>.

⁹⁵ Nick Duffy, “Department of Health ‘awaiting advice’ on extending HPV vaccine to gay men,” *Pink News*, March 13 2015, <http://www.pinknews.co.uk/2015/03/13/department-of-health-awaiting-advice-on-extending-hpv-vaccine-to-gay-men/>.

⁹⁶ Gillian Prue, “Why boys should get the HPV vaccine too,” *The Conversation*, February 9, 2015, <http://theconversation.com/why-boys-should-get-the-hpv-vaccine-too-36932>.

⁹⁷ Christopher Harrison et al., “Decreased Management of Genital Warts in Young Women in Australian General Practice Post Introduction of National HPV Vaccination Program: Results from a Nationally Representative Cross-Sectional General Practice Study,” *PLoS One* 9, no. 9 (2014): e105967, <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0105967>.

⁹⁸ German Lopez, “Australia’s free HPV vaccine program is a big success,” *Vox*, September 8, 2014, <http://www.vox.com/2014/9/8/6122575/hpv-vaccine-australia-success>.

⁹⁹ Simon Santow, “Vaccination success against HPV,” ABC News, August 13, 2014, <http://www.abc.net.au/pm/content/2014/s4066535.htm>.

¹⁰⁰ Megan Howe, “Witnessing protection via the human papillomavirus vaccine,” *The Saturday Paper*, February 28, 2015, http://www.thesaturdaypaper.com.au/2015/02/28/witnessing-protection-via-the-human-papillomavirus-vaccine/14250420001530#.VSP5_fzF-So.

¹⁰¹ Cancer Council Australia, “Has the program been successful?,” <http://www.hpvvaccine.org.au/the-hpv-vaccine/has-the-program-been-successful.aspx>.

Rwanda

A comprehensive national education campaign preceded nationwide implementation of a school-based HPV vaccination program in Rwanda in 2011.¹⁰² Despite public concerns surrounding the introduction of a new vaccine,¹⁰³ Rwanda has achieved coverage of more than 90 percent for girls by enlisting health professionals, religious leaders, prominent politicians, and teachers as advocates from the very beginning. This demonstrates that with sufficient planning and an active policy of engagement prior to implementation, high coverage can be achieved despite low knowledge of HPV-related diseases and vaccines.¹⁰⁴

Tanzania

The HPV vaccine is currently only available from demonstration projects in Tanzania.¹⁰⁵ While knowledge of HPV-related diseases and the vaccine is low in rural areas and there was concern among parents about the vaccine's effect on fertility^{106, 107}—an issue that may have stemmed from rumors surrounding the tetanus toxoid vaccination previously¹⁰⁸—vaccine acceptance is high at 93 percent. Information is mostly provided by clinicians (deemed trustworthy by the population), popular media sources, and community-based routes such as churches.

See Appendix 1 for a summary of country concerns and Appendix 2 for a timeline illustrating when these events occurred.

¹⁰² Agnes Binagwaho et al., “Achieving high coverage in Rwanda’s National Human papillomavirus vaccination programme,” *Bulletin of the World Health Organization*, May 23, 2012, <http://www.who.int/bulletin/volumes/90/8/11-097253/en/>.

¹⁰³ Nobila Ouedraogo et al., “Human papillomavirus vaccination in Africa,” *The Lancet* 378 (2011): 315–16, <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2961164-1/abstract>.

¹⁰⁴ Tom G. Hopkins and Nick Wood, “Female human papillomavirus (HPV) vaccination: Global uptake and the impact of attitudes,” *Vaccine* 31, no. 13 (2013): 1673–9, <http://vaccinesafetyresource.elsevier.com/sites/default/files/HPV-Hopkins-Female.pdf>.

¹⁰⁵ L. Bruni et al., “Human Papillomavirus and Related Diseases in Tanzania: Summary Report,” ICO [Institut Català d’Oncologia] Information Centre on HPV and Cancer (HPV Information Centre), March 20, 2015, <http://www.hpvcentre.net/statistics/reports/TZA.pdf>.

¹⁰⁶ Pieter Remes et al., “A qualitative study of HPV vaccine acceptability among health workers, teachers, parents, female pupils, and religious leaders in northwest Tanzania,” *Vaccine* 30, no. 36 (2012): 5363–7, <http://www.ncbi.nlm.nih.gov/pubmed/22732428>.

¹⁰⁷ Deborah Watson-Jones et al., “Reasons for receiving or not receiving HPV vaccination in primary schoolgirls in Tanzania: A case control study,” *PLoS ONE* 7, no. 10 (2012), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0045231>.

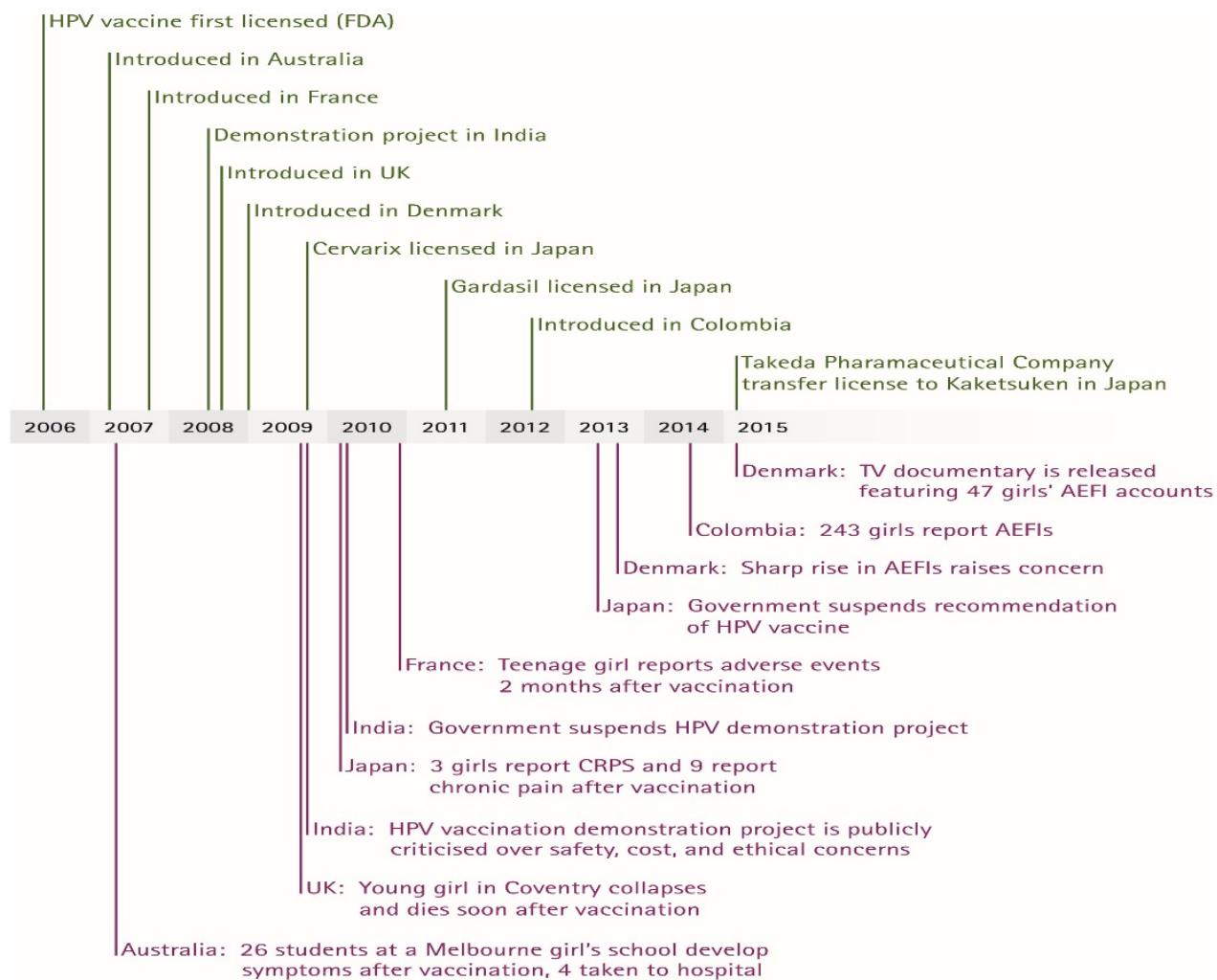
¹⁰⁸ Melissa S. Cunningham et al., “Cervical cancer screening and HPV vaccine acceptability among rural and urban women in Kilimanjaro Region, Tanzania,” *BMJ Open* 5, no. 3 (2015): e005828, <http://bmjopen.bmj.com/content/5/3/e005828.full>.

Appendix 1: Summary of Country Case Studies

Country	Date of licensing	Date of NIP inclusion	Date and prompters of vaccine concerns	When and what was the government response?
Australia	April 2007	April 2007	<p>May 2007: 720 girls receive HPV vaccination at Melbourne girl's school. 26 girls develop symptoms including dizziness, syncope, and neurological complaints. 4 taken to hospital.</p> <p>2016: plan to shift to primary HPV testing from Pap tests in response to successful vaccination program.</p>	<p>Radio interviews with then-federal health minister and Victorian state premier. State government funded new service, SAEFVIC (Surveillance of Adverse Events Following Vaccination in the Community) in April 2007. No vaccine suspension.</p>
Colombia	December 2006	September 2012	<p>August 2014: 243 cases of cold feet, malaise, headache, weight loss, numbness, fainting, paralysis, and seizures</p>	<p>President, government, and Ministry of Health stood by their confidence in vaccine's safety and efficacy. No vaccine suspension.</p>
Denmark	2006	2009	<p>March 2015: TV program about vaccinated girls having chronic headaches, muscle aches, and muscle failure.</p>	<p>Danish Health and Medicines Authority (DHMA) pharmacovigilance reports referring to suspected adverse events in May 2014 and September 2014. No vaccine suspension.</p>
New Zealand	July 2006	September 2008	<p>March 2015: PhD student report of low vaccination coverage among population in "other" category and suggests hypothesis of "white girls don't have sex theory" as reason. Family First NZ uses difference in coverage with ethnicity to support notion that "contrary to claims that 'well-off Pakeha girls' are rejecting the HPV vaccine, parents of all racial groups in New Zealand are rightly rejecting the pressure to have their children vaccinated for an infection which isn't a communicable disease but a consequence of behaviour."</p>	<p>No official government response. No vaccine suspension.</p>
Japan	October 2009	April 2013	<p>April 2013: Family of allegedly affected girl compensated by Suginami local government</p> <p>31 March 2015: Anti-vaccination groups protest outside MSD and GSK</p> <p>26 April 2015: National Cervical Cancer Vaccine Victim Liaison Committee announces plans for national "Vaccine Talk 2015" event</p>	<p>June 14, 2013: Government suspends HPV vaccination recommendation.</p> <p>January 2015: Ministry of Health, Labour, and Welfare (MHLW) panel of experts rules out possibility that adverse events after HPV vaccination were caused by immunological or neurological effects of vaccine, but recommendation for HPV vaccination was not reinstated.</p>

India	July 2008	Not yet included	<p>October 2009: Public criticism of HPV vaccine demonstration project, vaccine safety concerns, costs, and ethical concerns.</p> <p>April 2010: Press conference and memorandum to health minister highlighting previous concerns and four deaths associated temporally with HPV vaccination. Public interest litigation initiated.</p>	<p>April 2010: Government suspends HPV vaccination demonstration project.</p> <p>Ongoing parliamentary inquiry and Supreme Court hearings.</p> <p>Early 2015: National Immunization Technical Advisory Group invited to evaluate safety and efficacy of HPV vaccine.</p>
United Kingdom	June 2006	September 2008	<p>September 28, 2009: Young girl in Coventry collapses and dies soon after first dose of HPV vaccine</p>	<p>Evening of September 28, 2009: UK Department of Health acts quickly to inform media and public that death was not due to HPV vaccine. No vaccine suspension.</p>
France	July 2007	October 2007	<p>March 28, 2014 (to nine-year-olds). July 10, 2014 (push for further vaccination coverage): Henri Joyeux's makes cautionary statement and launches petition against school HPV vaccination with IPSN on September 15, 2014.</p>	<p>No new government response. No vaccine suspension.</p>

Appendix 2. Timeline of Safety Concerns



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