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The newsletter on Human Papillomavirus because we can envisage cervical cancer elimination

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Who or what are the greatest enemies of the Japanese HPV vaccination programme?

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The bivalent HPV vaccine was licenced in Japan in October 2009 and the quadrivalent vaccine in July 2011. From December 2010, special funding was provided for girls aged 12-16 years whereby the national government paid 50% of the vaccine cost, if local government also paid 50%. Due to unexpectedly high demand after public funding was introduced, the vaccine stock decreased drastically nationwide, and between March and August 2011, only those girls who had received the first dose could be vaccinated. Thus, many girls could not initiate vaccination until after September 2011. Ironically, during this period, the media fiercely criticized the government for not stocking enough of the cancer preventing vaccine.

From February 2013, however, after it became clear the government was to include the HPV vaccine into the national immunization programme (NIP), unconfirmed reports of adverse events after immunization (AEFI) began to appear in the media and a 'Victims' Support Group was established. The HPV vaccine was introduced into the NIP in April 2013 and just two months later, on June 14th, 2013, proactive recommendations for the HPV vaccines were suspended due to the unconfirmed media reports of AEFI. Very quickly uptake dropped from >70% to <1%,[1] and four and a half years later, this suspension remains, despite no evidence to suggest the vaccine is responsible for the reported symptoms. The reasons for this are complex and varied.

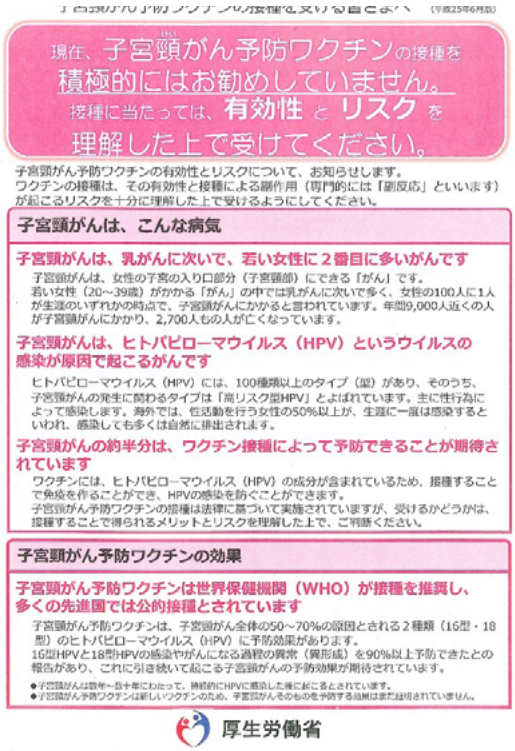
The first reason is poor risk management by the Ministry of Health, Labour and Welfare (MHLW). Japan has inadequate disease registries, no HPV vaccine registry and no national screening registry. Consequently, it is difficult to obtain background incidence rates on neurological and autoimmune diseases claimed by the Victims' support group to be caused by the HPV vaccine. Therefore, it is almost impossible to ascertain whether rates have actually increased after vaccine introduction. It is also difficult to show vaccine effectiveness at the population level. Fortunately, three reports have been published recently showing both a reduction in both HPV16/18 prevalence, as well as low-grade cervical abnormalities in vaccinated girls.[2-4]

The second reason is poor risk communication by the MHLW. Upon suspension of the proactive recommendations for the HPV vaccine, the MHLW told all prefectural governors not to actively recommend the vaccine and to cease all vaccine promotion. Prefectural governors also had to inform all health boards and medical professionals of this decision. However, at the same time, the vaccine remained in the NIP and health facilities were told to continue to offer full support to parents seeking the vaccine and facilitate vaccine access. The head of the special committee investigating the AEFI also stated that the decision to suspend proactive recommendations 'did not mean that the vaccine was problematic from the viewpoint of safety', but

Figure 1

Poor risk communication

The 'pink leaflet'
Prepared by the Ministry of Health, Labour and Welfare.
Must be distributed to all parents seeking vaccination.



現在、子宮頸がん予防ワクチンの接種を
積極的にはお勧めしていません。
接種に当たっては、有効性 と リスク を
理解した上で受けてください。

子宮頸がん予防ワクチンの有効性とリスクについて、お知らせします。
ワクチンの接種は、その有効性と接種による副作用（専門的には「副反応」といいます）が起こるリスクを十分に理解した上で受けるようにしてください。

子宮頸がんは、こんな病気

子宮頸がんは、乳がんに次いで、若い女性に２番目に多いがんです

子宮頸がんは、女性の子宮の入り口部分（子宮頸部）にできる「がん」です。
若い女性（20～39歳）がかかる「がん」の中では乳がんに次いで多く、女性の100人に1人が生涯のいずれかの時点で、子宮頸がんにかかると言われています。年間9,000人近くの人が子宮頸がんにかかり、2,700人もの人が亡くなっています。

子宮頸がんは、ヒトパピローマウイルス（HPV）というウイルスの感染が原因で起こるがんです

ヒトパピローマウイルス（HPV）には、100種類以上のタイプ（型）があり、そのうち、子宮頸がんの発生に関わるタイプは「高リスク型HPV」とよばれています。主に性行為によって感染します。海外では、性活動を行う女性の50%以上が、生涯に一度は感染するといわれ、感染しても多くは自然に排出されます。

子宮頸がんの約半分は、ワクチン接種によって予防できることが期待されています

ワクチンには、ヒトパピローマウイルス（HPV）の成分が含まれているため、接種することで免疫を作ることができ、HPVの感染を防ぐことができます。
子宮頸がん予防ワクチンの接種は法律に基づいて実施されていますが、受けるかどうかは、接種することで得られるメリットとリスクを理解した上で、ご判断ください。

子宮頸がん予防ワクチンの効果

子宮頸がん予防ワクチンは世界保健機関（WHO）が接種を推奨し、多くの先進国では公的接種とされています

子宮頸がん予防ワクチンは、子宮頸がん全体の50～70%の原因とされる２種類（16型・18型）のヒトパピローマウイルス（HPV）に予防効果があります。
16型HPVと18型HPVの感染やがんになる過程の異常（異形成）を90%以上予防できたとの報告があり、これに引き続いて起こる子宮頸がんの予防効果が期待されています。

●子宮頸がんは数年～数十年にわたって、持続的にHPVに感染した後に起こるとされています。
●子宮頸がん予防ワクチンは新しいワクチンのため、子宮頸がんそのものを予防する効果はまだ証明されていません。

厚生労働省

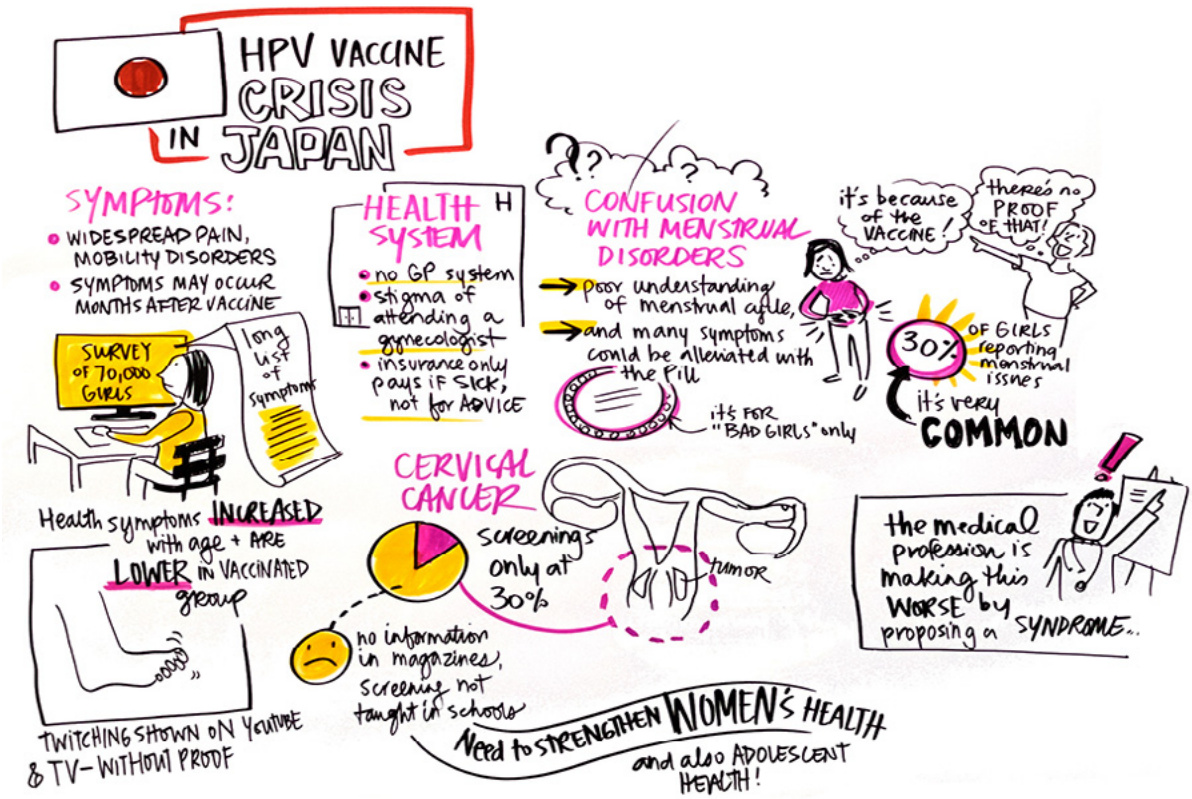
"At the moment we are not proactively recommending the cervical cancer vaccine. Before having your child vaccinated, **please understand the risks and benefits"**

Implies both the risks and benefits are equal

"Since it is a new vaccine **there is no evidence yet to show it prevents cervical cancer..."**

that they just wanted to implement an investigation to help reassure the public the vaccine was safe. Therefore, the decision to suspend proactive recommendations was not based on scientific evidence and caused enormous confusions for public health officials, doctors and the public.

The final reason for the present situation is an unrestrained media environment and an anti-vaccine group more organized than the government. Around the time the HPV vaccine was introduced into the NIP, the 'Victims Support group' made a DVD, sold for 500 yen ($5), showing the purported 'side effects' of the HPV vaccine. This DVD was broadcast extensively on news programmes, despite absolutely no evidence to show the vaccine had caused the symptoms. Media rhetoric quickly became 'scientific fact' and was rarely challenged by academic organizations or health care professionals. When two journalists dared to challenge the idea that the vaccine had caused the reported symptoms, one has ended up being sued for libel. The other



Initially Japan had a very successful HPV vaccine programme that was also supported by the media

journalist, working for the Yomiuri newspaper, had to cut short her series on HPV vaccine safety after the Victims' Support group contacted the CEO of the newspaper. The journalist was promptly 'demoted' to a position in a regional office.

In conclusion, initially Japan had a very successful HPV vaccine programme that was also supported by the media. However, poor risk communication and risk management, a public health infrastructure that makes it difficult to convince the public that the vaccine is both effective and safe, and an anti-vaccine movement more organized than the government and supported by the media, has made it difficult for the MHLW to restart proactive recommendations for the HPV vaccine. ■

an anti-vaccine movement more organized than the government and supported by the media, has made it difficult to restart proactive recommendations for the HPV vaccine

Project endorsed by

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