How to deal with an HPV vaccine safety crisis Perceptions and attitudes

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Improving health worldwide





"He threw poison in the fountain (...) He is paid by the government (...) Cholera is only a pretext to poison the poor world"

Jean Giono, Le Hussard sur le toit

Outline

The vaccine confidence project

Current issues in vaccine acceptance and challenges specific to the HPV vaccine

An example of an HPV vaccine safety crisis - from Japan to Denmark and EMA

Determinants of HPV Vaccine acceptance in Europe

Strategies to maintain and improve HPV vaccine confidence

The vaccine confidence project

The Vaccine Confidence Project

Vaccine confidence

System confidence



Team lead - Heidi Larson Co-lead - Pauline Paterson Communication - Jay Dowle





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UK: Give HPV vaccine to men who have sex with men, government told
Vaccine alternatives for children
US: Vaccine exemption rates higher in white, affluent Calif. communities
Vaccine affluent Calif. communities
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The State of Vaccine Confidence

Download the full report, including details of confidence challenges, strategies, research methods, and the Vaccine Confidence Index.

Confidence Commentary:

Blog archive

European Medicines Agency releases new report confirming HPV vaccine safety

Literature

Literature archive

Knowledge, attitudes and perceptions towards polio immunization among residents of two highly affected regions of Pakistan @

MU Khan, A Ahmad, T Aqeel, S Salman, Q Ibrahim, J Idrees and MU Khan. 2015. BMC Public Health 15:1100. doi:10.1186/s12889-015-2471-1

Vaccine: Special Issue on Vaccine

Current issues in vaccine acceptance and challenges specific to the HPV vaccine

Current issues in vaccine acceptance

- Many countries dealing with pockets of people who are delaying or refusing recommended vaccinations
- Factors underlying these decisions vary by population, context, time and vaccine, and include:
 - Safety concerns
 - Distrust in manufacturers and/or governments
 - Misinformation and rumours
 - Lack of perceived need, low perceived effectiveness/efficacy
 - Lack of recommendation from HCWs
 - Other priorities
- No single intervention strategy will solve the issue, but interventions have to be adapted to target local challenges

Characteristics of HPV vaccines and potential communication challenges

Targets pre-adolescent and adolescent girls

- Different place of delivery than for infants/young children
- Fear of injections
- Psychogenic or psychosomatic reactions

A new vaccine

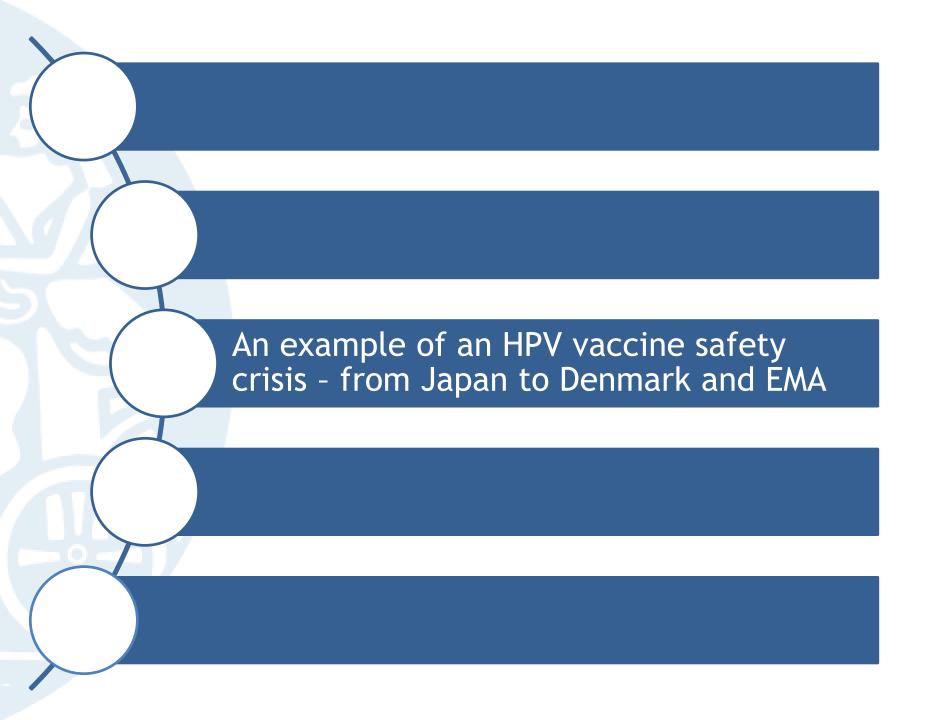
Safety and efficacy trials

Multi-dose schedule within six months

Maintaining support of schools and parents for 2-3 doses

Vaccine that protects against an STI

- Evokes moral judgments and religious and cultural taboos
- Issues of promiscuity



Concerns are global and varied

Japan.Mothers.jpg

japanese_girl.jpg

Japanese anti-HPV vaccine scientist



that could prevent a certain type of cancer? And what if it was free?

complications from the inoculation ever since

from Suginami Ward when she entered junior high school in the fall of 2011. As

a parent, she didn't think twice about accepting the offer — a decision she says she will regret for the rest of her life. Her daughter has suffered severe

The example of Japan

October 2009
Cervarix introduced
HPV vac. subsidised

March 2013 AEFIs reported in news April 13 2013 Compensation claims

June 14 2013 Recommendation Suspended

March 2010 3 CRPS, 9 chronic pain

July 2011 Gardasil introduced April 1 2013 A routine vaccination

June 13 2013
WHO declaration
November 2015
Still suspended

Japan - The triggers

Government to investigate reported cases, but did not publish any results for more than a year

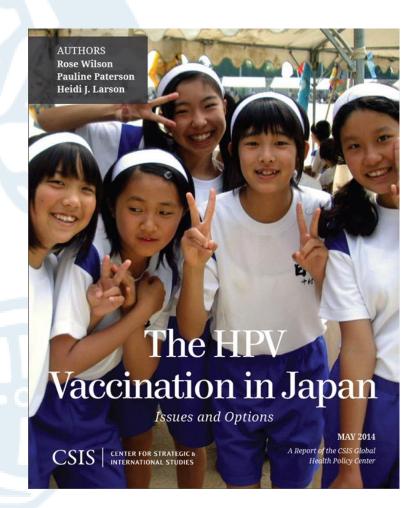
... Other actors filled the public information void and gained strength and public attention locally and globally

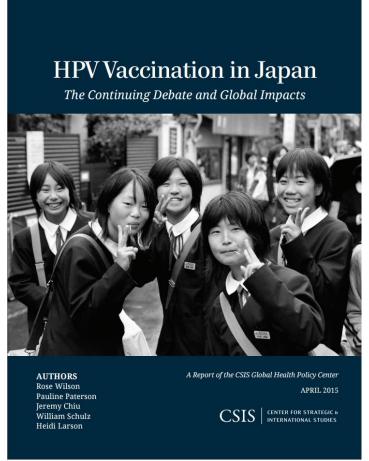
Parents of another girl tried to claim compensation for suspected CRPS. Government agreed after public criticism.

Public perceived this as an admission of guilt and the issue became a tipping point for current anti-HPV vaccine sentiment

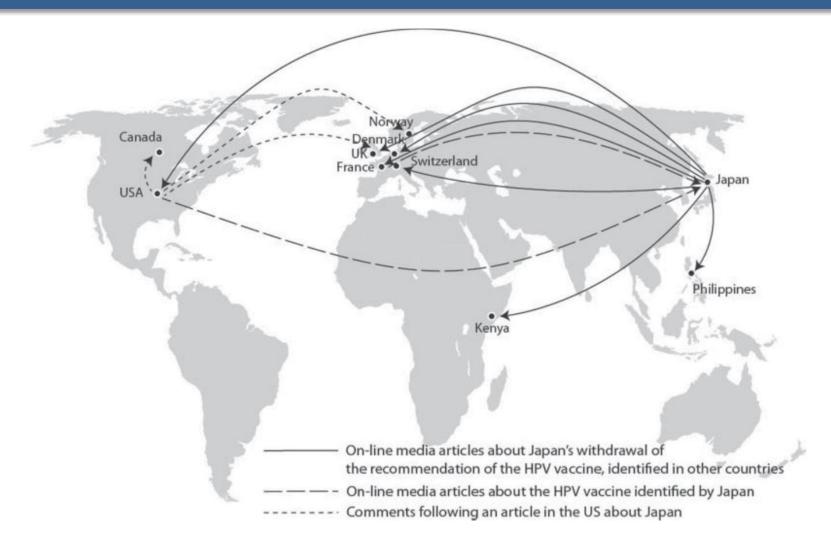
Drop in uptake from over 70% to under 5%

Japan - The triggers





Global transmission of HPV concerns



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 & Immunotherapeutic 9, no 10 (2014):1-8.

Global transmission of HPV concerns - England

2009 - Reports of a young girl's death after receiving the HPV vaccine

Government investigates and responds within 24h: the vaccine did not cause the girl's death

Rapid engagement with media/public crucial to contain spread of negative media and loss of public confidence

No vaccine suspension. Vaccine coverage rate 2014: 89.6% for two doses

Global transmission of HPV concerns - France

2010 - Contradictory reports released in response to teenage girl's complaint about AEFI

2013 - Criminal complaint filed against Sanofi Pasteur MSD and France's medicines safety agency, press conference.

Nov 2013 - Chair of national committee states no evidence to link Gardasil with AEFIs

CRCI acknowledges a link between pathology and vaccination. Sanofi Pasteur issues a press release supporting the safety profile of HPV vaccine

No vaccine suspension. Decreasing HPV vaccination coverage since 2010 (23% for 1 dose in 2010, 18% in 2013)

Global transmission of HPV concerns - India

Lack of public forum to discuss the vaccine led to advocacy groups feeling ignored → they intensified their efforts, culminating on World Health day 2010 where 68 public health organisations and professionals organised a press conference to highlight their concerns

Issue of a "Memorandum to the Health Minister" which called for the immediate halt of the HPV vaccine demonstration projects and an inquiry into and compensation for the reported side effects and alleged vaccine-related deaths of 4 girls

Government immediately suspended the HPV vaccination demonstration project.

From Japan to Denmark...

July 27 2014

Conference in Tokyo - Kusuki Nishioka claims a causal link between the HPV vaccine and pain symptoms.

March 2015

Documentary "De Vaccinered Piger" (the vaccinated girls) is televised in Denmark

August 7 2014

Danish website "HPV vaccine info" reports on the conference



Impact of the documentary

These stories were quickly republished on websites such as SaneVax

Reports of concerned parents and teenage girls in the media increased all over the world

A letter from Danish parents was sent to the Danish Parliament, health authorities and press as well as the international press, medical magazines and Facebook.

The HPV scandal in Denmark

This is an open letter, which will be sent to the Danish Parliament, the Danish Health Authorities, the Danish press and the international press in USA, England, France, Spain, India and Japan, medical magazines and Facebook.

The HPV vaccine was introduced in USA in 2006 and since then introduced in a lot of countries in the world. Slowly there has been a recognition, that the HPV vaccine is very poisoning and have the adverse events the manufacturer Merck is mentioning in the SPC. The adverse events frequency is about 3%, which Merck has to state to the consumers to avoid expensive fines.

The Danish Health and Medicines Authority have only informed about few a citizens and the Danish doctors.

India have prohibited the vaccine because of 7 deaths in the clinical studies, introduced in India. Subsequent there have been planned an Indian trial aga 2014. It is not the first time Merck have been accused. Merck have several judions

India prohibited the Danish India prohibited the beaths in the Carlos of the Carlos of

Japan's suspended to help the recommendation for HPV

the vaccine, until it is proved safe. In Spain the first trial of several have been planned accine injured. In France they discuss freely for or against the HPV vaccine. English vaccine seed HPV vaccine injuries in the Parliament. In Denmark we got aware of the HPV-vaccine in 2013. This led to attempt to stop the vaccination, this has still not been managed, the HPV and Medicines Authority have chosen to ignore the HPV criticism.

Vaccine recommendation

damaged by the HPV vaccine, have been absent from school in days, weeks, months and years. Lots of them can no longer attend a normal education. Lots of the elder girls falls completely out of the labor market and do not get any money for their daily living, because they cannot get cash benefit or sickness benefit because they do not have a diagnose. Lawsuit brought against

Lots of families' experience, that parents to the pressure and are on sick leave, loses their jobs and friends. It is a nuge load as parents and siblings to experience, that a young and healthy youngster decomposes to just being able to manage few basic needs. Young women lose their jobs and the ability to take care of just simple activities associated with a normal life as a young mother and a female.

The HPV vaccine draws a broad and sinister trail of ruined youth, disability and broken families. The affected families have been months and years in the Danish Health System without any help. They have been countless examinations and admissions, without any result. The Danish doctors are not skilled enough to diagnose HPV vaccine injuries.

Studies in other countries have shown clear signs of serious diseases such as meningitis, damaged centra

1,200 health professionals

in France refused to Interest have been the following activities in Denmark over the past year:

vaccinate against HPV vaccine damaged young people and their parents

France and Spain initiated action against the manufacturers

- an audience with the Health Committee in the Parliament
- 77 HPV vaccine damaged young people's medical history was sent to the Minister of Health and the Health Committee in the Danish Parliament

EMA review of evidence

2009

The Danish Health and Medicines Authority monitors reports of suspected adverse reactions to HPV vaccination

Sept-Oct 2015

Mostly neutral reports of EMA review in the media. Some use the review to justify their concerns about HPV vaccine side effects

Nov 2015

Most publications objectively report the results but with time, a growing number criticising the investigation



EMA starts a review of HPV vaccines at the request of Denmark to further clarify the safety profile of the vaccines

5 November 2015

EMA review concludes evidence does not support that HPV vaccines cause CRPS or POTS.

Perceived issues with the results of the EMA review identified in the media



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Chronic Symptoms After HPV Vaccination: Danes Start Study

Zosia Chustecka

November 13, 2015



EDITORS' RECOMMENDATIONS

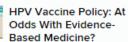


Europe Concludes Syndromes Are Not Caused by HPV Vaccine



Case Reports of 'Syndrome' Appearing After HPV Vaccination





RELATED DRUGS & DISEASES

Human Papillomavirus

Pap Smear

Viral Infections of the Mouth

The controversies surrounding the human papillomavirus (HPV) vaccination and a possible association with chronic symptoms in girls and young women appear to be ongoing, despite a recent major review that dismissed the link.

Last week, the European Medicines Agency (EMA) announced that a task force found no causality between the vaccination and two sets of chronic symptom syndromes in girls and young women, which echoes previous reassurances from the Centers for Disease Control and Prevention (CDC).

Now, some clinicians and scientists say the EMA report is "not valid" and is marred by conflict of interest and reliance on already published data and are calling for an independent study of the association.

Perhaps even more notably, Denmark has announced that it is conducting its own independent investigation. More than 1300 girls and young women with such symptoms have been referred to five specialist centers in the country.

It was Denmark that requested the recent review by the EMA into the safety of HPV vaccines. That review, which began in

July, focused in particular at reports of complex regional pain syndrome (CRPS), a chronic pain condition affecting the limbs, and postural orthostatic tachycardia syndrome (POTS), a condition in which the heart rate increases abnormally after sitting or standing up, causing symptoms such as dizziness and fainting, as well as headache, chest pain, and weakness.

MOST POPULAR ARTICLES

According to PHYSICIANS

- Chronic Symptoms After HPV Vaccination: Danes Start Study
- FDA Panel Says Fluoroquinolones Need Stronger Warnings
- Aerobic Exercise Has Disease-Modifying Effect in MCI
- Proton-Pump Inhibitors May Boost Death Risk in Inpatients
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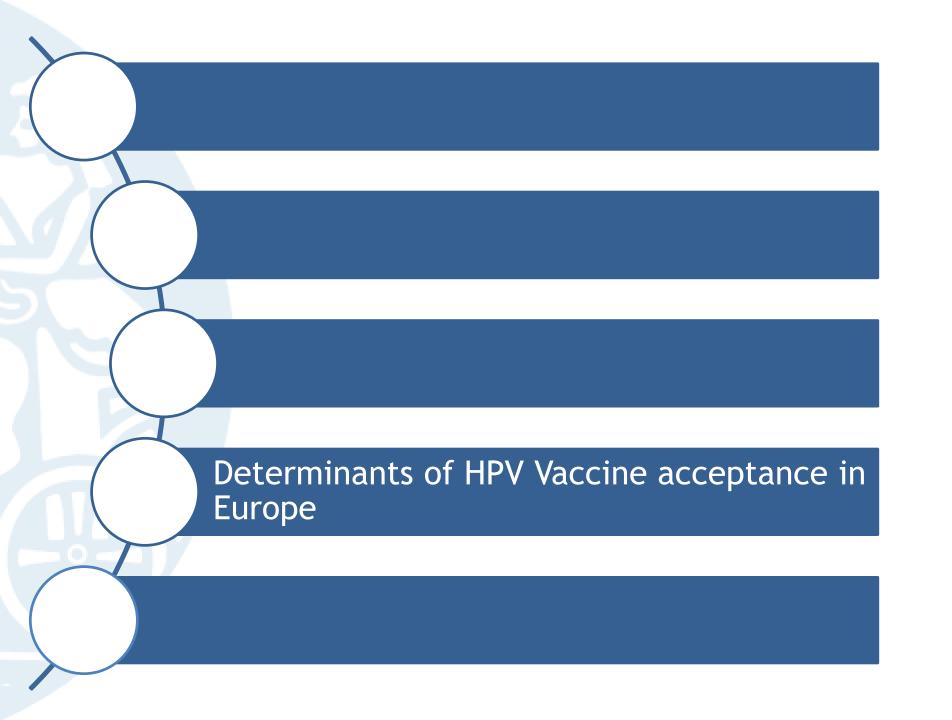
Rumours and communication

Rumours help people make sense of the world and offer an initial explanation for anxiety-provoking information/events.

The longer situations of uncertainty and anxiety persist, the easier it becomes for rumours to spread and the more difficult they become to counteract.

Five potentially disastrous mistakes in PH communication:

- 1. Mixed messages from multiple experts
- 2. Information released late
- 3. Paternalistic attitudes
- 4. Not countering rumours and myths in real time
- 5. Public power struggles and confusion.



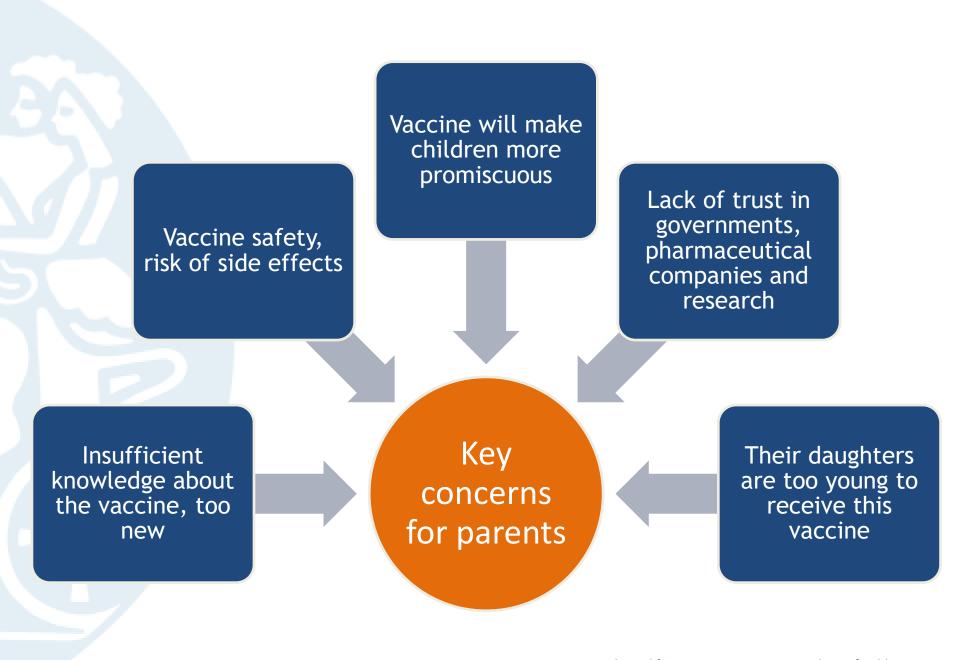
HPV vaccine acceptance in Europe

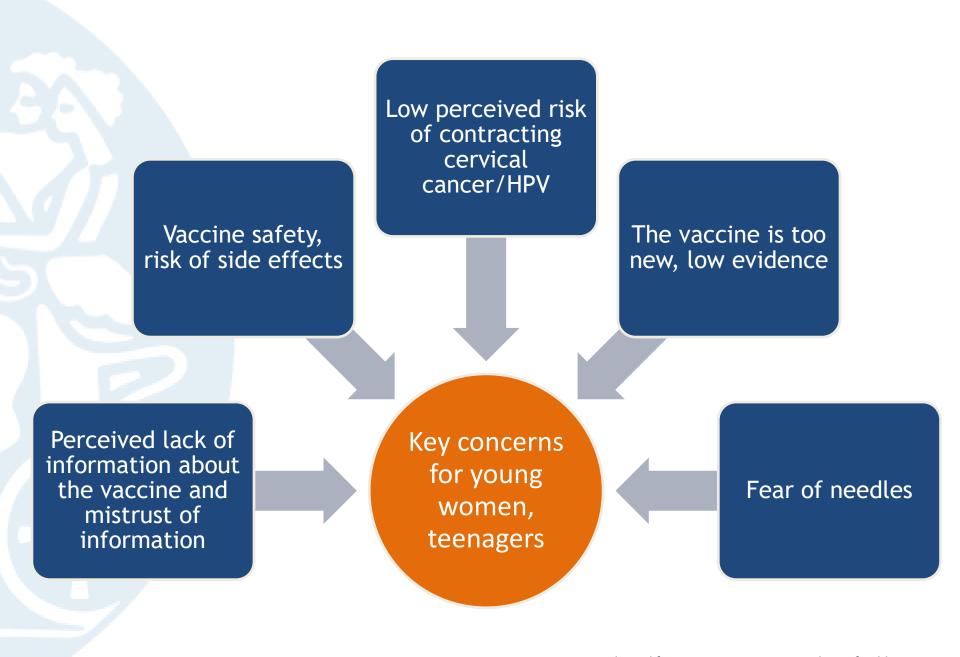
Systematic review of determinants of vaccine acceptance in Europe

Second most researched vaccine, after influenza

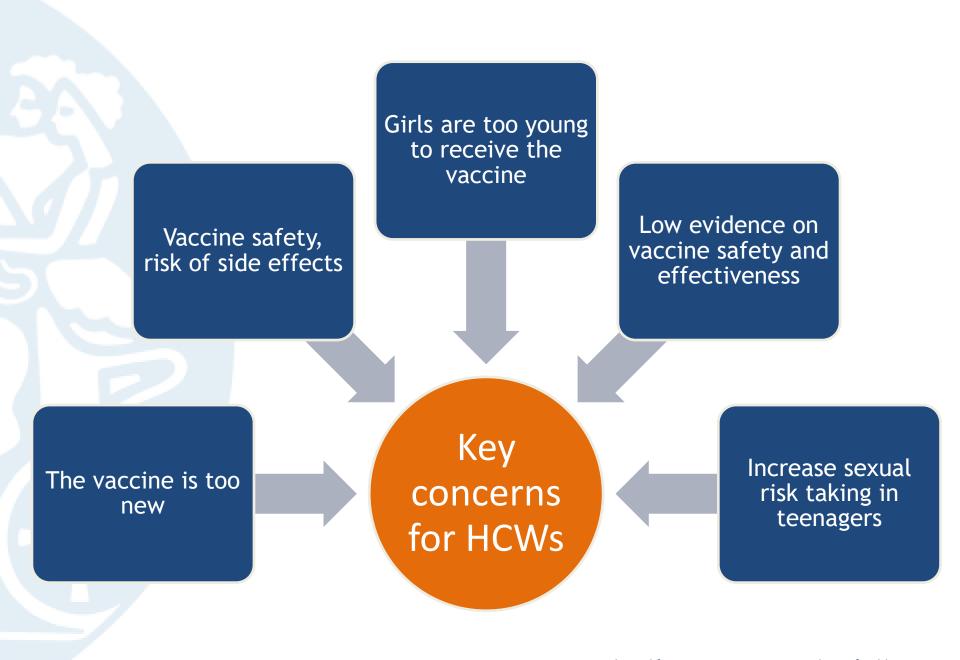
Most articles found on HPV focused on parents or mothers, but also on young women, teenagers, children and a few on HCWs and medical students

Majority of studies conducted in the UK. Other countries include: Sweden, NL, Denmark, France, Greece, Romania, Hungary, Italy, Spain

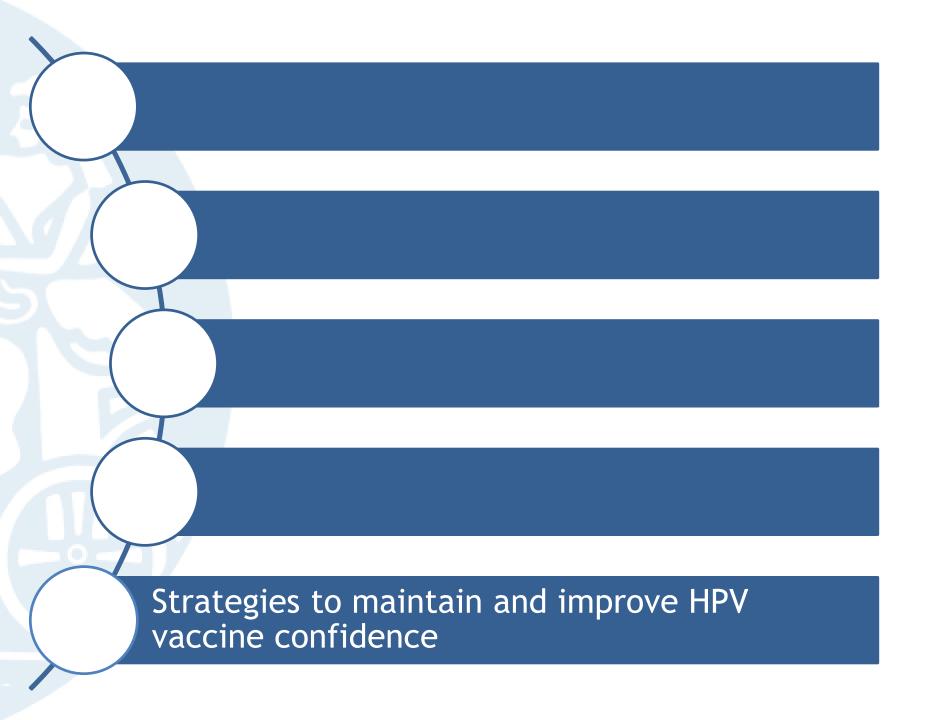




Adapted from ADVANCE report: Analysis of public concerns and perceptions related to benefits and risks of vaccines



Adapted from ADVANCE report: Analysis of public concerns and perceptions related to benefits and risks of vaccines



Dealing with vaccine hesitancy

- Develop an understanding of the scope and context of vaccine hesitancy
- Develop ways to monitor trends over time
- Aim to pin-point the root causes of vaccine hesitancy in the population
- Use context-specific, evidence-based strategies to address the causes
- Evaluate the impacts of the intervention and learn from successes and failure

Getting started with HPV vaccination

Start communication planning early

Allows for formative research & the anticipation of difficult issues

Build a cross-sectoral team

Programme planning team and communication team should integrate relevant sectors early

Plan for the hard-to-reach girls

May also be the girls who are at higher risk of developing cervical cancer and would benefit most from the vaccine Communication should reach girls through channels they trust

Communication on HPV vaccination Vaccine receivers



- Feel informed: discuss vaccination with daughters
- Opportunity to reach women with screening messages
- Most effective if administered before sexual activity.
- Factual and straightforward



- Why do they need multiple injections in 6 months
- Understand normal side effects
- When she is older she should still go for screening
- Channel of information for friends and family

Communication on HPV vaccination *Vaccine providers*



- Teachers should have:
 - Specific training
 - Formal opportunities to coordinate with HCW
 - Access to materials they can use



- May have questions about the HPV vaccine
- Need to be equipped to be a trusted source of information
- Benefit from: training on vaccine, interpersonal communication skills with girls and families.

Communication on HPV vaccination *Media*

Can be champions for HPV vaccination through accurate reporting and prominent placement of stories

Information gap: media report misinformation from other sources. May be targeted by anti-vaccination groups.

Organise special pre-campaign briefing sessions for journalists



Communication on HPV vaccination Governments

Be credible. Should not withhold information to avoid embarrassment or a possible public "panic"

Express empathy. Acknowledge what people are feeling, to build trust

Show respect. Never be paternalistic, either withholding information or dismissing concerns

Be the first to provide information. Don't withhold it.

Be accurate. And respond quickly.

Promote action. Positive steps people can take encourages them to feel more in control and empowered.

Materials and channels - keep it simple

- Use every opportunity
- Develop a frequently asked questions (FAQ) reference guide
- Language and materials girls can relate to and have fun with
- Telephone hotlines
- A mix of channels is important, including radio and television, school, health workers and church
- Targeted at hard-to-reach girls
- Internet and social media

Examples of public information material

six months after the first dose (five months after the

Girls, you need to get all three doses of the vaccine for it to be effective. Getting vaccinated shows that you care about your health.

Is the vaccine safe? Yes. The vaccine is safe, effective, and it has been



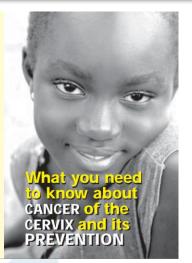


approved by the Government of Uganda. It has been tested in many countries, and the results show that it works. However, being vaccinated does not protect girls against pregnancy, HIV, or other sexually transmitted infections.

Remember: The HPV vaccine does not cause infertility.

For more information, contact your nearest health facility.

ockered by MOH, with support from CHOC, AOGU, and R 08







For more information, talk to your school nurse or GP surgery, or go to www.nhs.uk/hpv

Cada menina é de um jeits

mas todas precisam de proteci









Examples of public information material

Australia: http://hpv.health.gov.au/

ICO (Institut Català d'Oncologia) Information Centre on HPV and Cancer: http://www.hpvcentre.net/index.php

PATH: http://www.path.org/vaccineresources/hpv.php

British Colombia: http://immunizebc.ca/diseases-vaccinations/hpv

UK: http://www.nhs.uk/Conditions/vaccinations/Pages/benefits-and-risks.aspx

WHO: http://www.who.int/immunization/hpv/communicate/en/

Communication is....

A process. People need time to learn, absorb and confirm information and then make a decision and act on it.

Community engagement. It is a conversation and not a lecture.

Equity. It plans to reach harder-to-reach populations.

An investment. Effective communication activities cost money and time. The return on investment is improved immunisation coverage and improvement in the health and lives of women.

Imperfect. Communication involves human beings, and we cannot predict what people will think or do in every situation.

Adapted from: World Health Organization, 2013. HPV Vaccine Communication:

Considerations for a unique vaccine.

