

## Zorg.nl Radar on HPV vaccines - summary

This 27-minute programme was first broadcast in November 2016. It was produced by Jet Schouten from the Zorg.nl/Avrotos news affairs channel. The programme is in Dutch with English subtitles except for the interviews with English-speaking people (HPV vaccines recipients, their families and Cochrane researcher Dr Tom Jefferson and World Health Organization's (WHO) Uppsala Monitoring Centre's Dr Rebecca Chandler). The programme covers the topic of the possible relationship between Human Papillomavirus (HPV) vaccines and serious harms, such as autonomic dysfunction. HPV vaccines (Gardasil, Merck Sanofi and Cervarix, GSK) were first introduced in 2006 and as of June 30, 2015, the producers of Cervarix and Gardasil are estimated to have sold 57 million and 190 million doses respectively, at a value of approximately 25 billion USD. The number of healthy young women immunised is unknown but can be estimated by dividing the total doses sold by 3 (the number of inoculations in a vaccination course).

In the last few years a growing number of reports of harms (some very serious) have been generated across the globe (71,000 in total). These have led to several investigations by researchers including the WHO's Uppsala Monitoring Centre for Pharmacovigilance, which concluded that some of the cases needed further investigation. Other nations such as Japan have stopped promoting HPV programmes because of the number of harms reported. The Danish regulator referred the matter to the European Medicines Agency (EMA) - the European regulator. The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) investigated the evidence. In November 2016 PRAC published its conclusion that there was no evidence of an association. The evidence and most of the papers are confidential.

Researchers from the [Nordic Cochrane Centre](#) have challenged the findings on the basis of the full set of PRAC papers leaked to them and have filed two complaints to the European Ombudsman which are being investigated. The first complaint is over lack of independent scrutiny of the harms reports by PRAC which based its conclusions on unverified summary data provided by the manufacturers and lack of independence of some PRAC members. The second complaint is over excessive delay and redaction in the release to Dr Jefferson of HPV regulatory materials (parts of industry submissions to EMA, including clinical study reports). The PRAC papers are available in their entirety [online](#), including all the evidence on which the PRAC reached its conclusions.

The programme tells the story of the women recipients of the vaccines who suffered reactions, their families' distress, the lack of support and follow-up by the governments who supported the vaccination programme and the efforts of independent scientists to assess the possible risk of the vaccines -- an assessment which is of paramount importance given the uncertainty over the vaccine benefits.

The families come across as clear thinking moderates with one mother asking for an improvement in the vaccines and vaccine vigilance rather than their withdrawal. This television broadcast is an important "middle ground" in the increasingly polarised and politicised issue.

Tom Jefferson, Rome January 2017

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For a full discussion of the issues see

Jefferson T, Jørgensen L. Human papillomavirus vaccines, complex regional pain syndrome, postural orthostatic tachycardia syndrome, and autonomic dysfunction - a review of the regulatory evidence from the European Medicines Agency. *Indian J Med Ethics Publ Online* Oct 17 2016.

Access [here](#)