

HPV vaccination programs: country experiences and lessons learnt

Denmark

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www.hpvboard.org

❖ Timeline

- 2007: A Health Technology Assessment
 - Recommends HPV-vaccinations to girls at 12 years of age
 - Creation of a national immunization registry
- 2008: Start-up program to girls born in 1993-1995 (12-15 years)
 - Quadrivalent vaccine, GP based
- 2009: Routine vaccinations starts, 12 years
- 2012-13: Catch-up program, birth-cohorts 1985 to 1992 (i.e., up to 27 years)
- 2014: Two dose program approved
- 2016: Change to bivalent vaccine (results of a tender proces)

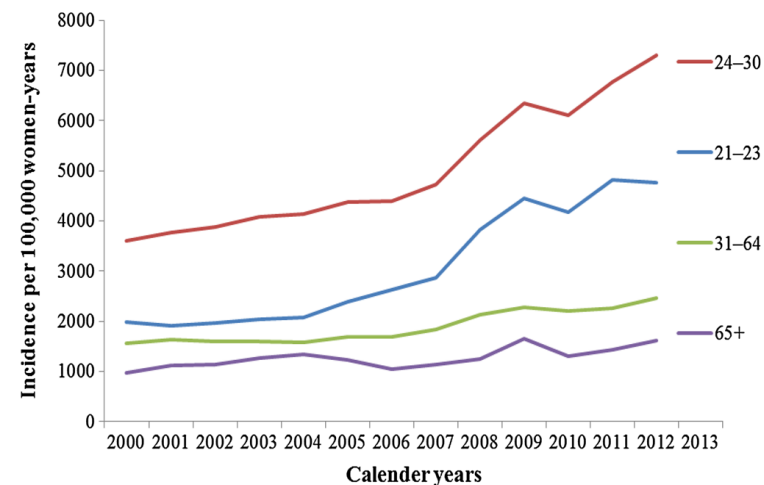
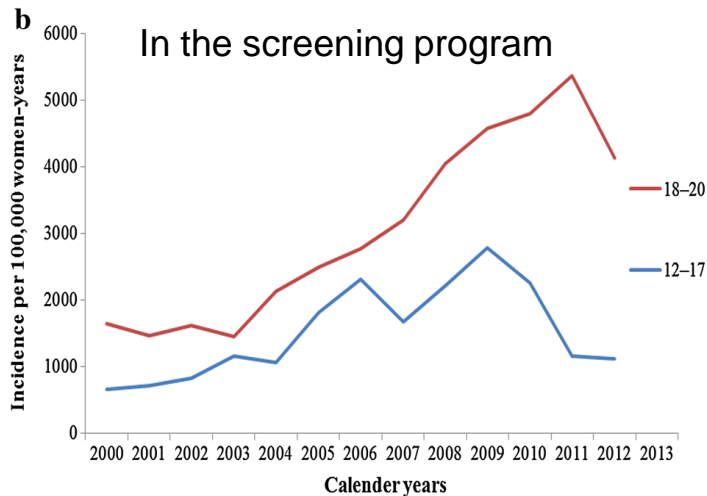
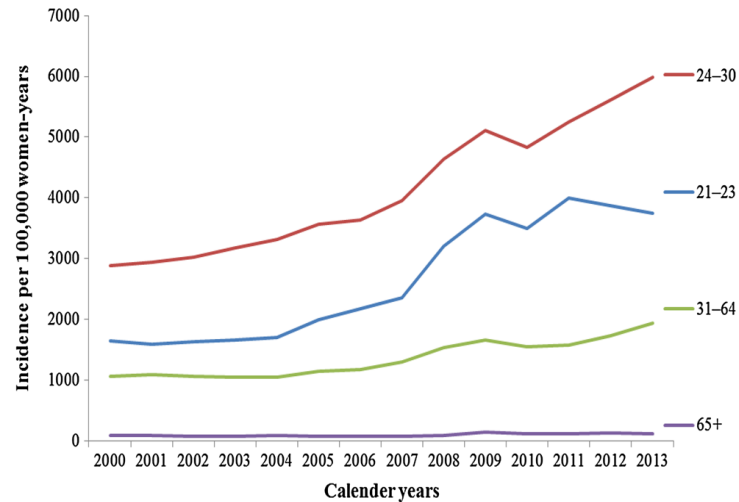
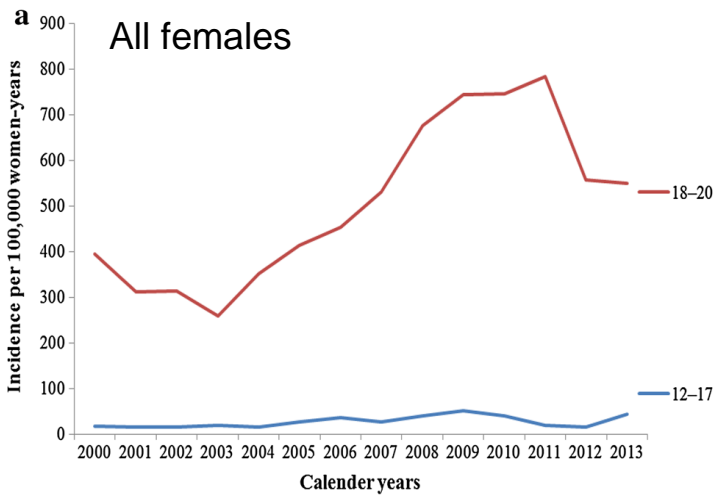
❖ Uptake

- > 500.000 women vaccinated (some 20% of all females)
- 90% of birth cohorts 1997 to 2000 recieved first dose

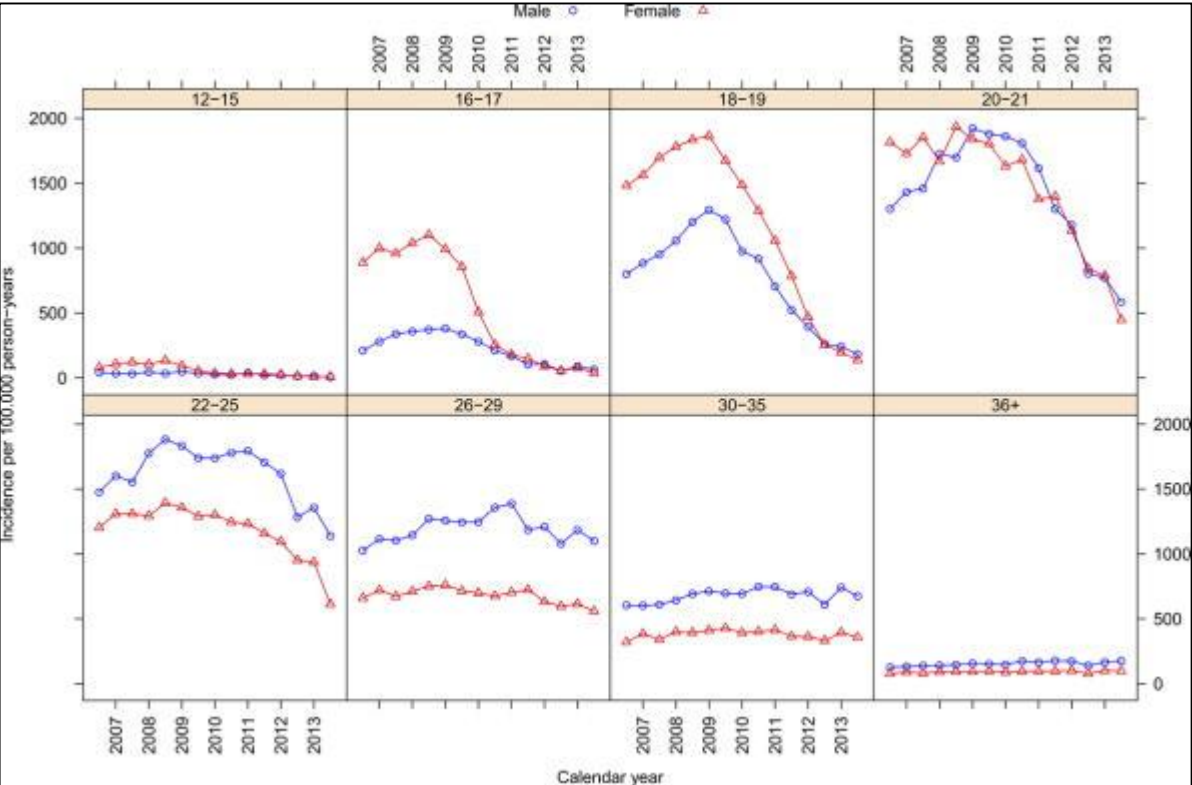
Conclusion The incidence of cervical lesions decreased significantly in age groups with high HPV vaccine coverage, indicating an early effect of HPV vaccination.

Baldur-Erikson et al,
Cancer Causes Control 2014

CIN2 +



Dramatic decline in the incidence of genital warts



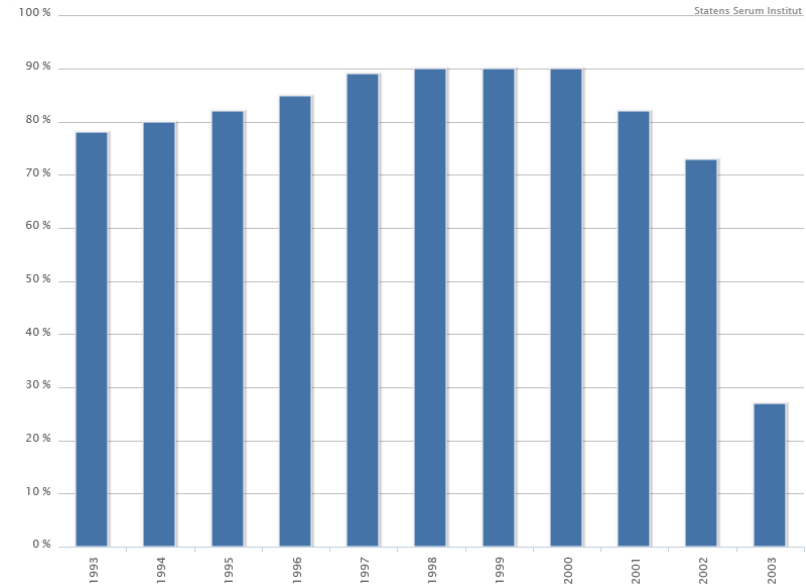
Significant Reduction in the Incidence of Genital Warts in Young Men 5 Years Into the Danish Human Papillomavirus Vaccination Program for Girls and Women.
 Bollerup, Signe; Baldur-Felskov, Birgitte; MD, PhD; Blomberg, Maria; MD, PhD; Baandrup, Louise; MD, PhD; Dehlendorff, Christian; Kjaer, Susanne; MD, MDSc

Sexually Transmitted Diseases. 43(4):238-242, April 2016.
 DOI: 10.1097/OLQ.0000000000000418

FIGURE 1 . Half-yearly IRs of GWs per 100,000 person-years in Denmark between 2006 and 2013, stratified by sex and age.

THE CURRENT SITUATION

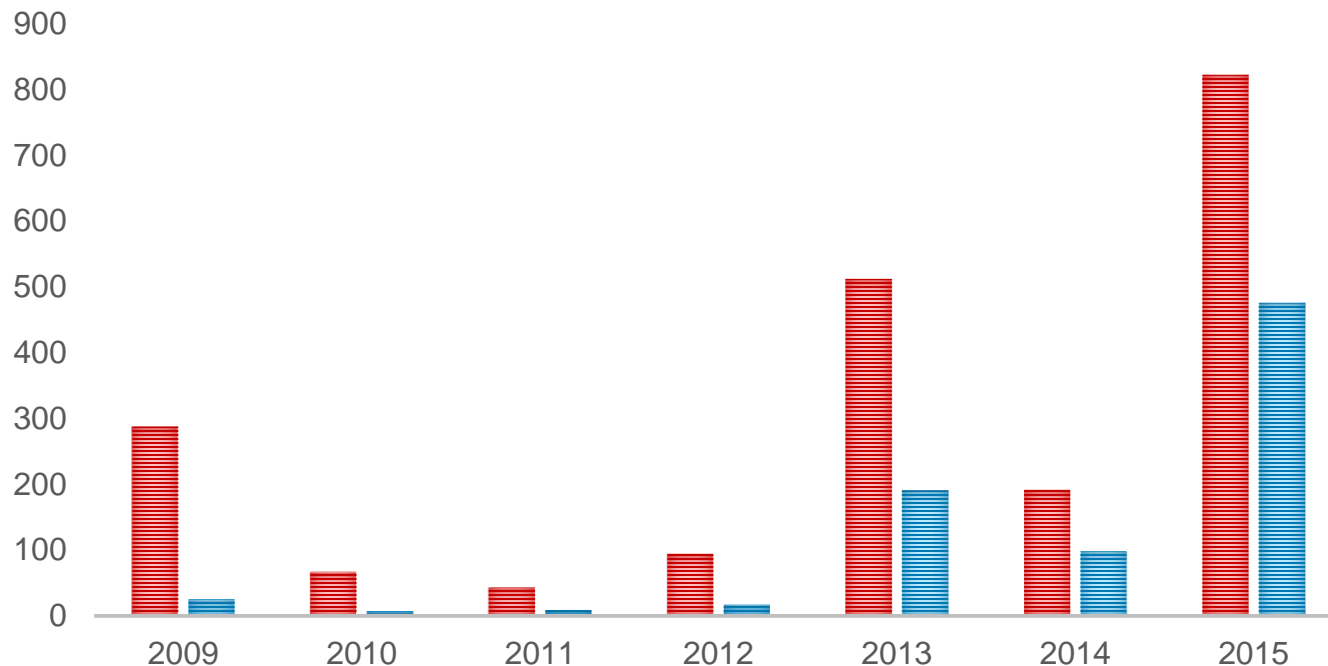
- ❖ There is a positive impact of the HPV vaccination
- ❖ Public debate is dominated by the safety concerns
 - Not the fact that we have a vaccine against cancer
 - And that it works
- ❖ Social media has a key role
- ❖ Vaccination coverage is going down
 - 37% of girls born in 2003 has received the first vaccine
- ❖ A crisis for public health



Uptake of first HPV vaccine by year of birth, females, 1993-2003

”THE DANISH SIGNAL”

- From 2013: Danish Medicines Agency receives an increasing number of reports of suspected adverse reactions
 - 2019 adverse reactions 2009-2015, of which 823 classified as severe (blue)
 - Persistent or significant incapacity
 - Only 10% of the reports received in 2015 had onset in 2015

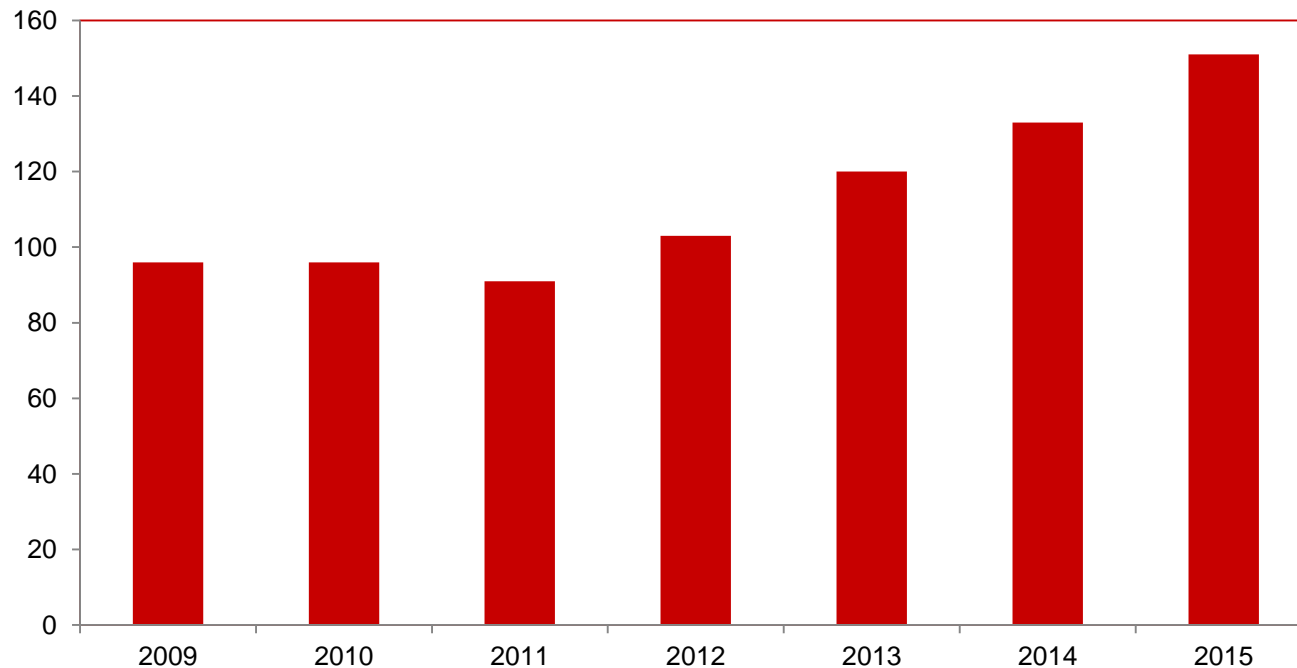


Source: Danish Medicines Agency

IN RELATION TO THE YEAR OF THE ONSET

- ❖ 1808 adverse reactions had onset in the period 2009-15
- ❖ 1.688.742 vacciner sold
- ❖ 107 suspected and reported adverse reactions per 100.000 vacciner

Reported adverse reactions per 100,000 vaccines



Source: Danish Medicines Agency

- ❖ Medically unexplained physical symptoms
 - Symptoms from the nervous systems
 - Including syncope, dizziness, weakness, headache, disordered sleep
 - Fatigue
 - Pain
 - Musculoskeletal symptoms

- ❖ Some received the diagnosis POTS – postural orthostatic tachycardia syndrome
 - 60-degree head-up tilt table
 - Orthostatic intolerance and a sustained heart rate increment according to defined criteria

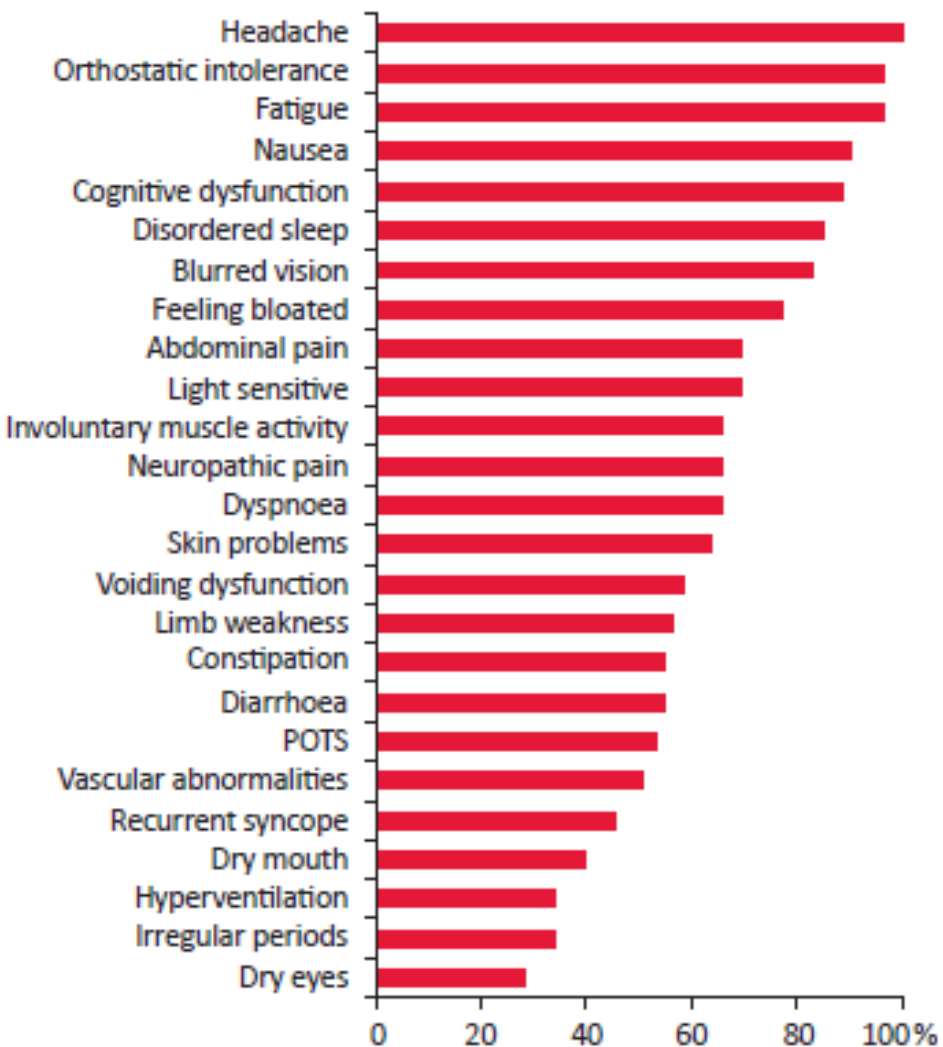
- ❖ Chronic fatigue syndrome

- ❖ Complex regional pain syndrome



FIGURE 1

Symptoms suspected to be side effects to vaccination against human papilloma virus. The frequency of the symptoms is given as percentages of patients reporting the given symptom out of all patients included in the descriptive analysis.



POTS = postural orthostatic tachycardia syndrome.

From Brinth L et al, Dan Med J 2015

53 patients seen at one centre

Considerable overlap in symptoms between POTS and Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME)

”THE DANISH SIGNAL”

- ❖ To the attention of EMA September 2013
- ❖ EU commission requested an assessment by PRAC (Pharmacovigilance Risk Assessment Committee), July 2015
- ❖ PRAC concluded, that there was no evidence that the HPV vaccines is a cause of POTS or CRPS
- ❖ December 2015 the WHO Global Advisory Committee on Vaccine Safety reiterated “no safety issue that would alter its recommendation of the use of HPV vaccines”
 - Despite the difficulties in diagnosing or fully characterizing CRPS and POTS, reviews of pre- and post-licensure data provide no evidence that these syndromes are associated with HPV vaccination.

- ❖ Key role of social media
 - Several groups at Facebook for the HPV vaccine victims
- ❖ Major role of the Chairman of the Health Committee Liselott Blixt (DF)
- ❖ Two strong patient organisations
 - HPV-update under the Danish Association for the Disabled
 - Landsforeningen af HPV bivirkningsramte
- ❖ Focus area of other media including Metroexpress

Reporting of adverse events: Stimulated by the programme “The Vaccinated Girls” broadcasted 26 March 2015, by TV2

Features interviews with families and vaccinated girls with medically unexplained symptoms .





HPV update

[Forside](#)[Om HPV vaccinen](#)[Bivirkninger og skader](#)[Livet med bivirkninger](#)[Patientforening](#)[Registrer bivirkninger](#)[Nyttige links](#)[Nyheder](#)[Kontakt](#)

Nyheder fra HPV-update

8. april 2016 — [Skriv kommentar](#)

Vi har netop udsendt nyhedsbrev til medlemmerne af HPV-update med nyt om forskning, erstatningssager og andet om Dansk Handicap Forbund og specialkredsens arbejde.

Der er desværre mange medlemmer, der ikke har opgivet deres mailadresser i forbindelse med indmelding i specialkredsen, så har du ikke modtaget vores nyhedsbrev, så skriv til mail@hpvupdate.dk

Der er også plads til dig

Selvom tilgangen af medlemmer er stor, så er der fortsat plads til flere. Så vil du støtte vores indsats for udredning og behandling af piger med symptomer efter HPV-vaccinen, og drage fordel af de mange tilbud, vi får som specialkreds under Dansk Handicap Forbund, så kan du tilmelde dig [her](#).

Læs om

Specialkredsen HPV-Update under
Dansk Handicap Forbund

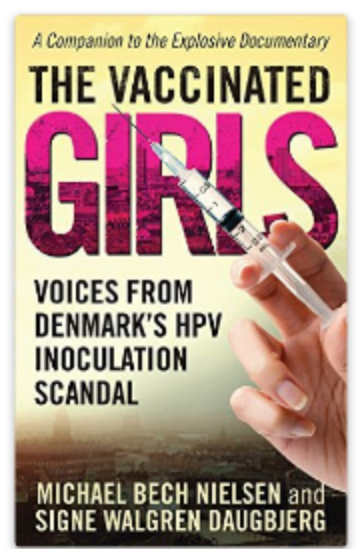


Dansk Handicap Forbund
- et liv med lige muligheder

De vaccinerede piger



Books > Medical Books > Medicine



 See this image

The Vaccinated Girls: Voices from Denmark's HPV Inoculation Scandal

Hardcover – July 15, 2016

by [Michael Bech Nielsen](#) (Author), [Signe Walgren Daugbjerg](#) (Author)

See all formats and editions

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Gardasil is a vaccine that protects women against human papillomavirus, or HPV, a common sexually transmitted disease that can give rise to cervical cancer. It's also the subject of hot debate both in the United States and abroad. After being approached by a young woman who linked a crippling illness to her recent vaccination, Danish journalists Michael Bech Nielsen and Signe Walgren Daugbjerg decided to dig deeper—and they were astounded by what they found.

Their 2015 documentary "The Vaccinated Girls" gave voice to roughly thirty women who suffered side effects coinciding with their inoculation. Doctors who had treated the women also came forward, explaining that the link between their vaccination and symptoms like dizziness, chest pain, and fainting was too strong to ignore—and reaching some frightening conclusions. The documentary also exposed government officers' caginess

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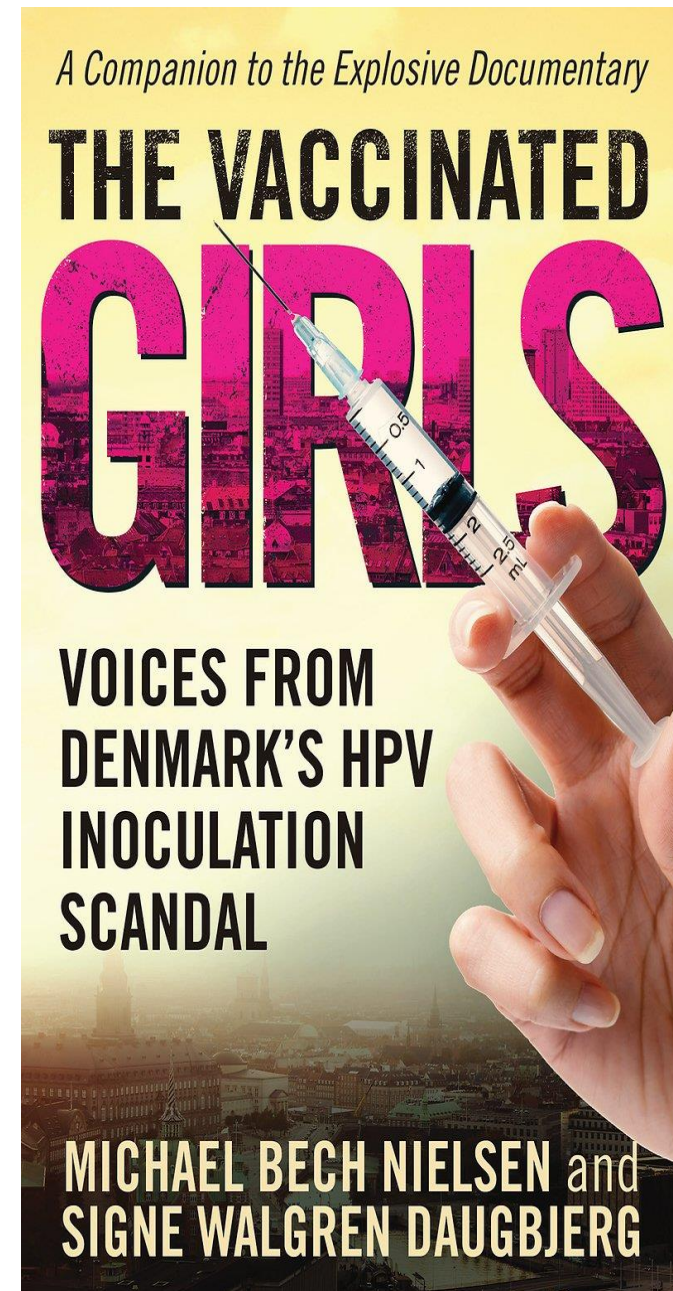
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Add to List

- *The Vaccinated Girls* features expanded interviews with and updates from the physicians, European government officials, victims, and families featured in the documentary.
- In asking what we're not supposed to ask in the United States, *The Vaccinated Girls* sheds light on just how many questions remain unanswered.
- Anyone interested in the state of vaccination will want to read this groundbreaking work.





[Gå til HPV-fokusside](#)



#MXHPV

Læge: Stor debat får mange til at klage over hpv-vaccine

De er anmeldt langt flere tilfælde af alvorlige bivirkninger som følge af hpv-vaccinen i Danmark end i Norge.



#MXHPV

Flere danske klager over hpv-vaccine end norske og svenske

I Norge og Sverige er det kun få piger, der har klaget over hpv-vaccinen. Flere hundrede har klaget i Danmark.



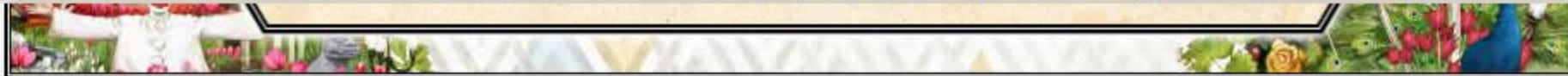
#MXHPV

Hver femte ung mangler tillid til HPV-vaccinen

21 procent i alderen 18-29 år har ikke fuld tillid til sundhedsmyndighedernes forsikringer om, at HPV-vaccinen undersøgelse.



#MXHPV



FORBRUG & LIV

Bolig Sundhed Digitalt Forbrug Biler Livsstil Guider Test



**KLARLUND
BREVKASSE**
Spørg om
sundh...

SUNDHED 26. NOV. 2015 KL. 21.45

Liselott Blixt affejer HPV-rapport: »Lavet af betalt lobby«

På trods af EMA-kritik stoler DF's udvalgsformand stadig fuldt ud på dansk HPV-center.



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SENESTE FORBRUG & LIV



Klarlunds brevkasse: Jeg har trænet så meget, at jeg ikke kan passe mine kjoler



Vestfrøde

Actress Mira Wanting dies of cervical cancer, 34 years of age, in 2012



KENDTE

Mira planlagde døtrenes fremtid før sin død

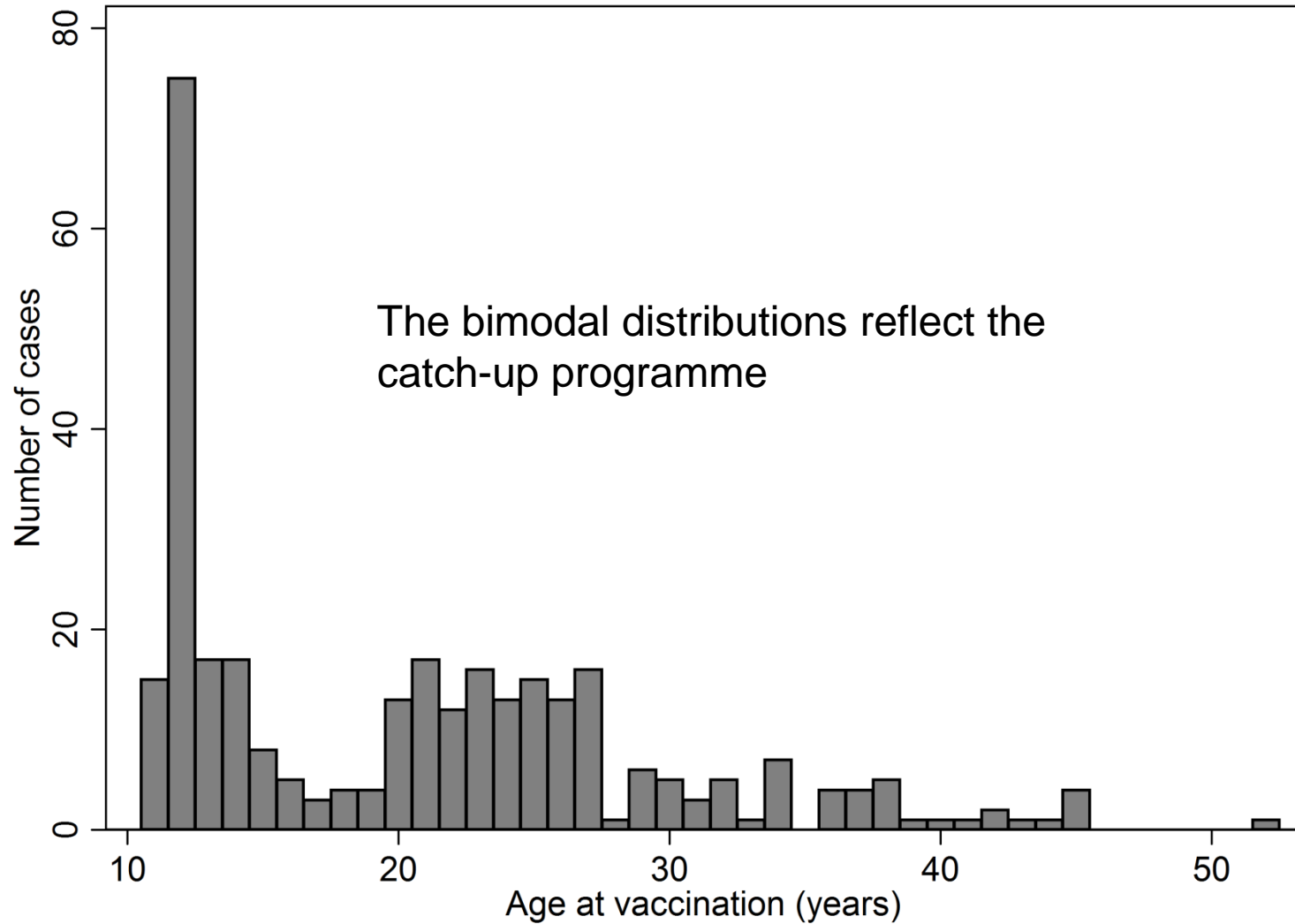


BLOG: Piger med vaccineskader og læger på herrens mark

Mor til syg pige forklarer, hvordan familien har taget sagen i egen hånd i kampen for at hjælpe Sara.

- ❖ Case-control study
- ❖ Cases: 361 females with severe adverse reactions reported to DMA
- ❖ Controls: 163.910 matched on municipality, age, year of first HPV vaccine
 - Females
 - Vaccinated
 - No reports of adverse reactions

AGE DISTRIBUTION (CASES)



THE CATCH-UP PROGRAMME

Year of first vaccine	AGE		In total
	< 18 yr	18 yr+	
2009	63	17	80
2010	20	11	31
2011	26	8	34
2012	16	72	88
2013	12	68	80
2014	3	0	3
Total	140	176	316

In total 140 of the 316 with reported adverse events were part of the catch-up programme

Health care-seeking in 316 Danish females who reported suspected adverse events to HPV vaccination compared with 163,910 matched controls.

Type of contact before first HPV vaccination	Percent exposed, cases	Percent exposed, controls	Multivariable odds ratio (95% CI) for care-seeking
Primary health care provider, phone or e-mail	95 %	87 %	1.91 (1.15-3.18)
Physiotherapy or chiropractor	30 %	12 %	2.13 (1.64-2.76)
Psychologist or psychiatrist	12 %	6 %	1.87 (1.31-2.66)
ICD 10 code K00-K93, the digestive system	7 %	3 %	1.57 (1.01-2.45)
ICD 10 code M00-M99, musculoskeletal system and connective tissue	12 %	5 %	1.56 (1.09-2.23)
ICD 10 code R00-R99, symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	14 %	6 %	1.77 (1.27-2.48)
ICD 10 code S00-T14, injuries	32 %	22 %	1.51 (1.18-1.93)

THREE MAJOR QUESTIONS

- ❖ Is there a cause for concern as regards the safety of HPV vaccines ?
 - Are there any safety issues not discovered in reviews of pre- and post-licensure data ?
- ❖ How can we explain the reported suspected adverse events ?
 - What is wrong with these girls ?
- ❖ The way forward
 - HPV vaccination policies ?
 - Communication strategies ?

WHY ARE THE GIRLS ILL ?

- ❖ Adverse events
- ❖ The vaccine is a trigger for a Body Distress Syndrome
 - BDS is a condition of autonomic arousal, gastrointestinal arousal, musculoskeletal tensions, and general symptoms
 - Often triggered by injuries and trauma, e.g. whiplash lesion
- ❖ Attribution
 - Coincidence (temporal association) between vaccination and symptoms
 - The tendency to link disease to exposure is deeply anchored in human nature
- ❖ Iatrogenicity
 - Artefact of medical specialization and poor research methodology
 - “Blame-X syndrome”
 - Makes doctors and patients believe that they know the cause, which reduces anxiety for the unknown
 - Avoids discussions of more fundamental issues

- ❖ There is no evidence of an association between HPV vaccines and Medically Unexplained Physical Symptoms (MUPS)
 - The idea is based on case series and stories in the media
 - In the population, MUPS were present before 1. vaccine
- ❖ But absence of evidence is not evidence of absence !
 - We must recognize that conditions such as POTS, CRPS and CFS/ME are controversial and ill-defined entities
 - Registry based studies have limitations
 - Novel methods and data sources may be needed to study links between HPV vaccines and MUPS/autonomic disorders

❖ HPV vaccination policies ?

- Is it wise to have a mass catch-up programme ?
- Should we vaccinate at younger age ?
- Boys ?
- Should vaccination be postponed when girls have “trouble in mind” ?

❖ Communication policies

- We must listen to the girls and their families
 - This is the first step in a dialogue
- On the other side: Stand the ground
 - The evidence for “new” adverse events is very poor
 - Benefits outweigh the risk
 - Fight “junk evidence”
- Social media are extremely important
 - Home page – just the name sounds old-fashioned



HPV Prevention
and Control Board

www.hpvboard.org

Denmark

SUMMARY SWOT-ANALYSIS

Strengths:

High vaccination coverage achieved
Impact demonstrated
No link to promiscuity

Weaknesses:

Not good to “tell stories”
Social media ?
Research unable to address safety concerns
Top-down communication counterproductive

Opportunities:

Public funding
Well-educated population
Concerns for cancer
Access to data
Stories / faces of HPV

Threats:

Safety concerns and crisis with drop in uptake
The post-factual society: Concerns, case-stories has the same status as evidence from high quality studies

