



HPV disease prevention Gender neutral vaccination via National immunisation program

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香港陰道鏡及子宮頸病理學會 The Hong Kong Society for Colposcopy and Cervical Pathology







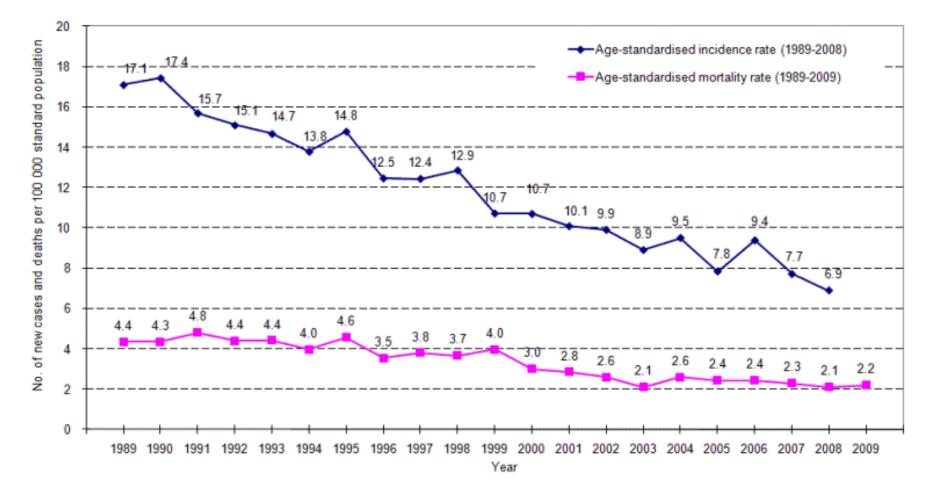
The following issues will be discussed in this CME lecture:

- The implementation of NIP experience in Malaysia
- How to collaborate with government
- The coverage of HPV vaccine
- Monitoring and education on cervical cancer prevention Public health impact after implementation of HPV NIP in Australia
- Any impact to screening system Consideration for universal male vaccination



About 400 new cases of cervical cancer per annum

Trend of Age-standardised Incidence¹ and Mortality Rates²⁻⁴of Cervical Cancer in Hong Kong (1989–2009)





.....

AND DESCRIPTION OF THE OWNER





Centre for Health Protection Department of Health The Government of the Hong Kong Special Administrative Region

Scientific Committee on Vaccine Preventable Diseases Scientific Committee on AIDS and Sexually Transmitted Infections

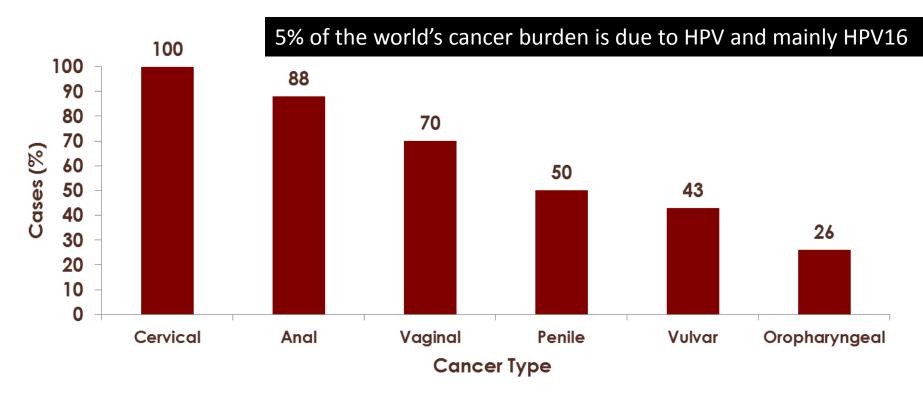
> Recommendation on the Use of Human Papillomavirus (HPV) Vaccine

- Cervical cancer is 8th leading cause of death in females however only 70% have had at lease 1 smear (25-64yrs) (Behavioural risk factor surveillance 2004-2012)
-it's applicability in Hong Kong should be further examined.... could be considered for introduction into HK's universal vaccination programme....must be supported by local economic evaluation. Information on logistics, feasibility and acceptability of such a programme, compared to alternative programmes should also be sought



Multiple Cancer Types Are Related to HPV

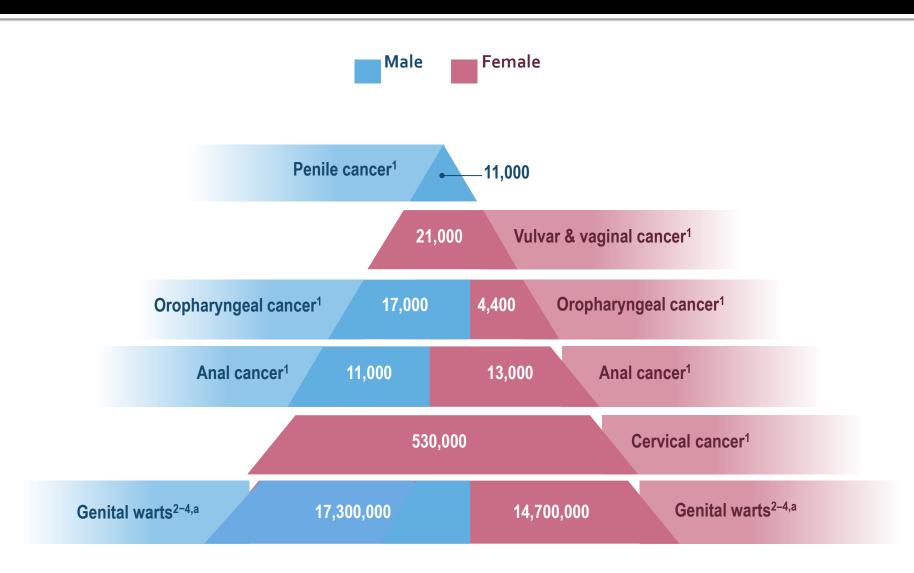
Estimated Percentage of Cancer Cases Attributable to HPV¹



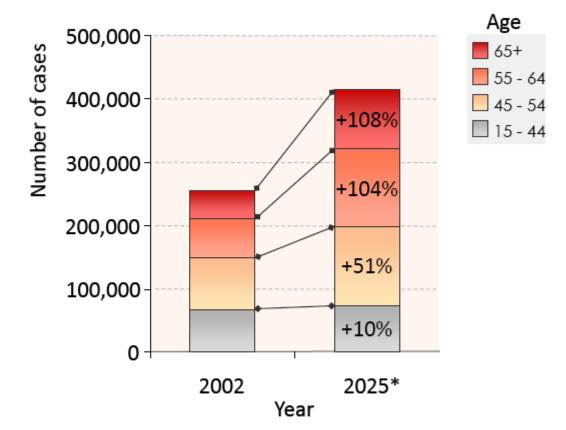
Data for oropharyngeal cancers vary from 26%¹ to 63%.^{1,2}

1. Forman D et al. *Vaccine*. 2012;30(Suppl 5):F12–23. **2.** Centers for Disease Control and Prevention (CDC). *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 12th ed. Washington DC: Public Health Foundation, 2012. http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hpv.pdf. Accessed March 15, 2013.

HPV related pathology in men and women

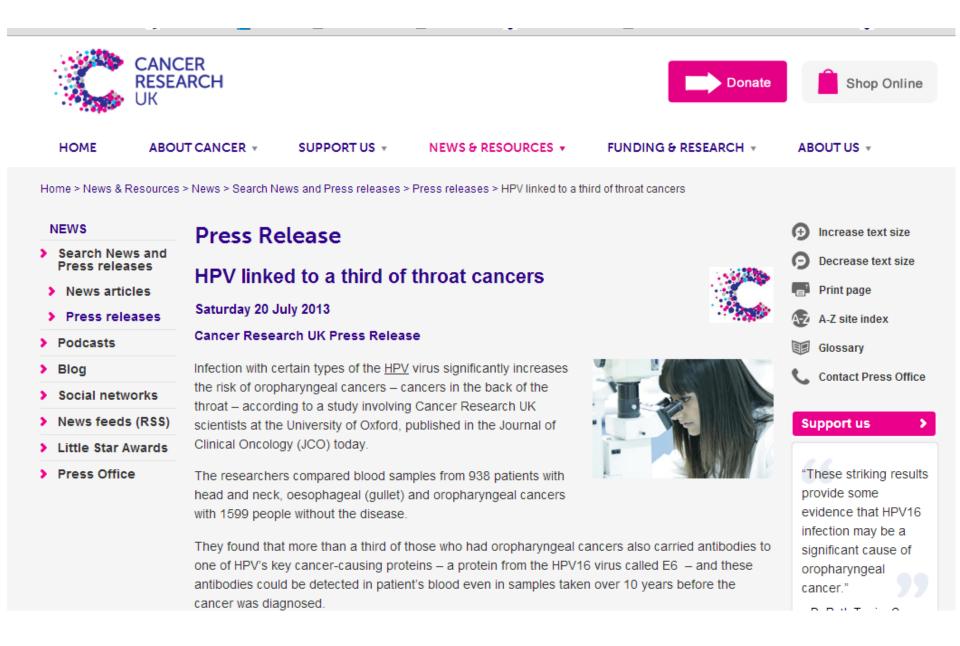


Estimated new cases of cervical cancer in Asia in 2002 and projected in 2025

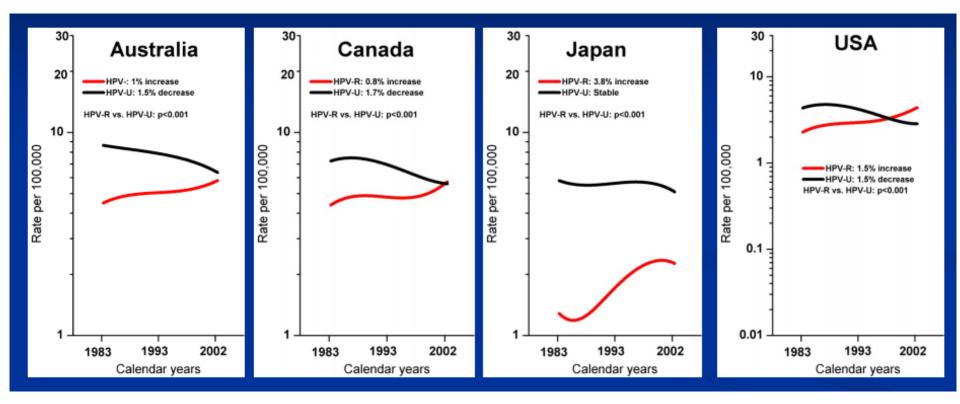


* Projected burden, assuming that current incidence rates will apply in the future, and incorporating population forecasts for the region.

Ferlay J, et al. GLOBOCAN 2002, Cancer Incidence, Mortality and Prevalence Worldwide. IARC Press, 2004 [1].



Dominant role of HPV in head and neck cancers in men in the developed world



HPV related head and neck cancers

HPV unrelated head and neck cancers

Exponential rise in genital warts

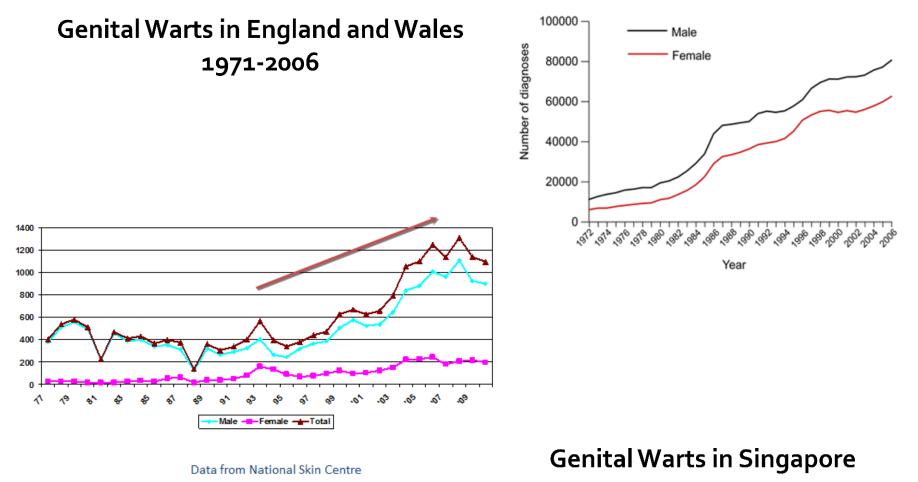


Figure 1 Diagnoses of genital warts (first, recurrent and re-registered) seen in GUM clinics in England, Wales and Scotland: 1971 to 2006

1977-2010

Indicators that HPV infection and related pathology on the rise

in both men and women!

Breakaway: The global burden of cancer challenges and opportunities

A report from the Economist Intelligence Unit



Summary

The

- In 2008, there were 12.4 million new cancer cases and 7.6 million cancer deaths worldwide
- > Lung cancer burden, in terms of incidence and mortality, is among the highest in the world
- > More than half of cancer cases and 60% of deaths occur in the less-developed countries
- > There are striking variations of cancer patterns by site from region to region
- > Future cancer burden will be influenced by trends in the elderly population of both the less-developed and more-developed areas
- >The role of prevention in cancer control programmes (tobacco control, vaccination, screening) will increase in the coming decades

The case for prevention

Escalating health care costs

HEALTH	CARE	COM	PA R	ISON
			UK	AUSTRALIA
12	Cost of a Hospital Bed (per day)	\$907	\$126	\$139
- 578	Cost of Bed in Intensive Care	\$1,616	\$224	\$246
	Cost of a Visit to the Doctor	\$366	\$49	\$25
	Cost to See a Specialist	\$768	\$102	\$115
	Life Expectancy	77.5	78.5	80.5

Prepare for high medical costs in retirement

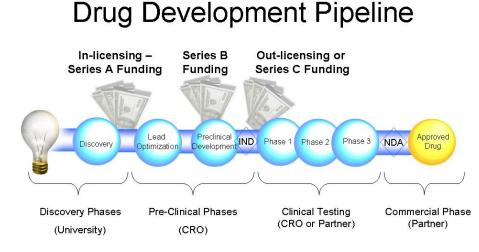
Medicare, on average, will cover only about half of your medical expenses. And the amount you need to save to cover the difference has been rising sharply:

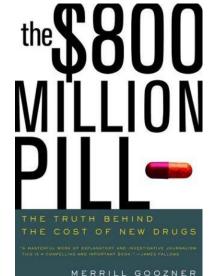
Savings a 65-year old couple need for health care in retirement:



Rising costs of diagnostic technology and cancer drugs







MERRILL GOOZNER

Proton-beam therapy with IBM technology

Processes the "Big Data" sets used in radiation treatment to quickly determine the right course of treatment for specific tumors.



Diagnosing the patient, calculating treatment variables and calibrating the machine can be done in **15 minutes**, instead of one week.

5 million specific treatment options instead of

the 100 generally available today.



Forbes -

Most Popular The Real Coup

Lists



2

reddit

Who's To Blame For Our Rising Healthcare Costs?

+ Comment Now + Follow Comments

By Louis Goodman & Timothy Norbeck

For many years and in countless articles, physicians have been the scapegoat for rising healthcare costs in the U.S. In fact, they have been blamed by many critics for the U.S. leading the world in healthcare expenditures.



(Photo credit: Images_of_Money)

A close

examination of

the data indicates that this blame is misplaced. Something else is revealed by digging deeper into the key components in healthcare spending: Technology, administrative expenses, hospital costs, lifestyle choice and chronic disease conditions have all had greater impacts on rising overall healthcare costs than physicians.



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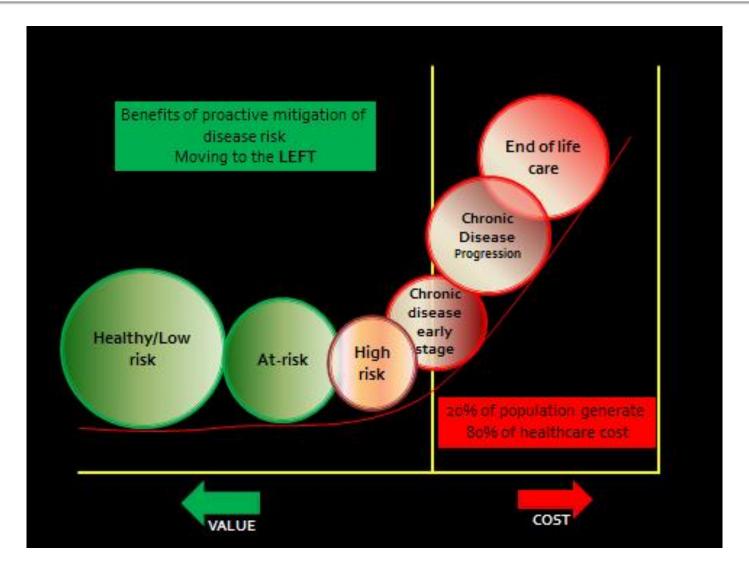
Perspective

Medicine's Ethical Responsibility for Health Care Reform - The Top Five List

Howard Brody, M.D., Ph.D. N Engl J Med 2010; 362:283-285 January 28, 2010 DOI: 10.1056/NEJMp0911423

'If physicians seized the moral high ground, we just might astonish enough other people to change the entire reform debate for the better'

High costs of cancer care The biggest threat to healthcare



HPV Vaccination: The basis of cancer control

Palliative care

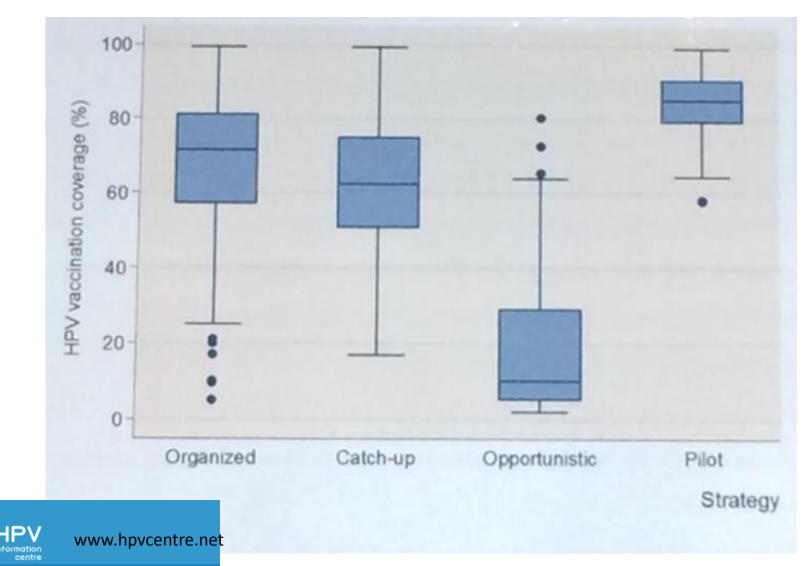
Cancer treatment

Secondary prevention: Screening and treatment of precancer lesions

Primary prevention: Vaccination

World Health Organization, United Nations Population Fund. *Preparing for the Introduction of HPV Vaccines: Policy and Programme Guidance for Countries*. Geneva, Switzerland: World Health Organization; 2006.

In 2014, 115 million women (3.4% of women globally) have received HPV vaccines



HPV vaccine introduction through national immunization programs (2008-2009)



10%





HPV vaccine introduction through national immunization programs (2010-2012)











HPV vaccine introduction through national immunization programs (2013-2014)





29%

to

33%





Chile introduces the Human Papillomavirus Vaccine (HPV) in its National Immunization Programme

Fernando Muñoz, Ministry of Health, Chile; Marta Prieto and Andrea Vicari, PAHO/WHO

On 2 September 2014, Chile's President Dr Michelle Bachelet launched the vaccine against human papillomavirus (HPV). This year, the Ministry of Health plans to vaccinate 125,000 girls aged nine to 10 years. The quadrivalent vaccine is being administered in a twodose immunization schedule with a 12-month interval between doses.

Health workers will administer the HPV vaccine at public and private schools. The vaccine introduction was jointly planned with the education sector, and a <u>manual</u> specifically directed at teachers was prepared and distributed. Additional <u>information</u> and <u>videos</u> are available online.



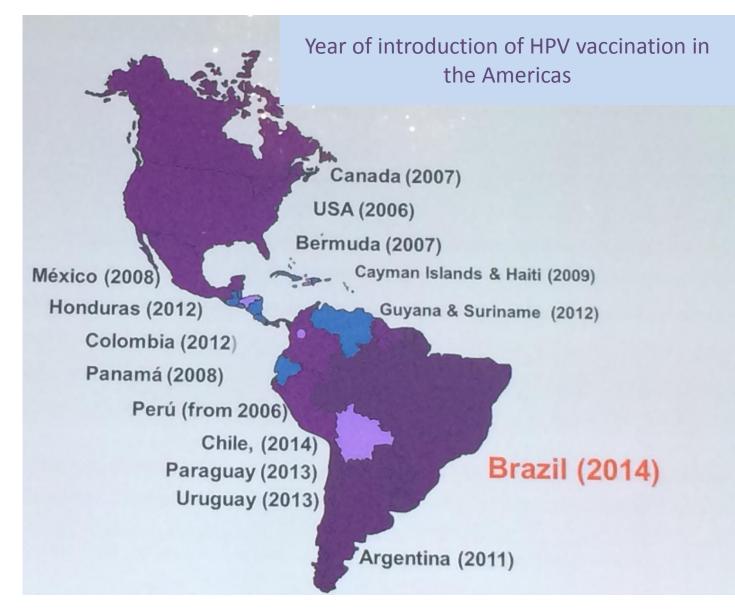
Chile's President Michelle Bachelet (center) and Health Minister Dr Helia Molina (second from left) at the launch of national HPV vaccination. Credit: MoH, Chile.

Every year, 587 women die in Chile of cervical cancer (equivalent to a 5.7 age-adjusted mortality rate per 100,000 women). The introduction of the HPV vaccine is the outcome of the joint work among the National Programme for the Control of Cervical Cancer, the National Immunization Programme, education and health experts, economists, political leaders and civil society representatives.

In Chile, the HPV vaccine has been available in the private health sector since 2006. The inclusion in the national immunization schedule thus achieves universal access to this vaccine throughout the target age cohorts, included for vulnerable population groups. The annual public investment for HPV immunization will amount to US\$ 2.5 million.

In the Americas, 22 countries (in addition to Chile) including Argentina, Antigua, Barbados, Brazil, Bermuda, Canada, the Cayman Islands, Colombia, Ecuador, Guyana, Mexico, Panama, Paraguay, Peru, Puerto Rico, Saba, Sint Maarten, Suriname, Trinidad and Tobago, the United States of America, and Uruguay—now offer the HPV vaccine in their publicly funded immunization programmes. Each year, 6.5 million adolescent girls (85% of a typical birth cohort of the Americas) have a guaranteed access to HPV vaccine in the Western Hemisphere.

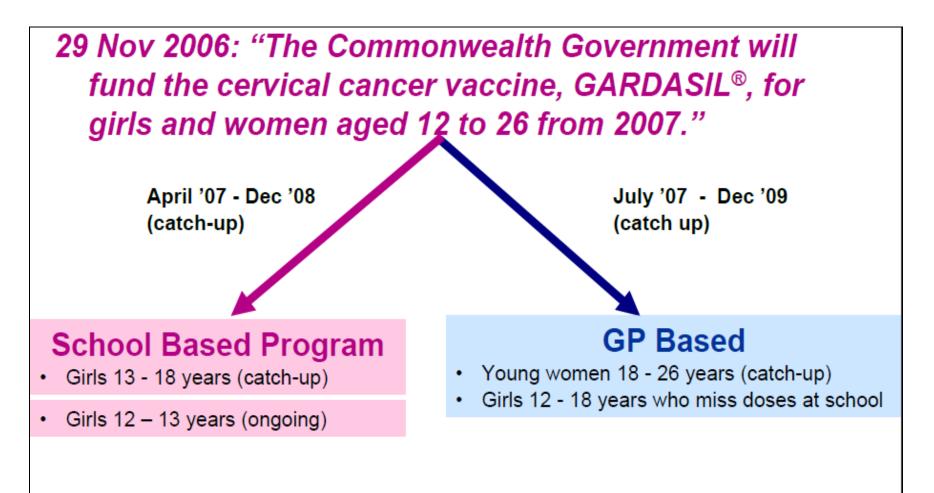
8 out of 10 adolescent girls in Americas have access to HPV vaccination



The Australian experience



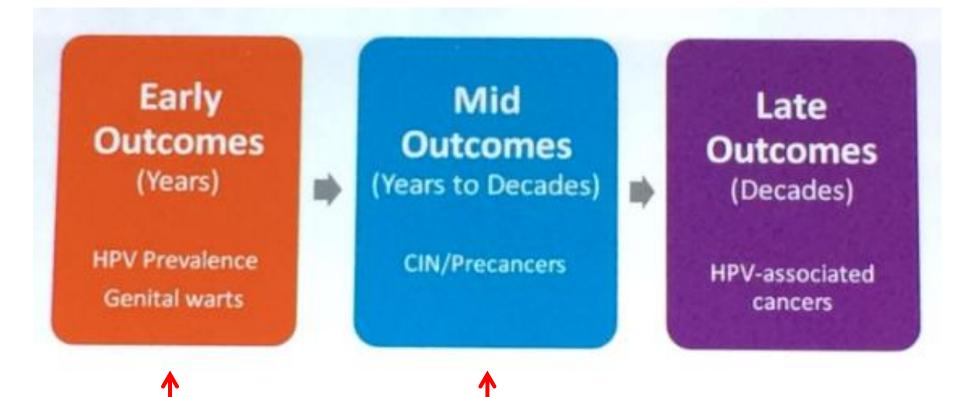
Australia HPV Immunization Program



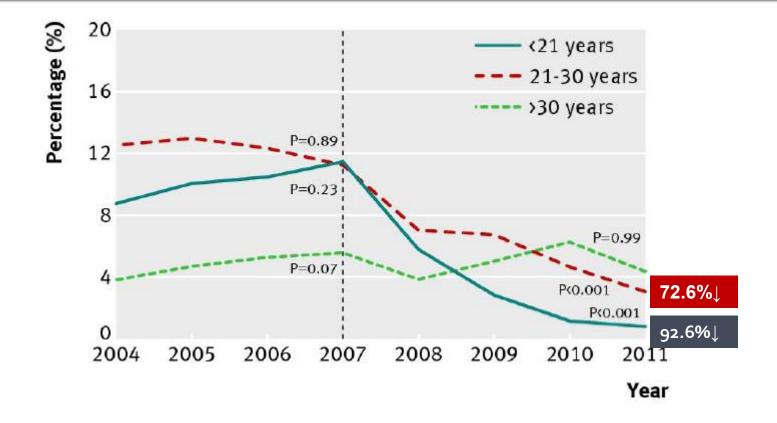
July 2013- vaccination of adolescent boys was rolled out.

Reference: Dept of Health and Ageing 2007

Monitoring HPV outcomes



Proportion of Australian born women diagnosed with genital warts at first visit

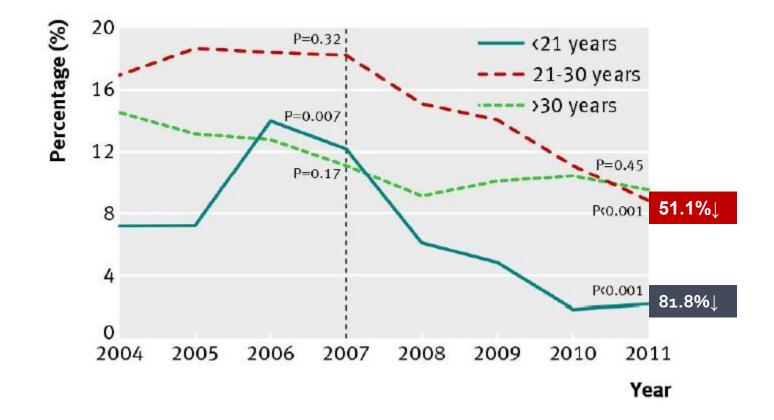


^aSignificant decline(*P_{trend}*<0.001) in the proportion of women diagnosed with genital warts at sexual health services. Trends were assessed with Poisson and chi-square tests.

Figure courtesy of Ali H et al. Presented at: International Union Against STI World Congress; October 2012; Melbourne, Australia.

- 1. Ali H et al. Presented at: International Union Against STI World Congress; October 2012; Melbourne, Australia.
- 2. BMJ 2013; 346:f2032

Proportion of heterosexual men diagnosed with genital warts at first visit

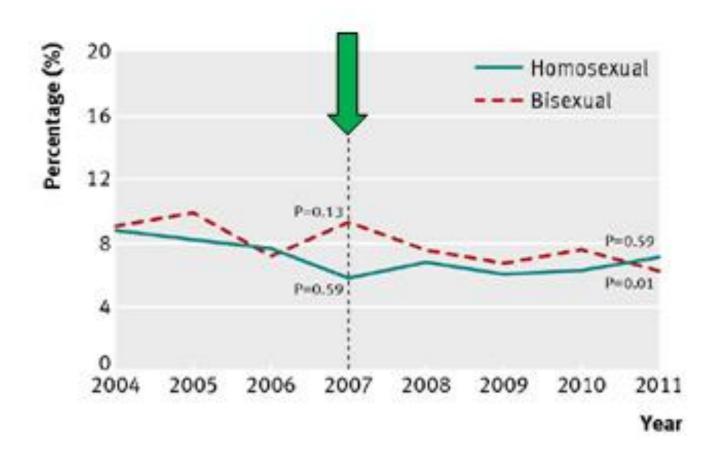


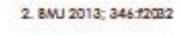
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Proportion of homosexual and bisexual men diagnosed with genital warts at first visit





Countries Reporting Effectiveness Data for qHPV Vaccine as of March 2013

	Australia	New Zealand	Denmark	Sweden	United States	Germany	Belgium	Canada
Program Started	2007 ¹	2008 ³	2008–2009 4	2006–2007 ⁵	2006 ⁶	2007 ¹⁰	200611	2007–2009 ¹³
Type of Program	School- and clinic-based ¹	School- and clinic- based ³	Clinic-based ⁴	Clinic-based ^{5,d}	Clinic-based ⁷	Clinic - based ¹⁰	School- and clinic- based ¹¹	School- and clinic- based ^{13,14,c}
Routine a Cohort (Age, Years)	M & F: 12–13 ²	11–12 (school- based only) ³	124	13–17 ^{5,e}	M & F: 11–12 ⁶	12–17 ¹⁰	10–13 11	F: 9–13 ^{13,c} M: 9–26 ^{13,h}
Catch-Up Cohort (Age, Years)	M: 14–15 through 2014 ² (F: 14–18 ended in 2008) ¹	13–20 (school- and clinic- based through 2010) ³	13–17 (2008–2010)⁴	NA	M: 13–21 ^{6,f} F: 13–26 ⁸	NA	NA	F: 14–26 ^{13,c,i}
Vaccination Rates ^b (%)	F: 64–80 (age 15, 2009) ^{1,c} F: 66–72 (ages 14–17, 2007–2009) ¹	73 (1st dose, ages 11–18, 2009) ³	76-82 (ages 14-16, 2012) ⁴ 78-83 (ages 17-19, 2012) ⁴	18 (ages 13–17, 2006–2010) ⁵ 27 (ages 18–19, 2006–2010) ⁵	F: 32 (ages 13–17, 2010) ^{9,c}	NA	79 (ages 12– 14, 2011– 2012 school year) ^{12,g}	F: 51–59 ^{15,j} (ages ~13–14)
Male Vaccination	Universal: 2013 ²	None	None	None	Permissive: 2009; Universal: 2011 ⁷	None	None	Universal: 2012 ^{13,k}

^a100% covered by national health programs except Belgium¹⁶ and the United States.¹⁷ ^bFull 3-dose completion, except for New Zealand. ^cVaries by region/province. ^dOpportunistic vaccination for females 13–17 years old began in October 2006 and has been partially subsidized since May 2007⁵; however starting in 2010 vaccination programs are school-based.¹⁶ ^eStarting in 2010, Swedish vaccination schedule now target females 10–12 years old.¹⁶ ^fMales 22–26 years old may be vaccinated. ^gEstimated overall coverage rate in Flanders for females born between 1998 and 2000.^hNo catch-up population but recommendation for MSM ≥9 years of age. ⁱFemales 27–45 years old may also be vaccinated. ⁱRange of coverage in Ontario, Canada for school years 2007–2008, 2008–2009, and 2009–2010; routine only, school-based only. ^kFunding for male vaccination to be determined at the provincial level.

MSM=men having sex with men; NA=no information available; qHPV=quadrivalent human papillomavirus.

Please see corresponding speaker note for references.



Weekly epidemiological record Relevé épidémiologique hebdomadaire

Human Papillomavirus vaccines: WHO position paper 2014¹

Organisation mondiale de la Santé

24 OCTOBER 2014, 89th YEAR / 24 OCTOBRE 2014, 89° ANNÉE No. 43, 2014, 89, 465–492 http://www.who.int/wer

- Reviewed and endorse by WHO Strategic Advisory Group of Experts(SAGE)²
- Comprehensive document for public health officials and immunization officials
- WHO position: cervical cancer and other HPV related diseases are global public health problems and reiterates its recommendations that HPV vaccines should be included in a national immunization programme

^{1. &}lt;u>http://www.who.int/wer/2014/wer8943/en/</u>,

^{2.} http://www.who.int/immunization/position_papers/position_paper_process.pdf



Weekly epidemiological record Relevé épidémiologique hebdomadaire Human Papillomavirus vaccines: WHO position paper 2014¹

Organisation mondiale de la Santé

24 OCTOBER 2014, 89th YEAR / 24 OCTOBRE 2014, 89' ANNÉE No. 43, 2014, 89, 465–492 http://www.who.int/wer

Strategy for implementation

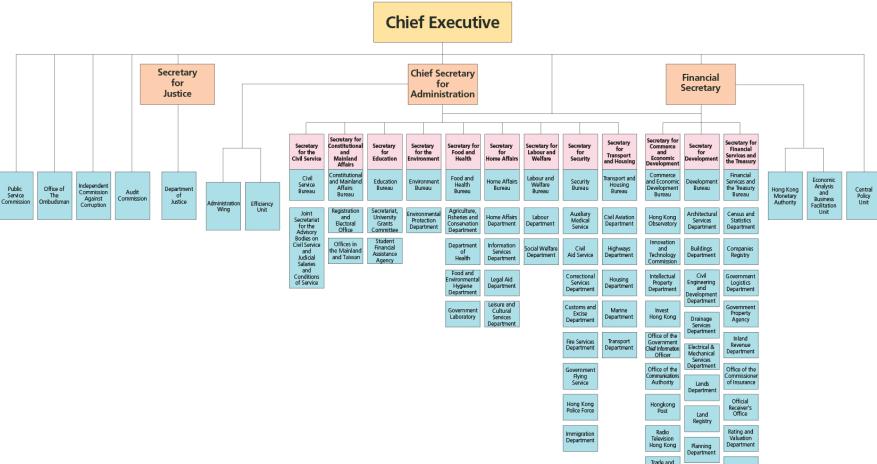
- ☑ Introduction should be coordinated and comprehensive
- **☑**Education
- ☑ Increased access to quality screening
- ☑Should not divert funds from screening
- ☑Compatible with their delivery infrastructure
- ✓Cost effective and sustainable
- ☑ Achieve highest possible coverage

Hong Kong governing structure



ORGANISATION CHART OF THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION

(1 July 2012)



Treasury

Industry

Department

Hong Kong Economic and Trade Offices (Overseas) Water

Supplies Department

MALAYSIAN POLICY ON HPV IMMUNISATION

- Mother Policy
 - Free HPV immunization to 13 years old Malaysian girls starting 2010
- Operational Policy
 - Voluntary HPV immunization Program : require written parental consent
 - School based immunization for all Form 1 (Year 7) students irrespective of actual age
 - Clinic based immunization for out of school 13 years old girl







SETTING UP MALAYSIAN NATIONAL HPV IMMUNISATION PROGRAM





PREPARATORY PHASE



CHALLENGES

- Vaccine Procurement
- Expensive vaccine
 - 'Halal certification' : concern of many Muslim parents
 - Vaccine storage and Cold chain maintenance
 - Timely vaccine delivery

ACTION TAKEN

- 4 levels of vaccine procurement committees
- Open bidding process
- 'Halal certification' stated as requirement in tender specification document
- Discussion with Malaysian Islamic Authority : Islamic ruling on HPV vaccination <u>http://www.e-fatwa.gov.my/fatwa-kebangsaan/hukum-pengambilan-vaksin-human-papilloma-virus-hpv</u>
- Packaging vaccine with WHO certified vaccine fridges to be delivered to pre identified health clinics throughout country
- vaccine procurement contract renew every 2 years
- Tracking vaccine delivery (e-cloud)







CHALLENGES

- 2. Grounding the stake holders
 - School children and parents
 - Ministry of Education (MOE)
 - GO and NGOs
 - MOH personals

ACTION TAKEN

- Involved MOE in planning and implementation stage
 - MOE official circular to all schools on HPV vaccination
- Meetings and dialogs with various stake holders
- Involved PTAs on board as MOH partners
- Health education materials circulations to schools
- Awareness campaigns and training at national and states
- 'Rumor surveillance'



IMPLEMENTATION PHASE

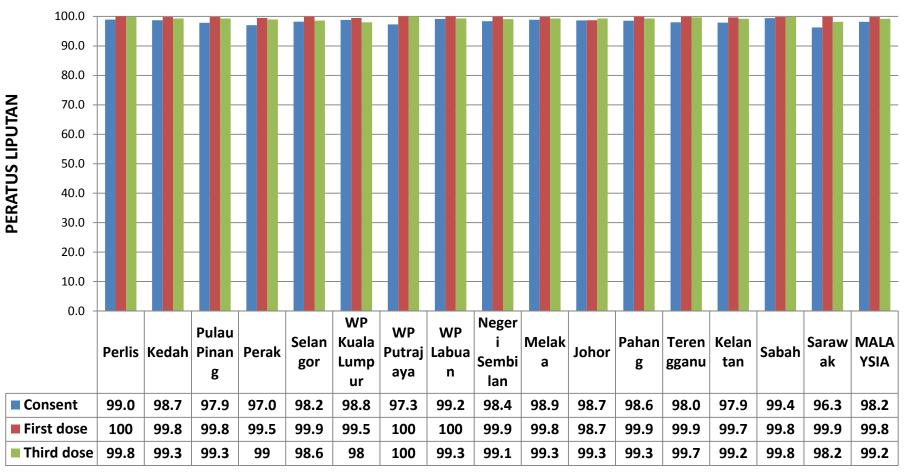


 3. 2010 Executing dose 1 and dose 2 within 4 to 8 weeks before school end 2010 2010 2011 Vaccinate 2 cohorts of students in 2011 (7 states) 3. 2010 Working committees at various levels Standardized guidelines, work process, consent forms, returns Training of staffs on protocols Mobilization of clinic staffs to support existing School Health Teams Setting up target dates Alternative Implementation Plan for 2010 and 2011 		CHALLENGES	ACTION TAKEN
	3.	Executing dose 1 and dose 2 within 4 to 8 weeks before school end 2010 2011 Vaccinate 2 cohorts of students in	 levels Standardized guidelines, work process, consent forms, returns Training of staffs on protocols Mobilization of clinic staffs to support existing School Health Teams Setting up target dates Alternative Implementation Plan



HPV VACCINATION ACHIEVEMENT

Written consent, first and third dose coverage of the HPV vaccine for 13 year old females in year 2013







COMMITMENT AND SUPPORT

- 1. Strong political will and leadership drive
- 2. Partnership with MOE
- 3. Involvement of stake holders during planning stage
- 4. Managing potential risk
- 5. Program monitoring at all levels

EXISTING ORGANISATION AND PROGRAM

- 1. MOH organization structure
- 2. Availability of School Health teams
- 3. Mobilization of health staffs from health clinics
- 4. Childhood and School Health Immunization program accepted by parents in Malaysia

Partnerships in successful HPV vaccination



Preparing the ground Communication package

- Journalists briefing/press release
- Medical societies and NGOs
- Social media
- Television
- Radio
- Information is consistent

Deadly vaccines and teenage girls

Athi Shankar | April 30, 2014



CAP calls for the scrapping of a costly and 'irrelevant' programme aimed at protecting youngsters from a sexually... More »

Govt defends vaccines for teen girls

FMT Staff | May 4, 2014



The Health Ministry rejects CAP's criticism, saying the HPV vaccination programme is safe and effective. More >>

Deadly vaccines and teenage girls

Athi Shankar | April 30, 2014

CAP calls for the scrapping of a costly and 'irrelevant' programme aimed at protecting youngsters from a sexually transmitted infection.



GEORGE TOWN: The Consumers' Association of Penang (CAP) has urged the Health Ministry to scrap the human papillomavirus (HPV) vaccination programme for 13year-old girls, saying the funds would be better used for cervical cancer screening.

CAP president SM Mohamed Idris said today that medical studies had shown HPV vaccines to have deadly side effects.

According to the US Centre for Disease Control and Prevention, HPV is the most common sexually

transmitted infection and goes away on its own in most cases.

Speaking at a press conference today, Idris called on the government to re-channel HPV vaccination funds towards improving its cervical cancer screening (CCS) programme.

He said the CCS programme should include pap smear tests for all women, particularly those who were pregnant, getting married or above the age of 17.

Govt defends vaccines for teen girls

FMT Staff | May 4, 2014

The Health Ministry rejects CAP's criticism, saying the HPV vaccination programme is safe and effective.



KUALA LUMPUR: The Health Ministry today defended its human papillomavirus (HPV) vaccination programme against criticism by the Consumers' Association of Penang (CAP).

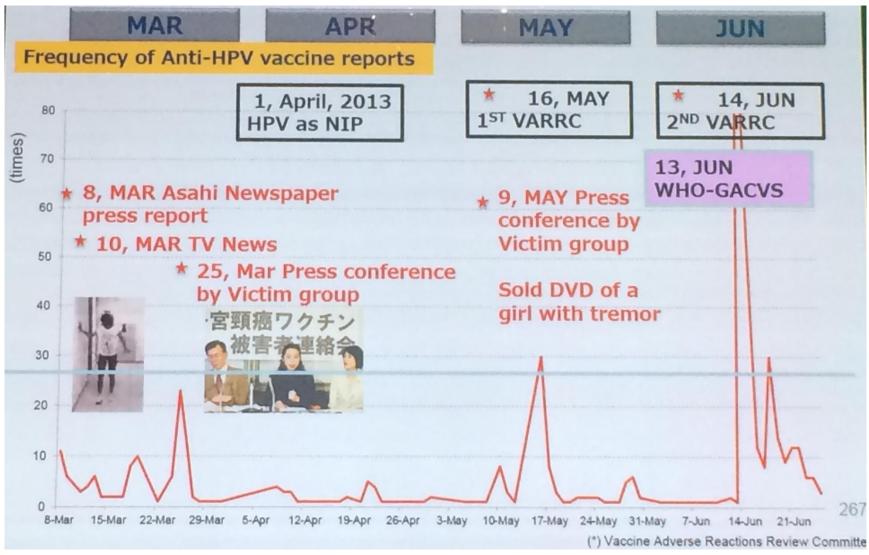
A ministry spokesman said in a media release that the vaccine worked effectively when administered on virgins.

Last week, CAP President SM Mohamed Idris urged the government to stop the programme, saying the vaccines used could have deadly side effects.

According to the US Centre for Disease Control and Prevention, HPV is the most common sexually transmitted infection and goes away on its own in most cases.

Idris said the programme was "irrelevant" because 13-year-old girls—the target group—were rarely promiscuous. He suggested that funds for the programme be used instead to boost the ministry's cervical cancer screening programme.

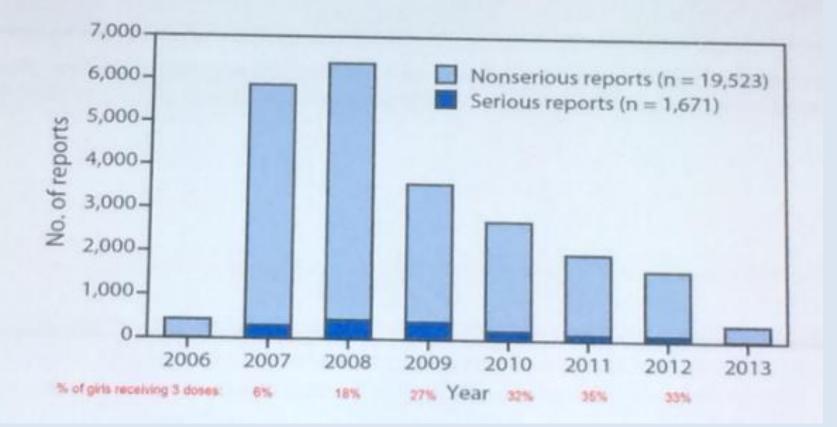
The impact of negative media reports on adverse events



Monitoring of adverse events

Number of serious and non-serious reports of adverse events after administration of quadrivalent HPV vaccine in females, by year.

Vaccine Adverse Event Reporting System, United States, June 2006-March 2013*. MMWR 2013



Consensus among Global Health Authorities (FDA, CDC,WHO, EMA, ECDC)

- To date, no safety concerns for the use of HPV vaccines have arisen from ongoing surveillance studies
- Post-licensure adverse events in males were similar to those observed in females and or those found in males in pre-licensure trials
- Recommend continued monitoring for the safety of qHPV vaccine in both genders

Cervical screening works

Table 1. Five decades of cervical cancer screening: observed and projected (in a scenario without screening) number of incident cases and ASRs of cervical cancer, age 30–74

Cumulative number of incident					it cases,	1961–2	2010	ASR (per 100000)			
		Observed	Pro	ojected ^{a,b}	Prever	nted by	y screening		Observed		Projected ^a
					Cumula	ntive	Average per year, 2006–2010	1961–1965	1986–1990	2006–2010	2006–2010
Country	Screening activities ^c	N	N	95% CI	N	%d	N				
Denmark	1967, regional; 1996, national	25 704	53210	48 038-58 806	27506	51.7	1239	70.9	32.4	19.2	102.0
Finland	1963, national; 1971, completed	9410	15 133	12814-18136	5723	37.8	202	33.0	7.1	7.5	21.8
Norway	1970s, opportunistic; 1995, national	15 146	24603	21 555-28 393	9457	38.4	552	35.2	25.3	19.0	62.8
Sweden	1967–1973, national	24 5 56	42777	38018-48312	18221	42.6	647	39.7	16.2	13.6	40.0
Total	-	74816	135723	127 463-145 715	60907	44.9	2640	-	-	-	-

Abbreviations: ASR= age-standardised incidence rate (world standard population); CI= confidence interval.

^aAssuming that the absence of screening activities would imply constant period effects.

^bModel-based confidence intervals for projections were obtained by simulation.

Year of onset and type of screening activity.

 $d_{Percentage computed = (prevented cases \times 100)/projected cases.$

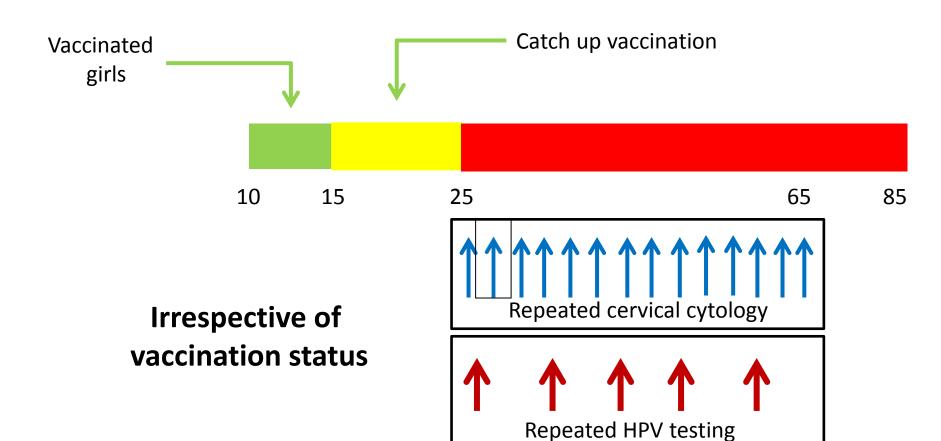
Why is HPV DNA testing an attractive option?

- More sensitive and reproducible than pap test
 - While sensitivity of cytology is variable in different countries, HPV testing is similar
- Can be automated, centralized and be quality checked for large specimen output
- Protection in HPV DNA negative women is high
- More applicable to vaccinated population

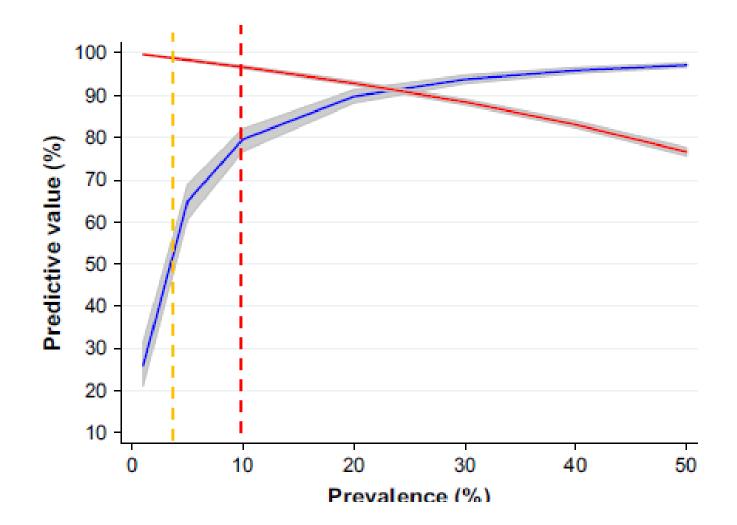
Screening in the era of HPV vaccination

- Should screening continue as it is?
- Intensity and modality
- Cost effectiveness of cytology is dependent on performance accuracy
 - Reduction in prevalence of cervical abnormalities
 - Decrease in PPV
 - Increase in false positives
 - Impact on cyto technician training and skills

Current screening strategy

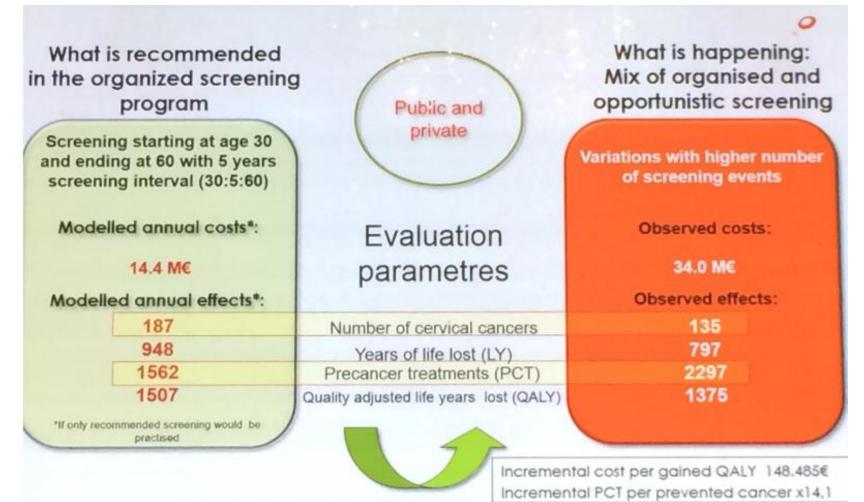


Influence of variation of HPV prevalence on PPV and NPV of cytology as primary screening



Franco E, Arch Med Res Vol 40, 2009

Inappropriate screening is costly



Recomended option and theoretical results obtained from models

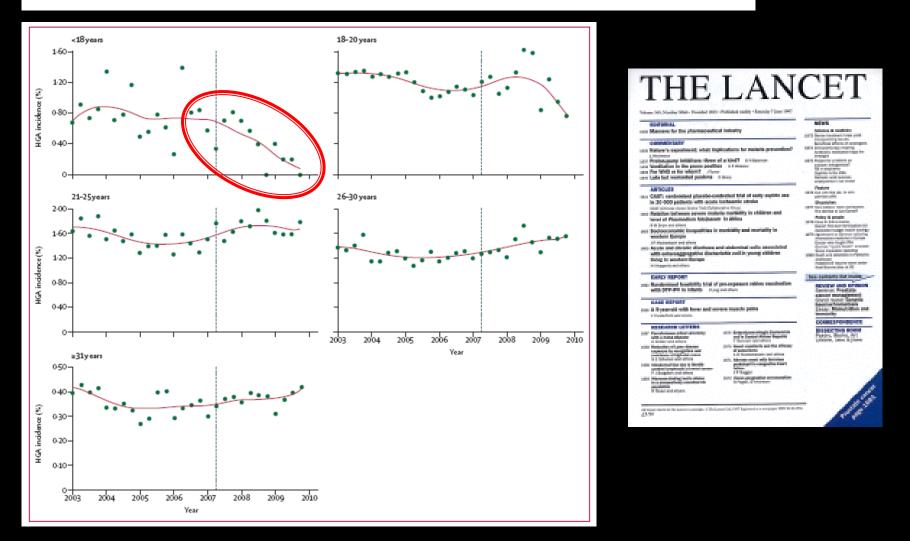
Non cost-effective option as observed in real life practice



- Reassess the evidence for screening tests and pathways for vaccinated and unvaccinated
- Determined a cost-effective screening pathway and program model
- Assessed the feasibility and acceptability of the renewed program for women

Early effect of the HPV vaccination programme on cervical abnormalities in Victoria, Australia: an ecological study

Julia M L Brotherton, Masha Fridman, Cathryn L May, Genevieve Chappell, A Marion Saville, Dorota M Gertig





New screening recommendations

- HPV test should be undertaken every 5 years;
- commence at 25 years of age;
- women should have an exit test between 70 and 74 years of age; and
- women with symptoms (including pain or bleeding) can have a cervical test at any age.









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Cancer Council has welcomed recommended changes to Australia's cervical screening program announced today by Australia's Medical Services Advisory Committee.

Cancer Council Australia CEO, Professor Ian Olver, said evidence showed a new HPV (human papillomavirus) test every five years, which is recommended to become the primary cervical screening tool, would be more effective than the Pap test and just as safe.

Professor Olver emphasised that the changes announced were recommendations only and that women should continue to have Pap tests every two years for now. Pending decisions by government, it is likely the changes would not be implemented before 2016.

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Media contact: For interviews please contact: Hollie Jenkins 02 8063 4153 or 0400 762 010 or hollie.jenkins@cancer.org.au

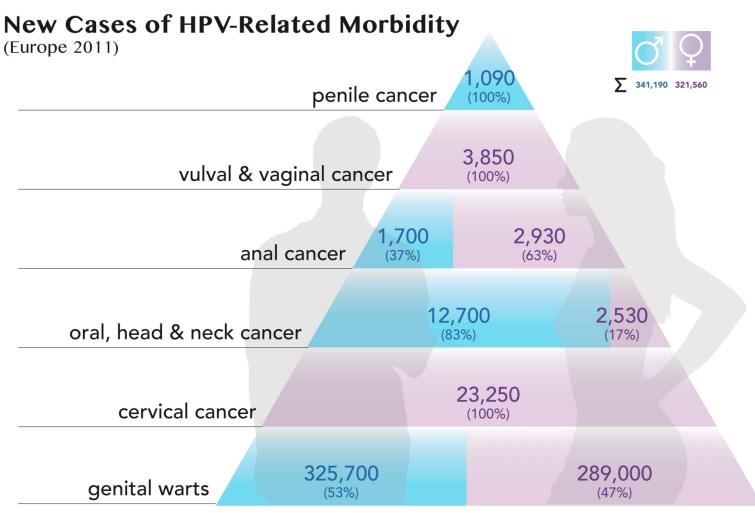
Why add males to current female vaccination?

- HPV infection occurs in both genders
- Herd protection requires more than 80% uptake
- HPV related diseases are increasing in both genders
- Equity
- Positive cost-benefit analysis

HPV vaccination in males

- Unlike cervical cancer, no screening methods to prevent other HPV related cancers
- In economically developed western countries where screening is effective, HPV related diseases in men approximate that of women
- Vaccinating males have dual purpose
 - Herd immunity
 - Protecting males

HPV is not a 'female' problem



ADAPTED FROM Stanley, M. Nature 488; 510 (30 Aug 2012)

Prevalence of HPV of HPV in men -49.4%

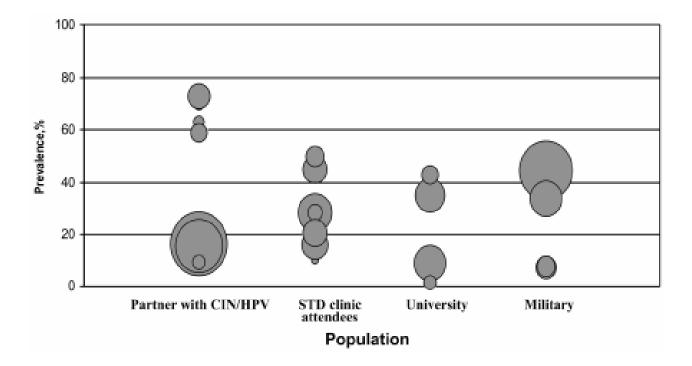
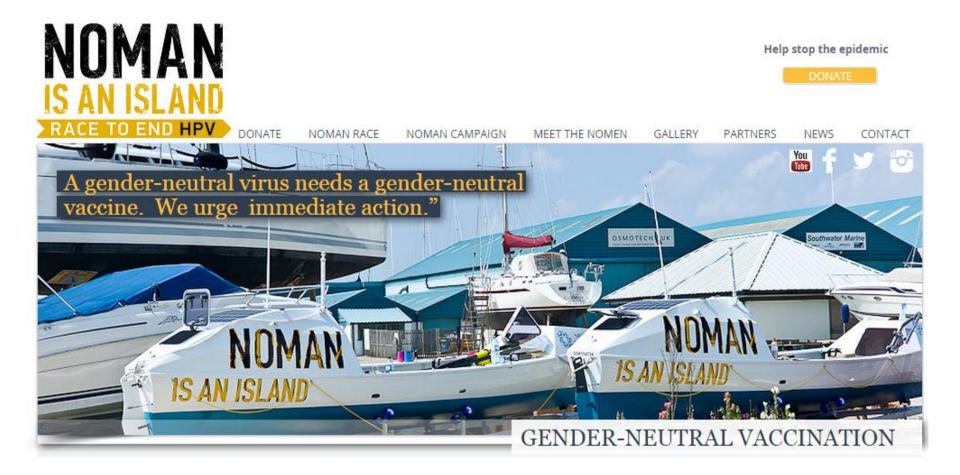


Figure 1. Human papillomavirus (HPV) prevalence in men of various populations. Each circle represents a study, the size of the circle indicates the no. of men tested, and the center of the circle is the point estimate of prevalence. CIN, cervical intraepithelial neoplasia; STD, sexually transmitted disease.

'A gender-neutral virus needs a gender-neutral vaccine'



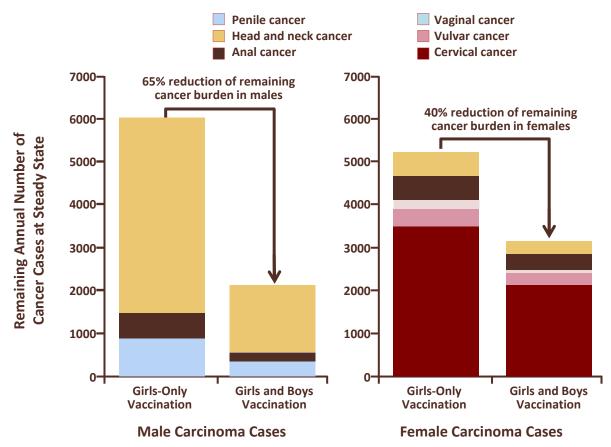
Vaccinating males in Australia





Estimated Impact of Gender-Neutral Vaccination^{1,a}

Annual Number of HPV 16/18–Related Carcinoma Cases Among Males and Females When Considering Gender-Neutral^b Vaccination Strategy Compared With Girls-Only^b Vaccination Strategy



^a70% vaccine coverage rates assumed for all cohorts; base case analysis presented at steady-state at 100 years.

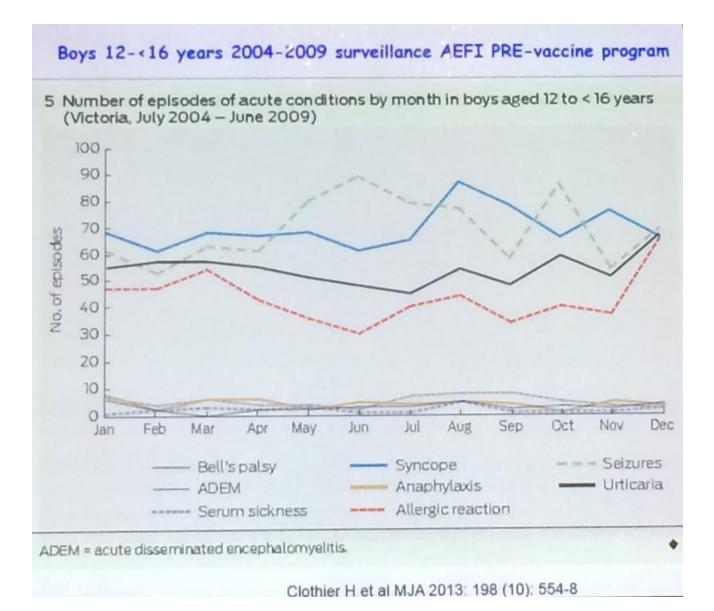
^bAge 12 years.

Figure adapted from Marty R et al. BMC Cancer. 2013;13:10, with permission from BioMed Central. 1. Marty R et al.

www.hpv.com.au/males/default.aspx

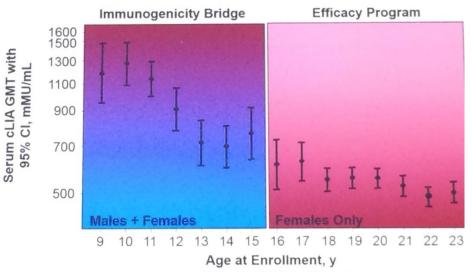


No episodes of acute events by month



Towards alternative dose schedules

- Logistical challenges
 - Attending 3 clinical visits in 6 months
 - Lack of provider reminder systems
 - Poor compliance to 3 doses



 High cost of 3 HPV vaccine doses Figure based on Block Pediatrics, 2006 and Reisinger PIDJ, 2007

Two dose schedule

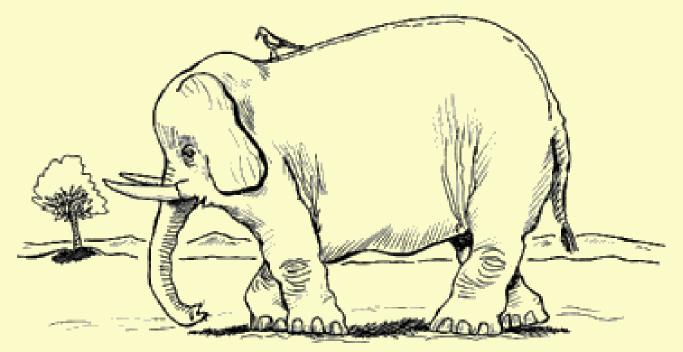
- STRICTLY for 9-13 year olds
- Non-inferior antibody levels compared to >15-24 year old with 3 doses (immunogenicity)
- Need to be given at least 6 months apart (memory B cells require at least 4 -6 months to mature)
- Cost effective and more pragmatic->WHO has changed its previous recommendation of a 3 dose schedule to a 2 dose schedule in females less than 15 years of age¹
- 2 dose schedule has been approved in Hong Kong Oct 2014

Conclusion

- Understand the context of where you are
- Engage multiple stakeholders
- Decide on the outcomes and model cost effectiveness for that country
- HPV prophylactic vaccines are highly effective
- Different protection profile

Engagement

can be much like giving birth to a baby elephant



- It starts off at a high level and works its way down
- The initiative often starts with much trumpeting and shouting
- It takes dozens of months to grow and develop before birth
- It becomes the focus of almost all of your attention

End result: Another Baby Elephant to take care of!

You cannot afford to wait for perfect conditions. Goal setting is often a matter of balancing timing against available resources. Opportunities are easily lost while waiting for perfect conditions.

(Gary Ryan Blair)