Human Papillomavirus Vaccination
The past, the present and the future

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National Immunisation Office

www.immunisation.ie
Conflict of interests

I have no conflict of interests

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Overview

• Decision making in immunisation

• HPV vaccination
  – school programme in Ireland
  – in other countries
  – inclusion of boys
The National Immunisation Advisory Committee (NIAC)

- Independent voluntary RCPI committee
- Variety of experts
- Advises the Department of Health
- Produces the National Immunisation Guidelines for Ireland

Based on
- best evidence regarding the safety and efficacy of vaccines
- the disease burden
- pharmacoeconomic analyses (for universal programmes)

- Not all recommendations are implemented by HSE

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Background

April 2008
– National Immunisation Advisory Committee (NIAC)
  • Human Papillomavirus (HPV) Vaccination for all girls aged 12 years of age
– HIQA HTA
  • HPV vaccine cost effective for 12 year old girls
  • recommended once off catch up programme for 13-15 year olds
Background

Minister of Health and Children
August 2008: “to start September 2009”

November 2008: “deferred due to rapidly and seriously deteriorated economic situation”

January 2010 “The vaccine will be offered free of charge this year for girls who are now in first year of secondary school. This is the same group of girls who would have received the vaccine under previous plans for 2009.”

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Aim & Objectives

Aim
To protect girls from their future risk of developing cervical cancer

Objectives
• Provide 3 doses of HPV vaccine to females before they reach an age when the risk of HPV infection increases and they are at subsequent risk of cervical cancer

• Achieve vaccine uptake of over 80% for 3 dose schedule

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Planning

• Programme delivery
  – HSE delivered
  – GP
  – 3rd party
• Funding
  – €4 million
    • vaccine
    • staffing
    • information/ training
    • IT


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HPV vaccine

- **Gardasil™** Sanofi Pasteur
  - quadrivalent HPV4
  - protects against premalignant genital lesions (cervical, vulvar and vaginal), cervical cancer and external genital warts related to HPV types 16/18 and 6/11

- **Cervarix™** GlaxoSmithKline
  - Bivalent HPV2
  - protects against premalignant cervical lesions and cervical cancer related to types 16/18 only

HPV Vaccines are not interchangeable

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HPV Vaccine

- Competitive tender process
- Contract awarded for supply of Gardasil (Sanofi Pasteur)
- Gardasil protects against
  - HPV 16 and 18 (causes 70% cervical cancers)
  - HPV 6 and 11 (causes 90% genital warts)
- 3 dose schedule at 0, 2 and 6 months
- Enhanced reporting of adverse events to IMB

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Computerised image of the human papillomavirus
Courtesy of Dept of Pathology, University of Cambridge
Training for HSE vaccination teams

- Programme developed with clinical guidelines
  - epidemiology of HPV
  - vaccine efficacy and safety

- Frequently Asked Questions produced and updated

- Medication protocols introduced to schools programme for nurses
  - allows for administration of vaccine without individual prescription

[Image: HUMAN PAPILLOMAVIRUS VACCINE Frequently Asked Questions for Health Professionals]
Is the cervical cancer vaccine good to go?  

NO

Gardasil has never been proven to prevent cervical cancer, hasn’t been sufficiently tested on the target age group, and not enough is known about adverse reactions.

Paula Byrne

Is IT WORTH THE RISK?

There are fears a national roll out of the HPV vaccine could lull young women into a false sense of security, writes Jennifer Hough.

Jennifer Hough

Vaccines are a modern medical marvel, and in the case of the HPV vaccine, it’s one that offers hope for the future.

The HPV vaccine targets the virus that causes cervical cancer, which is one of the most common cancers in women worldwide.

The vaccine is effective and safe, and it’s estimated to prevent up to 70% of cervical cancer cases.

But there are concerns that the vaccine may lead to complacency among women about their sexual health.

The vaccine is not a cure-all, and it’s important for women to continue regular cervical screenings even after getting vaccinated.

The HPV vaccine is recommended for girls aged 11-12 years, and it’s also available for men aged 11-26 years.

The vaccine is typically given in three doses, and it’s important to complete the full course to achieve maximum protection.

Vaccines are an important part of our public health strategy, and it’s important to stay informed about their benefits and potential risks.

Cervical cancer is a preventable disease, and with the availability of the HPV vaccine, we have a powerful tool to help protect women against this deadly cancer.

Cervical cancer is the second leading cause of cancer death in women worldwide, and it’s estimated that there are over 570,000 new cases of cervical cancer diagnosed each year.

The HPV vaccine is a significant step forward in our fight against cervical cancer, and it’s important for women to take advantage of this opportunity to protect themselves from this deadly disease.
Communications

- Parents (over 90% happy with content of materials)
- Department of Education
- School management bodies
- National parents council
- Other stakeholders
- Media

www.hpv.ie
- includes
  - Ask a question
  - Translated materials

Highlight the importance of cervical screening in the future

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HPV ICT system 2010/2011

- National ICT immunisation system planned
- Schools ICT immunisation system planned

⇒ Manual records for each dose collated locally
⇒ Data sent to National Immunisation Office to collate national HPV vaccine uptake

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Programme delivery

- 21 schools started May 2010
- Full roll out September 2010
- Double cohort 1st & 2nd year
- 575 schools
- Logistical challenge (many rural schools with small cohorts in West and South)
- 59,235 girls (includes those in special schools & home schooled)
- Blitz and mop up for each dose (3 weeks in school + 1 week clinics)
Constraints and Risks

• Programme issues
  • Resources – staff, ICT
  • Communications
  • Out of school/ Home schooled
  • Use of medication protocols

• Vaccine issues
  • Previous HPV vaccine
  • Interchangeability
  • Partial course
  • Vaccine given too early or too late
  • Adverse events

• Cervical cancer screening

Alternative schedule 0, 1, 4 months

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Monitoring adverse events

- 87 million doses distributed worldwide (2011)
- 111 million doses (2013)

- Side effects
  - local redness and/or swelling at the point of injection, and fever
  - fainting (adolescents)
  - anaphylaxis very rare

Coincidental deaths
- RTAs, drowning, malaria, undiagnosed tumour

WHO review of HPV vaccine safety in 2009
- “no concerns with the safety profile were identified”

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416 adverse events reported consistent with the known safety profile of the vaccine (injection site reactions, headache, dizziness, fainting, fatigue etc).
Vaccine uptake

HPV vaccine uptake 2010/2011

- Over 80% (81.8%) uptake achieved for 3 dose schedule
- Excellent cohort retention
- >95% girls who started dose 1 completed dose 3

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2011/2012 & 2012/2013

• Routine programme for all 1st year girls

2011 Programme for Government
“We will introduce a cervical cancer vaccination catch-up programme for all girls in secondary school.”

• Catch-up programme for all 6th year girls (18 years)
  • introduced 2011/2012
  • to continue until 2013/2014

• New national HPV IT system implemented

• Uptake 2011/2012 (3 doses)

<table>
<thead>
<tr>
<th>Target</th>
<th>Provisional</th>
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<tr>
<td>1st years</td>
<td>80%</td>
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<td>6th years</td>
<td>60%</td>
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HPV vaccination in other countries

- **USA 2006**
  - HPV4 recommended since 2006
  - 3 dose uptake ~35%

- **Australia 2007**
  - HPV4 routine programme & catch up to 26 years
  - 3 dose uptake 73% (decreasing with age)

- **Europe 2006 onwards**
  - routine programme in 19/29 countries
  - catch up in 10/29 countries
  - 3 dose uptake lower than expected

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Vaccine Impact in Australia
High Grade Cervical Lesions <18 years

2007: Start of nationwide vaccination programme

~50% decline in incidence of high grade cervical lesions

Figure 2: Incidence of high-grade cervical abnormalities, by age group
Incidence of high-grade cervical abnormalities (HGA; green dots) is the number of new diagnoses within a 3-month period per 100 women tested. Lowess smoothing trends are shown with red lines. The vertical lines, at the start of the second quarter in 2007, signify the introduction of human papillomavirus vaccination.

Brotherton et al Lancet 2011; 377: 2085–92
www.immunisation.ie
Vaccine Impact in Australia
Genital warts

- Women <21 years
  - HPV vaccine 83% 1st dose uptake
  - 2011
    - 93% decline in genital warts
    - no genital warts in vaccinated women

- Men
  - 82% decline in genital warts in heterosexual men
  - attributable to herd immunity


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Gardasil

- licensed for use for prevention of
  - genital warts in 2009/2010
  - anal cancer
    - in USA, Canada, Australia & NZ (not in Europe)
- not licensed for prevention of head and neck cancer
- elicits the same or higher immunogenicity
- most cost effective when uptake in girls is low
- reduce transmission in MSM (cost effective up to 26 years)


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HPV vaccination for boys

• USA & Austria
  • recommended - cost covered by recipients
• Australia
  • national programme introduced in 2013
  • 2 year catch up

“This change seems a conundrum, especially after female only vaccination has shown a positive effect through herd immunity and male vaccination was previously not cost effective”


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Estimating the clinical benefits of vaccinating boys and girls against HPV-related diseases in Europe

• Modelling study

• Benefits of adding boys dependent on coverage in girls

• Head and neck cancer
  Largest incremental impact
  66% reduction
  No efficacy studies

Marty et al. BMC Cancer 2013, 13:10 http://www.biomedcentral.com/1471-2407/13/10

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HPV vaccination for boys

- Epidemiology of HPV infection and disease in men
- Duration of protection
- Herd immunity
- Acceptability
- Cost (number of doses)
- Social and ethical considerations
- ? MSM outside a universal programme
Meningitis jab gets all-clear in Europe

But drug still faces HSE’s ‘value for money’ test

Shingles vaccine to be routine for people in their 70s

Every child to get flu vaccine in bid to prevent epidemic

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Next steps

• More evidence
  • impact of vaccination of boys
  • efficacy in prevention of HPV related cancers including head and neck cancers

? Review of addition of boys by NIAC with HTA

? Permissive or universal recommendation

? Implementation

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Summary

- HPV vaccination programme for 12 & 18 year old girls
- Vaccine safe and well tolerated
- Vaccine uptake has exceeded the target
- Impact on HPV related infections and pre cancers
- Herd immunity

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Acknowledgements

- All HSE vaccination teams
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- HSE Communications