The National Immunisation Schedule Update and Current issues

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Objectives

- To outline immunisation schedules in Ireland
 - Primary childhood schedule
 - Vaccine uptake rates
 - School immunisation programme
 - Flu vaccination programme

To highlight development of new vaccines





Dates vaccines introduced into the Irish immunisation schedule

1937 - 1999				
Vaccine	Date introduced			
1. BCG	1937			
2. DT	1930s			
3. DTP	1952			
4. Oral Polio Vaccine (OPV)	1957			
5. Rubella	1971			
6. Measles	1985			
7. MMR	1988			
8. MMR2	1992			
9. Hib	1992			

2000 - 2016				
Vaccine	Date introduced			
1. Men C	2000			
2. DTaP-Hib-IPV (5 in1)	2001			
3. Inactivated Polio (IPV)	2001			
4. Hib Booster	2006			
5. Hepatitis B (as part of 6 in 1)	2008			
6. PCV7	2008			
7. HPV	2010			
8. PCV13	2010			
9. Tdap	2012			
10. Men C (adolescent booster)	2014			
11. Rotavirus	2016			
12. Men B	2016			





Primary Childhood Immunisation (PCI) Schedule (up to 30th September 2016)

2 months 6 in 1 + PCV 4 months 6 in 1 + Men C 6 months 6 in 1 + PCV (+MenC*)

12 months MMR + PCV13 months Men C + Hib

* if born before July 1st 2015

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Vaccine uptake rate at 24 months 1999-2016





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Quarter 1 2016 D3 immunisation uptake rates (%) by LHO, in those 24 months of age in Ireland and Dublin (source HPSC)







Quarter 1 2016 MMR immunisation uptake rates (%) by LHO, in those 24 months of age in Ireland and Dublin (source HPSC)







Decline in vaccine uptakes

	Q1 2010	Q3 2010	Q1 2016
Men C ₃	93%	80%	89%
PCV ₃	-	88%	91%
Hib _b (booster dose)	89%	84%	91%

MenC_bbooster dose by LHO in those reaching 24 months Q1 2016



Source: HPSC







Decline in vaccine uptakes

Actions

- Highlight 5 visits at every opportunity
- Give an appointment for next visit
- Send a text reminder before appointment
- Follow up defaulters as soon as possible
- Send vaccine returns on time
- Defaulters need appropriate vaccines even if they are over the recommended age



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Primary school immunisation schedule 2016/2017

Age (years)	Vaccine
4 -5	Tdap/IPV MMR

Tdap/IPV low dose diphtheria Tetanus low dose pertussis Polio (IPV Boostrix)













Tdap/IPV adverse events

More reactogenic

- hot, swollen, red and tender arms from the shoulder to elbow
- large, localised swelling (diameter > 50 mm) occurring around the injection site
- Begin within 48 hours of vaccination
- Resolve spontaneously
- Antibiotic treatment or anti-inflammatory not indicated
- Not usually associated with significant pain or limitation of movement
- Inform parents in advance







Primary school immunisation uptake 2011/12 - 2014/15



CHO 6 4in1 90.9% MMR 91.1% CHO 7 4in1 94.8% MMR 94.6% CHO 9 4in1 88.8% MMR 88.4%





Second level school immunisation schedule 2016/2017

Age (years)	Vaccine
12-13	Tdap MenC
12 – 13 (girls only)	HPV (2 dose schedule)

Tdap	Tetanus,	low	dose	diphtheria	&	pertussis

- MenC Meningococcal C vaccine
- HPV Human papillomavirus

Tdap and MenC booster vaccines

Information for parents of children in First Year of second level school



Seco	nd level so	hool	me	۲	Here and the second
Name:				90(
Time of va	eccination:				
Your child	was given the follow	ing vaccines	today		
	HPV		Tdap	Me	enC
Common r sorenes (this us dizzines headac Occasiona	reactions expected a ss, swelling and redn ually passes after a d ss he lly your child may fe	Rer these va ess where th ay or two) el sick or hav	ccines may include le injection was giver le a mild fever. On ra	re occasions some	children
You can git	an itchy rash or nive ve vour child paracet	amol or ibur	profen to relieve ach	es and pains or to	lower the
fever. If yo	u are concerned abo	ut your child	d please seek medica	l advice.	
The schoo	l vaccination team c	in be contact	ted during office hou	rs from Monday t	o Friday at
If you core	tire medical advice a	fter there he	ur place contact u	aur familu daetar	
ir you requ	ure medical advice a	rter these ho	ours please contact y	our tamily doctor.	
Before the	e next vaccine, you sh	iould write t	o the vaccination tea	m if there has bee	en .
 any cha 	inge to your child's m	edical histor	ry or your consent	A C	2
You will ge when they	et a record of your ch y have all been comp	ild's vaccinat leted. Pleas	tions e keep this safe.	1	No. of the second secon
For more	e information see		6	man 1	-
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Second level school immunisation uptake Tdap



CHO6 CHO7 CHO9 89.0% 91.6% 79.2%



Adolescent MenC booster vaccine

- Peak rates in under 5 years and 15-19 years
- Concerns about waning immunity in adolescents
- Recent study
 - those vaccinated at <1 year, vaccine effectiveness decreased by 50% after 10 years
 - those vaccinated with one dose at 12–19 years showed no changes
 - vaccination at ≥12 years related to a low number of vaccine failures and a higher and longer protection over time
- MenACWY in UK since 2015/2016





Second level school immunisation uptake MenC



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HPV vaccination programme

Gardasil (Sanofi Pasteur)

- protects against
 - HPV 16 and 18 (causes 70% cervical cancers) and
 - HPV 6 and 11 (causes 90% anogenital warts)



Computerised image of the human papillomavirus Courtesy of Dept of Pathology, University of Cambridge





HPV vaccine uptake 2010/2011 - 2014/2015 Routine programme First years



Highest uptake achieved in 2014/15 Excellent cohort retention 97% girls who started dose 1 completed dose 2





ARE HPV VACCINES SAFE?





Gardasil vaccine safety

- Over 200 million doses distributed worldwide
- Used in over 25 European countries, the US, Canada, Australia and New Zealand
- WHO, EMA, CDC repeatedly review safety data no serious adverse events

Nov 2015 EMA review found no evidence the vaccine was linked to chronic fatigue like conditions
Dec 2015 WHO concluded that Gardasil continues to have an excellent safety profile.
Jan 2016 European Commission endorsed the conclusion of the EMA, no need to change the licensed documentation





HPV vaccine safety

May 2016 The UK Medicines and Healthcare Regulatory Agency reported :

"More than three million girls have been vaccinated so far in the UK with HPV vaccine, and tens of millions more have been vaccinated globally.

As with all vaccines, safety remains under continual review, and HPV vaccine has a **very good safety record**".





HPV vaccine safety May 2016

- 1065 reports to HPRA
 - consistent with the expected pattern of adverse effects for the vaccines
 - syncope (faints), gastrointestinal symptoms, malaise, headache
 - 2 reports of POTS (medically confirmed)
 - 2 reports of CRPS
 - 13 reports of chronic fatigue sysndrome
- 660,000 doses administered
- over 220,000 girls fully vaccinated





Known side effects of Gardasil



Very commonly (more than 1 in 10 patients):

 Pain, swelling and redness at injection site. Headache

Commonly (more than 1 in 100 patients):

 Bruising, itching at injection site, pain in extremity. Fever and nausea

Rarely (less than 1 in 1000 patients):

• Hives (urticaria)

Very rarely (less than 1 in 10,000 patients):

Syncope (vasovagal reaction), or fainting, Allergic reactions that may include difficulty breathing, wheezing (bronchospasm), hives and rash have been reported.

Patient Information Leaflet (PIL) at http://www.medicines.ie/medicine/11535/ PIL/ GARDASIL





HPV vaccine safety UK

Dr. Philip Davies, Director General of the European Cervical Cancer Association stated in January 2016:

"30,000 women die from cervical cancer each year in Europe; many of these deaths are preventable. Through CervicalCheck and the HPV vaccination programme, Ireland has one of the best cervical cancer prevention programmes in Europe and it's completely free."



CDC

CDC has carefully studied the risks of HPV vaccination.

HPV vaccination is recommended because the benefits, such as prevention of cancer, far outweigh the risks of possible side effects.

Benefits	Potential Risks
Cancer Prevention	Chance of fainting
Cervical, vaginal, and vulvar cancer in women Anal cancer in men and women	Pain, redness, or swelling in the arm where the shot was given
Likely penile cancer in men	
Likely oropharyngeal cancer in women and men	

http://www.cdc.gov/vaccinesafety/pdf/data-summary-hpv-gardasil-vaccine-is-safe.pdf





HPV vaccine impact in Australia High Grade Cervical Lesions <18 years



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.



By 2013 reductions also seen in 20-24 year age group

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Brotherton et al Lancet 2011; 377: 2085–92

HPV vaccine effectiveness - Australia Genital warts

• Women <21years

- 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

% Australian born diagnosed with genital warts by age group 2004 - 2011









HPV vaccine information

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HPV Vaccines and Cervical Cancer

Human papillomavirus (HPV)

- Human Papillomavirus (HPV) infection is spread by direct (usually sexual) contact with an infected person.
- About 80% of all women will have a HPV infection in their lifetime usually in their late teens and early 20s.
- · Most HPV infections clear naturally but some caused by high risk HPV types can progress to cervical cancer
- Two high risk HPV types (16 and 18) cause over 70% of cervical cancers.

Cervical cancer

- · Ireland has one of the highest rates of cervical cancer in Western Europe
- Each year in Ireland - over 90 women die from cervical cancer
- over 280 (many young) women need treatment (surgery, chemotherapy and/or radiotherapy) for invasive
- cervical cancer over 6,500 women need hospital treatment for a precancerous form of cervical cancer.

HPV vaccine

- There are three licensed HPV vaccines, HPV2, HPV4 and HPV9.
- · HPV vaccine is recommended by the World Health Organization. the International Federation of Obstetricians and Gynaecologists and the expert immunisation body in Ireland
- The HPV vaccine used in the HSE school HPV vaccination programme is HPV4 (Gardasil).
- Gardasil provides protection against
- two high risk HPV types (HPV 16 and 18) that cause 70% of cancers and precancers
- two HPV types that cause 90% genital warts.

- Gardasil has been licensed worldwide since 2006. Gardasil is currently used in over 25 European countries, the United States, Canada, Australia and New Zealand
- By May 2016, over 220 million doses of Gardasil have been distributed worldwide, either as part of national immunisation programmes or by private doctors. In Ireland more than 660,000 doses
- of Gardasil have been distributed and more than 220,000 girls have received the full vaccine course as part of the HSE school HPV vaccination programme.

Are HPV vaccines safe?

- All vaccines must go through extensive safety testing before they are licensed.
- Once in use, vaccine safety is continually monitored to identify side effects caused by the vaccine.
- Data is also collected on health conditions that happen after vaccination but are not caused by it.
- The European Medicines Agency, the Centers for Disease Control and Prevention in the US and the World Health Organization continue to say HPV vaccines are safe with no known long term side effects.

What are the side effects?

- The known side-effects are: About 1 girl in 10 will get nain. swelling and redness at the injection site and/or headache.
- · About 1 girl in 100 will get nausea, pain in the vaccinated arm and mild fever.
- About 1 girl in 1000 to 1 girl in 10,000 will get an itchy rash or hives
- Severe allergic reactions with difficulty breathing are very rare (about 1 in 1 million patients).
- · Occasionally girls faint after getting an injection. The girls are advised to sit down for 15 minutes after the vaccination. This helps prevent fainting

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Do HPV vaccines work?

- HPV vaccines are more than 99% protective against infection with cancer causing HPV virus types.
- HPV vaccines are most effective when given at the age of 12 to 13 years and will provide protection throughout adulthood. · Precancerous growths of the cervix
- have been reduced by more than 50% in countries such as Australia. Denmark and Scotland

Why does the HSE request that only HSE information should be given to parents?

- Parents should receive information that is
- scientifically accurate and endorsed by national and international expert and regulatory bodies
- in line with HIQA guidance "Communicating in Plain English" (July 2015).
- The information in the HSE leaflet
- includes all the known scientifically proven side effects from HPV vaccine
- is prepared from the licensed documentation for the vaccine and provides links where parents can go to read further information
- is presented in clear simple language and approved by the National Adult Literacy Agency so that it can be easily understood
- · provides link to further information on vaccine including the Patient Information Leaflet

The HSE strongly recommends

HPV Vaccine Key Facts

There is evidence that the recommendation of a known health professional leads to increased vaccine uptake. GPs and practice nurses provide a significant role in the promotion of all vaccines so please help to inform parents about the safety and effectiveness of HPV vaccine.

Human papillomavirus (HPV)

- Human Papillomavirus (HPV) infection is the most common sexually transmitted disease worldwide
- Spread by direct (usually sexual) contact with an infected person
- About 80% of all women will have a HPV infection in their lifetime usually in their late teens and early 20s
- HPV infection rates are rising rapidly among women and men in high income countries.
- Most HPV infections clear naturally but some caused by high risk HPV types can progress to cervical cancer
- Two high risk HPV types (16 and 18) cause over 70% of cervical cancers
- Ireland has one of the highest rates of cervical cancer in Western Europe
- Each year in Ireland
- cervical cancer - over 280 (many young) women need treatment (surgery, chemotherapy and/
- or radiotherapy) for invasive cervical cancer over 6,500 women are diagnosed with high grade cervical intraepithelial neoplasia (CIN) and require hospital treatment.
 - to HPV types 16 and 18
 - is licensed for use in females from 9 years of age

- Other cancers
- HPV is responsible for - more than 90% anal cancers - almost 70% vaginal and vulvar cancers
- more than 60% of penile cancers
- over 70% oropharvngeal cancers.
- Male incidence of oropharvngeal cancer will overtake cervical cancer incidence by 2020.

recommended by the World Health Organization (WHO), the International Federation of Obstetricians and Gynaecologists (FIGO) and the American Society

HPV Vaccine

- Should be administered before exposure to HPV at sexual contact.
- Recommended for all girls age 12-13 years.
- HPV vaccine is known to be most effective when given at this age.
- Two HPV vaccines (HPV2 and HPV 4) were licensed in 2006.
- HPV2 vaccine (Cervarix)
 - is licensed to prevent premalignant genital lesions and cervical cancer causally related

 two dose schedule at 0 and 6 months for girls less than 15 years at first dose

lished by National Immunisation Office August 2016

- three dose schedule at 0,1, 6 months for females age 15 to 26 years.
- HPV4 vaccine (Gardasil)
- is used in the HSE HPV school vaccination programme
- is licensed to prevent premalignant genital and anal lesions cervical and anal cancers causally related to HPV types 16 and 18
- provides protection against HPV types 6 and 11 that cause over 90% anogenital warts in men and women
- is licensed for use in females and males from 9 years of age
- two dose schedule at 0 and 6 months for those less than 15 years at first dose
- three dose schedule at 0,2, 6 months aged 15 to 26 years.

HPV types 16 and 18 cause 70% cervical cancers.

- HPV9 vaccine (Gardasil 9)
- was licensed in 2014
- provides protection against 9 HPV types 6,11, 16, 18, 31, 33, 45, 52, and 58 (7 of which cause almost 90% of cervical cancers).
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Cervical cancer

- over 90 women die from

More information



http://www.immunisation.ie/en/HealthcareProfessionals/ImmunisationGuidelines/



www.immunisation.ie

