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	





Primary Childhood Immunisation (PCI) Schedule

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

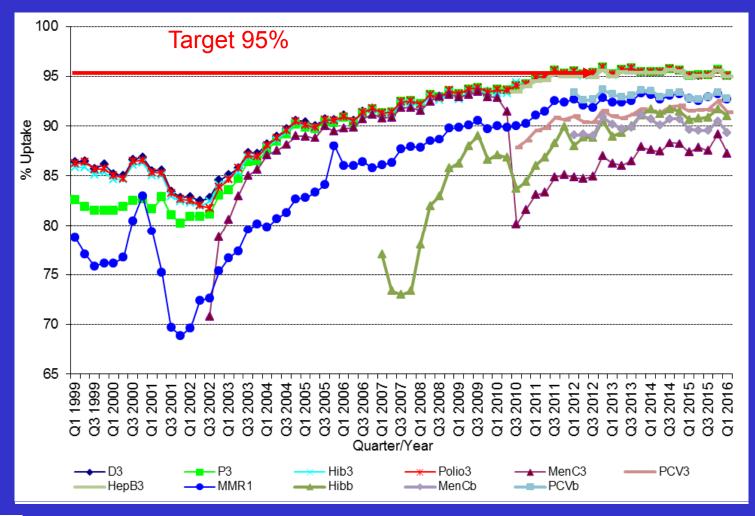




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Reidhmeannacht na Seirbhíse Sláime Health Service Executive

Vaccine uptake rate at 24 months 1999-2016

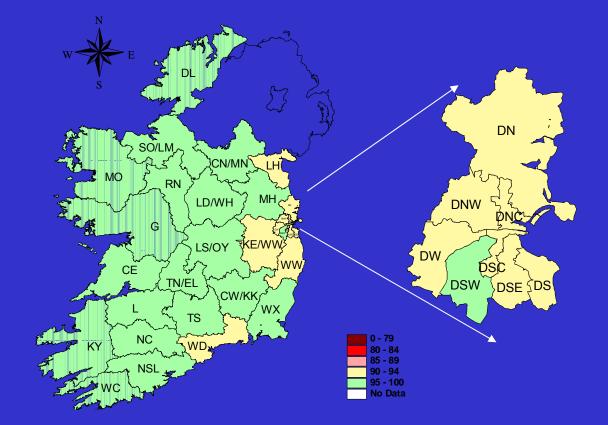




Source: HPSC

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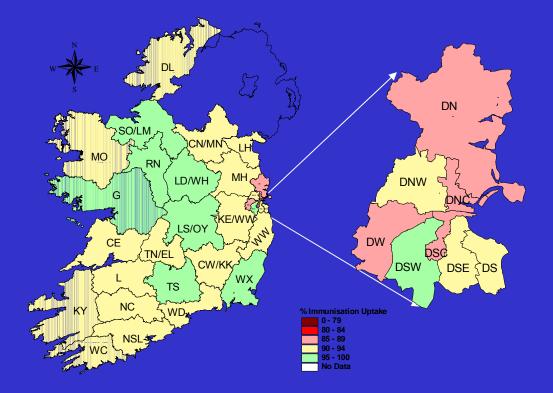
Quarter 1 2016 D3 immunisation uptake rates (%) by LHO, in those 24 months of age in Ireland and Dublin (source HPSC)







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



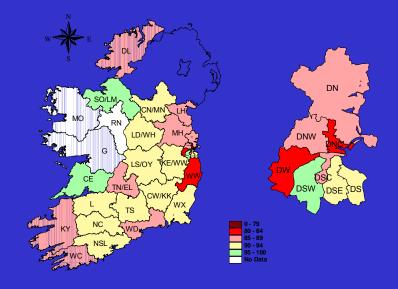




Decline in vaccine uptakes

MenC_bbooster dose by LHO in those reaching 24 months Q1 2016

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



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



Remember, it takes 5 GP visits to fully vaccinate your baby.

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Primary Childhood Immunisation (PCI) Schedule

CURRENT SCHEDULE		
Babies born on or after 1st July 2015		
Immunisations	Comment	
6 in 1 + PCV	2 injections	
6 in 1 + MenC	2 injections	
6 in 1 + PCV	2 injections	
MMR + PCV	2 injections	
MenC + Hib	2 injections	

6 in 1 Diphtheria, Tetanus, Pertussis, Polio, Hepatitis B, Haemophilus influenzae B

PCV Pneumococcal conjugate vaccine

MenC Meningococcal C vaccine

MMR Measles, Mumps Rubella

Hib Haemophilus influenzae B







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)





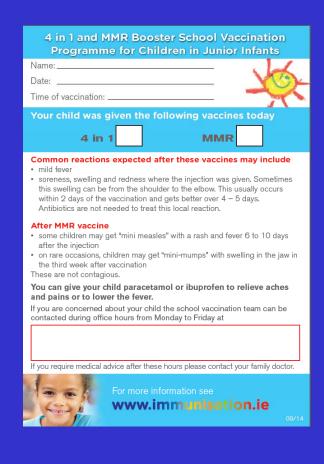
MMR Measles, mumps and rubella





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 (Target 95%)



OTECT HEALTH

CHO5 4in1 95% MMR 95.3%



Second level school immunisation schedule 2016/2017

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

- Tetanus, low dose diphtheria & pertussis Tdap MenC Meningococcal C vaccine
- HPV Human papillomavirus

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



Stor Market

			000
Name:			
Date:			
Time o	f veccination:		
Your ch	ild was given the following	vaccines today	
	HPV	Tdap	MenC
Occasie may ha You car	we an itchy rash or hives. ngive your child paracetam f you are concerned about	ick or have a mild fever. On rare oc tol or ibuprofen to relieve aches an your child please seek medical adv	d pains or to lower the
The sch	ool vaccination team can i	be contacted during office hours fn	om Monday to Friday at
If you r Before • a se • any	equire medical advice afte the next vaccine, you shou rious reaction to these vac	r these hours please contact your f ids write to the vaccination team if icies lical history or your consent	amily doctor.





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 Tdap (Target 95%)



OTECT HEALTH

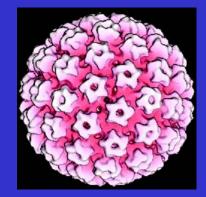
MenC uptake 87.9% CHO5 93.2%



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





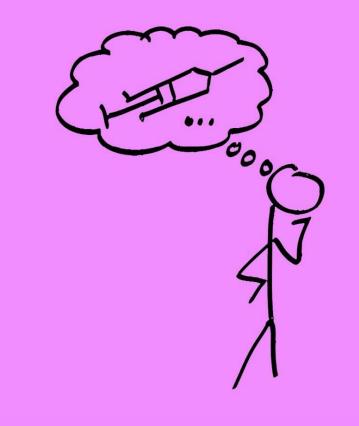
HPV vaccine uptake 2010/2011 - 2014/2015 Routine programme First years





Highest uptake achieved for 3 dose schedule in 2014/15 Excellent cohort retention >95% girls who started dose 1 completed dose 3





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 conditionsDec 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**".





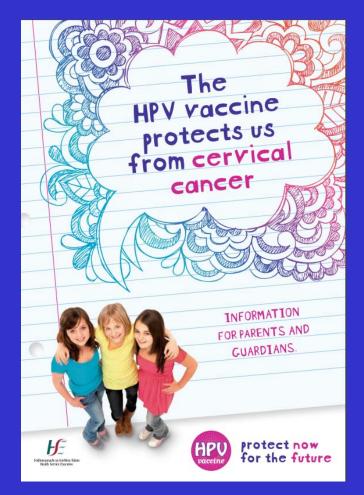
HPV vaccine safety May 2016

- 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 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

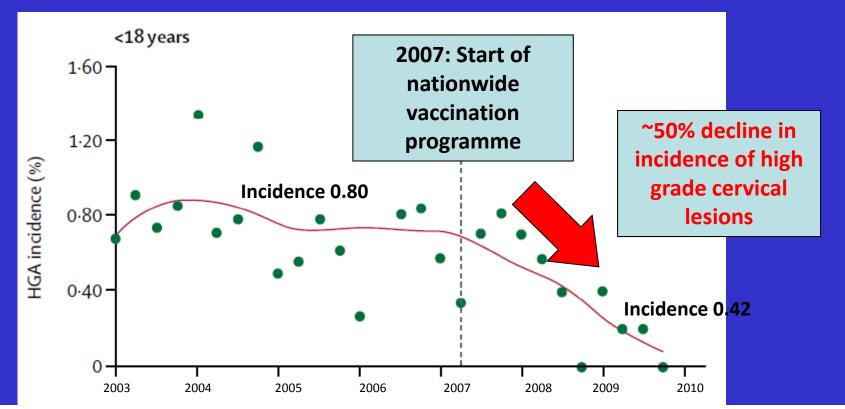


Figure 2: Incidence of high-grade cervical abnormalities, by age group

ECT A

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

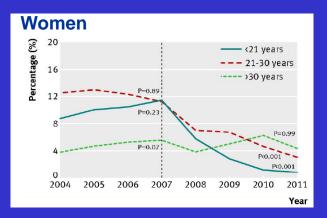
Brotherton et al Lancet 2011; 377: 2085–92

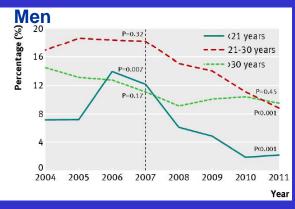
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HPV vaccine effectiveness - Australia Genital warts

- 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







Ali H et al BMJ 2013;346:f2032 doi: 10.1136/bmj.f2032 (Published 19 April 2013)



HPV vaccine information

2

HPV Vaccines and Cervical Cancer

Gardasil has been licensed

7ealand

worldwide since 2006. Gardasil

Furopean countries, the United

States Canada Australia and New

is currently used in over 25

doses of Gardasil have been

received the full vaccine course

as part of the HSE school HPV

vaccination programme.

Are HPV vaccines safe?

All vaccines must go through

Once in use, vaccine safety is

Data is also collected on health

conditions that happen after

are licensed.

extensive safety testing before they

continually monitored to identify

side effects caused by the vaccine

vaccination but are not caused by it.

the Centers for Disease Control and

Prevention in the US and the World

The European Medicines Agency,

Health Organization continue to

say HPV vaccines are safe with no

known long term side effects.

What are the side effects?

About 1 girl in 10 will get pain

injection site and/or headache.

pain in the vaccinated arm and

About 1 girl in 1000 to 1 girl in

Severe allergic reactions with

10,000 will get an itchy rash or

difficulty breathing are very rare

Occasionally girls faint after getting

an injection. The girls are advised

(about 1 in 1 million patients).

About 1 girl in 100 will get nausea.

swelling and redness at the

The known side-effects are:

HPV Vaccine Key Facts

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 By May 2016, over 220 million a HPV infection in their lifetime usually in their late teens and

distributed worldwide, either as part of national immunisation Most HPV infections clear naturally programmes or by private doctors but some caused by high risk HPV In Ireland more than 660,000 doses types can progress to cervical of Gardasil have been distributed and more than 220.000 girls have

 Two high risk HPV types (16 and 18) cause over 70% of cervical cancers.

Cervical cancer

early 20s.

cancer

- Ireland has one of the highest
- rates of cervical cancer in Western Furone 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.
 - to sit down for 15 minutes after the vaccination. This helps prevent fainting.

mild fever.

hives.

Published by National Immunisation Office August 2016

There is no scientific evidence of any long term side effects of HPV vaccines.

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

he HSE strongly recommend IPV vaccination to prevent

www.immunisation.ie

vaccine uptake. GPs and practice nurses provide a significant role in the promotion of all vaccine: so please help to inform parents about the safety and effectiveness of HPV vaccine.

HPV is responsible for

cancers

more than 90% anal cancers

- almost 70% vaginal and vulvar

HPV vaccine is recommended by the World Health Organizatior

WHO), the International

ederation of Obstetrician

nd Gynaecologists (FIGO)

for Clinical Oncology to reduce the burden of cervical cancer in wome

Human papillomavirus (HPV) Other cancers

 Human Papillomavirus (HPV) infection is the most common sexually transmitted disease worldwide

 Spread by direct (usually sexual) - more than 60% of penile cancers contact with an infected person. - over 70% oropharyngeal cancers. About 80% of all women will have a HPV infection in their lifetime

 Male incidence of oropharyngeal cancer will overtake cervical cancer usually in their late teens and early incidence by 2020.

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.

Cervical cancer

20s

- 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

or radiotherapy) for invasive cervical cancer

with high grade cervical intraepithelial neoplasia (CIN)

- to HPV types 16 and 18

- · 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.
- premalignant genital lesions and cervical cancer causally related
- is licensed for use in females

• two dose schedule at 0 and 6 months for girls less than 15 years at first dose 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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- over 90 women die from (surgery, chemotherapy and/
- over 6,500 women are diagnosed

HPV Vaccine

- HPV2 vaccine (Cervarix) is licensed to prevent

- from 9 years of age





and require hospital treatment



More information



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



