The National Immunisation Schedule Update and Current issues

Dr Brenda Corcoran National Immunisation Office





Objectives

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





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	





Pneumococcal polysaccharide vaccine PPV23

23 serotypes

Only for those age 2 and older (poor antibody response if under 2 years of age). Recommended for

- aged 65 years and over
- aged over 2 years and less than 65 in at risk group:
 - asplenia or splenic dysfunction (including splenectomy, sickle cell disease and coeliac disease)
 - cochlear implant
 - children under 5 years of age with a history of IPD
 - chronic heart, lung, liver, renal disease or nephrotic syndrome
 - diabetes mellitus
 - immunosuppressed by disease or treatment
 - CSF leaks either congenital, complicating skull fracture or neurosurgery
 - intracranial shunt
 - post haematopoietic stem cell transplant / solid organ transplant





Revaccination

Severe local reactions especially if given within 5 years of previous injection.

Aged 65 years and older

A **once only booster** vaccination 5 years later if given a dose at less than 65 years of age.

Those aged age 65 or older who have received one dose of PPV do not require any further dose regardless of immune status.

Less than 65 years of age

One booster vaccination 5 years after the first vaccination for those whose antibody levels are likely to decline rapidly e.g. asplenia, hyposplenism, immunosuppression including HIV infection, chronic renal disease, nephrotic syndrome or renal transplant.





If PPV23 is given during chemotherapy or radiotherapy a further dose vaccine is recommended 3 months after treatment.

When is a 3rd dose of PPV23 required?

Those whose antibodies are likely to decline rapidly should receive 2 doses of PPV23 while aged less than 65.

They will need a 3rd dose of PPV23 when they turn 65 at least five years after their 2nd dose.

Depending on age and risk factors a person may require 1, 2 or 3 doses PPV.





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*)

NEW
Childhood
Immunisation
Schedule 2008
Information Pack

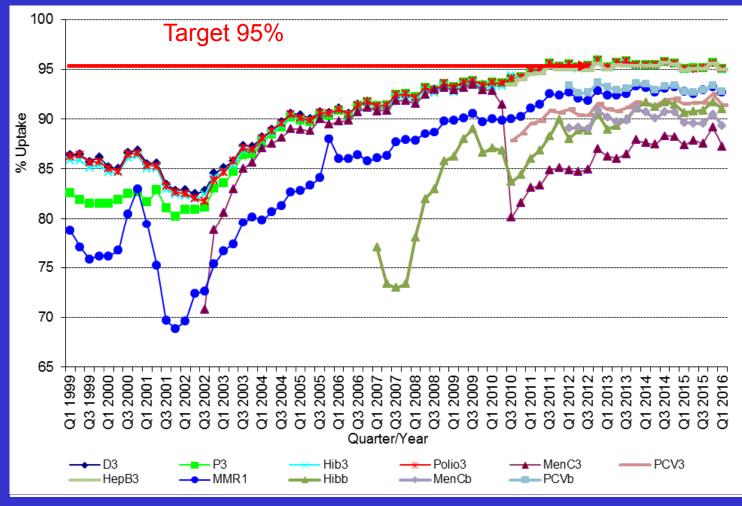
12 months MMR + PCV 13 months Men C + Hib

* if born before July 1st 2015





Vaccine uptake rate at 24 months 1999-2016

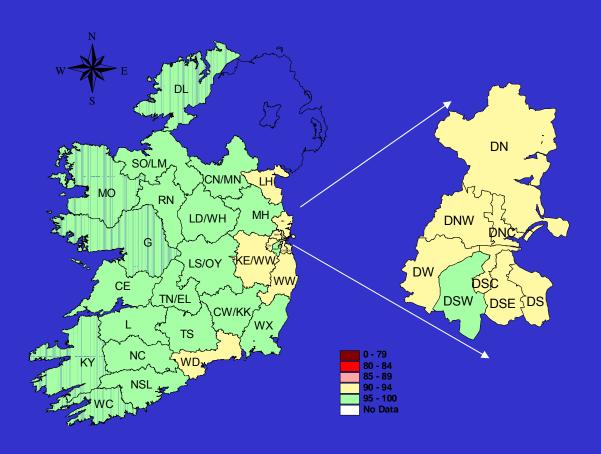








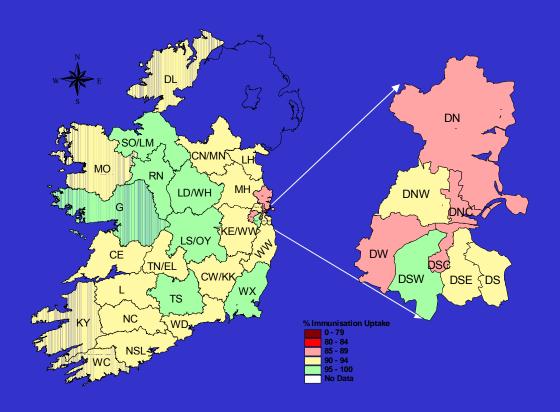
Quarter 1 2016 D3 immunisation uptake rates (%) by LHO, in those 24 months of age in Ireland and Dublin (source HPSC)







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



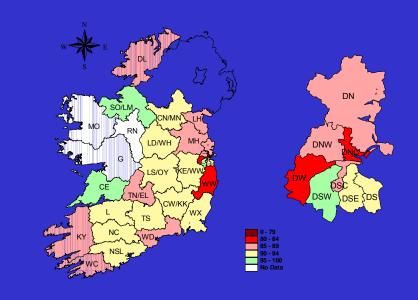




Decline in vaccine uptakes

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



can my child get after being vaccinated and what should I do? Please ask your pharmacist for a sugar-free mixture suitable for your child's age. Using paracetamol or ibuprofen over a lo may be harmful. ember, if your child is very unwell after getting a vaccine, they may e sick for some other reason. If you are worried about your child, plear ontact your GP, practice nurse or public health nurse for further advice REMEMBER to bring your child's vaccine passport to each GP visit so that your child's vaccines are recorded and you have this information when they are older.







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



www.immunisation.ie





Primary school immunisation schedule 2016/2017

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

Tdap/IPV low dose diphtheria

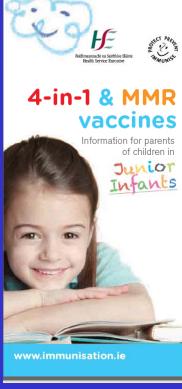
Tetanus

low dose pertussis

Polio

(IPV Boostrix)





MMR Measles, mumps and rubella





Tdap/IPV adverse events

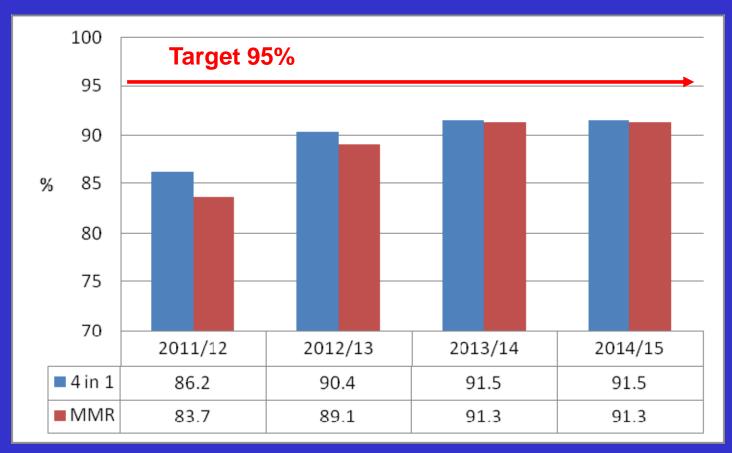
- More reactogenic
 - hot, swollen, red and tender arms from the shoulder to elbow
 - large, localised swelling (diameter > 50 mm) occurring around the injection site
 - Begin within 48 hours of vaccination
 - Resolve spontaneously
- Antibiotic treatment or anti-inflammatory not indicated
- Not usually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

4 in 1 and MMR Booster School Vaccination Programme for Children in Junior Infants			
Name: Date: Time of vaccination:			
Your child was given the following vaccines today 4 in 1 MMR			
Common reactions expected after these vaccines may include mild fever soreness, swelling and redness where the injection was given. Sometimes this swelling can be from the shoulder to the elbow. This usually occurs within 2 days of the vaccination and gets better over 4 – 5 days. Antibiotics are not needed to treat this local reaction.			
After MMR vaccine • some children may get "mini measles" with a rash and fever 6 to 10 days after the injection • on rare occasions, children may get "mini-mumps" with swelling in the jaw in the third week after vaccination These are not contagious.			
You can give your child paracetamol or ibuprofen to relieve aches and pains or to lower the fever. If you are concerned about your child the school vaccination team can be contacted during office hours from Monday to Friday at			
If you require medical advice after these hours please contact your family doctor.			
For more information see			





Primary school immunisation uptake 2011/12 - 2014/15







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









Second level school immunisation uptake Tdap







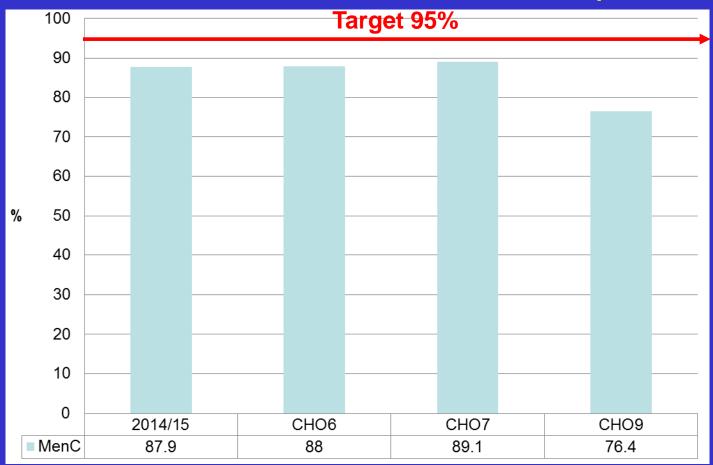
Adolescent MenC booster vaccine

- 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



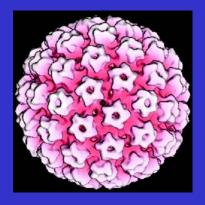




HPV vaccination programme

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 - 2015/2016 Routine programme First years

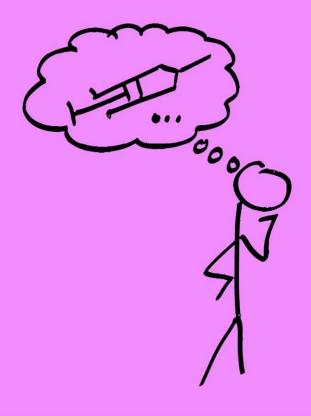


5000 more girls not vaccinated in 2015/16

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 September 2016

- 1072 reports to HPRA
 - consistent with the expected pattern of adverse effects for the vaccines
 - syncope (faints), gastrointestinal symptoms, malaise, headache
 - 14 reports of chronic fatigue syndrome
 - 10 reports of post viral fatigue
 - 3 reports of an auto immune condition
- 660,000 doses administered
- over 220,000 girls fully vaccinated





Chronic fatigue syndrome (CFS)

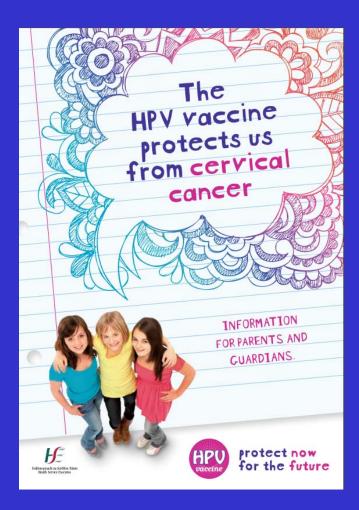
- known for over 200 years
- is 3-4 times more common in females and younger adolescents
- 10,000 cases in Ireland
- estimated prevalence rate in Ireland 0.2-0.4%
- 220,000 girls vaccinated
 - => at least 440-880 cases expected

Reported numbers much lower than expected





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





Gardasil Patient Information Leaflet

4. Possible side effects

3

Like all vaccines and medicines, Gardasil can cause side effects, although not everybody gets them.

The following side effects can be seen after the use of Gardasil:

Very commonly (more than 1 in 10 patients), side effects found at the injection site include: pain, swelling and redness. Headache was also seen.

Commonly (more than 1 in 100 patients), side effects found at the injection site include: bruising, itching, pain in extremity. Fever and nausea have also been reported.

Rarely (less than 1 in 1000 patients): hives (urticaria).

Very rarely (less than 1 in 10,000 patients), difficulty breathing (bronchospasm) has been reported.

When Gardasil was given with a combined diphtheria, tetanus, pertussis [acellular, component] and poliomyelitis [inactivated] booster vaccine during the same visit, there was more headache and iniection-site swelline.

Side effects that have been reported during marketed use include:

Fainting, sometimes accompanied by shaking or stiffening, has been reported. Although fainting episodes are uncommon, patients should be observed for 15 minutes after they receive HPV vaccine.

Allergic reactions that may include difficulty breathing, wheezing (bronchospasm), hives and rash have been reported. Some of these reactions have been severe.

As with other vaccines, side effects that have been reported during general use include: swollen glands (neck, armpit, or groin); muscle weakness, abnormal sensations, tingling in the arms, legs and upper body, or confusion (Guillain-Barré Syndrome, Acute disseminated encephalomyelitis), dizziness, vomiting, joint pain, aching muscles, unusual tiredness or weakness, chills, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection at the injection site.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In Ireland

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6764971; Fax: +353 1 6764971; By reporting side effects you can help provide more information on the safety of this medicine.

Side effects seen after use => Scientific evidence of causation

Side effects reported during general use => No scientific evidence of causation





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

Cancer Prevention

Cervical, vaginal, and vulvar cancer in women

Anal cancer in men and women

Likely penile cancer in men

Likely oropharyngeal cancer in women and men

Potential Risks

Chance of fainting

Pain, redness, or swelling in the arm where the shot was given

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





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

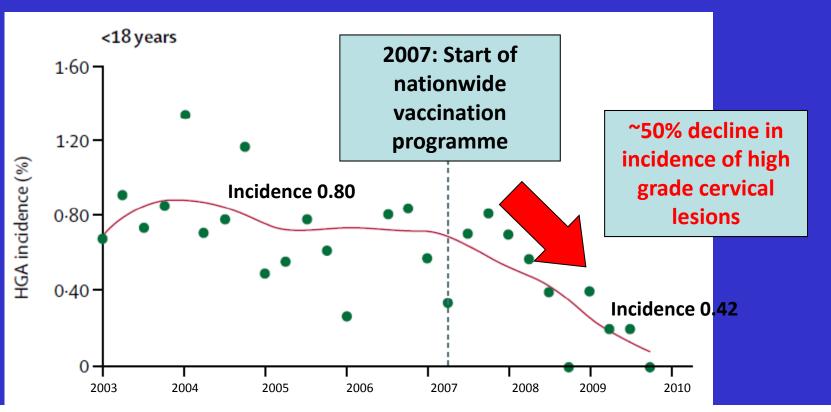


Figure 2: Incidence of high-grade cervical abnormalities, by age group

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.



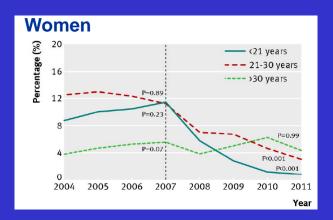
By 2013 reductions also seen in 20-24 year age group

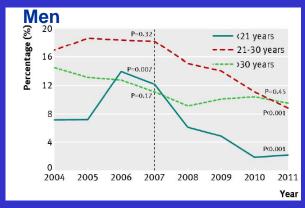


HPV vaccine effectiveness - Australia Genital warts

- 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 update

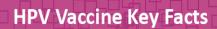
- Liaison with the Irish Cancer Society, HSE Communications and National Cancer Screening coordinating proactive social media, local and national media response. Two public meetings held.
- Regular meetings held with the Department of Education and school management bodies.
- Flyer sent to school principals, management bodies and National Parents Councils on HPV and Cervical Cancer.
- Flyer sent to GPs on HPV vaccine key facts.
- Meeting held with Marie Keating Foundation.
- Short information video developed for website www.hpv.ie and www.immunisation.ie
- Articles written for Forum and other heath publications.
- HSE social media campaign underway.
- Collaboration with ICGP in production of elearning module on HPV vaccine.
- Attendance at World Health Organization meeting with Danish Health authorities and international experts to discuss drop in HPV vaccine uptake (October 2016) and offer of WHO mission to review immunisation activities in Ireland.





HPV vaccine information

HPV Vaccines and Cervical Cancer





Human papillomavirus (HPV)

- Human Papillomavirus (HPV) infection is spread by direct (usually sexual) contact with an infected
- 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
- Each year in Ireland
- over 90 women die from cervical
- 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 hody
- The HPV vaccine used in the HSF school HPV vaccination programme is HPV4 (Gardasil)
- Gardasil provides protection
- two high risk HPV types (HPV 16 and 18) that cause 70% of cancers and precancers
- two HPV types that cause 90%

 Gardasil has been licensed worldwide since 2006. Gardasil is currently used in over 25 Furopean countries, the United States Canada Australia and New 7ealand

- 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 HSF 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 pain 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
- 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

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

- · 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 HSF leaflet

- · includes all the known scientifically proven side effects from HPV
- · 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

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
- 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
- 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 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 are diagnosed with high grade cervical intraepithelial neoplasia (CIN) and require hospital treatment

· HPV is responsible for - more than 90% anal cancers

incidence by 2020.

- almost 70% vaginal and vulvar cancers

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.

- more than 60% of penile cancers
- over 70% oropharyngeal cancers. · Male incidence of oropharyngeal cancer will overtake cervical cancer
- ederation of Obstetrician ind Gynaecologists (FIGO) for Clinical Oncology to reduce the burden of cervical cancer in wome

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 to HPV types 16 and 18
- is licensed for use in females from 9 years of age

- 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 HSF 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
- 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.

- 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).





More information

National Immunisation News

The newsletter of the HSE National Immunisation C

July 2016

Changes to the Primary Childhood Immunisation Programme The National Immunisation Advisory Committee (NIAC) has recommended the addition of meningococcal B (MenB) and rotavirus vaccines to the primary childhood programme.

The new schedule outlined below will be introduced for all babies born on or after October 1st 2016. CURRENT SCHEDULE Babies born on or after

CORRENT SCHEDOLE			1st October 2016		
Age (months)	Vaccine	No of injections	Vaccine	No o	
2	6 in 1 +PCV	2	6 in 1 + PCV+ MenB		
4	6 in 1 + MenC	2	6 in 1 + MenB + Rot	B#E Roy	
6	6 in 1 + PCV	2	6 in 1 + PCV + Men		
12	MMR + PCV	2	MMR + MenB		
13	MenC + Hib	2	Hib/MenC + PCV	OI.	

Contents

- · Changes to the PCI Programme
- · Measles outbreak, Ireland 2016
- BCG vaccine shortage
- · Primary School Vaccination Programme 2016/2017
- · Tdap vaccination in pregnancy
- HPV Vaccine Safety
- Fatal diphtheria case in unvaccinated 3-year-old child in Belgium 2016
- · Students going to college
- Common Queries



6 in 1

PCV MenB Rotavirus MenC MMR Hib/MenC

Measles or

An outbreak Ireland. Seve the areas mo affected are East, South. and Midwest Most of these cases are under 30 yea of age. Most of those who have be had been in not had the ! vaccine. See

MainBody,15



No of injections



HSE National Immunisation Office













- > Check vaccine records
- » Make an appointment
- > Order information materials > Contact the local office
- > Ask a guestion
- > Order HSE vaccines
- > Your Child's Immunisation A Guide for Parents
- Translation of Immunisation Material
- > Current Vaccination Schedule
- Previous Vaccination Schedule

- > Immunisation Guidelines for Ireland
- > Vaccination in General Practice
- > Vaccine Preparation
- > What is in Vaccines? > Catchup Vaccines



