Introduction to Childhood Immunisation 2016

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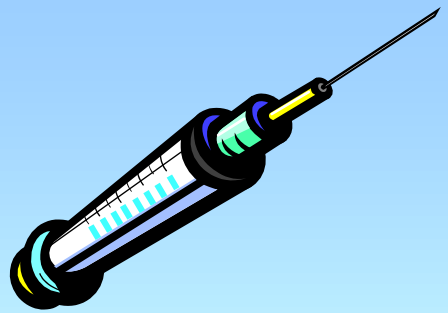
www.immandvacc.co.uk

Aim

- To provide participants with sufficient knowledge and confidence to promote and offer immunisations and to raise awareness of the issues surrounding immunisation uptake.

Public health



- The two public health interventions with the greatest impact are clean water and vaccination
- Vaccination is the most effective medical intervention in the world

History of Vaccination

- **Historical recordings of attempts of vaccination from 7th century but not really recognised or successful until:**
- 1796**: Edward Jenner demonstrated that inoculation with cowpox virus produced protection from infection with smallpox.**
- **(Hence "Vaccination": taken from *vacca* – the latin word for cow)**

- 1860s-1890s**: Louis Pasteur produced vaccines against chickenpox, cholera, diphtheria, anthrax and rabies**
- Early 20th Century**: toxoid vaccines against diphtheria and tetanus produced following discovery of effective inactivation with chemicals**
- Post World War 2**: successful live viral vaccines developed using cell culture techniques**
- Present and future**: new technologies constantly developing: recombinant protein vaccines, DNA and conjugate vaccines**

Development of a vaccination programme

- The aim of a vaccination programme is to control a disease successfully
- Before designing a vaccine programme, important to establish:
- Is there a need for the programme?
- Is a suitable vaccine available that is safe and effective?

Aim of an immunisation programme

- Need to decide overall aim:
- **To protect those at highest risk**
- **(**selective immunisation strategy**)**
  - Flu
  - Pneumococcal
  - Shingles
  - BCG
  - Hep B (Hep A)

- **To eradicate, eliminate or contain disease**
- **(**mass immunisation strategy**)**
  - The routine national programme

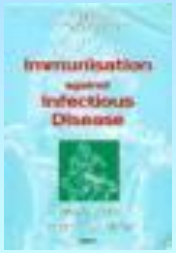
Vaccination Coverage
COVER (Cover of Vaccination Evaluated Rapidly)

- It is important to know what proportion of any targeted population has received each vaccine
- Since 1988 computerised child health registers across the country have held vaccination details for all children resident in the area
- Every 3 months, information collected by CfI from each child health computer as to number of children who have completed scheduled vaccine courses at 1,2 & 5y of age
- This information used to evaluate and improve immunisation coverage by regular feedback to local areas

Vaccine Policy

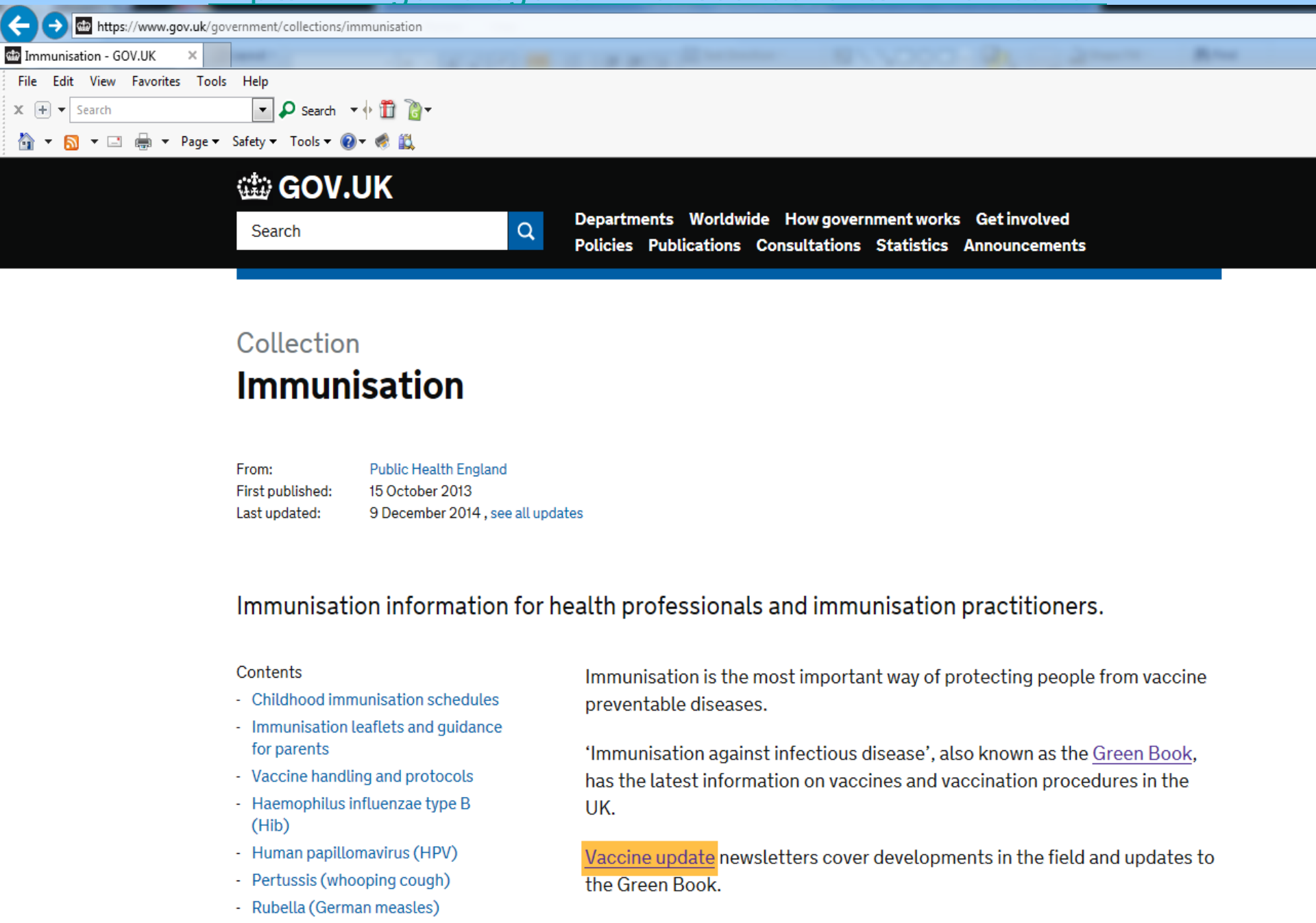
- **JCVI** – Joint Committee on Vaccination and Immunisation: Make recommendations for vaccine policy
- **DH** – Department of Health, Public Health England: Vaccine policy decisions, purchase of vaccines from pharmaceutical companies,
- **PHE** - commissioning of vaccination services from providers
- **MHRA** – Medicines and Healthcare Regulatory Authority: License vaccines

UK Vaccine Policy published in:



- Immunisation against Infectious Disease
- (the ‘Green Book’)
- Currently available on PHE website
- Chapters can be individually downloaded from the website and printed off - updated chapters will replace previous versions as they become available
- Chief Medical Officer Updates, Letters, Publications and Urgent Communications. Cascaded via PHE to Primary Care
- These detail any changes to vaccine policy and recommendations
- **Green Book information supersedes any info on the SPC**

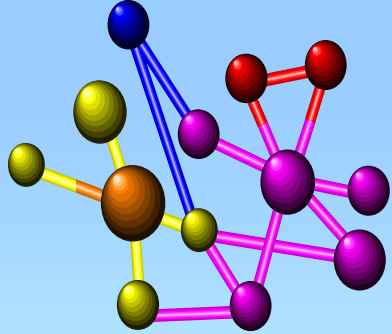
http://www.gov.uk/government/collections/immunisation



Immune response to vaccination

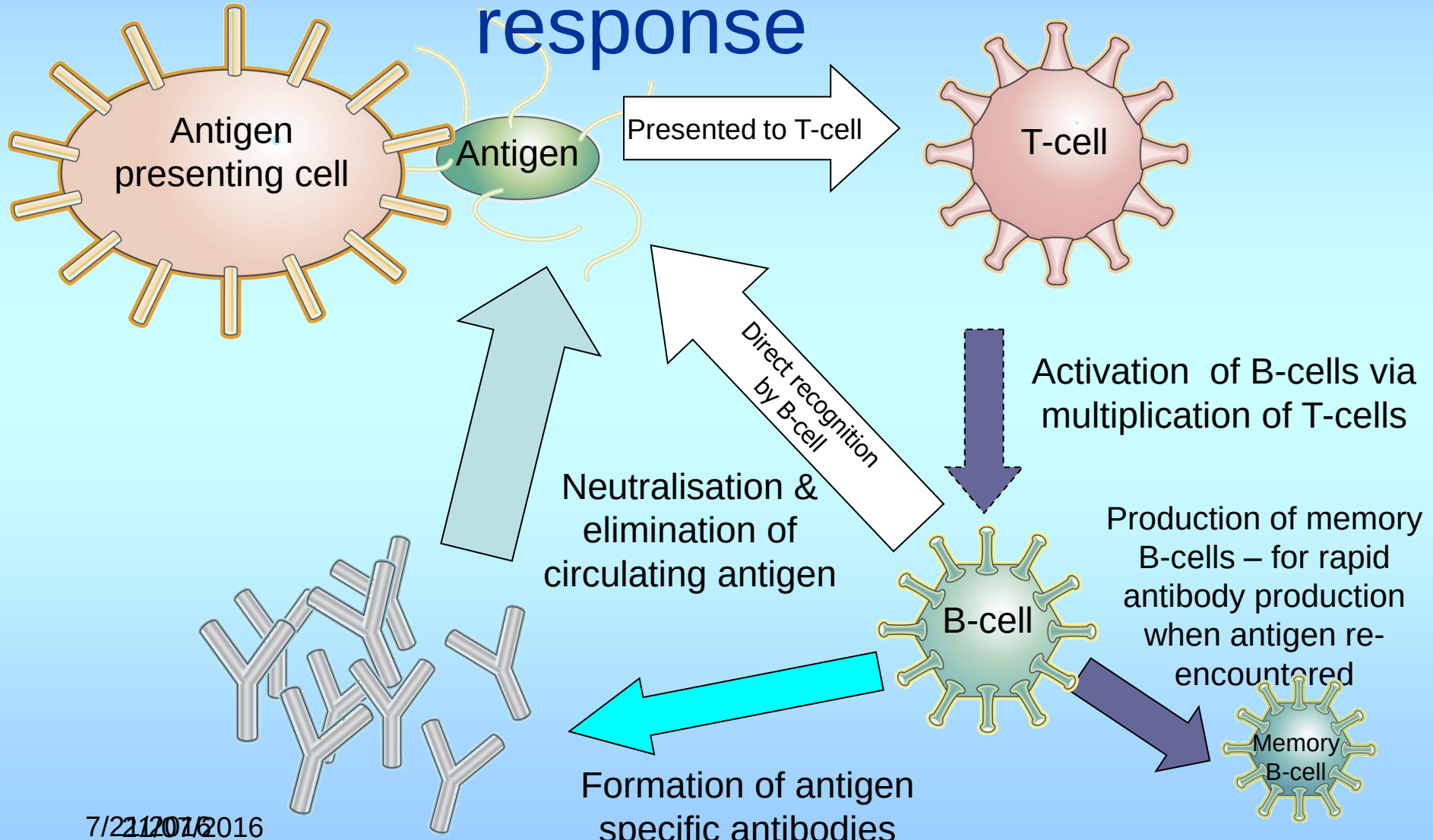
- Aim of an ideal vaccine:
- To produce the same immune protection which usually follows natural infection but without causing disease
- To generate long-lasting immunity*
- To interrupt spread of infection

Immunology

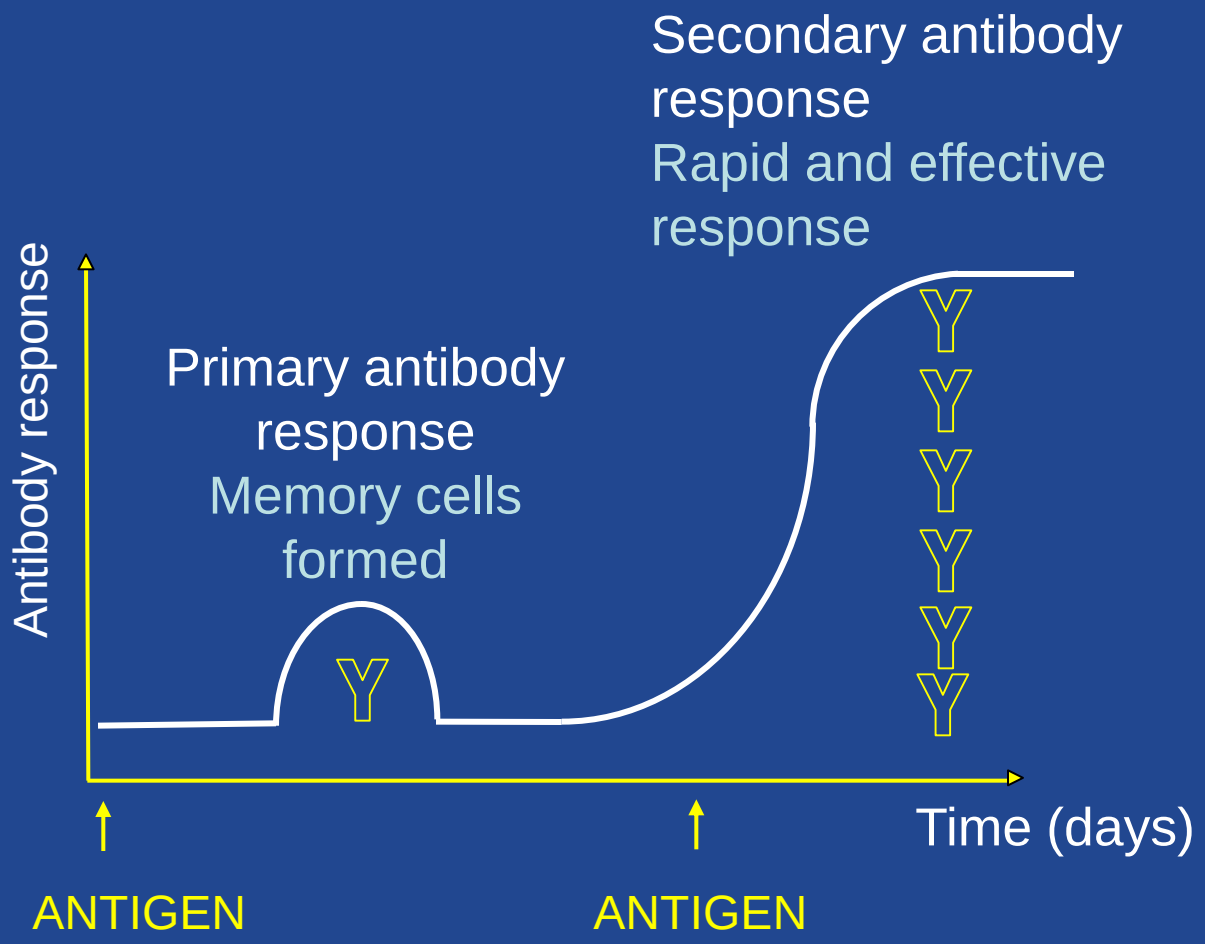


- **A basic understanding of immunology helps explain**
  - How vaccine failure occurs
  - Adverse events
  - Intervals between vaccines
  - Why vaccines can’t overload the immune system
  - Timing of adverse events

Humoral immunity B cell response



Adaptive Immunity - Summary



Gaps needed between each dose of vaccine

- **To allow each immune response to develop – eg primary immunisation (1 month)**
  - This allows the next response to be a true secondary response – ie faster and bigger and with higher affinity IgG
- **To avoid immune interference**
  - If another live vaccine is given while the immune system is making a primary immune response, the activation of the innate immune system may neutralise the second live vaccine so that it does not work. Hence we wait 4 weeks to allow the immune system to recover **with some of the live vaccines**.
  - Human normal immunoglobulin contains antibodies to many infections including measles. These antibodies will neutralise any live vaccine. Hence we wait 3 months for the antibody level to fall

Minimum Gap

- If a subsequent dose in the primary course is given early, the minimum gap is 21 days to make that dose count.
- If the dose is given earlier than 21 days the dose should be disregarded and repeated 1 month later. (2months with PCV)
- The 21 day rule is for ***exceptional circumstances.***

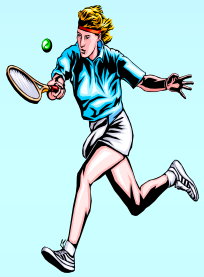
(Vaccine Incident Guidance, HPA, 2012)

Herd immunity

- **Herd immunity only applies to diseases which are passed from person to person**
- **For each disease there is a certain level of immunity in the population which protects the whole population because the disease stops spreading in the community**
  - –Herd immunity provides indirect protection of unvaccinated as well as vaccinated individuals. This may be the most important aspect of how they work. For example, PCV given to children, protects the older vulnerable population.

Type of vaccines

- Passive immunisation
- **antitoxins and immunoglobulins which provide immediate source of antibody**



- Active Immunisation
- Live vaccines
  - attenuated (weakened) organism which replicates in the host
- Killed/inactivated/subunit vaccines
  - killed micro-organisms, inactivated toxins or other subunits

Passive immunity

- Immunoglobulins (IG)are concentrated antibody preparations (given IM or IV) which provide immediate short-term protection against disease
- Given to individuals who are at high risk of experiencing severe disease or of developing serious complications from the disease
- They provide immediate protection but this is short-lasting (only a few weeks or months)
- IG available for measles, chickenpox, tetanus

Live vaccines

- attenuated strains which replicate in host
- **attenuation means the virus or bacterium has been weakened to reduce virulence so it cannot cause disease in healthy people**

- act like natural infection
- **live vaccines are the closest to actual infection and therefore elicit good, strong, long-lasting immune responses**

Live vaccines

- Advantages
- **Single dose often sufficient to induce long-lasting immunity**
- **Strong immune response evoked**
- **Local and systemic immunity produced**

- Disadvantages
- **Potential to revert to virulence**
- **Contraindicated in immunosuppressed patients**
- **Interference by viruses or vaccines and passive antibody**
- **Poor stability**

Examples of Live vaccines

- MMR
- BCG
- Yellow Fever
- Intranasal flu vaccine (Fluenz®)
- Varicella (Varilix®)
- Rotavirus (Rotarix®)
- Shingles (Zostavax®)

Inactivated /Killed vaccines

- Either:
- suspensions of whole intact killed organisms
  - eg. whole cell pertussis, rabies, HepA
- Or:
- acellular and sub-unit vaccines
  - contain one or a few components of organism important in protection
  - eg. acellular pertussis vaccine contains between 2-5 components of the whole cell pertussis bacteria
  - e.g. diphtheria toxoid
  - e.g.Hib polysaccharide

Inactivated vaccines

- <u>Advantages</u>
- Stable
- Constituents clearly defined
- Unable to cause the infection

- <u>Disadvantages</u>
- Need several doses
- Local reactions common
- Adjuvant needed
  - keeps vaccine at injection site
- Shorter lasting immunity

Examples of inactivated vaccines

- Pediacel
- Infanrix-IPV
- Repevax
- Boostrix - IPV
- Hib/MenC
- Prevenar
- Revaxis
- Flu
- Pneumococcal

In Summary

- **Killed or inactivated** vaccines are completely and absolutely **DEAD!**
- They cannot cause the disease they are designed to prevent

- **Live** vaccine antigens have been weakened, so *can* come back to life if a person's immune system is not working very well, due to illness or drug therapy

Changes to guidance on use of Live Vaccines

- Changed following the recent introduction into the routine schedule of two live vaccines not given by a parenteral route (live attenuated nasal influenza vaccine and oral rotavirus vaccine)
- Based upon the available evidence and on the different immune mechanisms used by the various vaccines, the JCVI agreed that the guidance to either administer the vaccines on the same day or at the four week interval period was not generalizable to all live vaccines.
- They concluded that intervals between vaccines should be based only upon specific evidence for any interference of those vaccines and that the current immunisation guidance should be updated to reflect this change.

Vaccine combinations	Recommendations
Yellow Fever and MMR	A four week minimum interval period should be observed between the administration of these two vaccines. Yellow Fever and MMR should **not** be administered on the same day.
Varicella (and zoster) vaccine and MMR	If these vaccines are not administered on the same day, then a four week minimum interval should be observed between vaccines.
Tuberculin skin testing (Mantoux) and MMR	If a tuberculin skin test has already been initiated, then MMR should be delayed until the skin test has been read unless protection against measles is required urgently. If a child has had a recent MMR, and requires a tuberculin test, then a four week interval should be observed.
All currently used live vaccines (BCG, rotavirus, live attenuated influenza vaccine (LAIV), oral typhoid vaccine, yellow fever, varicella, zoster and MMR) and tuberculin (Mantoux) skin testing.	Apart from those combinations listed above, these live vaccines can be administered at any time before or after each other. This includes tuberculin (mantoux) skin testing.

Mucosal Immune System

- Protects mucous membrane from colonisation and invasion
- Prevents uptake of degraded antigens.
- Prevents development of harmful immune responses.

Mucosal vaccines

- Prevent antigen attaching to mucosa
- Prevent pathogens from penetrating or multiplying in mucosa
- Block toxins from binding to epithelial cells

Vaccines stimulate IgA responses in mucosa (local, NOT systemic)

Generic names/antigen content

- Infanrix – IPV Hib, Pediacel (5 in 1)
- ➢ *Tetanus, Diphtheria, acellular pertussis, Inactivated polio, Haemophilus Influenza B*
- Infanrix –IPV, Repevax (4 in 1)
- ➢ *Tetanus, Diphtheria, acellular pertussis, Inactivated polio*
- Menitorix
- ➢ *Meningitis C, Haemophilus Influenza B*
- Prevenar 13
- ➢ *Pneumococcal conjugate vaccine*
- Menjugate, Neisvac, Meningitec
- ➢ *Meningitis C*
- Priorix
- ➢ *MMR*

Generic names cont..

- Boostrix – IPV
- ➢ *Acellular Pertussis, Tetanus, Diphtheria, Polio*
- Gardasil
- ➢ *Human Papilloma Virus*
- Revaxis
- ➢ *Tetanus, Diphtheria, Inactivated polio*

Combination Vaccines

- Many vaccines are combined to make it easier to give several vaccines at one time
- Combination vaccines reduce both number of clinic visits and number of injections needed
- Before combination vaccines are licensed, studies are carried out to ensure that:
- - the immune response to any of the combined antigens is just as good as the response to the individual vaccines
- - the rates of adverse reactions are the same as they would be if the vaccines were administered separately

Stages of Vaccine Trials

- **Vaccine research and development is a carefully controlled and very lengthy process**
- **Vaccines are rigorously tested to ensure quality, safety and efficacy**
- **The development process starts with extensive laboratory testing**
- **Before trials begins in humans, regulatory bodies must approve laboratory results and give ethical approval**
- **Vaccines then pass through 4 phases of vaccine evaluation in humans**

Clinical Trials

- Phase 1 – Safety.

Trials done on small numbers (10-12) volunteers – monitored for short term side effects

- Phase 2 – Safety and Immune response.

Vaccine tested on several hundred people from the age group for which the vaccine is intended. Carried out in several different centres.

- Phase 3 – Safety, immune response and efficacy.

Uses thousands of volunteers of the relevant age group. International trials are also needed, especially if the vaccine is going to be used outside of the country of manufacture. Information gathered is then examined to ensure safety standards are met. The MHRA will issue a licence before distribution.

Phase 4 – Post licensing evaluation

On going surveillance through the Black Triangle scheme.

Reporting adverse events

- The black triangle symbol indicates that the product is new. Any reaction that may be linked to the vaccine should be reported via the *yellow card system.*
- The yellow card is used to report any concerns regarding medications, vaccines and medical devices.
- For non black triangle products, only serious adverse events need to be reported

- Fluenz Tetra
- Fluarix Tetra
- Optaflu

www.mhra.gov.uk

Premature infants

- Premature infants are vaccinated according to chronological age.
- Immune responses may be sub optimal. Additional doses of vaccine may need to be considered.

Can vaccines overload the immune system?

- Babies are naturally exposed to more immune challenges from the environment than from all the childhood immunisations added together
- When a baby gets a cold the immune system has to respond to 5-10 antigens; one bacterial strain in the gut may contain 15-50 antigens
- In theory, a baby's immune system could respond to 10,000 vaccines at one time

Do antigens overload the immune system?

- D T Wp OPV

  10 10 3500 40 = 3560

D /T/aP/Hib/IPV PCV MenC Rotarix Men B

12 13 2 1 4

= 32

There is no limit on the number of vaccines you can give at one visit!

General Immunisation principles

- No need to restart courses.
- Only 1 dose of Hib, necessary if children present over the age of 1 year, up to 10 years of age. (This does not apply to Hib if given as a course as part of a 5 in 1 vaccine to complete a primary)
- 1 dose of Men C required over 1 year of age up to 10 years.
- 1 dose men ACWY required over 10 years up to 25 years.
- 1 dose of PCV between 1 & 2 years of age. No pneumococcal vaccine required over age of 2 years unless child has underlying medical condition.
- Premature babies begin vaccination programme according to chronological age.
- Different antigens – no gap required. Same antigens, 1 month gap required.
- **The Green Book advice supersedes the advice in the SPC**

Vaccine ordering

Storage, distribution and disposal of vaccines
June 2013

Ordering centrally purchased vaccines in England

In England, vaccines for the routine immunisation programmes are ordered and delivered from a specialist pharmaceutical distribution company via the Department of Health's ImmForm website www.immform.dh.gov.uk (see Chapter 11 and ImmForm helpsheet 13 immunisation.dh.gov.uk/immform-helpsheets).

To register for an ImmForm account, please register online at www.immform.dh.gov.uk/registration.

You will need to provide:

- NHS organisation code (e.g. GP practice code)
- the distributor account number(s)
- name, email and phone details (of the key individual responsible for placing vaccine orders)

Diphtheria

- Infectious respiratory disease caused by toxin producing bacteria that infect the throat
- Patients can be infectious for 4 weeks
- Early signs: Mild fever, swollen neck glands, anorexia, malaise, cough
- 2-3 days: membrane of dead cells forms in throat tonsils, larynx or nose
- May narrow or occlude the airway leading to respiratory distress

Photo courtesy of CDC

Diphtheria (Strangling Angel)

- This is Mary Elizabeth Klauder's funeral picture. She died of diphtheria in 1887. It was a common custom for these pictures were taken as a remembrance for parents. A common custom for an all too common event. Massachusetts death records kept from 1860 to 1897 showed that diphtheria caused three to ten percent of all the deaths each year -- an enormous, today almost unimaginable toll.

Severe Symptoms of Diphtheria

- Toxin can travel through bloodstream causing extensive organ damage, neurological and heart complications.
- Death occurs in 5-10% of cases
- Milder infection can still occur in people who are vaccinated or were vaccinated a long time ago.

Photo courtesy of CDC

Current issues for Diphtheria

- **Currently individuals living in the UK are unlikely to come into contact with toxigenic strains of *C. diphtheriae* as a result of successful childhood immunisation programmes**
- **It is estimated approx 50% of U.K adults over 30 years are susceptible**
- **Last death in UK from Diphtheria 2011 (*C.ulcerans*) Prior to that 2008 in a child. Child was European immigrant – unimmunised. Family member had visited Africa 1 month before child became ill.**
- **14 notifications of Diphtheria in 2014**

Tetanus

- Caused by bacterium *Clostridium tetani*
- Non-Communicable
- Bacteria form spores that can survive in the environment for years
- Tetanus may occur if a wound or cut is infected by soil or manure
- Incubation period 4-21 days
- Affects people of all ages
- People who recover from tetanus do not have natural immunity

Transmission
Tetanus

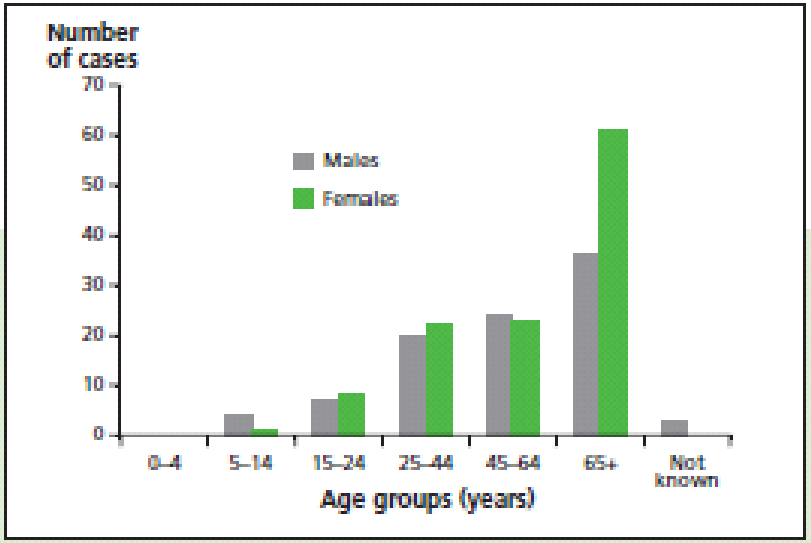
- Reservoir
  - Ubiquitous
  - Soil, dust, human and animal faeces
- Transmission
  - Puncture wound, burn or scratch and injecting drug use
  - Incubation period 4 to 21 days

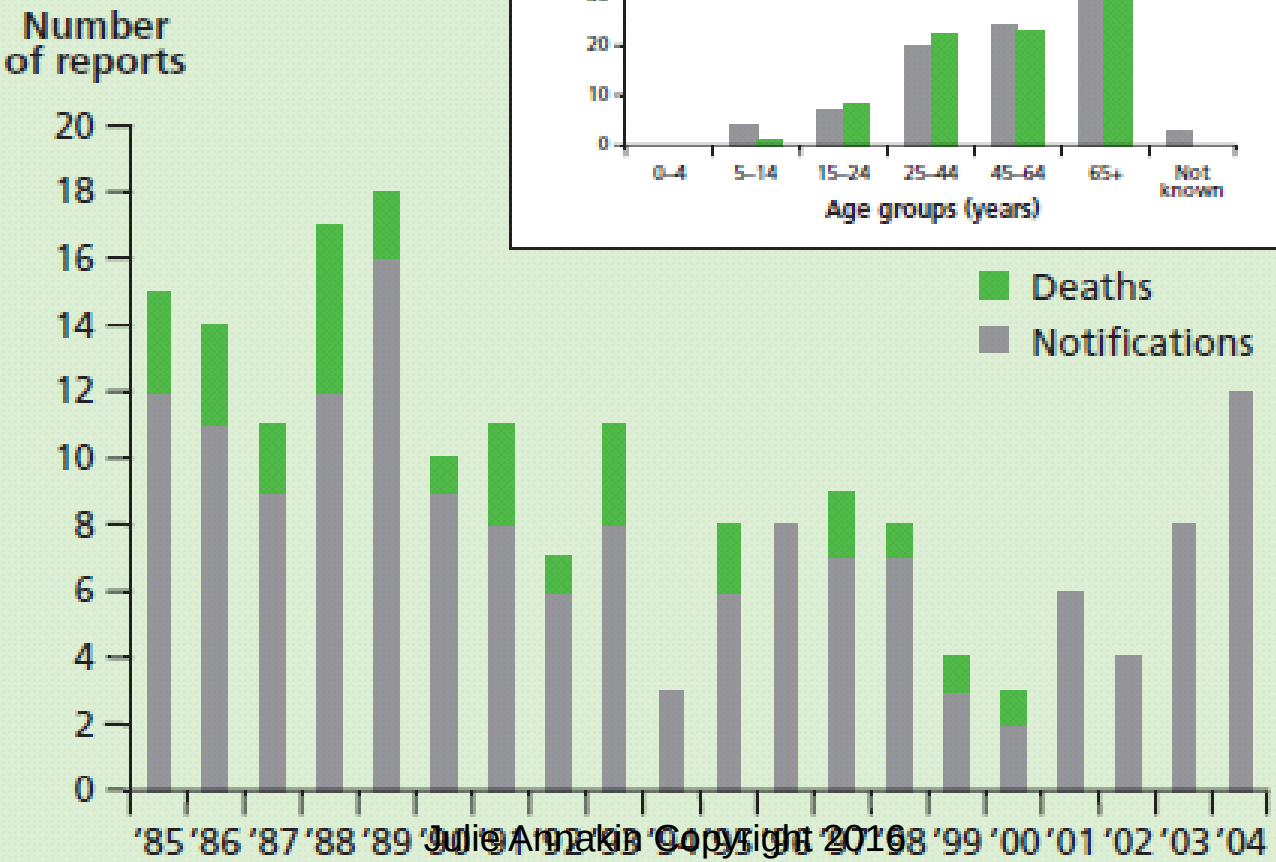
Symptoms of Tetanus (*Generalised)*

- **Initially: muscle stiffness of the jaw ("Lockjaw") 50% cases**
- ***Followed by*: neck stiffness, difficulty swallowing, stiffness of stomach muscles, muscle spasms, sweating and fever**
- **Complications Include**;
  - Fractures
  - Hypertension
  - Laryngospasm
  - Pulmonary embolism
  - Aspiration
  - Death

http://www.youtube.com/watch?v=RG9kR3rYZzA

Tetanus





IMMUNISATION STATUS	CLEAN WOUND	TETANUS-PRONE WOUND	
	Vaccine	Vaccine	Human tetanus immunoglobulin
Fully immunised, i.e. has received a total of five doses of vaccine at appropriate intervals	None required	None required	Only if high risk (see p 379)
Primary immunisation complete, boosters incomplete but up to date	None required (unless next dose due soon and convenient to give now)	None required (unless next dose due soon and convenient to give now)	Only if high risk (see p 379)
Primary immunisation incomplete or boosters not up to date	A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity)	A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity)	Yes: one dose of human tetanus immunoglobulin in a different site
Not immunised or immunisation status not known or uncertain	An immediate dose of vaccine followed, if records confirm the need, by completion of a full five-dose course to ensure future immunity	An immediate dose of vaccine followed, if records confirm the need, by completion of a full five-dose course to ensure future immunity	Yes: one dose of human tetanus immunoglobulin in a different site

Management of patients with tetanus-prone wounds

Tetanus-prone wounds include:

- wounds or burns that require surgical intervention that is delayed for more than six hours
- wounds or burns that show a significant degree of devitalised tissue or a puncture-type injury, particularly where there has been contact with soil or manure
- wounds containing foreign bodies
- compound fractures
- wounds or burns in patients who have systemic sepsis.

Thorough cleaning of wounds is essential. If the wound, burn or injury fulfils the above criteria and is considered to be high risk, human tetanus immunoglobulin should be given for immediate protection, irrespective of the tetanus immunisation history of the patient. This is a precautionary recommendation since there is insufficient current evidence to support other alternatives. High risk is regarded as heavy contamination with material likely to contain tetanus spores and/or extensive devitalised tissue.

Current issues for tetanus

- Jan – Dec 2014 - 7 cases 15-87 years. 1 death, female 80+ years. 2 cases born after 1961.
- Cases born prior to 1961 had no or incomplete vaccination status. Both cases born after 1961 had complete age appropriate status. These cases had mild (grade 1) symptoms.
- All cases with H/O injury. 4 sustained in home or garden, plus street, stable, woodland.
- 5 doses of tetanus at appropriate intervals
- Early treatment with tetanus immunoglobulin for heavily contaminated wounds
- Early recognition of potential tetanus wounds
- Continued vigilance for early signs and symptoms of tetanus in IDUs.

Pertussis (Whooping cough)

- Disease of respiratory tract caused by Bordetella Pertussis bacterium
- Initially: appears to have a common cold, with runny nose, watery eyes, sneezing, fever and a mild cough
- Followed by: gradually worsening cough, develops to paroxysms of coughing until whoop
- Most dangerous in infants and young children
- **Can last 2-3 months**

Photo courtesy of WHO

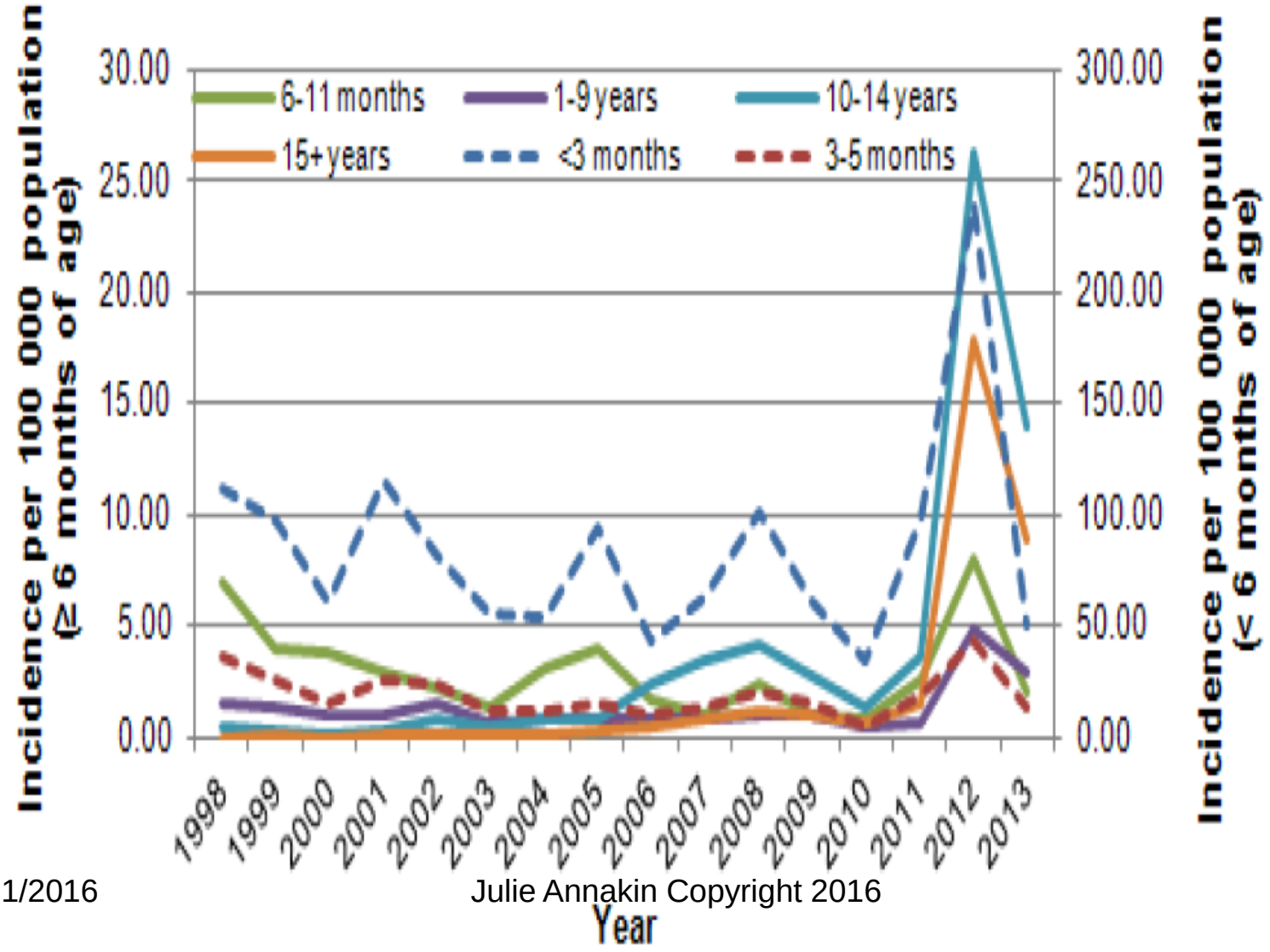
Complications of Pertussis

- Respiratory –the majority of cases involve some degree of collapsed lung and /or pneumonia
- Neurological – lack of oxygen leading to altered consciousness, convulsions, permanent brain damage, death
- Severe weight loss and dehydration due to vomiting
- Sudden death- babies may stop breathing, apnoeic attacks

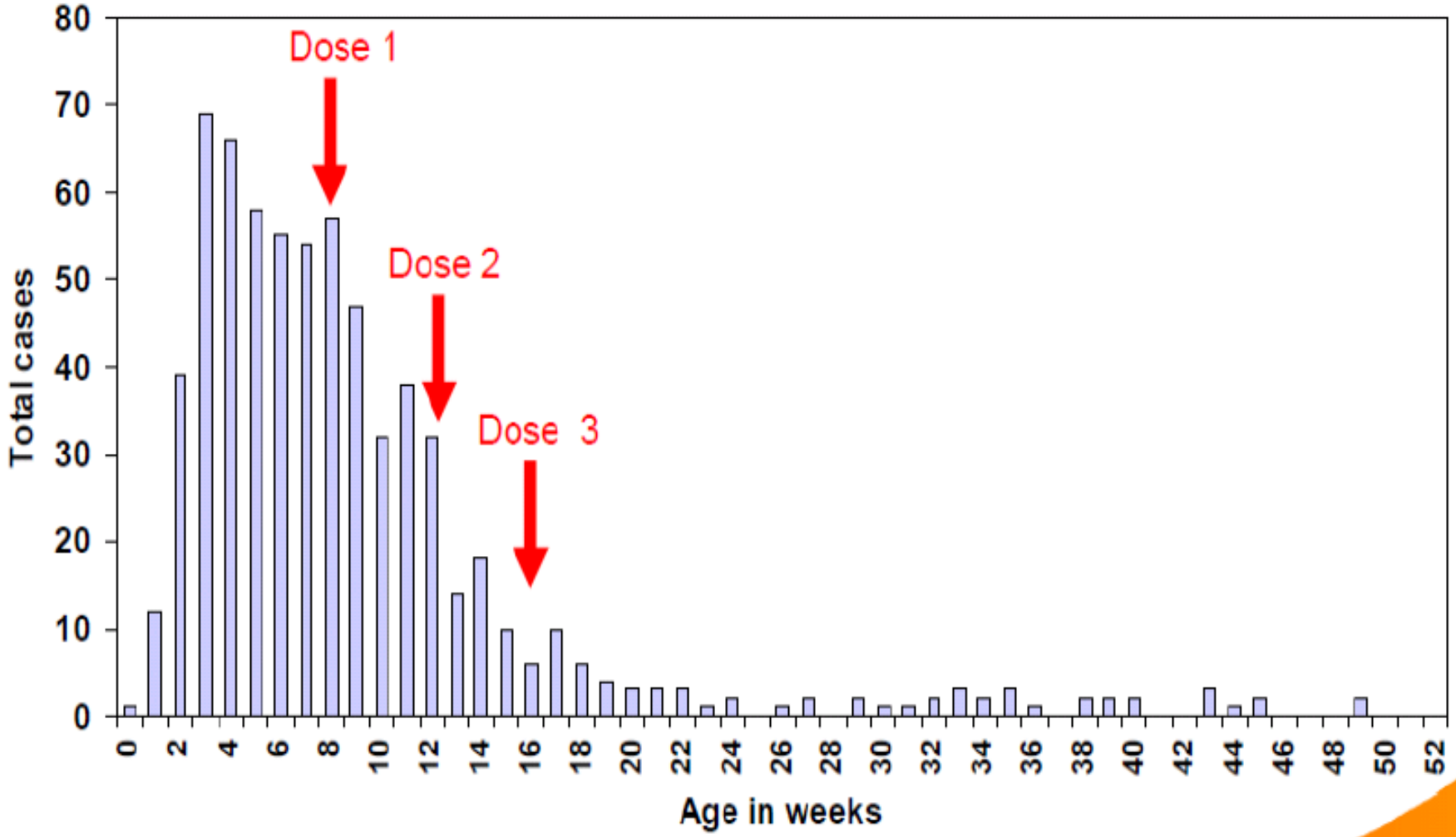
Pertussis in England and Wales

- Before the introduction of pertussis vaccine in the 1950's, the average annual number of notifications in England exceeded 120,000
- In 1975 public anxiety about the safety of the vaccine led to a decrease in vaccine uptake rates to about 30%.
- Major epidemics followed with over 100,000 notified cases in E&W in 1977/79 and in1981/83.
- Since the mid 1990s coverage has consistently been over 90% by second birthday with less than 6000 notifications per year.

Figure 2. Incidence of laboratory-confirmed pertussis cases by age group in England: 1998-2013



Confirmed cases in infants under 1 year, by week of age at onset* (2011-end August 2012), England and Wales



* Where provided; specimen date used when onset not available

Pregnant Women Whooping Cough vaccination programme

- Boostrix –IPV should be offered to all pregnant women between (16) 20 and 38 weeks of pregnancy and to all postpartum women who have never been previously vaccinated against pertussis, up to when their child receives their first vaccinations. Pregnant women beyond 38 weeks should be offered vaccination up to onset of labour.
- http://www.youtube.com/watch?v=S3oZrMGDMMw

Why has vaccination advice changed recently?

- A recent study showed that reasonable levels of pertussis antibodies were demonstrated in neonates through transplacental transfer from mothers vaccinated earlier in pregnancy.
- It is now recommended that women should be offered pertussis-containing vaccine between gestational weeks 16 and 32 to maximise the likelihood that the baby will be protected from birth
- Offering the vaccine from week 16 of pregnancy gives pregnant women greater opportunity to take up the offer of vaccination and will offer some protection to infants born prematurely.
- Vaccination is probably best offered on or after the foetal anomaly scan at around 18- 20 weeks. Offering at this time will also avoid any associations with unrelated adverse events identified at the routine anomaly antenatal scan.
- Women may still be immunised after week 32 of pregnancy until delivery but this may not offer as high a level of passive protection to the baby.

Epidemiology cont:

- There have been 2 deaths in infants with pertussis in 2016.
- Sixteen deaths have been reported in young babies with confirmed pertussis who were born after the introduction of the vaccination in pregnancy programme on 1 October 2012, to June 2016.
- Fourteen of these 16 babies under 10 weeks of age, were born to mothers who had not been vaccinated against pertussis.
- 2 infants were born to mothers vaccinated late in pregnancy.

Pertussis cont..

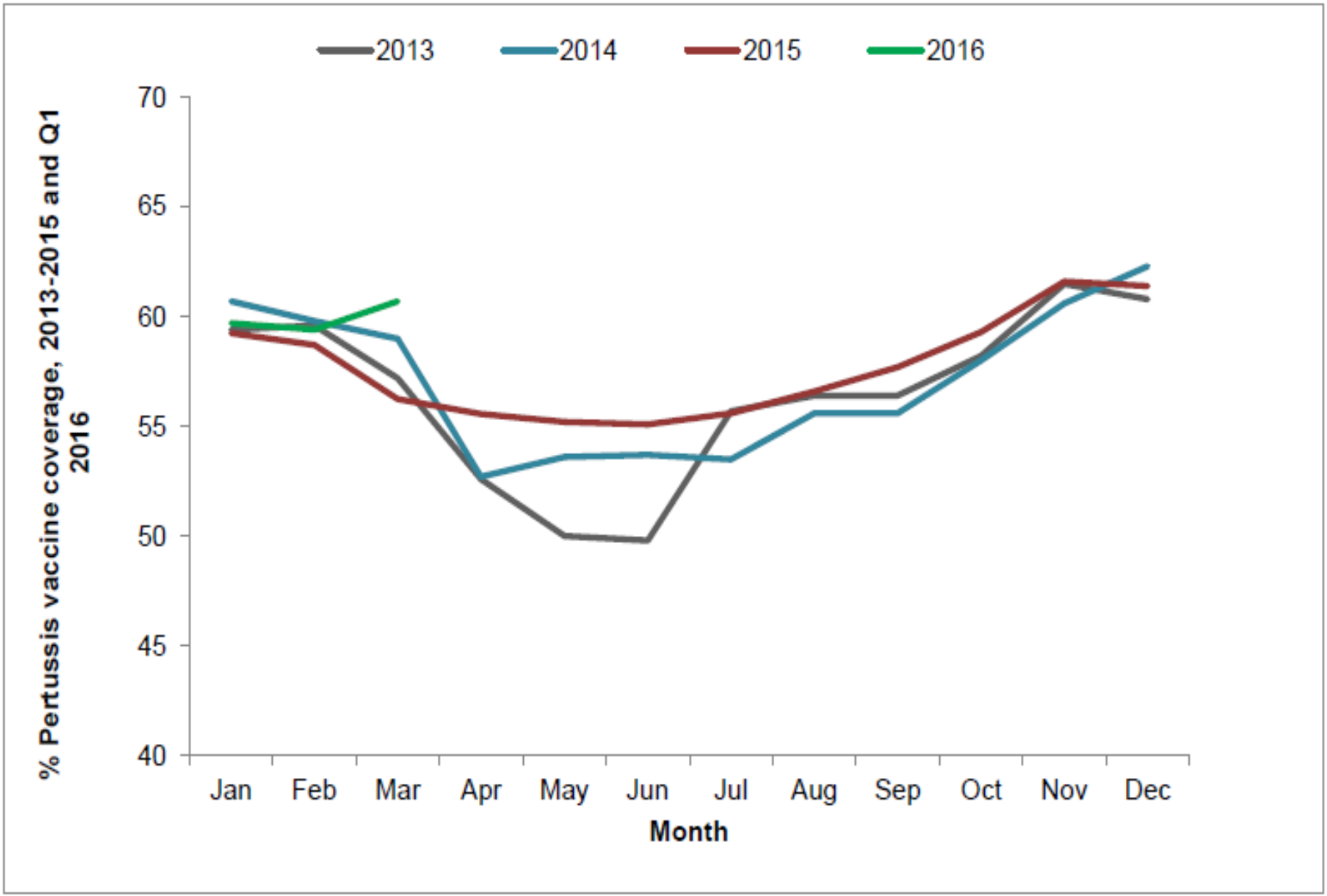
- Effectiveness of the vaccine at preventing disease under the age of 3 months now estimated as 91%
- Pertussis activity in infants under 1 year very low, case numbers now at pre 2012 levels
- Current uptake for Pertussis vaccination in pregnancy 60% nationally **
- Lab confirmed cases over 1 year of age still higher than pre 2012
- The programme will continue for another 5 years as Pertussis is circulating at high levels in the population.

Which vaccine?

- Boostrix-IPV is vaccine of choice (This vaccine has a higher pertussis antigen content than the other boosters)
- If Boostrix-IPV not available, offer Repevax
- If neither of the above available, offer Infanrix-IPV to avoid delay (This vaccine has high content Diphtheria)

Note: Menitorix and Boosterix-IPV have very similar packaging!

Figure 1. Monthly pertussis vaccination coverage (%) in pregnant women: England, 2013-2015 and Q1 2016.



How often should the women be offered the vaccine?

- It is important for all women to be vaccinated with each subsequent pregnancy while the temporary programme is in place. This will maximise antibody production and transfer to protect each neonate.

Can a pregnant woman be vaccinated after 38 weeks of pregnancy?

- Yes. Vaccination can be offered up to the point of delivery. Although this is unlikely to provide passive immunity, it will protect the mother in the first weeks of the infant's life.
- If not given in pregnancy, the mother could also receive the vaccine in the first two months following birth, until the infant receives the first dose of pertussis containing vaccine.

If a woman has received a tetanus containing vaccine recently, should she still have the Boostrix - IPV vaccine?

- Yes. The vaccine can be offered from 16 weeks as long as there is a gap of 4 weeks between the two vaccines. Evidence shows that is safe to do; the woman may experience some increased localised reaction.

Can a woman still have the vaccine if she has confirmed or suspected whooping cough during the pregnancy?

- Yes, to confer maximum protection.

If a pregnant women is travelling to a Pertussis endemic country before she is 16 weeks pregnant, can she have the vaccine early?

- Yes. However, she should have a repeat dose of the vaccine at 16 – 38 weeks to ensure maximum protection. A minimal interval of 4 weeks should be observed between the vaccines.

Pregnant Women Whooping Cough vaccination programme

- Vaccination should be offered with each subsequent pregnancy
- Vaccine can be ordered through the Immform website as with the childhood vaccinations.
- Vaccine can be given at the same time as influenza vaccination.
- Practices will be paid £9.80 per vaccine admin fee
- Major issues with coding of EDD's and data collection for DH and payments

- http://www.youtube.com/watch?v=S3oZrMGDMMw

Pertussis

- Recent outbreaks in several countries including Australia, Canada, New Zealand. “Cocooning” not recommended by Health bodies as no evidence to support this strategy.

Haemophilus influenzae type b (Hib) disease

- Caused by infection with *Haemophilus influenzae* bacteria
- 99% of typeable strains in pre-vaccine era were type b
- Transmission occurs from coughing, sneezing, close contact with infected person.
- Healthy individuals can carry Hib bacteria in their nose and throat without symptoms
- Incubation period less than 10 days

Hib disease

- Caused by haemophilius influenza B bacteria droplet infection
- Most common presentation of invasive Hib is meningitis, frequently accompanied by bacteraemia (60%)
- 15% of cases present with epiglottitis
- Septicaemia without any other concomitant infection, occurs in 10% of cases
- Remainder made up of cases of septic arthritis, osteomyelitis, cellulitis, pneumonia, and pericarditis

Complications of Hib meningitis

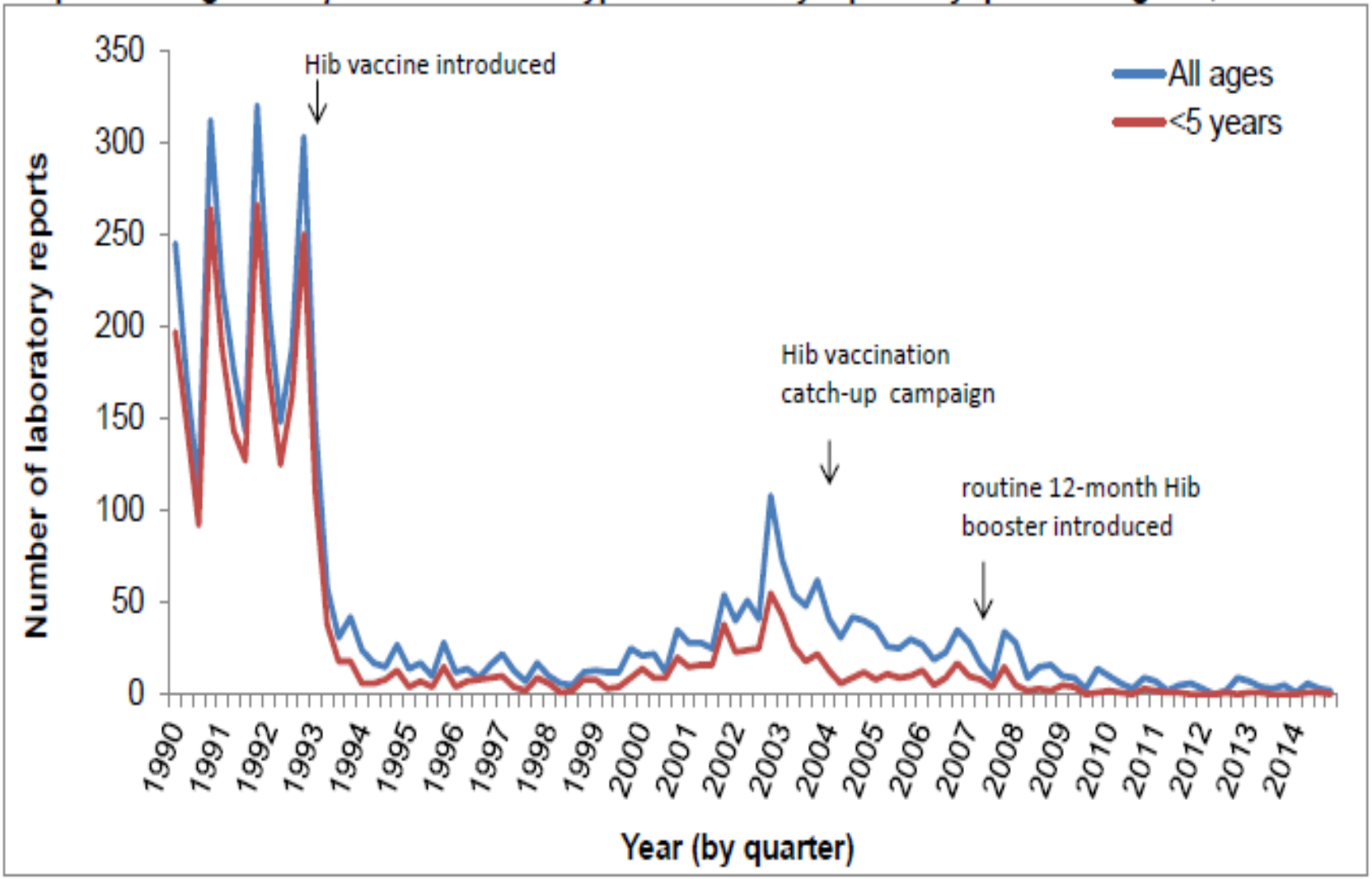
- Deafness
- Convulsions
- Intellectual Impairment
- Case fatality rate 2-5% in spite of effective antimicrobial therapy

Courtesy of Children's Immunization Project, St. Paul, Minnesota

Hib disease in England and Wales

- Before 1992:
- 1 child in 600 developed some form of Hib disease by 5th birthday
- Hib Meningitis caused 30 deaths each year
- Approximately 80 children a year were left with deafness or permanent brain damage

Graph showing *Haemophilus influenzae* type b laboratory reports by quarter: England, 1990-2014*



*Provisional data

Source: Routine laboratory data combined with reference laboratory data

Current Issues for Hib

- 3 million cases worldwide 700,000 deaths annually
- 90% reduction in invasive Hib in UK since introduction of vaccine programme.
- During 2015, there were one case of Hib among children who were eligible for immunisation; a three year old who had been fully immunised presented with Hib meningitis and made a partial recovery. This was the first case of invasive Hib disease in a fully immunised child since 2012.
- In 2014, there were three cases of Hib among children who were eligible for immunisation; none of whom had been immunised. One child presented with pneumonia, one with bacteraemic-tonsillitis, and one with bacteraemia; all subsequently recovered.
- There were no deaths attributed to invasive Hib disease in 2015 or 2014.

➢ Hib is sometimes recommended by Specialists for COPD patients with repeated hospital admissions due to exacerbations. Can be given on a PSD.

Polio Virus

- Virus enters via the mouth
- Replicates in pharynx and GI tract
- Invades local lymph tissue
- Enters blood stream and may infect cells of central nervous system causing aseptic meningitis
- More rarely replicates in and destroys the motor neurones which activate the muscles

Paralytic Polio

- **Less than 1% of all polio infections result in flaccid paralysis**
- **Paralysis develops 1-10 days after prodromal illness and progress for 2-3 days**
- **The use of one or both arms or legs may be lost and breathing may not be possible without help of a respirator.**
- **The degree of recovery varies from person to person.**

Photo courtesy of WHO

Polio

- **WHO declared Public Health Emergency of International Concern May 2014. Extension of temporary IHR as of 31st May 2016 for another 3 months:**

- **Countries exporting Polio – Pakistan, Afghanistan**
- Recent exportations of polio from Pakistan to Afghanistan

Polio

- **Travellers who have been in Pakistan or Afghanistan for one month or more** and do not produce a valid International Certificate of Vaccination or Prophylaxis IVCP, indicating that they have received a dose of polio vaccine between 4 weeks and 12 months of the date of departure from Pakistan, may be given oral polio vaccination at the airport of departure

Polio

- Children should be in date for the polio vaccination course as recommended in the UK schedule. Adults should have had a booster dose of polio vaccine within the last 10 years. Further boosters before travel are not currently recommended unless the traveller is in one of the groups listed above. Further guidance may follow. *(NaTHNaC)*
- Children should complete their polio-containing vaccines according to the British schedule. This means most will have completed the primary course of 3 doses by the age of 4 months. If a child travelling to Pakistan for more than 1 month has completed the primary course and has had no doses of polio-containing vaccine within 12 months of the intended date of departure from Pakistan, they should receive a booster dose of an age-appropriate polio-containing vaccine before travel and the parents should be issued with a Certificate of Vaccination. (*Travax)*

Circulating Vaccine Derived Polio Virus

- As of 27 November 2015, five countries are affected by outbreaks of circulating vaccine derived polio virus (cVDPV) with cases detected within the preceding six months: Guinea, Laos , Madagascar, Nigeria and Ukraine.
- CVDPV, like Wild Poliovirus (WPV), has the potential to cause paralysis in unvaccinated or partially vaccinated individuals. CVDPVs can arise in populations who are inadequately vaccinated with polio vaccine and where sanitation and personal hygiene is poor.

Vaccination requirements

- ICVP is not required in these countries, however, same rules for vaccination apply as the IHR, and travellers are strongly advised to carry proof of vaccination.

Current issues

- As a result of successful vaccination programmes and surveillance, cases of natural polio no longer occur in the U.K
- Risk of importation from endemic countries considered low, however recent outbreak of paralytic polio in Kenyan refugee camp caused concern as 80 refugees from that camp had already arrived in the North of England and could have been infectious. Potential is still there.
- WHO recently stated that the UK is at intermediate risk of polio (use of IPV instead of OPV)
- Outbreaks in Syria due to breakdown of vaccination programmes. Refugee children under 5 years should be tested.

Meningitis

- 75% 0f all meningitis cases occur in children under the age of 5 years
- Case fatality rate 50% even with treatment
- 12 types of N Meningitidis, 90% of cases caused by A,B,C,W,Y
- Meningitis, Hib and Pneumococcal bacteria directly responsible for as many childhood deaths as HIV/Aids, Malaria and TB together!

Since the introduction of the Men C vaccine in 1999, the incidence of disease has decreased by 94% in immunised population and by 67% in unimmunised populations.

Risk factors

- **Age**
  - - Highest incidence in children under 5 years, peak incidence in those under 1 year of age.
  - - A second peak in incidence is noted in young people aged 15-19 years of age
- **Season**
  - - Seasonal variation, peak levels in winter, declining to low levels by late summer
- **Social**
  - - Living in closed or semi–closed communities
  - e.g. university halls of residence and military barracks
- **Smoking**
  - - **Exposure to tobacco smoke increases the risk**

2014 – Freshers: Why the need to vaccinate?

- Freshers *(temporary catch up for new starters at university setting under 25 years commencing in August 2014)* are also being offered another dose of MenC vaccine because of an increased risk of disease and sub-optimal protection from vaccination under 10 years of age
- There is an increased risk in the first few days and weeks of entering university
- 5.1 cases per 100,000 in the first year of university in comparison to 1.4 cases in the general population

Meningitis epidemiology

(HPR 10:8 26/02/16)

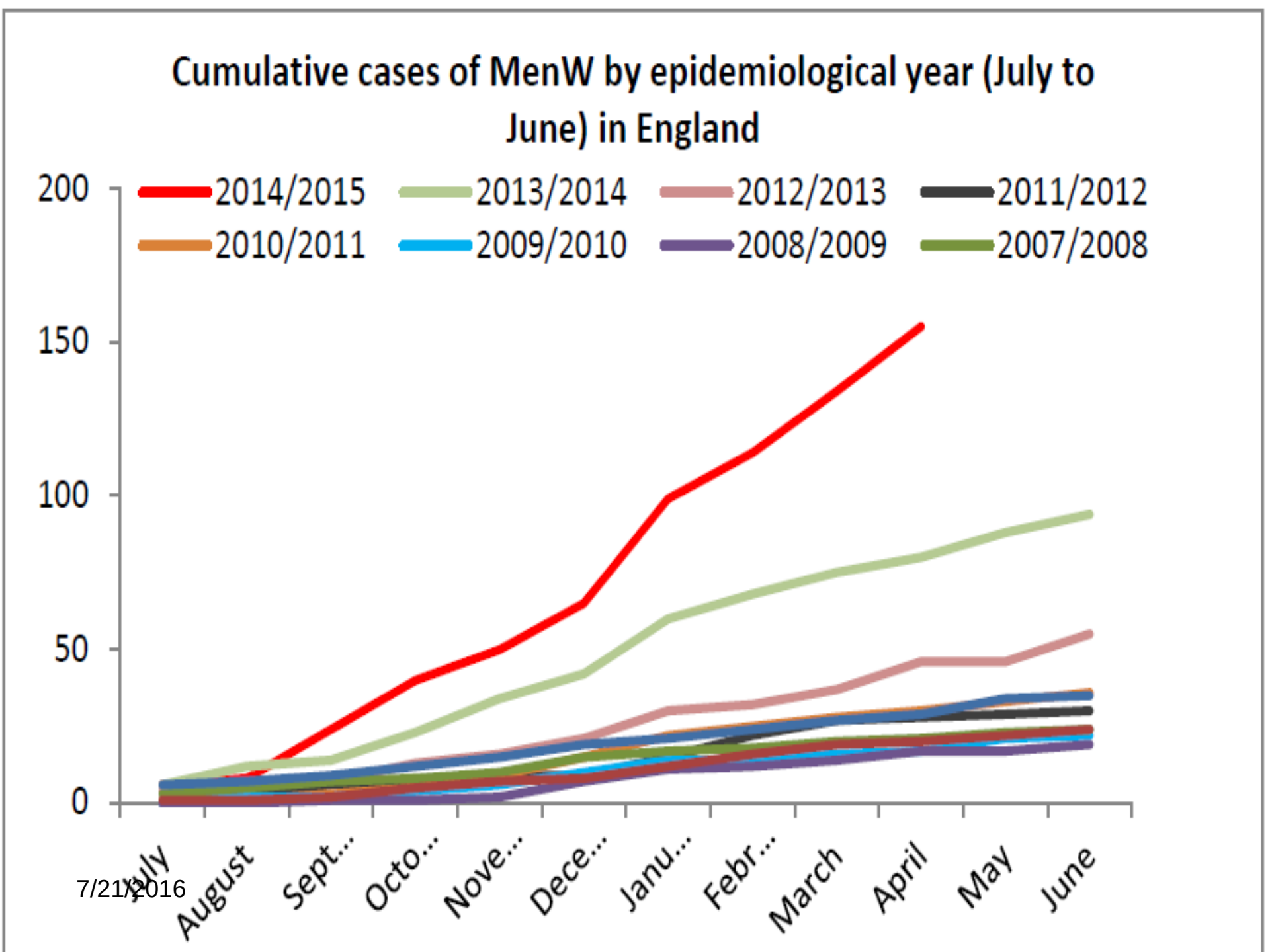
Oct - Dec 2015 reported cases of IMD

- Group B – 57% (134)
- Group Y – 11% (25)
- Group C – 4% (10)
- **Group W -26.6%** Highly aggressive strain, increase likely to continue. St-11 Clonal complex (also associated with previous Men C outbreak) has high case fatality ratio. Latest figures 51% increase on same period 2014/15 (62 cases)

➢ 16% under 5 years

➢ 34% over 65 years

➢ 24% 15-24 years


Cumulative cases of MenW by epidemiological year (July to June) in England
2014/2015
2013/2014
2012/2013
2011/2012
2010/2011
2009/2010
2008/2009
2007/2008
200
150
100
50
0
July
August
Sept...
Octo...
Nove...
Dece...
Janu...
Febr...
March
April
May
June

Background

- The highest carriage rates for meningococcal bacteria are in adolescents and young adults who are believed to drive most transmission of MenW infection amongst them and to other age groups.
- Public Health England (PHE) has advised that this may be the start of a rise in incidence which could continue for several years, as happened with MenC in the mid-1990s, and the situation could get worse if early action is not taken to protect the population by interrupting transmission through immunisation.
- Immunity in the population is low

Background

- JCVI advised at its meeting on 4 February 2015 that a temporary programme to vaccinate all adolescents aged 14-18 years of age with MenACWY conjugate vaccine should be undertaken as soon as practicable, in order to protect them and generate herd protection against MenW for the rest of the population, including infants.

MenACWY implementation in general practice

- The vaccination of current school year 13 aged young people (ie **DOB 01/09/1996 – 31/08/1997**) began in general practice from 1 August 2015, before the start of the 2015/16 academic year (usually early September), and continues through to 31 March 2016.
- **Vaccination is for all young people in the cohort and not limited to those continuing in further education, and these young people should be actively called and recalled on the basis of age.**
- The cohort should have been vaccinated during a period from August 2015 to the 31st March 2016.

2016/17 roll out

- For financial year 2016/17, the MenACWY programme is again targeted at 17/18 years olds (born between 01/09/1997-31/08/1998) who are leaving school in summer 2016 and for freshers (born between 1/4/1991-31/08/1997) who start university/further education in Autumn 2016.
- The new specification also allows for catch-up with MenACWY vaccine for those who were school leaving age in summer 2015 (as above) but did not receive vaccination during 2015/16. These individuals will remain eligible up until the age of 25 years.
- This vaccine should be given regardless of prior MenC status, but vaccination is not required for those who have already received a dose of MenACWY conjugate vaccine after the age of 10 years.

Ongoing catch up

- The General Medical Service (GMS) Statement of Financial Entitlement (SFE) also makes provision for GP practices to offer vaccine opportunistically to children who miss out on the routine school based MenACWY vaccination programme usually given in year 9/10. Any patient born on or after the 1 April 2001, who has missed the school based dose, will remain eligible for this vaccine up to the age of 25 years.

Programme rollout 2016

Yr 9	Yr 10	Yr11	Yr 12	Yr 13
2016 School	2015/16 School	January 2016 school	April 2017 TBC (?primary care)	April 2016 Primary care

Mature students

- All students attending university for the first time should have their vaccination status checked. Those unvaccinated against MenC, irrespective of age, should be offered a single dose of a MenC conjugate containing vaccine (determined by availability) before they enrol or as soon as possible thereafter.

(*GB, Chapt 22 updated 28/07/15*)

Vaccine brand names

- Both Menveo® and Nimenrix® are provided for this programme. A single dose of either vaccine is considered adequate to help provide protection to most adolescents.
- A certain volume of Nimenrix® will be supplied in general export pack rather than a UK pack (foreign language with English inserts).

Age	Quadrivalent vaccine	
	Conjugate MenACWY	Polysaccharide MenACWY (ACWY Vax)
Infants under one year*	Menveo® • First dose of 0.5ml • Second dose of 0.5ml one month after the first dose.	• Not recommended
Children aged one year to four years	Menveo® or Nimenrix® • Single dose of 0.5ml.	• Not recommended
Children aged five years to ten years	Menveo® or Nimenrix® (either preferred to polysaccharide vaccine) • Single dose of 0.5ml.	• Single dose of 0.5ml.
Individuals aged 11 years and older	Menveo® or Nimenrix® (either preferred to polysaccharide vaccine) • Single dose of 0.5ml.	• Single dose of 0.5ml.

* Replace the MenC vaccine with MenACWY conjugate vaccine if the infant requires MenACWY conjugate vaccine at the same time as the routine MenC vaccinations. If the infant has already had two MenC vaccinations then two MenACWY conjugate vaccines should also be given.

Presentation

- Menveo® supplied in a five dose pack as a powder in a vial and a solution in a vial (10 vials per pack).
- The vaccine must be reconstituted by adding the entire contents of the MenCWY solution vial to the vial containing the powder (MenA).
- No needles are supplied with this product. Additional patient information leaflets (PIL) will be supplied with each pack of five vaccines ordered, as there is only one PIL in each pack.

Presentation

- Nimenrix® supplied in a single pack as a powder in a vial (MenACWY) and 0.5ml solvent in a pre-filled syringe.
- Two needles are included in the pack.
- The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe to the vial containing the powder.

Adverse events

- For both Menveo and Nimenrix:
  - Injection site pain, swelling (very common)
  - Itching at injection site
  - Headache
  - Nausea
  - Malaise

- Any reported adverse incidents, errors or events during or post vaccination must follow determined procedures. In addition teams must keep a local log of reports and discuss such events with the local immunisation co-ordinator.

Men C Vaccination

- A child presented over the age of 10 years with an incomplete vaccination schedule, and was given a Men C. Several years later would they still require the ACWY vaccination offered with the School leaver boosters?
- **yes**

Men ACWY

Q. Should ACWY conjugate vaccine be given to someone who has had the ACWY polysaccharide vaccine previously?

A. Year 13 pupils and university freshers who have had ACWY polysaccharide for travel within the last 12 months do not require the conjugate vaccine. The younger cohorts in the catch up and SLB programmes should receive the conjugate vaccine regardless of what they have had previously and irrespective of the time interval between the vaccines.

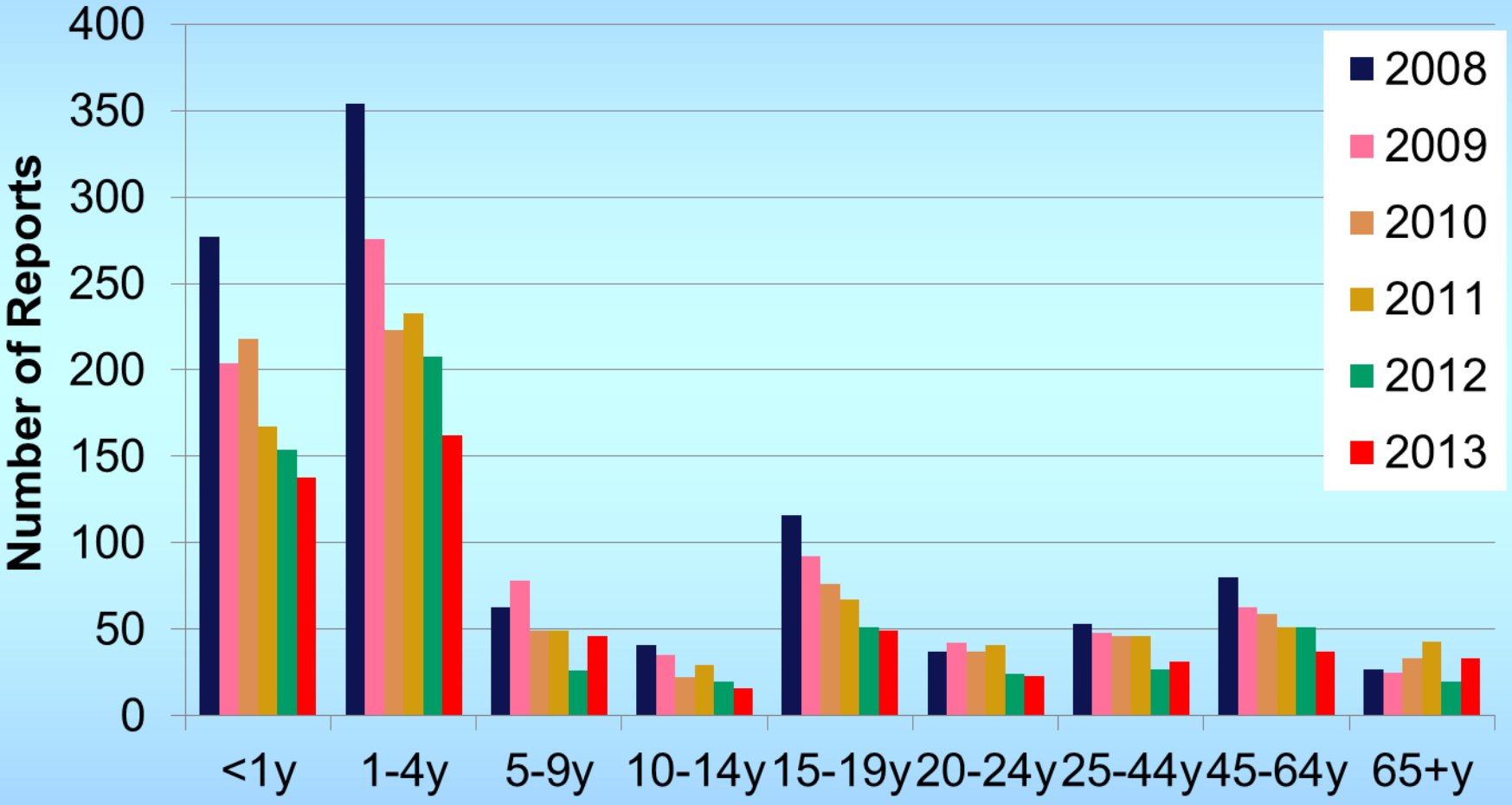
Background

- Incidence of Men B disease has decreased by half since the early 2000s
- In 2014 – 400 cases and 15 deaths attributable to Men B.
- Cases in infants peaked at 5 months of age before declining slowly.
- Half of all cases occur in children under the age of 5 years
- A tenth of survivors of Men B disease have major physical and or neurological deficits: amputation epilepsy, learning difficulties.
- One third of cases result in less severe physical or neurological disability

Public Health England

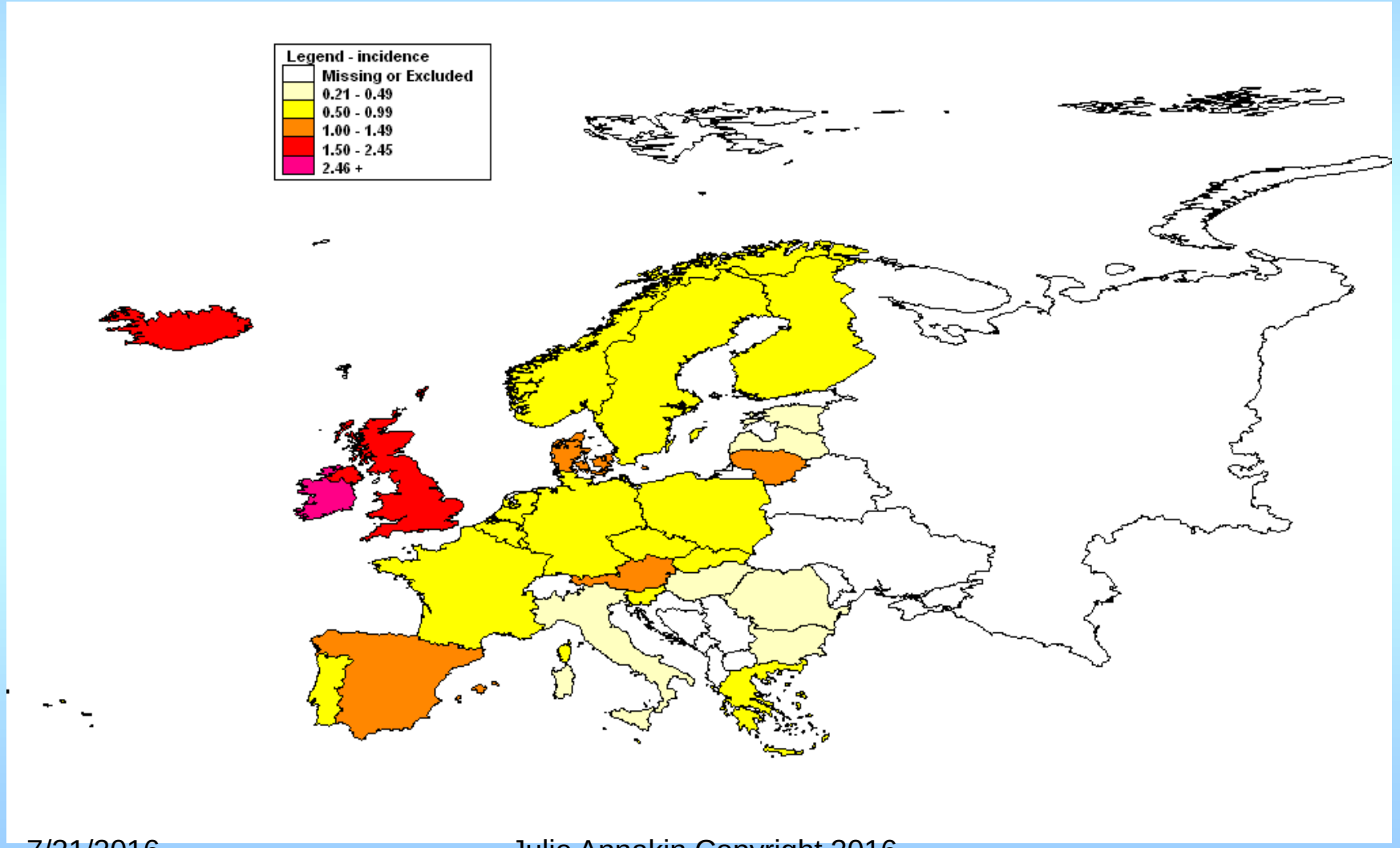
MenB disease by age-group

(England & Wales, 2008-13)

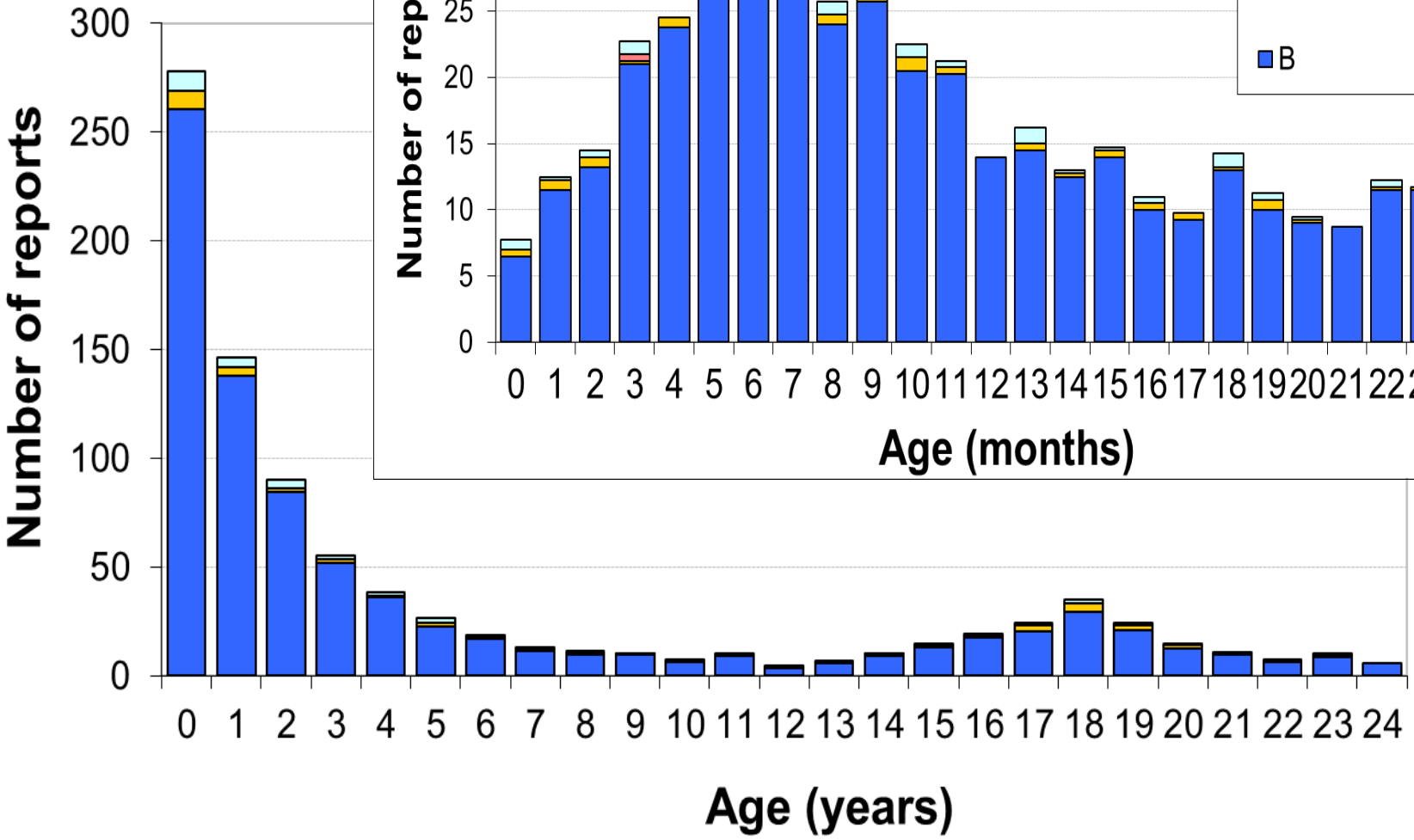


Public Health England

IMD incidence in Europe, 2009



Inv



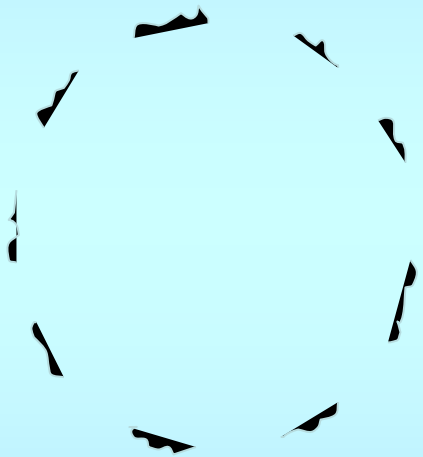
The vaccine - Bexsero® (4CMenB)

- Difficult vaccine to develop; the polysaccharide capsule of the meningococcus is poorly immunogenic.

- The polysaccharide membrane contains polysialic acid which is found in other glycoproteins. It is similar to carbohydrates found in feotal brain tissue.

The Vaccine

- Made using a technique called “Reverse Vaccinology” Uses DNA technology to pick out antigens (outer membrane capsule proteins) that will provide broad coverage against all strains



4CMenB proteins

- fHbp – helps the bacteria to survive in blood
- NadA – Assists attachment and invasion of host cells by the bacteria
- NHBA – Binds Heparin to the bacteria to promote bacteria survival
- PorA – Immunodominant portion of the OMV, strain specific – increases the immune response when put with the other vaccine components.

The vaccine stops the bacteria from invading, replicating and reduces virulence.

The Vaccine

- Data from clinical trials show Bexsero® to be immunogenic in infants, children, adolescents and adults, resulting in high concentrations of bactericidal antibodies that can kill most MenB strains in laboratory tests.
- Bexsero® is expected to have high short-term vaccine effectiveness against most (88%) MenB strains causing invasive disease in England.
- Licensed to be given from 2 months of age

The Vaccine

- 7800 subjects from 2 months of age received at least 1 dose of vaccine in initial trails.
- 1 million doses given in 20 countries
- Studies show that the vaccine provides good protection for the first few months following the 2 dose primary, with a dip prior to 12 months. After the booster dose, antibodies go back to previous levels.
- Protection is estimated to be approx 18 months following primary course, 36 months after booster. Maximum protection is necessary through the 2nd year of life as there are still a high number of cases into the 2nd year.

Public Health England

Serum bactericidal antibody killing of UK MenW cc11 strains by serum from infants immunised with Bexsero®

Lab number	Site	Type	Pre-	Pool1	Pool2	Pool3	Pool4 Post 4th
							>128
							64
							>64
							128
M11-240798	Blood	W:NT:P1.5,2 cc11	<2	>64	>64	>64	>64
M12-240754	Blood	W:NTP1.5,2 cc11	<2	64	64	>64	>64

This work suggests that children immunised with Bexsero may have some protection against the emerging strain of MenW

The Vaccine

Vaccine brand name and supplier

- Bexsero® – supplied by GlaxoSmithKline (NB. Initially packaging will say 'Novartis' (name of original manufacturer) but this is likely to change in 2016).

Presentation

- Bexsero® is supplied as a prefilled syringe in a **pack of 10,** without needles and with one patient information leaflet (PIL). Additional PILs will be supplied with each pack of Bexsero® ordered.
- The vaccine is presented as a clear, colourless liquid, free of visible particles, for **intramuscular** administration.
- The vaccine is ready to use **(no reconstitution or dilution is required).**
- The vaccine is to be administered **intramuscularly** without mixing with any other vaccines or solutions.
- Upon storage a fine off-white deposit may be observed in the pre-filled syringe containing the suspension. Shake well before use.

Bexsero – administration

- The vaccine should be used immediately after opening.
- Bexsero® vaccine is given intramuscularly into the upper arm or anterolateral thigh.
- It is recommend that all doses of Bexsero® be given in the **left thigh**, **ideally on their own,** so that any local reactions can be monitored more accurately. If another vaccine needs to be administered in the same limb, then it must be given at least 2.5cm apart.
- *4 injections will be administered at the 12 month visit from May 1st. It is recommended that all 4 limbs are used. If this is not possible, Men B can be administered in the Left leg with MMR vaccine, PCV and Menitorix in the right leg.*

Paracetamol use

- In the trials, temperatures over 38.5°C were considered to be febrile.
- Some children presented with temperatures between 39-40°C
- A very small number presented with temperature over 40°c

Infants given prophylactic paracetamol had a 50% reduction in temperature overall with no cases over 40ºc.

Ibuprofen did not give the same results

Paracetamol

- Further studies have concluded that non of the routine vaccines are affected in terms of immunogenicity/protetctive antibody levels with paracetamol use.
- Use of paracetamol also reduces, pain, swelling, irritability.
- **The first dose is the most important in terms of reducing fever ie given at or around the time of vaccination.**

Paracetamol use

- Administration of a 2.5ml dose of paracetamol oral suspension (120mg/5ml) by the parent or guardian at the time of or shortly after the first two MenB vaccinations (with a further two doses at four to six hour intervals) should reduce the likelihood or intensity of fever without diminishing the immune response.

Fever

- In clinical trials, temperature spiked 6 hours post vaccination, resolving within 24 hours.
- Children at 12 months generally do not have the spikes in temperature
- Tepid sponging is not recommended (Caring for children with fever, RCN, 2013)

Paracetamol

- Product license recommends that GP advice should be sought after 2 doses.
- MHRA approached to change licence advice. As of June 18th, now recommends **for post vaccination only**:

➢ If after 3 doses, the infant is still febrile but otherwise well, give further doses 4-6 hourly for 48 hours. Do not give more than 4 doses in 24 hours. (GB change imminent)

Drug manufacturer will change guidance accordingly

Other adverse events...

- Infants and children under 10 years:
- ➢ Injection site reactions
- ➢ Malaise
- ➢ Headache
- ➢ Diarrhoea, vomiting
- ➢ Irritability
- ➢ Sleepiness
- ➢ Unusual crying

❑ All suspected vaccine reactions should be reported via the yellow card – MHRA – reporting system.

Contraindications

Contraindications

- There are very few individuals who cannot receive meningococcal vaccines. When in doubt, appropriate advice should be sought from a consultant paediatrician, consultant in communicable disease control, or screening and immunisation team staff, rather than withholding immunisation.

Bexsero® should not be given to:

- infants with a confirmed anaphylactic reaction to a previous dose of Bexsero®
- infants with a confirmed anaphylactic reaction to any component of the vaccine

Contraindications

- Administration of Bexsero® should be postponed in infants suffering from acute severe febrile illness.
- Other minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.

Immunosuppression and HIV infection

- Bexsero® can be given to infants with HIV infection (regardless of CD4 count) or immunosuppression in accordance with the routine schedule

Vaccine Components

- Recombinant *Neisseria meningiditis* group B NHBA protein 50 mcg
- Recombinant *Neisseria meningiditis* group B NadA protein 50mcg
- Recombinant *Neisseria meningiditis* group B fHbp fusion protein 50mcg
- OMV from *Neisseria meningiditis* group B strain 25mcg
- Sodium Chloride
- Sucrose
- Histadine
- Water for injections

Payment for both Meningitis programmes

- GMS contract for 2016/17: an increase in the item of service fee for vaccinations to £9.80

Posology

Table 1. Summary of posology

Age Group	Primary Immunisation	Intervals between Primary Doses	Booster
Infants, 2 months to 5 months	Three doses each of 0.5 ml, with first dose given at 2 months of age [a]	Not less than 1 month	Yes, one dose between 12 and 15 months [b, c]
Unvaccinated infants, 6 months to 11 months	Two doses each of 0.5 ml	Not less than 2 months	Yes, one dose in the second year of life with an interval of at least 2 months between the primary series and booster dose [c]
Unvaccinated children, 12 months to 23 months	Two doses each of 0.5 ml	Not less than 2 months	Yes, one dose with an interval of 12 months to 23 months between the primary series and booster dose [c]
Children, 2 years to 10 years	Two doses each of 0.5 ml	Not less than 2 months	Need not established [d]
Adolescents (from 11 years of age) and adults*	Two doses each of 0.5 ml	Not less than 1 month	Need not established [d]

[a] The first dose should be given at 2 months of age. The safety and efficacy of Bexsero in infants less than 8 weeks of age has not yet been established. No data are available.

[b] In case of delay, the booster should not be given later than 24 months.

[c] See section 5.1. The need for, and timing of, further booster doses has not yet been determined.

[d] See section 5.1.

* There are no data in adults above 50 years of age.

Men B Vaccine Uptake as of 26/02/16

- July cohort – 94% 1st dose 84.8% 2nd dose
- May catch up – 76.6%
- June Catch up – 88.8% 1st dose 72.5% 2nd dose

- *Preliminary vaccine coverage estimates for those eligible for infant Meningococcal B immunisation are 95.5% for one dose and 87.9% for two doses by six months of age (evaluated at the end of April 2016).*

Can vaccine be offered to infants outside of the national programme?

- Vaccines for use outside of the NHS criteria must not be taken from central stock.
- GP's are not able to charge their own patients (i.e those registered at the practice) a private fee for the vaccine.
- List price £75 exl VAT

Other issues..

- Fridge capacity
- Vaccines for use outside of the NHS criteria must not be taken from central stock.
- Data on vaccine coverage will be automatically uploaded in Feb 2016
- Supporting leaflets, posters, guidance, are available through the publications order line.
- Q&A factsheet for HCP's are available on the PHE website.

Can Bexsero® be administered earlier than 8 weeks (2 months) to eligible infants travelling abroad?

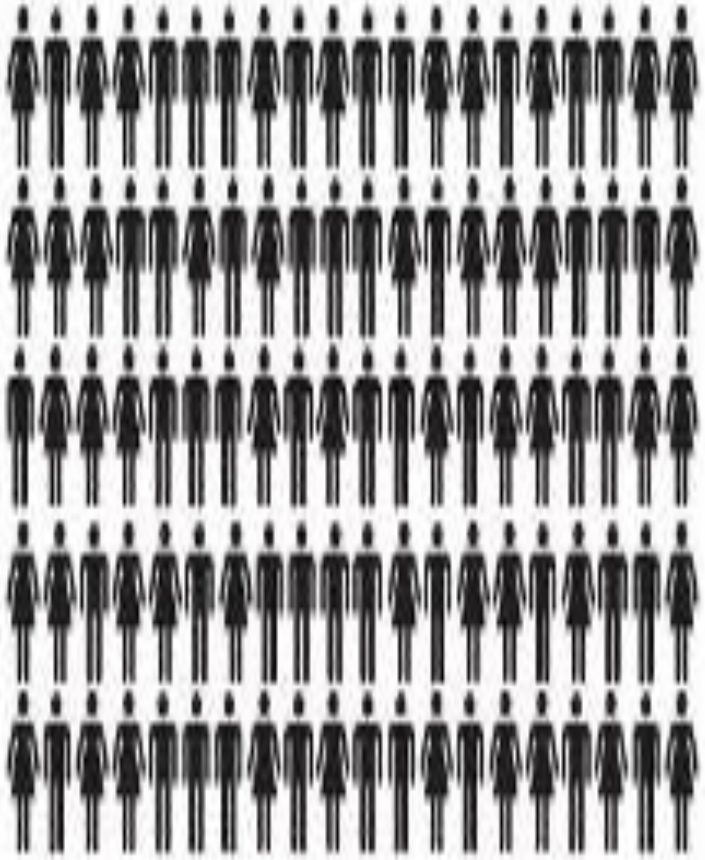
- The level of risk from men B is higher in the UK than in other countries.
- Bexsero® is only licensed for use from the age of 2 months, thus those wishing to administer the vaccine earlier than recommended will be using an “off-label” licensed vaccine that will require a patient specific direction (PSD).
- Administering the vaccine earlier than recommended will also affect the administration of infant strength liquid paracetamol to infants aged less than 8 weeks as this contraindicates PHE's homely remedy protocol.
- It is not recommended that Bexsero® is administered earlier for travel purposes.

Measles

- Extremely contagious viral illness caused by Morbillivirus
- Most common in 1-4 year olds
- Spread by contact with nose and throat secretions and in airborne droplets released when an infected person sneezes or coughs
- Transmission period is from beginning of first symptoms to 4 days after appearance of the rash
- Incubation period ranges from 7 to 18 days

100 susceptible people

(e.g. not vaccinated against measles)



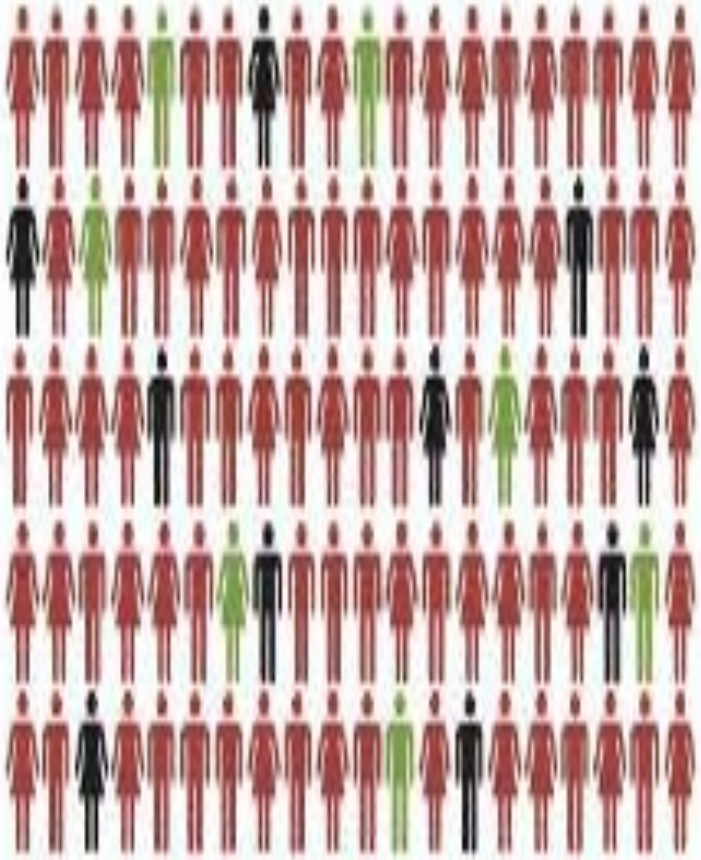
+

One person

infected with measles

=

About 90 people will catch measles, 7 with complications.



Symptoms of Measles

- Early symptoms include:
- runny nose
- cough
- red and watery eyes and
- small white spots inside the cheeks (Koplik's spots)

Photo courtesy of CDC

Symptoms of Measles (cont)

- **Followed by:**
- **- A slightly raised rash develops, spreading from the face and upper neck to the body and then to the hands and feet over a period of three days**
- **- Rash lasts 5-6 days**
- **- Loss of appetite and loose stools**

Photo courtesy of CDC

Complications

- **Complications occur in approximately 30% of reported cases**
  - Infants, adults and immunocompromised are at highest risk of severe complications
- **Severe diarrhoea may be a problem especially for infants, causing dehydration**
- **Pneumonia is the commonest cause of death associated with measles (1-6 per 100 cases)**
- **Blindness and Encephalitis may also develop (1 per 1000 cases)**
- **SSPE is a rare but fatal complication of measles infection (1 per 25,000 measles infections. 1in 8000 in children infected under the age of 2 years)**
- **Death (1 in 5000 cases) – last UK death 2006 in immunocompromised child**

http://www.ovg.ox.ac.uk/measles

The Wakefield Factor

- 1971 MMR introduced into USA
- 1988 MMR introduced into UK schedule
- 1996 Andrew Wakefield hired by JABS lawyer to find link between MMR and autism. 12 children were used in the study – 11 of them were claimants
- 1997 Wakefield files patents for single measles vaccine and products to treat autism.
- 1998 Reports in the Lancet advising single jabs – no declaration of interests

Cont…

- 2004 Times investigates – Lancet apologises – research was fatally flawed
- 2005 Rise in autism in Japan following withdrawal of MMR vaccine
- 2008 Cochrane report validating research carried out all over the world – no link between MMR vaccine and autism.
- GMC misconduct hearing notes selective reporting and changes to findings. Wakefield struck off for professional misconduct 2011

Measles in England

- Deaths in recent years:
- 2006 13 year old unvaccinated with underlying lung condition
- 2008 unvaccinated child with congenital immunodeficeinecy
- 2013 25 yr old died from pneumonia as complication of measles
- 26 deaths since 1992 due to complications of measles acquired prior to 1980

Current issues for measles

- An increase in measles was observed at the end of 2015 with 2 identified clusters in South East England: 1 associated with an importation from Somalia (5 confirmed); and the second following an importation from Spain (25 confirmed) between October 2015 and January 2016
- Current outbreak in London. Since the beginning of February 2016, 60 cases of measles have been confirmed predominantly in unimmunised adolescents and young adults (aged 14 to 40 years) without a history of recent travel. Many of these cases have been admitted to acute medical wards without isolation including 1 in intensive care. *(HPR April 2016)*

Measles and HCW's

- **All Health care workers should have 2 doses of MMR vaccine *or* documented evidence of immunity to measles**
- Healthcare workers who do not have satisfactory evidence of protection should be excluded from work from the 5th day after exposure, unless they can be tested and shown to be IgG positive. The Association Of National Occupational Health Physicians (ANHOPs) recommends that susceptible healthcare workers (HCW) exposed to measles should receive one dose of MMR and be excluded from work from day 5 after exposure. The HCW can return to work 21 days after the final exposure, or earlier if symptom-free and found to be measles IgG positive at least 14 days after MMR was given.
- Exposure: any face to face contact, or exposure of 15 mins or longer in the same room with a confirmed, linked or likely case. *(HPA National Measles guidelines, 2010)*

Mumps

- Acute viral illness transmitted via droplet infection
- Complications of symptomatic mumps include:
- Pancreatitis (4%) oophoritis(5% of post –pubertal women) orchitis (25% of post pubertal men)
- Neurological complications including meningitis and bilateral or unilateral deafness
- Nephritis, cardiac abnormalities and rarely death have been reported

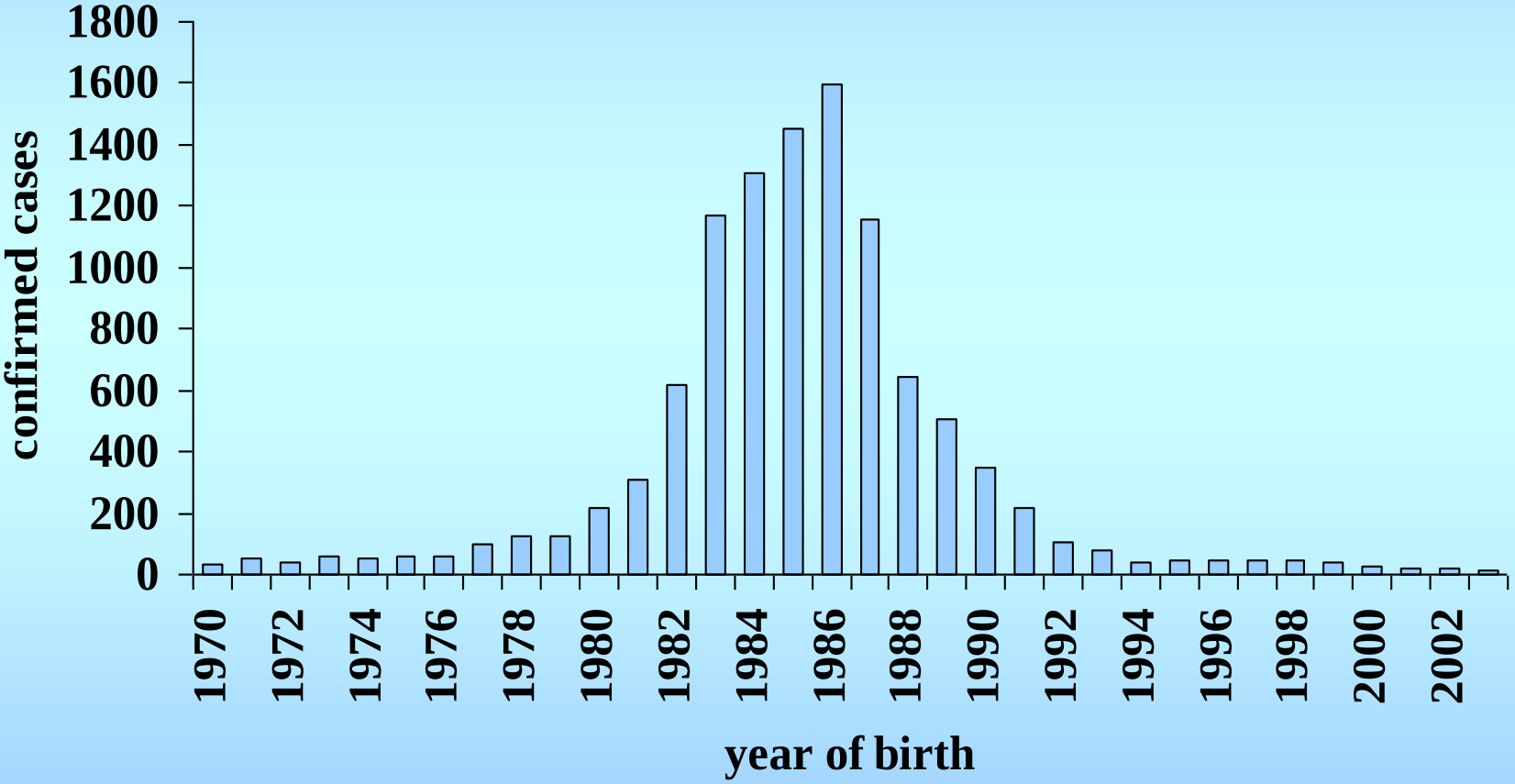
Symptoms of Mumps

- Early symptoms include:
- Headache and fever
- parotid swelling which may be unilateral or bilateral
- Photophobia, neck stiffness (meningism) can develop

Photo courtesy of CDC

- At least 30% of cases in children have no symptoms
- Most severe in adults

Confirmed cases of Mumps by year of birth *England and Wales, 1999-2004*



7/21/2016

*provisional

Current issues for Mumps

- There were only 122 laboratory confirmed mumps infections in England with onset dates in the period between January and March 2016, similar to the number confirmed in the last quarter of 2015 (121), continuing the trend of very low incidence as observed for the last five quarters.

- Cases are predominantly in young adults between 18 and 35 years of age (66/122 54%). About a third (42/122) of all cases this quarter reported receiving one or two doses of MMR vaccination in childhood. For these cases where the vaccination date was known, the average number of years since last MMR vaccination was 14.6 years. Mumps cases were reported in all regions of England

Current issues for Mumps

- Two doses of MMR are required for full protection from mumps
- Opportunistic vaccination at “school leaving” booster and university entrance for those who have only received 1mumps containing vaccine. (MMR introduced in 1988. In 1994 all children aged 5 – 16 were offered MR vaccine to prevent measles epidemic. A second dose was introduced in 1996.)

Rubella

- Also known as German measles caused by Toga virus droplet contact
- Seasonal variation with peaks in late winter and early spring.

Symptoms of Rubella

- Often a mild illness
- May begin with swollen lymph glands, low grade fever, malaise & conjunctivitis
- Maculo-papular discreet rash develops on face, neck and body
- Swollen joints and joint pain common in adults.

Photo courtesy of CDC

Complications of Rubella infection in pregnancy

- Congenital rubella syndrome (CRS)
- Risk of foetal damage is estimated at:
  - 90% in first 10 weeks
  - 10-20% by 16 weeks
  - Rare after 20 weeks
- Defects include cardiac, auditory, ophthalmic, neurological problems

Photo courtesy of CDC

Rubella infection in England & Wales

- Prior to selective rubella immunisation for all pre-pubertal girls and non-immune women of childbearing age in 1970:
- Up to 70 cases of Congenital Rubella Syndrome (CRS) were reported during epidemic years
- Ratio of therapeutic abortions to cases of CRS was 10:1
    - *(for the 70 cases of CRS a further 700 pregnancies would have been aborted)*

Current issues for Rubella

- Susceptibility and risk of infection in immigrant women (e.g. infected abroad)
- NSC– review of screening, replacement of Rubella susceptibility blood tests to Vaccination screening from April 2016
- Continues to be cases predominantly in young males with small numbers in pregnant women
- Only one case of rubella infection was confirmed in the period between January and March 2016. The case was a male who acquired rubella infection abroad.
- 1 confirmed CRS case in Q2 2014, a neonate born to unvaccinated mother who contracted Rubella abroad
- 39,000 cases in 25 reporting European countries 2013, (99% cases from Poland – programme only offered vaccine to girls 1989-2004)
- Present in developing countries

MMR Vaccine

- Doses of vaccine given less that 12 months of age should be discounted – maternal antibodies may destroy antigen.
- Doses given below 18 months – 3 months between doses (this is classed as 2nd dose)
- If protection urgently required below 18 months, a minimum1 month gap is allowed. Ignore this 2nd dose and give dose with PSB as per schedule.
- Over 18 months, 1 month between doses.
- 2 doses required irrespective of history of disease and/or age
- Vaccine can be given as prophylaxis to individuals susceptible to measles if given within 3 days of contact.

Referrals to special Immunisation clinic

Almost all individuals can be safely vaccinated with all vaccines. In very few individuals vaccination is contraindicated or should be deferred. Referral to the Special Immunisation Clinic for advice or immunisation under controlled conditions can be made in exceptional circumstances, as listed below.

- A confirmed anaphylactic reaction to a previous dose of vaccine containing the same antigens
- A confirmed anaphylactic reaction to another component contained in the relevant vaccine that may be contained in the vaccine in trace amounts (e.g. neomycin, streptomycin or polymixin B)
- A confirmed anaphylactic hypersensitivity to egg products (Seasonal flu vaccine only)

MMR vaccine

MMR vaccine contains less than the minimum amount of egg antigen required to elicit a reaction.

The Alder Hey study reported that 91% of referrals to hospital since 2006 did not meet criteria issued by RCPCH/BSACI and guidance in GB.

BSACI guidelines updated in 2007 suggest that all egg allergic children may be given MMR vaccine in primary care.

Requests for single vaccines

- Single vaccines are not licensed as EU/UK products. They come into the country under Regulator Import licences as “unlicensed relevant medical products”
- Clinics refer to registration with CQC This means that basic qualifications of staff and hygiene requirements are met; it does not monitor clinical practice or protocols.
- A study in 2008 showed that rate of anaphylactic reactions was higher following single vaccines and probably an underestimation as private clinics are not obliged to report SAE’s
- (“Single vaccines” into search engine on PHE website)

Current issue (HPR April 2016)

- 2000 children per month not receiving MMR at 12 months of age.
- National uptake for children at 2 years of age 92%

Pneumococcal disease

- Describes infections caused by the bacterium *S.pneumoniae*
- Over 90 serotypes identified
- 20 – 30 serotypes responsible for majority of disease
- 13 serotypes responsible for burden of disease in children under 5 years of age

Pneumococcal

- Transmission by aerosol, droplets or direct contact with respiratory secretions
- Transmission usually requires either prolonged or frequent close contact
- Seasonal variation in pneumococcal disease with peak levels in the winter months.
- Major cause of serious disease – meningitis, septicaemia and severe pneumonia (invasive pneumococcal disease – IPD)
- Less serious but more common disease – otitis media, mild pneumomia and bronchitis

Prior to introduction of vaccine

- 5000 cases of invasive pneumococcal disease (IPD) per year
- 530 children IPD < 2 years (England & Wales)
- Around 50 children < 2yrs die from IPD per yr[1]
  - 2 thirds from pneumococcal meningitis
- 50% who survive pneumococcal meningitis have disabilities[2]

1. IspahaniP, Slack RC, Donald FE, et al (2004) Twenty-year surveillance of invasive pneumococcal disease in Nottingham: serogroups
responsible and implication for immunisation. *Arch Dis Child* 89: 757-62

2. Bedford H, de Louvois J, Halket et al (2001) Meningitis in infancy in England and Wales: follow-up at 5 years. *BMJ* 323: 533-6

Current Issues

- IPD due to serotypes in PCV7 virtually eliminated in all age groups.
- IPD due to additional serotypes in PCV13 declined steeply in children, less steeply in older adults.
- Carriage of PVC 13 serotypes fallen to almost zero. If this trend continues, the incidence of IPD caused by PCV13 would be extremely low by 2015/16 and almost be eliminated by 2019 in adults over 65 years of age.
- Recent GB changes for at risk children over 5 years and adults – 1 or 2 doses of PCV 13 + PPV

Pneumococcal Risk groups over 2 years of age

- Splenic dysfunction
- Chronic respiratory disease (not asthma unless continuous use of systemic steroids is indicated)
- Heart disease
- Renal failure
- Liver disease
- Diabetes
- Immunosuppression
- CSF leaks
- Cochlear implants

Immunocompromised: diagnosed from 5 years of age

- PCV13 followed by PPV 2 months later irrespective of vaccine history
- Leukaemia – PCV 6 months after chemo
- Bone marrow – 9-12 months after transplant
- If severely immunocompromised and already had PPV, give PCV 6 months later

What is rotavirus?

- Rotavirus is a virus that causes gastroenteritis, in particular in infants and young children

- Estimated that all children will become infected with rotavirus at least once by the time they are 5 years old

- Estimated that rotavirus causes around half of all gastroenteritis in children aged under 5 years

Image courtesy of PHE/SPL

Clinical presentation of rotavirus

- Rotavirus gastroenteritis usually begins with the symptoms of
- Diarrhoea
- Vomiting
- The child may also have
- A fever (high temperature) of 38ºC or above
- Abdominal pain
- The symptoms of vomiting usually pass within 1 to 2 days. In most children, vomiting will not last longer than 3 days
- The symptoms of diarrhoea usually pass within 5 to 7 days. Most children's diarrhoea symptoms will not last longer than 2 weeks

Complications of rotavirus

- Gastroenteritis can cause dehydration:
- This can be more serious than the rotavirus infection itself and can require hospitalisation for intravenous rehydration
- Approximately 12,700 children were estimated to be admitted to hospital each year with rotavirus in England and Wales with 3-4 deaths each year prior to introduction of the programme.

Transmission of rotavirus

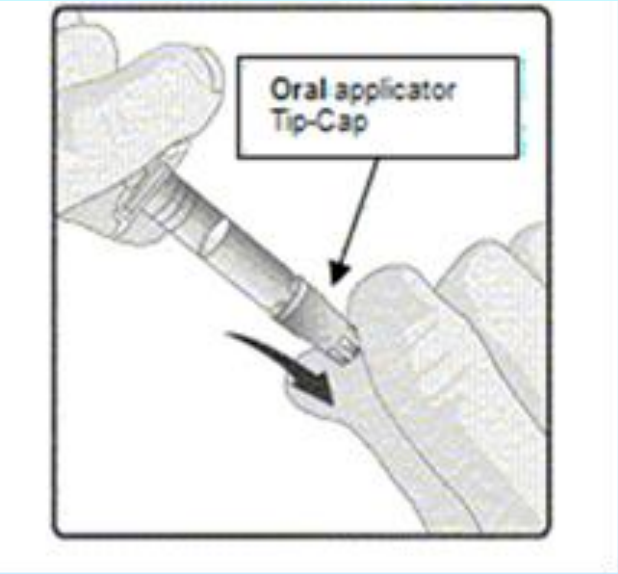
- Rotavirus is **highly** infectious
- As few as 10-100 virus particles may cause disease
- Transmission mainly via the faecal-oral route
- If a child leaves tiny samples of infected faeces on surfaces or utensils e.g. after not washing their hands properly after going to the toilet, they can be picked up by another child
- Small droplets of infected faeces can also be carried in the air, which children can breathe in

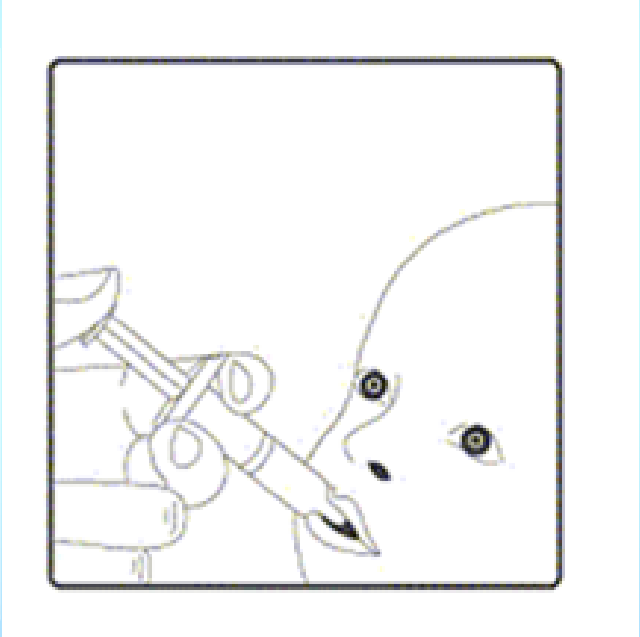
Administration of Rotarix®

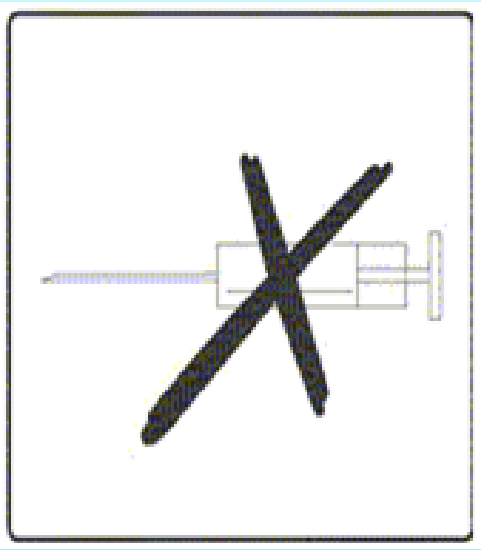
- Rotarix is different from the other infant vaccines, as it is a **LIVE ORAL** vaccine and must **not** be injected

- Rotarix® can be administered at the same time as other childhood vaccines **including BCG**

Administration of Rotarix®







Rotarix® dosage and schedule

- **2 dose schedule**
- First dose of 1.5ml at 8 weeks (two months) of age
- • Second dose of 1.5ml at least four weeks after the first (i.e. 12 week appointment)
- It is preferable that the full course of two doses is completed before 16 weeks of age. Rotarix® must be given no later than 24 weeks (i.e. 23 weeks and 6 days)
- • The first dose must be given before 15 weeks of age. If infant does not have first dose before 15 weeks then do not give Rotarix®
- • If the course is interrupted it should be resumed but not repeated, provided that the second dose can be given before 24 weeks
- • If infant spits out/regurgitates most of dose, a replacement dose may be given at same visit

Intussusception

- Research from some countries suggests that Rotarix® may be associated with a very small increased risk of intussusception (2 cases per 100,000 1st doses) This usually occurs within 7 days of receiving the first dose of vaccine.
- Naturally occurring intussusception (120 per 100,000 cases) peaks at 5 months of age – hence the cut off point for 1st dose to be given before 15 weeks.

- Even with this small potential risk, the benefits of vaccination in preventing the consequences of rotavirus infection outweigh any possible side effects

Contraindications

- Confirmed anaphylactic reaction to a previous rotavirus vaccine
- Confirmed anaphylactic reaction to component of vaccine
- Previous history intussusception
- Over 24 weeks of age
- Infants presenting for their first dose of Rotarix® over 15 weeks of age
- Severe Combined Immunodeficiency (SCID) disorder
- Malformation of GI tract that could predispose to intussusception.
- Rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency
- There are very few infants who cannot receive rotavirus vaccine

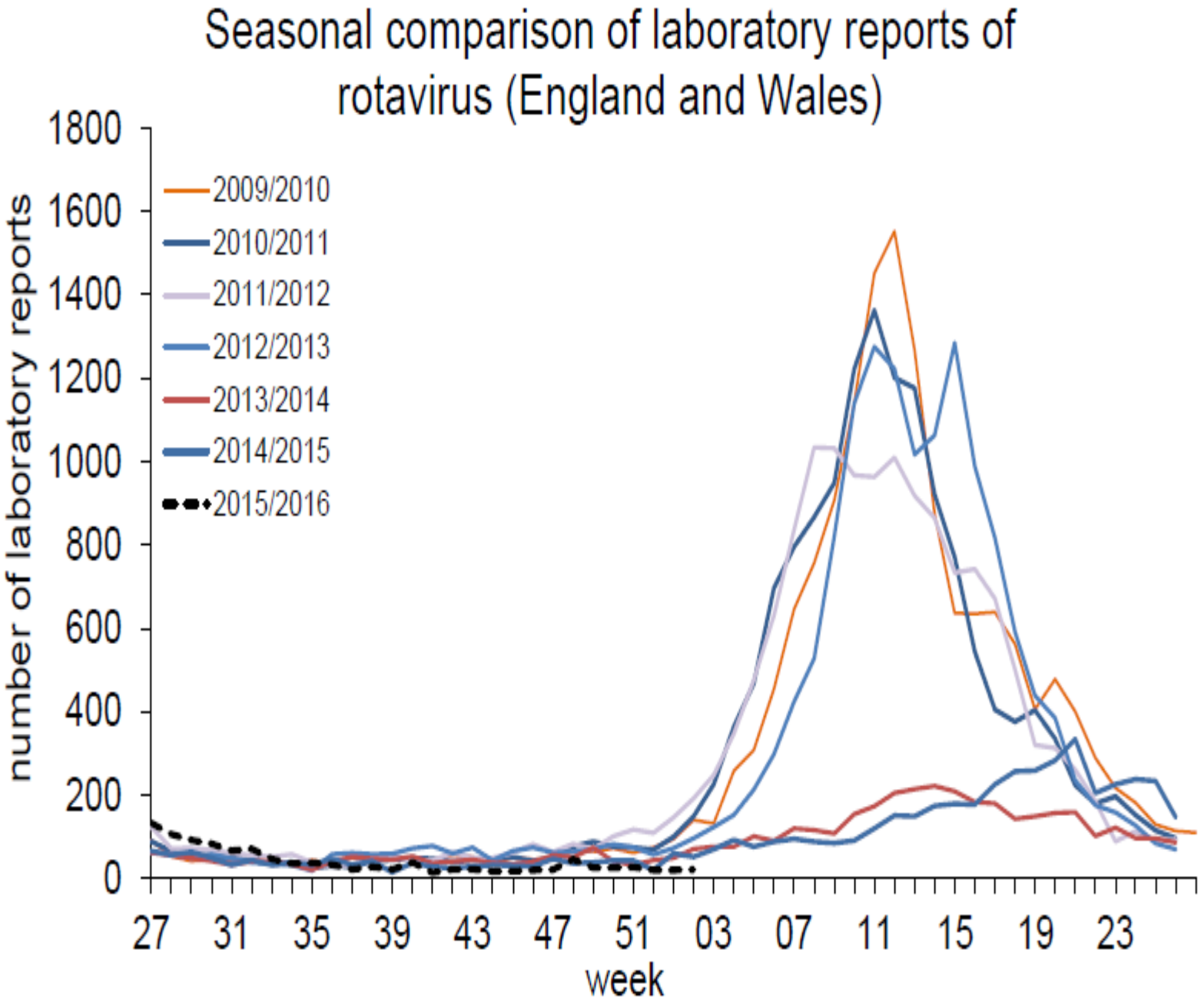
Immunosuppression and HIV

- Rotarix® should not be administered to infants known to have severe combined immunodeficiency disorder (SCID)
- For infants with other immuno-suppressive disorders rotavirus vaccination should be actively considered, if necessary in collaboration with the clinician dealing with the child's underlying condition
- Rotarix® vaccination is advised in HIV infected infants. Additionally infants of unknown HIV status, but born to HIV positive mothers should be offered vaccination

Precautions

- Potential transmission of live attenuated vaccine from infant
- Vaccination of the infant will offer protection to household contacts from wild-type rotavirus disease and outweigh any risk from transmission of vaccine virus to any immunocompromised close contacts
- • Those in close contact with recently vaccinated infants should observe good personal hygiene

Figure 8: Seasonal comparison of laboratory reports of rotavirus (England and Wales)



Age group	Epidemiological year	Rotavirus coded hospitalisation
<1 year	2010 (July 2010-June 2011)	1165
<1 year	2011	1135
<1 year	2012	1214
<1 year	2013	424

Cont..

- Issues may arise if practices have treatment centre queues or delays in clinic scheduling, as the timeframe for offering the vaccine is very tight.
- Practices will need to consider offering additional clinics to address queues *and* practice nurse cover for holidays.
- Recording and reporting to CHIS must be done asap after clinics are completed, to ensure timely scheduling.

HPV and Cervical cancer

- DNA virus > 100 virus types
- 40 affect anogenital tract
- Sexual transmission
- Infection transient and mainly asymptomatic
- 80% of sexually active women exposed
- “Low risk” types anogenital warts,benign lesions, sub-clinical infection
- “High risk” types cause 95% of cervical cancers
- Time from infection to invasive cervical cancer is ~ 15 years

HPV transmission

- HPV is spread by direct physical contact.
- Any genital contact is important, not just sexual intercourse.
- Hand to genital contact may cause some infections.
- Anyone who is sexually active is at risk.
- The risk of acquiring HPV increases with the number of sexual partners.

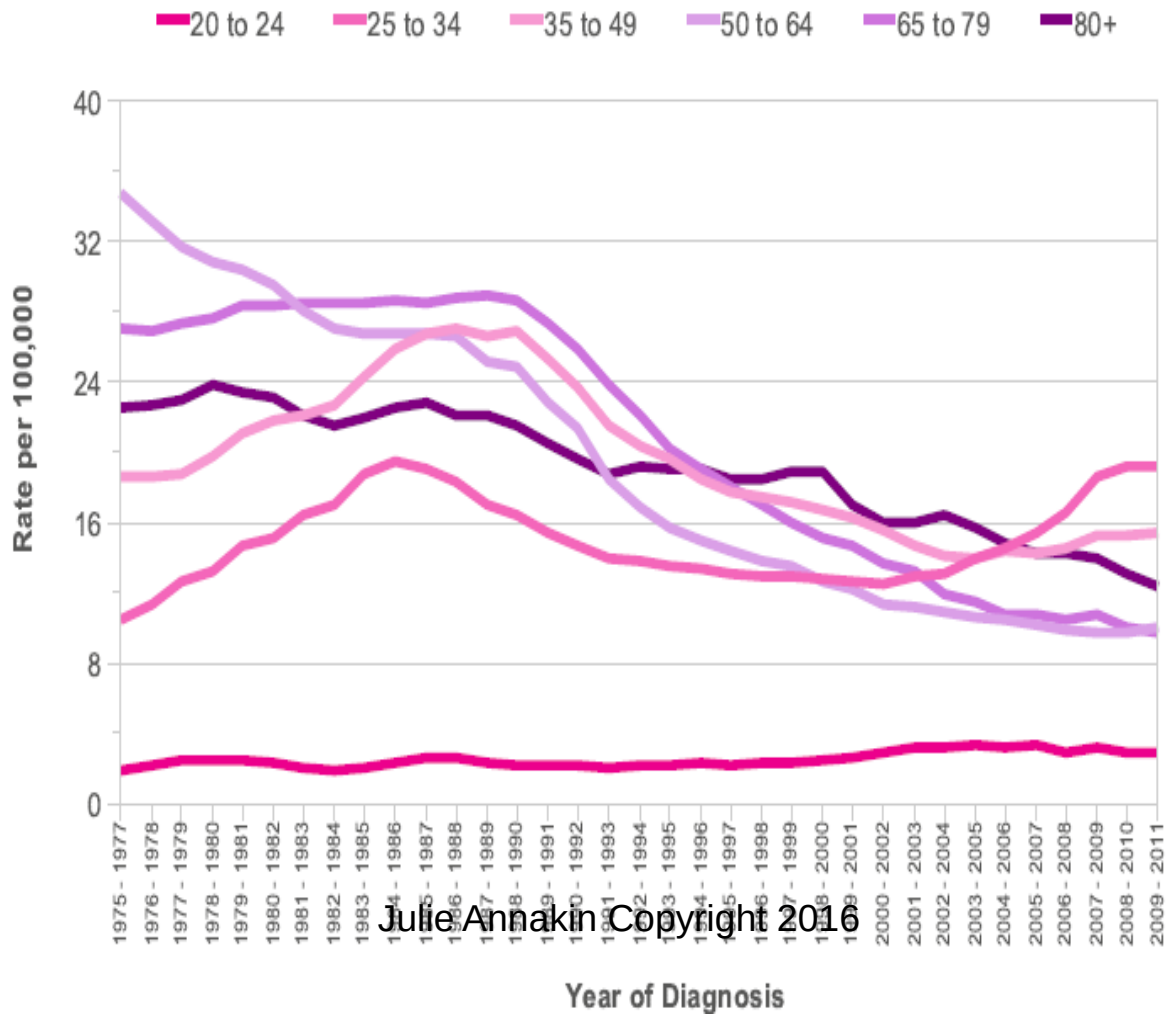
Computerised image of the human papillomavirus
Courtesy of Dept of Pathology, University of Cambridge

Categories of genital HPV infection

- Genital HPV types are categorised as either:
  1. high-risk (oncogenic) types - that cause cervical intraepithelial neoplasia and invasive cancer, and
  2. low-risk types - that cause genital warts.
- 99% of all cervical cancer cases are caused by HPV infection.
- Two high-risk types, HPV 16 and 18, cause over 70% of cervical cancers.
- Other HPV types can also cause cervical cancer.

Cervical Cancer (C53): 1975-2011

European Age-Standardised Incidence Rates per 100,000 Population, by Age, Females, Great Britain



Gardasil

- Protects against high risk HPV 16, 18
- Low risk HPV 6,11
- Low risk types responsible for genital warts – most common viral sexually transmitted infection in the UK.
- Types 6 and 11 cause over 90% of all genital warts

Previous incomplete vaccination with Cervarix

- If a patient has started a course of Cervarix, then this course can be completed with Gardasil.
- It is not advisable to complete a course of Gardasil following a course of Cervarix. There is no safety data on courses of vaccines that could involve more than 3 HPV vaccine doses.
- Repeat courses are not available on the NHS.

Gardasil Schedule up until September 2014 and for girls commencing the programme aged over 15 years from September 2014

- First dose 0.5ml
- Second dose 0.5ml, one to two months after the first dose
- A third dose 0.5ml, at least 3 months after the 2nd dose

Gardasil schedule change for September 2014
2 doses for girls 12-14 years of age

- the first dose can be given at any time during school year 8
- the minimum time between the first and second dose should be six months where the priming dose is received at less than 15 years of age
- the maximum time between the first and second dose is 24 months
- for operational purposes, PHE recommends around a 12-month gap
- If the girl has received 2 doses without a 6 months gap on the original schedule, a third dose must be given
- Girls presenting for the first time over the age of 15 years should receive 3 doses of the vaccine as per the original schedule. The vaccine is not as effective in older girls.

Gardasil Schedule

Girls who did not attend the original catch up programmes and present now to commence a vaccine course, who are older than 18 years are not eligible for the vaccine.

Current issues

- 2.3 million complete courses given since start of programme. 3.3 million girls eligible.
- Chlamydia screening survey 2010-13 shows prevalence of HPV 16/18 66% lower than in 2008 (pre vaccine)
- First vaccinated cohort to commence screening programme this year
- Different screening protocols for vaccinated women. Tailored invitations for screening. Recording of vaccination status vital.
- Genital warts diagnosis in females aged 15-19 years declined by 33% and in males in same age cohort by 24% between 2009 – 2014
- Decrease of 9.6% in females 19- 24 years and 9.9% in males in same age cohort.

Evidence that the bivalent vaccine had moderately protective effect against HPV 9,11

(*HPV Vaccination Coverage in England 2008-2014, PHE 2015*)

(HPR, 9, 22) 26/6/15

HPV continued...

- Need for guidance on use in sexual health clinics for MSM. (HPV 16/18 found in majority of anal cancers and laryngeal papilloma and in 40% of penile cancers) Studies ongoing into cost effectiveness of programme offered to MSM age 16- 40 years.
- Use in adolescent boys - Modelling on cost effectiveness on going, available later in 2015
- Current vaccination programme estimated to save 400 lives annually.

Why vaccinate children against flu?

•Extension of the seasonal flu vaccination programme to all children aims to appreciably lower the public health impact of flu by:

▪**Providing direct protection** thus preventing a large number of cases of flu in children

▪**Providing indirect protection** by lowering flu transmission from:

- Child to child
- Child to adult
- Child to those in the clinical risk groups of any age

•Reducing flu transmission in the community will avert many cases of severe flu and flu-related deaths in older adults and people with clinical risk factors

•Annual administration of flu vaccine to children is expected to substantially reduce flu-related illness, GP consultations, hospital admissions and deaths

Live attenuated influenza vaccine (LAIV)

- A live attenuated intranasal spray called Fluenz Tetra® is the recommended vaccine for the childhood flu programme
- **The live attenuated influenza vaccine (LAIV) has been shown to be more effective in children compared with inactivated influenza vaccines**
- It may offer some protection against strains not contained in the vaccine as well as to those that are
- Since this vaccine is comprised of weakened whole live virus, it replicates natural infection which induces better immune memory (thereby offering better long-term protection to children than from the inactivated vaccines)
- In addition to being attenuated (weakened), the live viruses in Fluenz Tetra® have been adapted to cold so that they cannot replicate in lungs efficiently at body temperature
- Fluenz Tetra® has a good safety profile in children aged two years and older and a very similar trivalent vaccine has an established history of use in the United States

- ***Recent studies on 2015/16 efficacy against confirmed disease of 58%***

How many doses?

- Two doses of the **inactivated** influenza vaccines are required to achieve adequate antibody levels in younger children
- However a **single dose of LAIV** should provide protection to previously unvaccinated healthy children
- Only modest additional protection provided by a second dose of LAIV
- JCVI advise greater population health impact can be achieved if the limited quantity of LAIV available is given as one dose schedule to larger number of children
- Only children who are in clinical risk groups aged two to less than nine years who have not received influenza vaccine previously should be offered a second dose of LAIV (given at least 4 weeks apart)

Fluenz Tetra®

- Brand name: Fluenz Tetra®
- Marketed by AstraZeneca
- Licensed from 24 months to less than 18 years of age
- Nasal spray (suspension) in a prefilled nasal applicator
- Supplied as pack containing 10 doses
- *Short shelf life:*

Image courtesy of AstraZenica

Fluenz® composition 2016/17

an A/California/7/2009 (H1N1)pdm09-like virus

an A/Hong Kong/4801/2014 (H3N2)-like virus

a B/Brisbane/60/2008-like virus

- An additional B virus

- **Excipients:**
- Sucrose
- Dibasic potassium phosphate
- Monobasic potassium phosphate
- **Gelatin (porcine type A)**
- Arginine hydrochloride
- Monosodium glutamate monohydrate
- Water for injection

- **Residues:**
- **Egg proteins (e.g. ovalbumin)**
- **Gentamicin**

Change to guidance 2015

- Preliminary results of “SNIFFLE2” study:
- ➢ LAIV safe to use in egg allergic children
- ➢ Children with stable asthma regardless of degree of treatment, not at increased risk of wheezing 72 hours post vaccination.
- ➢ Safe to use ***except*** in children with severe anaphylaxis to egg, or in children with uncontrolled asthma (oral steroids within previous 2 weeks, current wheezing, increased use or bronchodilators in previous 72 hours) Defer until well.

Inactivated Seasonal flu vaccination for children unable to receive Fluenz Tetra

- Children aged 6-35 months – 0.5ml (SPC may state 0.25) repeat 4-6 weeks later if receiving for the first time
- Children aged 3-9 years – 0.5ml repeat after 4-6 weeks if receiving for the first time.
- Over 9 years of age – a single dose of 0.5ml

❖ Children aged 6 months - 5 years should not be given Enzira flu vaccine (Pfizer) due to risk of febrile convulsions. Caution with 5-9 year olds as increased risk of fever.

Porcine gelatine

- Fluenz Tetra® contains porcine gelatine
- Gelatine is used to stabilise live viral vaccines and is contained in many pharmaceutical products, not just Fluenz Tetra®
- There is currently no alternative vaccine of equivalent efficacy that does not include porcine gelatine
- Anyone who does not wish to be vaccinated with Fluenz Tetra® can refuse vaccination. However, current policy is that only those who are in clinical risk groups or have clinical contra-indications are offered an inactivated injectable vaccine as an alternative to Fluenz Tetra®
- See PHE's website (www.gov.uk/government/news/vaccines-and-gelatine-phe-response) for Q&As, responses from different faith groups and more information on vaccines and gelatine

Precautions to Fluenz Tetra®

- Acute severe febrile illness:
  - defer until recovered
- Heavy nasal congestion:
  defer until resolved or consider inactivated influenza vaccine

- Fluenz Tetra® should not be administered at the same time or within 48 hours of cessation of treatment with flu antiviral agents
- Administration of flu antiviral agents within two weeks of administration of Fluenz Tetra® may adversely affect the effectiveness of the vaccine

Inadvertent administration of Fluenz Tetra®

- If an immunocompromised individual receives LAIV in error, the degree of immunosuppression should be assessed
- If patient is severely immunocompromised, antiviral prophylaxis should be considered, otherwise they should be advised to seek medical advice if they develop flu-like symptoms in the four days following administration of the vaccine
- If antivirals are used for prophylaxis or treatment, the patient should also be offered inactivated influenza vaccine in order to maximise their protection in the forthcoming flu season. This can be given straight away

Healthy child flu programme

- The only change to eligibility for flu vaccination this year is the extra offer of live attenuated influenza vaccine (LAIV) to children of appropriate age for school year 3.
- all children aged two to seven (but not eight years or older) on 31 August 20161
- all primary school-aged children in former primary school pilot areas

Results from Pilot areas

- The GP consultation rate for ‘influenza-like illness’ among primary school aged children was 94% lower compared to non-pilot areas
- A&E respiratory attendances by primary school aged children were 74% lower
- Hospital admissions of primary school aged children caused by confirmed influenza were 93% lower
- A positive impact could also be measured among the adult population. The GP consultation rate for ‘influenza-like illness’ among adults was 59% lower compared to non-pilot areas

Vaccine uptake ambitions

Children

Age (years)	Uptake in 2014/15	Uptake in 2015/16	Uptake ambition for 2016/17
2	38.5%	35.4%	40-65% across all cohorts and settings
3	41.3%	37.7%	
4	32.9%	30.0%	
5 (School year 1)	N/A	54.4%	
6 (School year 2)	N/A	52.9%	
7 (School year 3)	N/A	N/A	

Uptake

- Deprivation and Muslim religion are independent predictors of lower uptake5
- Overall uptake for children of school years 1 and 2 age by Local Authority ranged from 5.1% in Tower Hamlets to 83.3% in the Isles of Scilly.
-

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-

PHE guidance...

- All eligible patients should be vaccinated by the end of December before flu starts circulating.
- Every practice should have **a lead member of staff** with responsibility for running the flu immunisation campaign.
- All staff should know who the lead person is.
- Include health visitors, midwives, pharmacists and other healthcare professionals linked to your practice in your planning.

Cont..

- Set a higher goal than the previous season.
- Create computer searches to measure uptake and assess progress towards the goal.
- Calculate practice income depending on uptake – each extra 1% of uptake = £xxx income.
- Advertise the practice goal and have a ‘Blue Peter’ style ‘Totaliser’.

Hepatitis B

- Infection of the liver caused by Hepatitis B virus
- The incubation period ranges from 40 to 160 days
- Extremely infectious (x 100 more infectious than HIV)
- The virus is transmitted by exposure to infected blood or body fluids
- Perinatal transmission : Mother to child
- Parenteral transmission: exposure to blood/other infective fluids
- Sexual transmission: contact with an infected person

Chronic Complications

- Hepatic cirrhosis
- Necrosis
- Chronic active hepatitis
- Hepatocellular carcinoma

Photo courtesy of Dr. Patricia Walker, Ramsey Clinic Associates, St. Paul, MN

Schedule for children born to Hep B +ve mothers

- Timely vaccination is essential to prevent development of Hep B disease
- HBIG* and 1st Hep B vaccine given at birth
- Further doses at 1,2 and 12 months (Bloods/heel prick should be taken at 12 months for disease markers)
- Booster dose with pre school immunisations for those at continued risk

GP Contract changes

http://bma.org.uk/practical-support-at-work/gp-practices/vaccination

Programme	Specification or SFE	Timeframe	Cohort	Vaccine/dosage	Vaccine Supply	Payment details	Payment £	Additional information
Hepatitis B (newborn babies)	SFE	In line with SFE - 1 April to 31 March	Newborn babies Babies whose mother has hepB have an increased risk of contracting hepB. This programme ensures they receive vaccination within the first 3 months after birth and a 4th dose at 12 months. Patients will present for other vaccinations for at least 1 of the doses and there are no contra-indications to this.	4 doses – 1st dose expected to be delivered in hospital. 1st dose @ newborn 2nd dose @ 1 month 3rd dose @ 2 months (4 weeks between doses) 4th dose after 12 months AND deliver or refer for a heel prick blood test 1st dose will be provided by the hospital or midwife at birth. If it is not, practices should administer 1st dose. Women with hepB are not recommended for home birth so numbers should be minimal. Practices must update the patient record with the results of the blood test and notify parent/guardian and make referral to paediatrics as necessary.	Direct from manufacturer	Manual reporting via CQRS Payment for 2nd dose made after delivery of 3rd dose. Payment for 4th dose after results of blood test recorded and parent/guardian updated.	£9.80 per dose PA fees available to claim	It is expected that generally hospitals will provide the 1st vaccination and inform the babies/mothers practice (or intended practice) of the child's health/conditions and immunisations. Due to the risk of babies being registered elsewhere or details not being provided by the hospital, practices are required to identify newborn babies registered with the practice (by checking mother's status, not relying on hospital notice) who are at risk of hepB and provide appropriate vaccinations.
HPV booster	SFE	In line with SFE - 1 April to 31 March	14-18 years (girls) (14 years on 1/4/16 but not yet 18 years on 31/3/17)		Central supply (no PA fees)	Manual reporting via CQRS	£9.80 per dose	Practices are not required to proactively offer or encourage patients to be vaccinated. Vaccination only where the patient has missed schools provision.
Meningococcal ACWY (menACWY) booster	SFE	In line with SFE - 1 April to 31 March	14-25 years (14 years on 1/4/15, therefore 14 and 15 years olds only for 16/17)		Central supply (no PA fees)	Manual reporting via CQRS	£9.80 per dose	Practices are not required to proactively offer or encourage patients to be vaccinated. Vaccination only where the patient has missed schools provision.
Meningococcal ACWY (MenACWY) freshers	Specification	In line with SFE - 1 April to 31 March	19-25 years attending university for the first time, who have not been previously vaccinated (19 years on 31/8/2016 but not yet 26 on 31/3/17)	1 dose	Central supply (no PA fees)	CQRS with GPES anticipated	£9.80 per dose	Practices are not required to proactively offer or encourage patients to be vaccinated.
MMR	SFE	In line with SFE - 1 April to 31 March	16 years and over Immunise patients that have no record or incomplete vaccination.	1 or 2 doses as required	Central supply (no PA fees)	Manual reporting via CQRS	£9.80 per dose	Practices are not required to proactively offer or encourage patients to be vaccinated.
Rotavirus	SFE	In line with SFE - 1 April to 31 March	6 weeks and 6 months (but not over 24 weeks)	2 doses	Central supply (no PA fees)	Payment made on completion of dose 2 CQRS with GPES anticipated	£9.80 per completed course	Included in the SFE as an IoS fee for providers of routine schedule.
Seasonal influenza and pneumococcal polysaccharide vaccination programme	Directions and specification	**Influenza** 1/9/16-31/3/17	**Influenza** At-risk patients as defined in the service specification and Green Book	**Influenza** 1 dose except for children aged 5–9 defined as at-risk require 2nd dose where no previous influenza vaccination. Where 2 doses are required, they must be at least 4 weeks apart.	**Influenza** Central supply for patients under 18	CQRS with GPES anticipated Influenza and	£9.80 per dose per vaccine PA fees available	**Influenza** The DES Directions reflect the scope of influenza immunisations NHS England commission as primary medical care services. The specification reflects that NHS England commissions influenza immunisation

Vaccines for use in infant schedule 0,1,2,12

- Engerix B Paediatric
- HB vax PRO Paediatric

- It is good practice to use the same vaccine for a course, but the vaccines are interchangeable.

Hepatitis B

- Discuss:

- Should we complete Hep B schedules that have been started abroad?

BCG - SCHOOLS PROGRAMME DISCONTINUED AS NO LONGER TARGETS HIGH RISK GROUPS

Focus is now on:

- Infants and children living in areas with TB incidence of 40/100,000 or greater
- Those arriving from areas with a TB incidence of 40/100,000 or greater
- Those with parents or grandparents who were born in country with a TB incidence of 40/100,000 or greater
- Those under 16 years of age travelling to live or work with local people for longer than three months to a country with TB incidence of 40/100,000 or greater
- Healthcare workers

Vaccine additives

- Aluminium (adjuvant) The most common element on earth, present in breast milk.
- Antibiotics, neomycin, streptomycin, polymixin B (Residual) prevent bacterial contamination during manufacture
- Gelatin (Stabiliser) added to vaccines to prevent damage from freeze drying/heat process. Keep svaccine potent during storage
- Formaldehyde (Residual) used to inactivate viruses or toxins used in manufacture of some vaccines. Naturally present in the human body, needed to make DNA and amino acids. Traces in vaccines less than one tenth of naturally circulating levels in a 2 month old.
- Lactose (Stabiliser)
- Egg protein (Residual)

Planning schedules for individuals of uncertain or incomplete immunisation status

- Transfer individual onto UK schedule if come from abroad
- No need to restart schedule if evidence of previous immunisation or longer than recommended intervals between vaccine doses –restart schedule where left off
- Plan catch-up immunisation schedule with minimum number of visits and minimum possible timescale
- Aim to protect individual in shortest time possible
- Consider vaccines that may not have been given to children coming from abroad e.g. MenC, Hib

Pol3	_	96	96	95
Rota_last	_	0	0	0

Number of districts in the country 64

% of coverage reports received at national level vs number of reports expected 100

Proportion o districts reporting DTP3 coverage

Immunization Schedule (2013 or latest available)

Hovering over an antigen reveals its

Vaccine	Schedule	Entire country	Comment
BCG	birth;	Yes	
DTwPHibHepB	6, 10, 14 weeks;	Yes	
MR	38 weeks; 15 years	Yes	dose at Y15
Measles	15 Months;	Yes	
OPV	6, 10, 14, 38 weeks;	Yes	
TT	15 years; +1, +6 months; +1, +1 year;	Yes	
VitaminA	6-59 months;	Yes	

Immunizaton indicators

Indicator	Expected answer	2013	2012	2011
Planning and management				
Has the country a Multi-Year Plan (MYP) for immunization?	Yes/No/NR	Yes	Yes	Yes
What years does the MYP cover?	number	2011-2016	2011-2016	2011-2016
Nº of districts with microplans that include activities to raise immunization coverage	number	64	70	64
National Immunization Advisory Mechanism				
Has the country a standing technical advisory group on immunization (NITAG)?	Yes/No/NR	Yes	Yes	Yes

General rules for incomplete/uncertain status

- If no record and parents are not sure what has been given previously, vaccinate with UK schedule.
- Never any need to restart courses if delayed attendance – just complete.
- Only 1 dose of Hib and/or Men C required over 1 year and up to 10 years of age – unless using Pediacel/Infanrix IPV/Hib to complete primary course.
- 1 dose of Men C over 10 years and up to 25 years of age (ACWY for duration of current guidance)

General rules..

- Only1 dose of PCV required over the age of 1 year up to 2 years of age. PCV not required over the age of 2 years (unless indicated due to underlying medical condition)

- Ignore any single doses of Measles vaccine given in country of origin and offer 2 doses of MMR 1 month apart (3 months apart between the age of 12 - 18 months to make the second dose count!)

- Ignore any 4th tetanus/polio doses given around the age of 15 -18 months. Give PSB as scheduled in the UK.

Other considerations

- TB screening/BCG vaccination to at risk children: Those born in a highly endemic country (more than 40/100,000 cases TB), or who have parents/grandparents born in an endemic country.

https://www.gov.uk

Public Health England

World Health Organization (WHO) estimates of tuberculosis incidence by country, 2013

Definition of high incidence

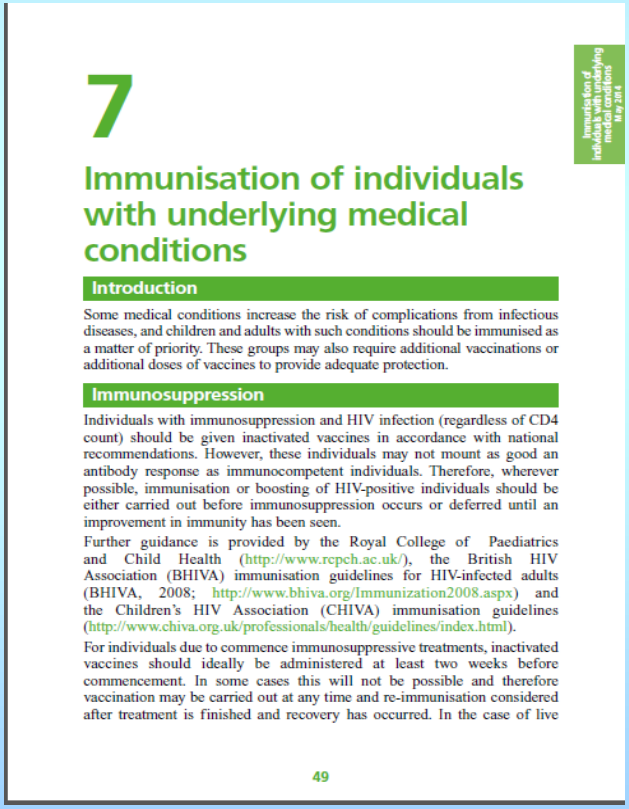
With reference to the National Institute for Health and Clinical Excellence (NICE) recommendations for BCG vaccination and screening in England and Wales, countries/territories with an estimated incidence rate of 40 per 100,000 or greater are considered to have a high incidence of tuberculosis.

Table 1: High incidence countries (estimated incidence rate of 40 per 100,000 or greater)

Country/Territory	WHO Region	Estimated number of cases	Estimated rate per 100,000 population
Afghanistan	Eastern Mediterranean	58,000	189
Algeria	Africa	32,000	81
Angola	Africa	69,000	320
Armenia	Europe	1,500	49
Azerbaijan	Europe	8,000	85
Bangladesh	South-East Asia	350,000	224
Belarus	Europe	6,500	70
Benin	Africa	7,200	70
Bhutan	South-East Asia	1,300	169
Bolivia (Plurinational State of)	The Americas	13,000	123
Bosnia and Herzegovina	Europe	1,700	46
Botswana	Africa	8,400	414
Brazil	The Americas	93,000	46
Brunei Darussalam	Western Pacific	240	58
Burkina Faso	Africa	9,100	54
Burundi	Africa	13,000	128
Cambodia	Western Pacific	61,000	400

Vaccination schedules for those with underlying medical conditions

Refer to GB chapter 7



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Immunisation of individuals with underlying medical conditions

Introduction

Some medical conditions increase the risk of complications from infectious diseases, and children and adults with such conditions should be immunised as a matter of priority. These groups may also require additional vaccinations or additional doses of vaccines to provide adequate protection.

Immunosuppression

Individuals with immunosuppression and HIV infection (regardless of CD4 count) should be given inactivated vaccines in accordance with national recommendations. However, these individuals may not mount as good an antibody response as immunocompetent individuals. Therefore, wherever possible, immunisation or boosting of HIV-positive individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen.

Further guidance is provided by the Royal College of Paediatrics and Child Health (http://www.rcpch.ac.uk/), the British HIV Association (BHIVA) immunisation guidelines for HIV-infected adults (BHIVA, 2008; http://www.bhiva.org/Immunization2008.aspx) and the Children's HIV Association (CHIVA) immunisation guidelines (http://www.chiva.org.uk/professionals/health/guidelines/index.html).

For individuals due to commence immunosuppressive treatments, inactivated vaccines should ideally be administered at least two weeks before commencement. In some cases this will not be possible and therefore vaccination may be carried out at any time and re-immunisation considered after treatment is finished and recovery has occurred. In the case of live

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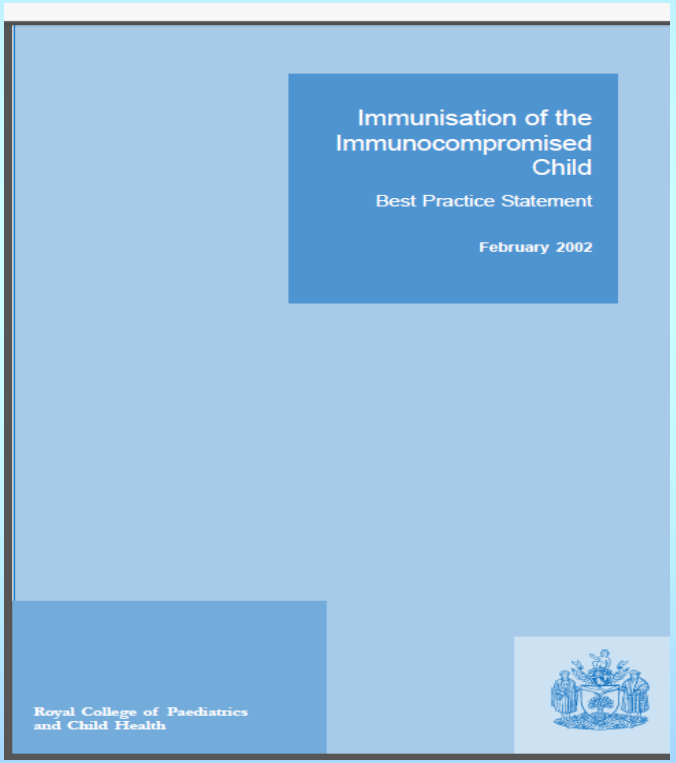
RCPCH Guidelines



Vaccine Administration

- **Site**
- **Choice of needle length**
- **Injection technique**

- These are all important considerations as each factor can affect both immunogenicity and the risk of local reactions

Reconstitution of vaccine

- **Each vaccine should only be reconstituted and drawn up** <u>when required</u> **in order to:**

- Avoid errors
- Maintain efficacy and stability

- **Reconstitution of freeze-dried vaccines:**

- -Only use diluent supplied and use within specified time period
- -Only mix vaccines that are licensed and recommended to be mixed with other vaccines
- -Diluent should be drawn up using a green (21G) needle and added slowly to vaccine to avoid frothing

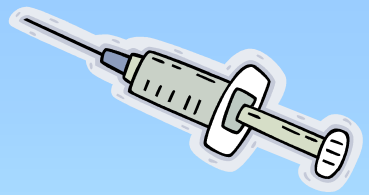
- **Before administration:**

- -Check colour and composition of vaccine is as specified in description in vaccine's SPC
- -Check vaccine to ensure is right product and correct dose for patient
- -Check expiry date

Skin cleansing?

- Clean skin does not require cleansing
- Visibly dirty skin requires only soap and water

Route of Injection



- Vaccines should not be given intravenously
- Most vaccines* should be given intramuscularly:
- This reduces the chance of local reactions and leads to a better immune response to the vaccine
- It is important the vaccine is injected into muscle and not into fat. This is why the deep subcutaneous route is no longer recommended for most vaccines
- However:
- Individuals with a bleeding disorder should receive their vaccines by deep subcutaneous injection to reduce risk of bleeding
- ***exceptions are BCG (intradermal injection), Varicella vaccines [Varilix](subcutaneous injection) Rotavirus [Rotarix] Flu for children[Fluenz] Cholera vaccine (oral) Oral Typhoid Yellow Fever (sub cut)**

Needle Size

Orange	25 gauge	16 mm long 25 mm long
Blue	23 gauge	25 mm long
Green	21 gauge	38 mm long

- For IM injection, needle needs to be long enough to ensure vaccine is injected into muscle
- A 25mm needle length is preferable and suitable for all ages (ref; BMJ 2006;2006;333:571[16 September] Effect of needle size on immunogenicity and reactogenicity of vaccines in infants)
- 16mm needle length is only recommended for pre-term or very small infants
- In larger adults, a longer length (38mm) may be required – individually assess patients

Changing needles

- Unless the vaccine is supplied in a pre-filled syringe with an integral needle, a new needle of a size appropriate to the individual patient should be used to inject the vaccine

Injection site

- For infants under 1 year:
- Anterolateral aspect of the thigh is preferred site as it provides a large muscle mass
- For older infants and adults:
- Deltoid area of upper arm generally preferred but anterolateral aspect of thigh can also be used

- When 2 or more injections need to be given at the same time, they should preferably be given at separate sites in different limbs
- If more than one injection needs to be given into the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be recorded

Anatomy and physiology

- The most effective place to inject a vaccine is into a muscle. This is because muscles have a good blood supply and this increases the processing of the antigen. In adults the preferred site is the deltoid muscle.

Injection Site

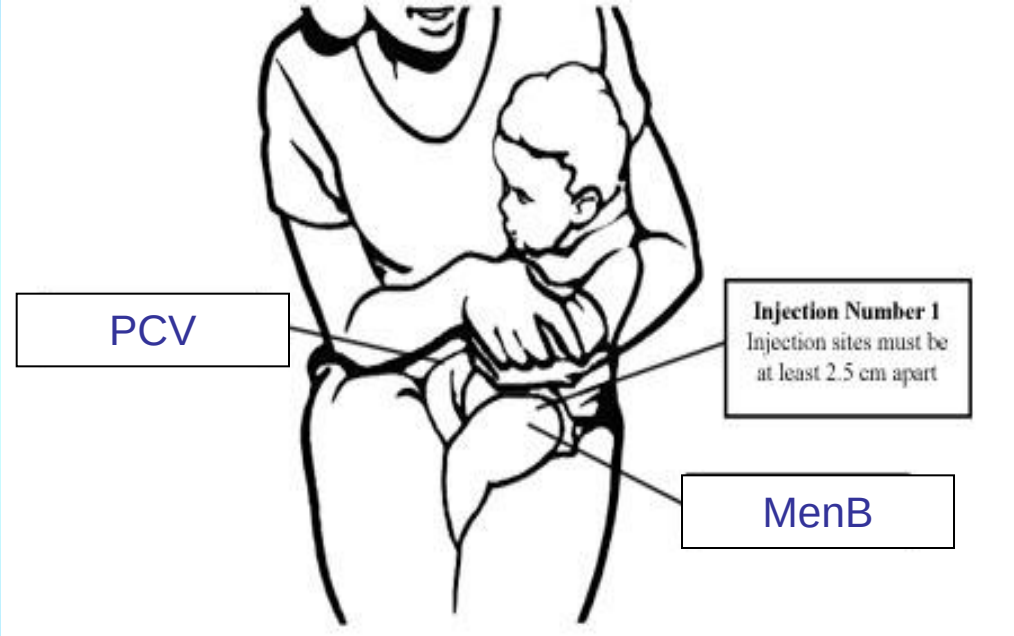
- The injection site needs to avoid major nerves and blood vessels
- Immunisations should not be given into the buttock due to risk of:
- -sciatic nerve damage
- -injecting the vaccine into fat rather than muscle

- Injection of vaccine into fatty tissue of the buttock has been shown to reduce the immunogenicity of HepB and rabies vaccines

Injection Technique

- **IM injections should be given with needle at a 90º angle to the skin**
- **The skin should be stretched flat (NOT bunched)**
- **It is not necessary to aspirate the syringe after the needle is put into the muscle (DH 2011,WHO 2004, Plotkin and Orenstein 2004)**

Simultaneous administration



http://www.youtube.com/watch?v=WRVCptt-wpg

World Health Organisation (2004)

Parental Demeanour

- Parental demeanour significantly influences the amount of pain and distress children experience
- Excessive parental reassurance, criticism, apology, giving control to the child were associated with increased child distress.
- Humour, distraction, matter of fact, supportive non apologetic approach tend to decrease distress

(Schetcer et al. Pain reduction during paediatric immunizations; Evidence based review and recommendations paediatrics 2007 e1184 – e1198)

Simultaneous or sequential Vaccination?

- The Green Book does not advocate either sequential or simultaneous vaccination, however, the UK Guidance on Best Practice in Vaccine Administration (2001) states

  "Where a child needs to be given more than one injection at a visit it can be helpful for two members of staff to inject simultaneously, as the child is usually not aware that two injections have been given and hence distress is minimised. This is usually appropriate for children who are old enough to receive injections in the upper arm"

- Dr Linda Diggle, a leading specialist in vaccine administration, cites Horn et al on the subject of simultaneous administration " Studies show no detectable decrease in discomfort compared with administering injections sequentially, however, the technique is effective in reducing anxiety in older children" *(Children's responses to sequential vaccination versus simultaneous immunisation injections, J Paediatric Health care, 13, 18-23*

Pain reduction in infants during vaccination?

- New research claims that infants who are kept warm show fewer markers of pain and for a shorter length of time..
- Infants given glucose prior to vaccination show fewer markers of pain
- Giving Rotavirus appears to pacify infant – due to glucose?
- Sucking reduces pain (or is this distraction?)
- Distraction techniques

Q: **Should air bubbles be expelled from prefilled syringes prior to injection?**

- Air bubbles should not be expelled from syringes that come with a needle attached and pre-filled with vaccine as they are part of the design. The small bolus of air injected following administration of medication clears the needle and prevents a localised reaction from the vaccination by preventing medication from seeping out along the needle track and into subcutaneous tissue.

Q. Should needle be primed when drawing up a vaccine?

- When expelling large air bubbles from syringes healthcare workers should avoid priming the needle. This can be avoided by first drawing back on the syringe before carefully expelling the air. Priming needles increases the risk of localised reactions. Unnecessarily expelling small air bubbles from syringes without airlocks may increase the risk of accidentally losing some vaccine.

In Summary

- No Need to warm, cleanse, aspirate, prime, remove air in prefilled syringes
- Speedy approach is best for IM injection delivery
- Most immunisations are IM
- Deltoid is the preferred site in adults
- 25mm, 23 gauge blue needle for infants, adolescents and adults (use clinical judgement with larger adults)
- Practice should be evidence based!

Case Study

- A mother arrives with her daughter for the 12 month boosters. She is adamant that she does not want 4 vaccines to be given at once because it is “too much” for her baby. She asks which of the vaccines she should delay for a month.
- What advice would you give to this mother?

Can one vaccine be delayed?

- DH recommends that all necessary vaccines be given at the same time to ensure children are fully protected from serious disease as early as possible
- Parents have the right to refuse one or all injections
- HCW should ***never*** recommend delaying
- Could leave HCW open to criticism if relevant vaccine preventable infection occurred in the interim

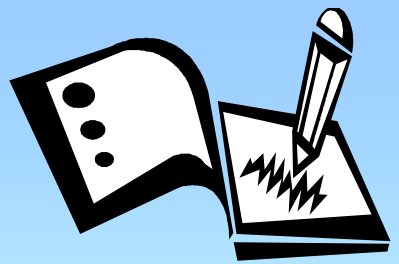
Prior to Administration…..

- Vaccinators should ensure that:
- There are no contraindications to the vaccines being given
- Consent has been obtained
- The vaccinee or carer is fully informed about the vaccines that are being given and understands the vaccination procedure
- The vaccinee or carer is aware of possible adverse reactions and how to treat them

Recording

- Registered nurses have a professional responsibility to maintain accurate records of drug administration.
- Date, time, injection site, batch numbers and expiry dates should be recorded.
- The health professional carrying out the immunisation is responsible for signing the documentation
- Child health information sheets, scheduled and unscheduled should be completed **in full** and returned promptly.

Recording



- The following information should be recorded accurately:
- **Vaccine name, batch number and expiry date**
- **Dose administered**
- **Site(s) used – including clear description of which injection was administered in each site, especially where two injections were administered in the same limb**
- **Date immunisation(s) were given**
- **Name and signature of vaccinator**

- This information should be recorded in:
  - Patient held record or Personal Child Health Record (PHCR) for children
  - Patient's GP record or other patient record depending on location
  - Child Health Information System
  - Practice computer system

Vaccine	Contraindication	Precautions
All vaccines (live and inactivated)	•A confirmed anaphylactic reaction to a previous dose of the vaccine or to a component of the vaccine	•If individual acutely unwell on day of vaccination, postpone until recovered •Pregnancy •If evidence of evolving neurological abnormality or current neurological deterioration, including poorly controlled epilepsy, immunisation should be deferred until condition stabilised
Influenza	•As above and additionally: •Individuals with confirmed anaphylactic hypersensitivity to egg products	•Where possible, thiomersal free influenza vaccines recommended for pregnant women and infants
Live vaccines (MMR, varicella)	•As above and additionally: •Immunocompromising treatment or condition •Pregnancy	•If ITP following previous MMR vaccine, perform antibody test •If confirmed anaphylactic reaction to egg, seek further advice with view to immunisation under controlled conditions

Commonly reported reactions following immunisation

- Local Reactions
- Pain, swelling or redness at injection site (Arthrus reaction)
- Small nodules may form at injection site (reduced by correct needle size)
- General Reactions
- Fever, irritability, malaise, fatigue, headache, nausea, vomiting, diarrhoea, loss of appetite

Arthrus reaction

- Occurs in response to high levels of circulating antibodies to the vaccine antigen.
- Usually resolves spontaneously within 7 days.
- Treat with cold compress/paracetamol
- Not a contraindication to further vaccination

Adverse events

- Live vaccines: frequency of adverse events falls with number of doses
  - Eg MMR
  - Because if antibody is made in response to live vaccine, it neutralises the small amount of vaccine virus in any subsequent vaccine dose

- Inactivated vaccines: frequency of adverse events increases with number of doses
  - Eg tetanus, pertussis
  - Because if antibody levels are good following previous vaccination, the antibody binds to the vaccine antigen in a subsequent dose of vaccine making an inflammatory response (such as a sore arm).

What to expect after vaccinations

NHS

This leaflet tells you about the common side effects of vaccinations that might occur in babies and young children up to five years of age.

After a vaccination, your baby may cry for a little while, but that usually settles soon with a cuddle or a feed. Most babies don't have any other reaction.

Reactions at the site of the injection

Some babies have some swelling, redness or a small hard lump where the injection was given and it may be sore to touch. This usually only lasts two to three days and doesn't need any treatment.

Fevers

A fever is a temperature over 37.5°C. Fevers are quite common in young children, but are usually mild. If your child's face feels hot to the touch and they look red or flushed, he or she may have a fever. You can check their temperature with a thermometer.

If your baby has a fever:

- make sure they don't have too much clothing or bedding on them, and
- give them plenty of cool fluids
- do not put them in a bath, sponge them down or put a fan on them

After vaccination with MenB

Fever can be expected after any vaccination, but is very common when the MenB vaccine is given with the other routine vaccines at two and four months. The fever shows the baby's body is responding to the vaccine, although not getting a fever doesn't mean it hasn't worked. The level of fever depends on the individual child and does not indicate how well the vaccine has worked. Giving paracetamol will reduce the risk of fever, irritability and general discomfort (including pain at the site of the injection) after vaccination.

After each of the two-month and four-month vaccinations you will need to give your baby a total of three doses of paracetamol (2.5ml of infant paracetamol 120mg/5ml suspension) to prevent and treat any potential fever. You should give the first dose of paracetamol as soon as possible after your two-month vaccination visit. You should then give the second dose four to six hours later and the third dose four to six hours after that. You will need to follow the same steps after

True Contraindications

- Vaccination in moderately or severely unwell individuals

- Live vaccines in immunocompromised individuals
- ***Anaphylaxis*** to previous dose of vaccine or a vaccine component

◆ Definition of anaphylaxis:

- Typically rapid and unpredictable with variable severity and clinical features including cardiovascular collapse, bronchospasm, angioedema, pulmonary oedema, loss of consciousness and urticaria

How common is anaphylaxis following immunisation?

- Study on children in UK and Ireland under 16 years of age suspected of anaphylactic reaction following immunisation 2008/09: *(Archives of disease in childhood, 2011)*
- 15 cases reported
- 7 confirmed as anaphylaxis
- 3 of these children already carried an Epipen
- 2 cases associated with single measles vaccines (12 per 100,000 doses given)
- 3 cases following HPV vaccination (1.4 per million doses)
- All children fully recovered
- Non of the reactions were associated with the infant or preschool programme.
- 5.5 million doses given during that time without anaphylaxis.

Anaphylactic shock after immunisation extremely rare!

Stings	**47**	29 wasp, 4 bee, 14 unknown
Nuts	**32**	10 peanut, 6 walnut, 2 almond, 2 brazil, 1 hazel, 11 mixed or unknown
Food	**13**	5 milk, 2 fish, 2 chickpea, 2 crustacean, 1 banana, 1 snail
Food possible cause	**17**	5 during meal, 3 milk, 3 nut, 1 each - fish, yeast, sherbet, nectarine, grape, strawberry
Antibiotics	**27**	11 penicillin, 12 cephalosporin, 2 amphotericin, 1 ciprofloxacin, 1 vancomycin
Anaesthetic drugs	**39**	19 suxamethonium, 7 vecuronium, 6 atracurium, 7 at induction
Other drugs	**24**	6 NSAID, 3 ACEI, 5 gelatins, 2 protamine, 2 vitamin K, 1 each - etoposide, acetazolamide, pethidine, local anaesthetic, diamorphine, streptokinase
Contrast media	**11**	9 iodinated, 1 technetium, 1 fluorescein
Other	**3**	1 latex, 1 hair dye, 1 hydatid

Table 1. Suspected triggers for fatal anaphylactic reactions in the UK between 1992-2001[15]

Signs and Symptoms

Sudden Onset and Rapid progression of symptoms

- Patient will look and feel unwell
- Reactions occur over several minutes
- Patient usually anxious and can experience sense of impending doom

Symptoms cont…….

Skin and/or mucosal changes

- Often the first feature and present in over 80% of anaphylactic reactions
- Subtle or dramatic
- Erythema – patchy or generalised red rash
- Urticaria – Hives, weals which appear anywhere, look like nettle stings and are usually itchy
- Angiodema – swelling of deeper tissues – eyelids, lips, mouth, throat

Differential diagnosis

Diagnostic difficulty may occur with vasovagal attacks after immunisation procedures, The absence of the following are useful distinguishing features:

- Rash
- Breathing difficulties
- Swelling
- Rapid pulse (usually slow in vasovagal attack)
- Child will respond once lying down with legs raised

Non life threatening conditions

- Faint
- Panic attack
- Breath holding
- Non allergic urticaria/angiodema

Severe allergic reactions (not anaphylaxis)

- **are not** a contraindication
- specialist advice should be sought before continuing
- http://www.youtube.com/watch?v=31hptHYscX4

The following are also **NOT** contraindications to vaccination:

- Family history of any adverse reactions following immunisation
- Previous history of pertussis, measles, rubella or mumps infection
- Prematurity: immunisation should not be postponed
- Stable neurological conditions such as cerebral palsy and Down's syndrome
- Contact with an infectious disease
- Asthma, eczema, hay fever or 'snuffles'
- Treatment with antibiotics or locally-acting (eg topical or inhaled) steroids
- Child's mother is pregnant
- Child being breast fed
- History of jaundice after birth
- Under a certain weight
- Over the age recommended in immunisation schedule
- 'Replacement' corticosteroids

Post Vaccination

- Observe vaccine recipients for immediate adverse reactions
- Suspected adverse drug reactions (ADRs) to vaccines should be reported to the Committee on Safety of Medicines using the Yellow Card Scheme:
- -For established vaccines, only serious ADRs should be reported
- -For newly licensed vaccines labelled with an inverted black triangle (▼), serious and non-serious reactions should be reported
- -All suspected ADRs occuring in children should be reported by healthcare professionals or parents

Disposal of vaccination equipment

- **All:**
- -reconstituted vaccines
- -opened single and multidose vials
- -empty vials and ampoules
- -used needles and syringes
-
- **should be disposed of in yellow sharps bins**

- **Sharps bins should be replaced once 2/3rds full**

Safe sharps disposal

FAQs

What does each colour represent?

Sharpsafe® sharps container lids are available in four colours:

Orange – Sharps for incineration or alternative treatment. Marked "Fully Discharged Sharps" for use with fully discharged sharps not contaminated with prescription only medicines (POMs).

Yellow – Sharps including infectious sharps for incineration only. Marked with "Medicinal Sharps" For use with sharps waste including those contaminated with medicines other than those which are cytotoxic/cytostatic.

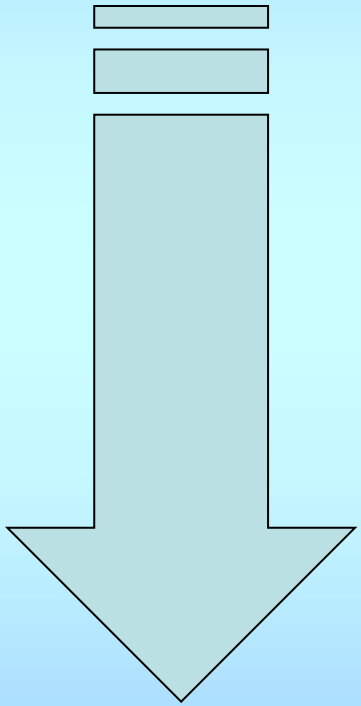
Purple – sharps which are contaminated with cytotoxic and cytostatic medicines. Marked "Cyto sharps".

Blue Lid - Sharpsafe® Pharma waste containers are available with labels designating "Solid Pharmaceutical Waste". These containers comply with UN 3249 and the in-mould labels reflect this fact.

Vaccine Stability

MOST SENSITIVE

- Sensitivity to HEAT
  - BCG
  - Varicella
  - MMR
  - MenC
  - Hepatitis B
  - DT and/or aP/IPV/HIB
  - Flu
  - HPV



LEAST SENSITIVE

- Sensitivity to COLD
  - Conjugated vaccines
  - HepB and combination
  - DTand/or aP/IPV/HIB
  - Influenza
  - MenC
  - *MMR
  - *Varicella
  - *BCG

In summary..

- Below 0°c vaccine adjuvants precipitate causing loss of effect and potency. All aluminium based adjuvants are at higher risk of damage.
- Frozen vials can have hairline cracks leading to contamination.
- Store diluents at same temperature as vaccine to avoid thermal shock.
- Live reconstituted vaccines must be used immediately due to heat sensitivity
- The closer to expiry date, the more vulnerable the vaccines are to degradation above 8°c

Vaccine Storage

- <u>Use a dedicated vaccine fridge</u>

✓ *No food/ medical specimens*

✓ *Safeguard electricity supply*

✓ *Do not place in direct sunlight or near heat source*

✓ *No more than 50% full*

✓ *Defrost/calibrate regularly*

✓ *Ensure back up facilities are available in the event of fridge failing*

✓ ***Use maximum/minimum thermometers inside fridge***

✓ *Monitor and record maximum/minimum and current temperature daily*

Ordering and Delivery

- Named trained designated person and deputy who have overall responsibility for ordering, receipt and care of vaccines.
- Responsibilities include:
  - *Ensuring cold chain has been maintained during transport and managing receipt of vaccines directly into refrigeration*
  - *Checking delivery for leakage, damage and discrepancies*
  - *Rotation of stock*
  - *Maintaining stock information system to keep track of orders, expiry dates and running total of vaccines*
  - *Ensuring adequate supply/ Minimising over ordering or stockpiling*

Cool Boxes and Transporting vaccines

- **Use a validated cool box and ice packs from recognised medical supply company**
- **Monitor maximum/minimum temperature, recording at regular intervals**
- Vaccines should be wrapped in bubble wrap or similar insulation material to prevent direct contact with ice packs
- Use insulating material to fill any spaces within the cool box
- Only take enough vaccine for particular session and minimise exposure of the vaccines to room temperatures

What to do if there has been a Cold Chain failure

- *Prior to administration*

➢ *Any vaccine that has not been stored at a temperature of 2-8ºC as per its licensing conditions is no longer a licensed product*

- *Where there is any doubt that cold chain has not been maintained, vaccines should not be used*

➢ Written procedure for the disposal of vaccines by incineration should be available locally

Post administration

- Treat as Serious Untoward Incident
- Inform Practice Manager/Line Manager/PCT of the incident
- Suspend all immunisation clinics until resolved
- Full guidance on actions required following cold chain failure and vaccine incidents can be found at:

http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1267551139589

"Vaccine Incidents Guidance" (HPA, 2012)

DH vaccine audit (VESPA)

- COVER does not match vaccines dispatched.
- 1 dose Pediacel = £23.43
- If every practice in country (8000) wastes 1 dose per month, £2.9 million lost
- Last annual birth cohort 655,000. 1,965,00 doses required. 2,053,800 ordered. 88,000 missing doses.
- 94% uptake, a further 118,000 missing doses
- **Total wastage of 4,845,600**

Vaccine payments

- DES target payments – based on practice list of 5000:
- Primary course (3 doses) 70% uptake £2,655 90% uptake £7,965
- Preschool Booster – 70% uptake £822
- 90% uptake £2,465

(2004 figures BMA) uplift of 3.225% following 2 years, 0.41% uplift 2010

Factors associated with low vaccine uptake - Parents

- Socio-demographic variables
  - Certain groups of children, such as those:
  - in deprived, inner city areas
  - in mobile families
  - in large families
  - with chronic illness
  - in lone parent families
  - under local authority care
  - Well educated, older parents
- Parental attitudes

Consider immunisation service offered

- Need to offer a flexible and accessible service to maximise uptake:
- **Are your clinics held at convenient times for patients?**
- **Can you hold evening or weekend immunisation clinics?**
- **Are you flexible - do you only offer immunisations at ‘baby’ or ‘child health’ clinics?**
- **Are clinics adequately staffed with sufficient administrative support?**
- **Are clinic appointments of sufficient length to allow discussion with parents/patients**

Opportunistic Vaccination

- **Every effort should be made to vaccinate individuals – even if they are older than the recommended age**
- **No opportunity to vaccinate should be missed**
- **If seeing the individual for a different reason, take the opportunity to check their vaccination status and bring them up to date**
- **Remember – there is no limit to the number of vaccines that can be given at any one time**

Strategies to improve uptake

- All Healthcare Professionals who immunise need to:
- **Keep up to date with changes to policy and parental concerns**
- **Ensure they have access to current vaccine policy**
- **Ensure they know who to contact when they need further advice or information**
- **Attend regular training updates**
- **Make time to discuss parental concerns about immunisation**
- **BE KNOWLEDGABLE AND CONFIDENT**
- **PROMOTE VACCINATION**

Consent

- Consent must always be obtained before immunisation
- Must be given voluntary and freely, after achieving an understanding of what is involved
- Person providing consent should be offered as much information as they reasonably need to make their decision
- Giving and obtaining of consent should be viewed as a process and not a one-off **event**

Written consent

- No legal requirement for consent to be in writing
- Where individuals/parent(s) disagree with immunisation, this should be shared/ recorded with all members of the Primary Health Care Team

Written Consent cont..

- **Completion of a consent form is not a legal requirement**. A signature on a consent form does not itself prove that the consent is valid but it does serve to record the decision that was reached, and the discussions that have taken place. The Bristol Royal Infirmary Inquiry Final Report (2001) (www.bristol-inquiry.org.uk/final%5Freport/report/sec2chap23%5F15.htm) reported that ‘too great a regard is paid to the symbolic act of signing a piece of paper rather than to the real task …which involves explaining what is to take place.’

Who can consent?

- ADULTS: aged 18 or over
- ➢ must consent to their own treatment
- ➢ no-one can give consent for an adult who is unable to consent for him/herself
- INCOMPETENT ADULT (*Mental Capacity Act - April 2005)*
- ➢ overall decision of health care professional in patient's best interests
- ➢ may involve discussions with relatives

Adolescents and children

- Young people can consent to their own treatment provided they are:

✓ Aged 16 + years **or**

✓ Considered “Fraser competent” (Gillick)

Infants and young children

For young children not competent to give or withhold consent, such consent can be given by a person with parental responsibility, provided that person is capable of consenting to the immunisation in question and is able to communicate their decision. Where this person brings the child in response to an invitation for immunisation and, following an appropriate consultation, presents the child for that immunisation, these actions may be considered evidence of consent.

Who has parental responsibility?

- Mother - automatic responsibility for her children
- Father – IF…

✓ married to mother or was when child was *conceived* or born

✓ granted by courts (Parental Responsibility Order)

✓ Parental responsibility agreement in place (Step parents, unmarried fathers pre 2003)

✓ name appears on birth certificate (post 2003)

- Residence Order - e.g Local Authority *and* parents have parental responsibility

Delegated responsibility

- The person with parental responsibility does not necessarily need to be present at the time the immunisation is given. Although a person may not abdicate or transfer parental responsibility, they may arrange for some or all of it to be met by one or more persons acting on their behalf (Section 2(9) of the Children Act 1989).

Delegation of responsibility

- There is no requirement for such arrangements to be made in writing. Children may be brought for immunisation by a person without parental responsibility, for example, a grandparent or childminder.

Where a child is brought for immunisation by some one who does not have parental responsibility the health professional would need to be satisfied that:

- The person with parental responsibility has consented in advance to the immunisation (i.e. they received all the relevant information in advance and arranged for the other person to bring the child to the appointment)
- The person with parental responsibility has arranged for this other person to provide the necessary consent (i.e. they asked the other person to take the child to the appointment, to consider any further information given by the health professional, and then to agree to immunisation if appropriate).

Prescribing

- A vaccine may only be administered:
- Against a prescription written manually or electronically by a registered medical practitioner or another authorised prescriber
- Against a Patient Specific Direction or Patient Group Direction

Patient Specific Directions

- “written instruction from an independent prescriber (*doctor, dentist*) to another healthcare professional, to supply and/or administer a medicine directly to a named patient, or several named patients.”

- *Chapter 6 (DRAFT) Immunisation by nurses and other healthcare professionals.*
  - *Immunisation Against Infectious Disease (The Green Book)*
  - http://www.dh.gov.uk/assetRoot/04/12/33/48/04123348.pd

PSD use

- A Patient Specific Direction is used once a patient has been assessed by a prescriber and that prescriber, (doctor, dentist or other independent prescriber) instructs another healthcare professional in writing to supply or administer a medicine directly to that named patient or, to several named patients (e.g. patients on a clinic list). ***A PSD is a direct instruction and does not require an assessment of the patient by the healthcare professional instructed to supply and / or administer***, unlike a PGD. It is the responsibility of the person issuing the PSD to ensure that the individual supplying or administering the medicine is competent to do so.

Patient Group Directions

- “a written instruction for the sale, supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment.”

  - ***NHS National Prescribing Centre Patient Group Directions(2004):A practical guide and framework of competencies for all professionals using patient group directions***
    www.npc.co.uk/publications/pgd/pgd.pdf

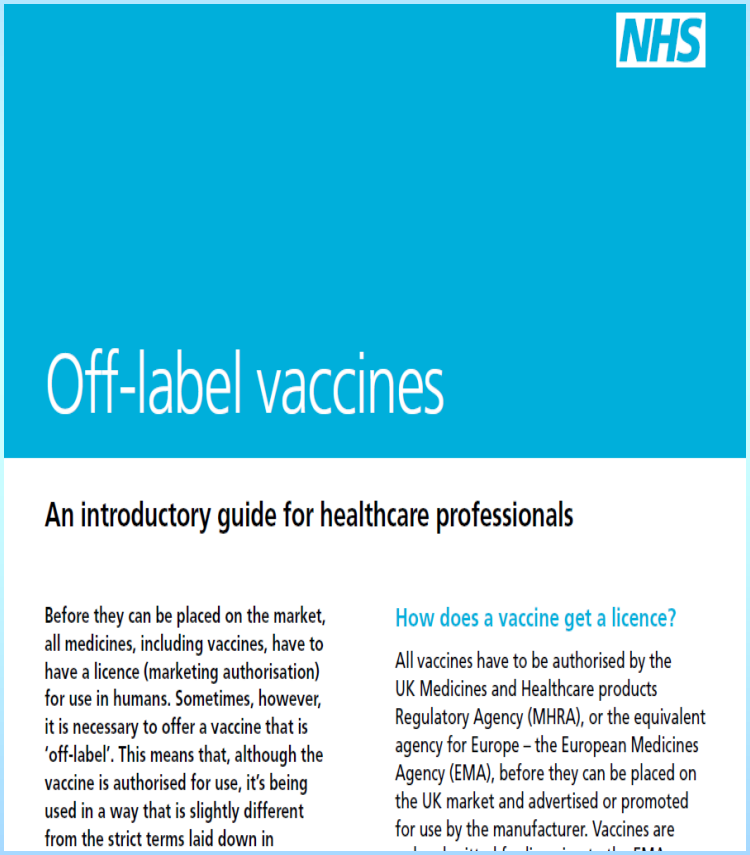
Scope and Limitations of PGDs

- PGDs are not a form of prescribing but provide a legal framework for the supply and/or administration of vaccines
- Pt's may present directly to a healthcare professional using PGDs in their service, without seeing a doctor
- Healthcare professionals working with PGD is responsible for assessing that the patient fits the criteria in the PGD
- Healthcare professionals signing up to PGDs must be fully competent qualified and trained in all aspects of immunisation
- Full details at: www.pgd.nhs.uk

When should a PGD be used?

- Limited situations where it offers advantages for patient care without compromising safety
- A nurse led clinic may have several PGDs which cover immunisation of the patient groups they are likely to see
- eg : Travel & Flu vaccination clinics
- Immunisation sessions in schools/prisons
- Vaccination of refugees, asylum seekers, looked after children

Off label vaccines



NHS

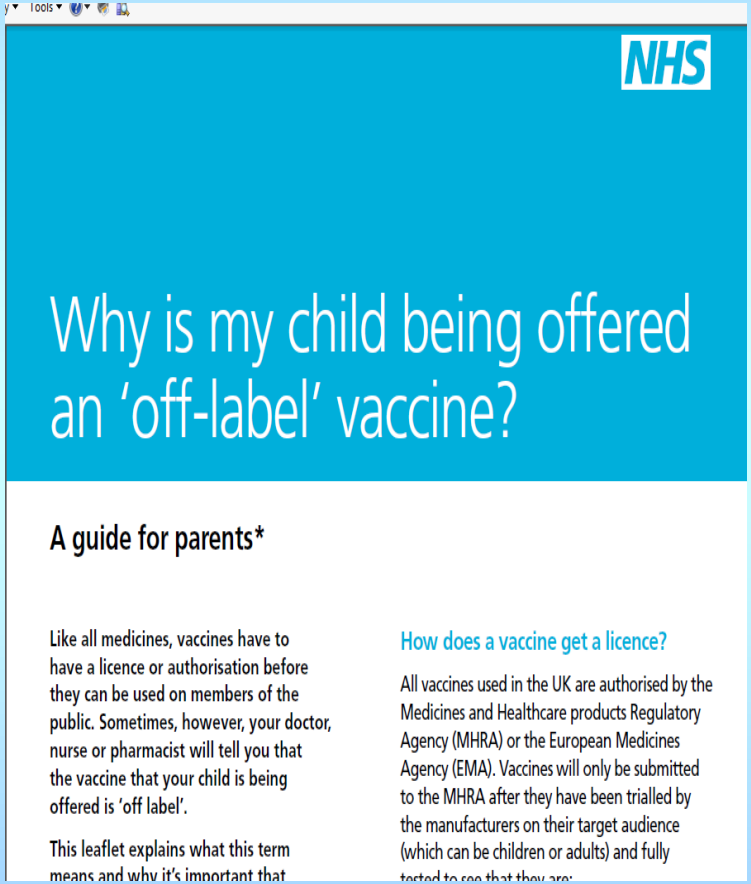
Off-label vaccines

An introductory guide for healthcare professionals

Before they can be placed on the market, all medicines, including vaccines, have to have a licence (marketing authorisation) for use in humans. Sometimes, however, it is necessary to offer a vaccine that is 'off-label'. This means that, although the vaccine is authorised for use, it's being used in a way that is slightly different from the strict terms laid down in

How does a vaccine get a licence?

All vaccines have to be authorised by the UK Medicines and Healthcare products Regulatory Agency (MHRA), or the equivalent agency for Europe – the European Medicines Agency (EMA), before they can be placed on the UK market and advertised or promoted for use by the manufacturer. Vaccines are



NHS

Why is my child being offered an 'off-label' vaccine?

A guide for parents*

Like all medicines, vaccines have to have a licence or authorisation before they can be used on members of the public. Sometimes, however, your doctor, nurse or pharmacist will tell you that the vaccine that your child is being offered is 'off label'.

This leaflet explains what this term means and why it's important that

How does a vaccine get a licence?

All vaccines used in the UK are authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). Vaccines will only be submitted to the MHRA after they have been trialled by the manufacturers on their target audience (which can be children or adults) and fully tested to see that they are:

Can patients receive unlicensed vaccines under PGD?

- No, the PGD framework does not allow for unlicensed medicines to be supplied and / or administered.

Example:

- Verorab rabies vaccine

Revised NMC code January 2015

Communicate clearly

- To achieve this, you must:
- use terms that people in your care, colleagues and the public can understand
- take reasonable steps to meet people's language and communication needs, providing, wherever possible, assistance to those who need help to communicate their own or other people's needs
- use a range of verbal and non-verbal communication methods, and consider cultural sensitivities, to better understand and respond to people's personal and health needs
- check people's understanding from time to time to keep misunderstanding or mistakes to a minimum, and
- be able to communicate clearly and effectively in English.

Risk Communication

- **Parents should be provided with all the facts and information they require to make an informed decision**

- **This includes:**
  - the risks of the disease
  - the benefits and risks of vaccinating
  - the risks of not vaccinating

- **In this way, they can make decisions that are in the best interests of the child**

Definition of “Risk”

Risk in public health terms could be defined as:

“The probability that a particular adverse event occurs during a stated period of time or results from a particular challenge. It can never be reduced to zero”

Pencheon D, Guest C,Melzer D, Muir Gray JA 2001 Oxford Handbook of Public Health (Oxford: Oxford press)

Fright factors for risk communicators

- No time to plan, prepare and marshal the facts
- Fear of getting it wrong, or putting your foot in it
- Uncertain about how to explain scientific fact
- Uncertain about how to debate with people whose values are different from your own

Complications of measles

- ear infection (1 in 20)
- pneumonia/bronchitis (1 in 25)
- convulsions (1 in 200)
- diarrhoea (1 in 6)
- meningitis/encephalitis (1 in 1000)
- conditions affecting blood clotting (1 in 6000)
- late onset subacute sclerosing panencephalitis (SSPE) (1 in 8000 children under 2 years)
- deaths (1-2 deaths in 1000 reported cases in recent years)

Complications of mumps

- viral meningitis (1 in 20)
- encephalitis (1 in 1000)
- permanent hearing loss (1 in 20,000)
- inflammation of testicles (4 in 10 adult males)
- inflammation of ovaries

Complications of rubella

- encephalitis (1 in 6000)
- birth defects (90% chance baby will have birth defects if mother catches rubella early in pregnancy). Birth defects include blindness, deafness, learning difficulties and heart disease
- conditions affecting blood clotting (1 in 3000)

How could you describe the numbers/odds in a different way?

Bronchitis/ pneumonia following measles	1: 25	One child in a class
Deaths from measles	1:1000	One child in a high school
Orchitis in males following Mumps	4:10	30,000 of the men attending an Old Trafford Match!
Damage to the foetus following Rubella in early pregnancy	9:10	9 out of 10 of your female friends

STARCC is about making the message:

- **Simple** – frightened people don't want to hear big words
- **Timely** – frightened people want information immediately
- **Accurate** – make it direct; frightened people won't grasp nuances
- **Relevant** – give action steps and answer specific questions
- **Credible** – use empathy and openness to achieve credibility
- **Consistent** – keep messages consistent, but qualify areas of uncertainty where there may need to be a change to the message, as changes are unsettling and will be scrutinised closely for their significance.

Role of the nurse: Revised NMC code 2015

- **Practise effectively**
- Always practise in line with the best available evidence
- To achieve this, you must:
- make sure that any information or advice given is evidence-based, including information relating to using any healthcare products or services
- maintain the knowledge and skills you need for safe and effective practice.

Revised NMC code

- **Preserve safety**
- Recognise and work within the limits of your competence
- To achieve this, you must:
- ask for help from a suitably qualified and experienced healthcare professional to carry out any action or procedure that is beyond the limits of your competence
- complete the necessary training before carrying out a new role.
- **Be open and candid with all service users about all aspects of care and treatment, including when any mistakes or harm have taken place**

Under consideration. . . .

- Men B in adolescence ?
- Norovirus vaccine (intranasal) within next 5 years
- Universal Hep B (Hexavalent vaccine)
- Strep B vaccine within next 5 years (single dose in pregnancy)
- HPV for all males
- Conjugate Shingles vaccines

Key References

- The Green Book
- https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Immunisation Guidelines (Algorithm)
- https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status
- Reference guide to consent for examination or treatment https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition
- Children Act, 1989, section 2(7)
- http://www.legislation.gov.uk/ukpga/2004/31/contents

- Publication orders (leaflets/posters) DH orderline:
- http://www.orderline.dh.gov.uk/ecom_dh/public/home.jsf
- Immunisation schedule poster
- https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule
- WHO vaccination schedules globally
- http://apps.who.int/immunization_monitoring/globalsummary/

Sources of Vaccine and Disease Information

- **Public Health England (formerly Health Protection Agency)**
- **https://www.gov.uk/government/collections/immunisation**
- **World Health Organisation (lots of vaccine information in various sections)** http://www.who.int/en/
- **Royal College of Paediatrics and Child Health www.rcpch.ac.uk/ (Best Practice Statements for vaccinating immunocompromised children and injection technique)**
- **Institute of Medicine (IOM) of the National Academies www.iom.edu/ (extensive unbiased vaccine study reviews and evidence-based scientific advice)**
- **National Travel Health Network and Centre (NaTHNaC) www.nathnac.org (detailed up-to-date travel immunisation information)Vaccine product information**

  http://emc.medicines.org.uk/ (for spc PILs)

- Minimum slide set created by:
- Immunisation Department,
- Centre for Infections,
- Health Protection Agency
- Public Heath England

- Additional slides: Julie Annakin Independent Immunisation Nurse trainer
- For queries regarding this presentation (not clinical advice) email: julie@immandvacc.co.uk
- Website: www.immandvacc.co.uk