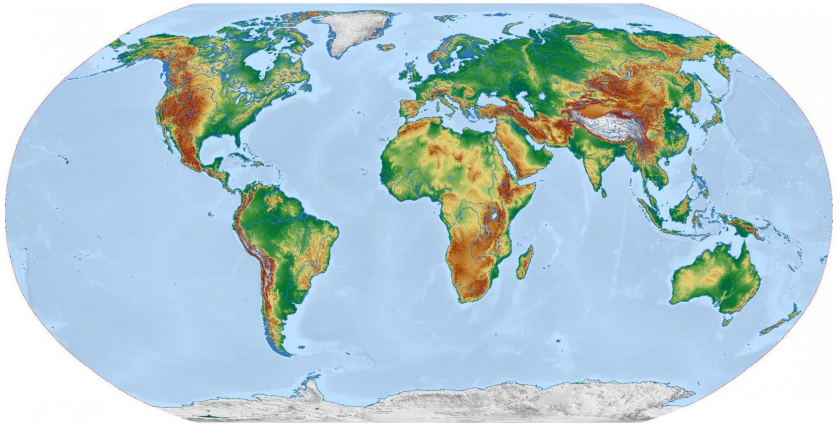
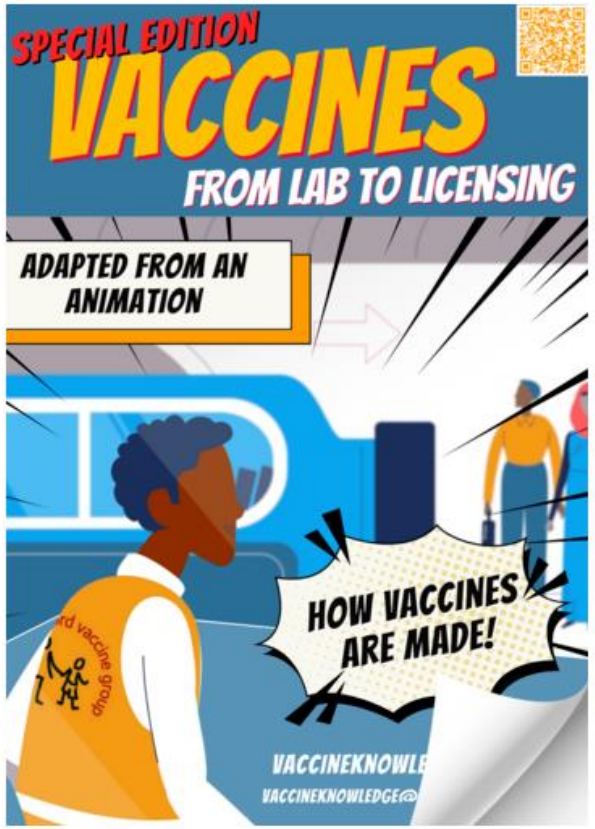


Responding to incomplete and uncertain immunisation schedules



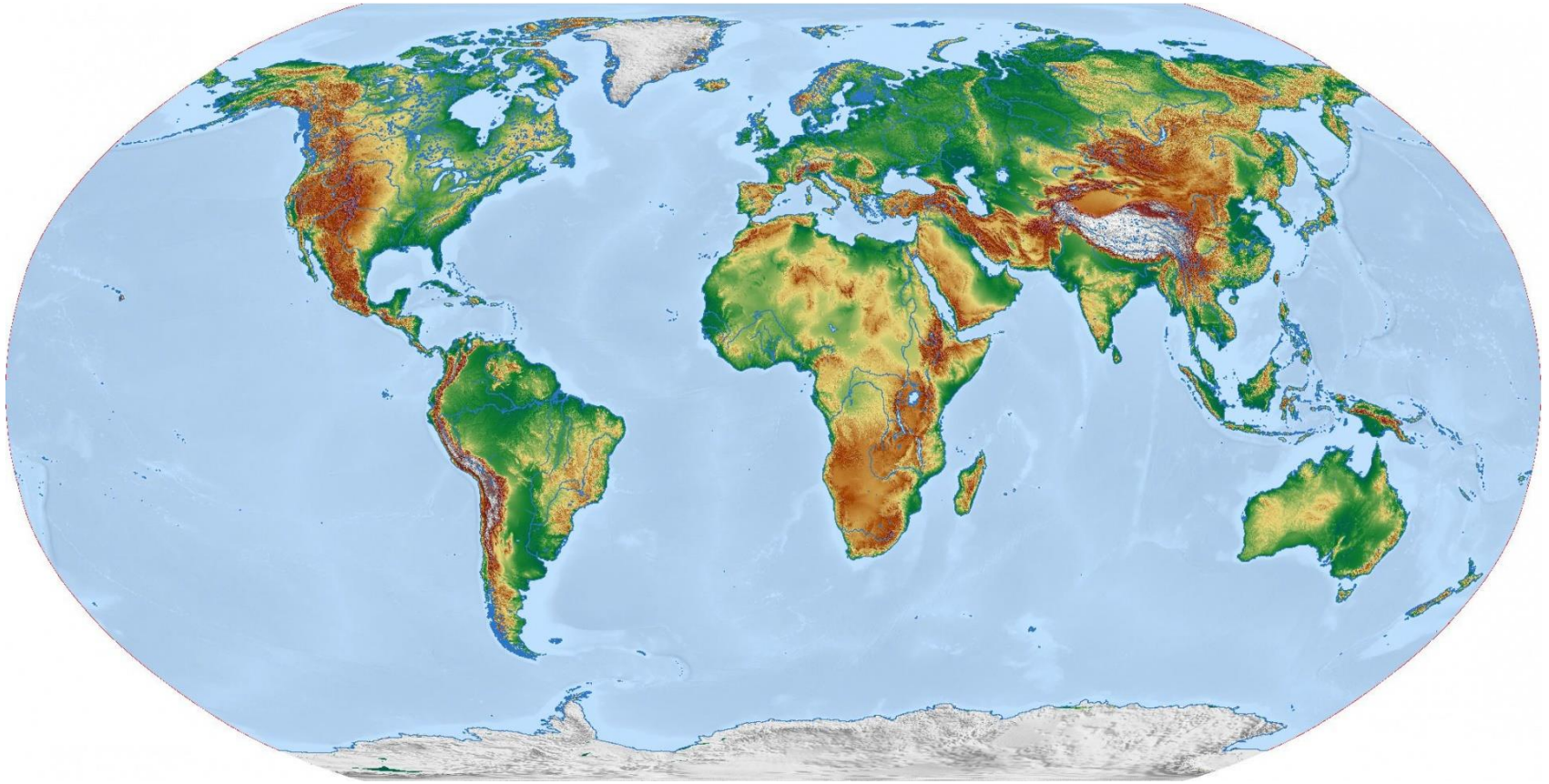
An overview of the vaccine research process

DEPARTMENT OF PAEDIATRICS

Karen Ford

Immunisation Specialist and Senior Research Nurse

OXFORD VACCINE GROUP



Responding to incomplete and uncertain immunisation schedules

Acknowledgement – content of some slides with thanks to Dr Ben Curtis OVG Research Fellow

DEPARTMENT OF PAEDIATRICS

OXFORD VACCINE GROUP

Content

- Consider reasons why immunisation schedules may be incomplete
- To identify resources to assist you in your practice to plan schedules for people with uncertain or incomplete vaccination status

Reasons why individuals may not be up to date with immunisations

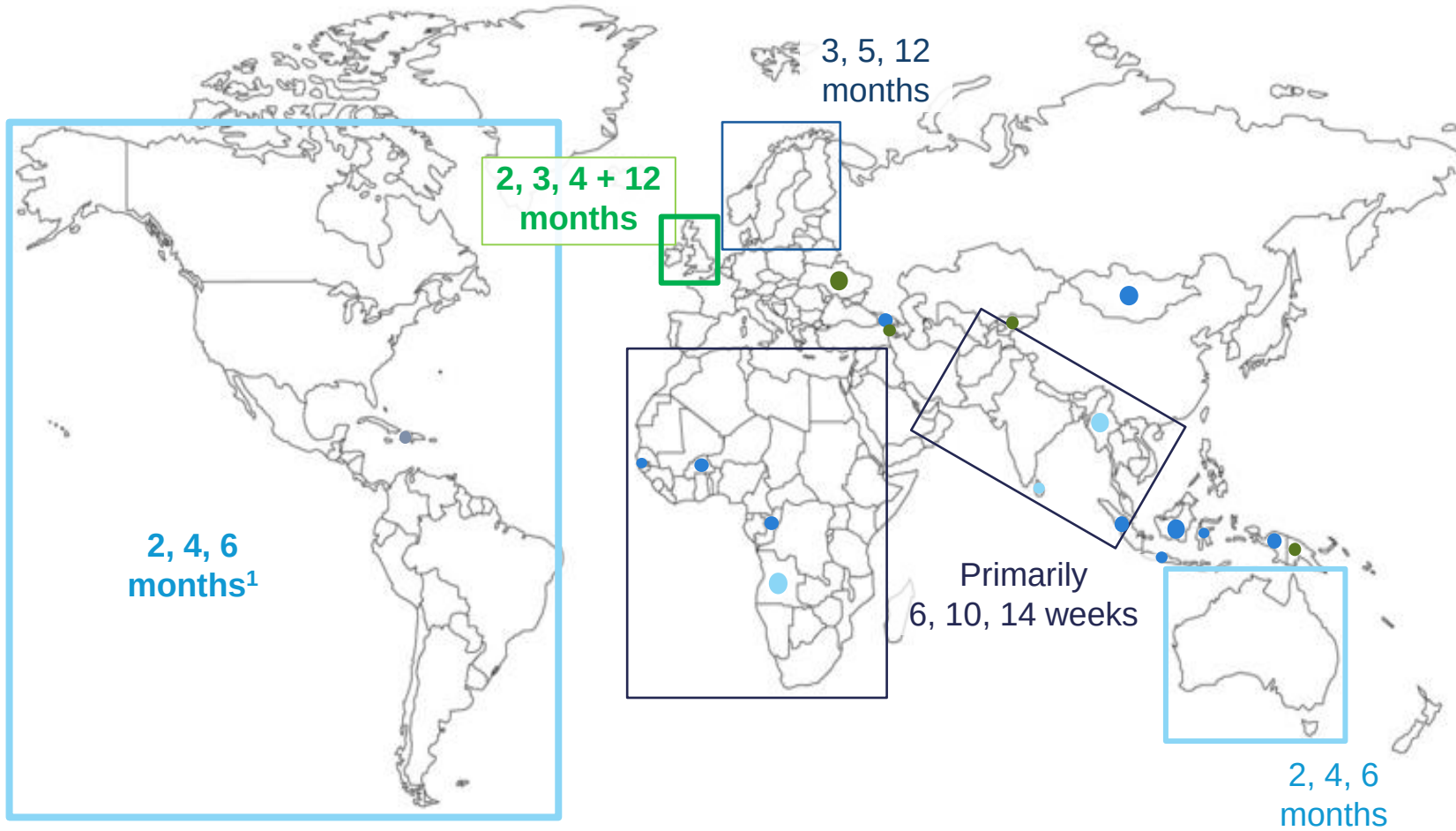
Delay in consenting to vaccination:

- Recommended ages to receive vaccines informed by age-specific risk for a disease, complications, ability to respond to vaccine and the impact on spread on the population
- Follow schedule as close as possible

Coming from other countries, area of conflict, refugees, poor access to immunisation services
Different countries have different schedules

A period of ill health

Globally, there is significant variation in routine immunisation schedules



Even in GAVI countries, there is some variation from the recommended 6, 10, 14 weeks

Immunisation schedules in 73 Gavi-supported countries:

6, 10, 14 weeks: 68% of countries

2, 3, 4 months: 14% of countries

2, 4, 6 months: 12% of countries

Other non-standard schedules**
: 5% of countries

GAVI – Vaccine Alliance is an international organisation aiming to increase equitable and sustainable use of vaccines in lower-income countries

*Country schedule based on time of Penta administration; **Non-standard schedules include 6, 12, 18 weeks; 2, 3.5, 5 months; 1, 2, 3 months; and 3, 4 months

1. Except Haiti (6, 10, 14 weeks), Jamaica (1.5, 3, 5 months), and St. Lucia (3, 4, 5 months).
2. Source: WHO vaccine-preventable diseases monitoring system, 2015 global summary; Australian Government Department of Health: National Immunisation Program Schedule, 20 April 2015; Vaccine Almanac, 2015

Varying vaccination history may be due to

Mobile Populations

Political Instability and Conflict

Variability in Childhood Immunisation Schedules

New Vaccines entering global schedules

Supply Chain interruptions

Geographical obstacles to accessing vaccination

Financial obstacles to accessing vaccination

Vaccine hesitancy and fatigue

Variable vaccine record keeping

So what do we do about individuals who have missed immunisations?

Steps to take …

- Q 1: Which vaccines have they had?
- Q 2: How old are they now?
- Q 3: Which vaccines are they missing for their current age?
- Q 4: When shall I give the missing doses?

Establishing vaccine history

Review all reliable records:

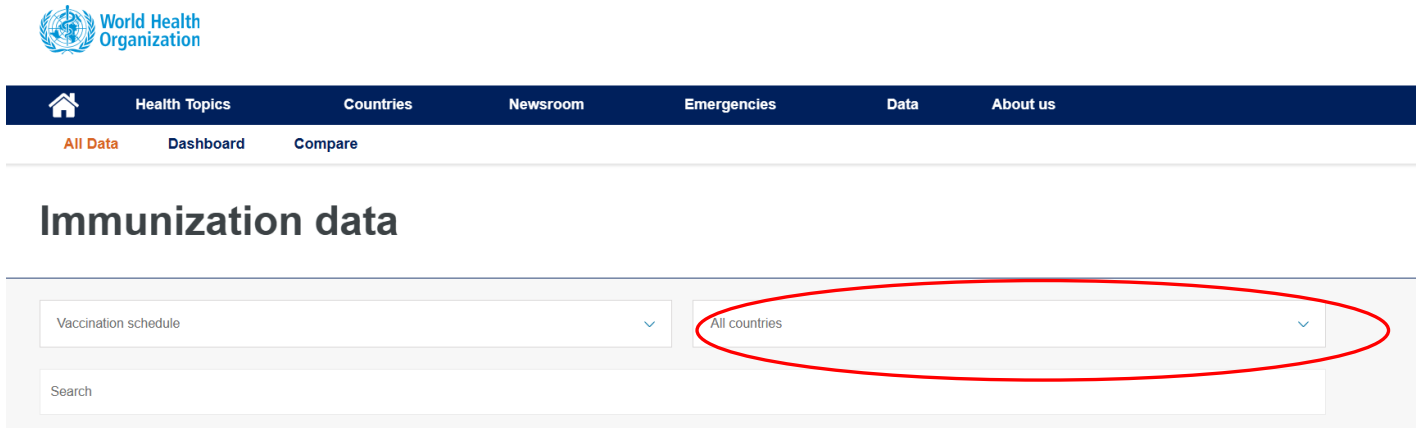
- Personal Child Health Record (Red Book)
- CHIS (Child Health Information Services)
- Previous GP surgery
- Assess parents' verbal history
- Non UK schedule: use online resources to translate

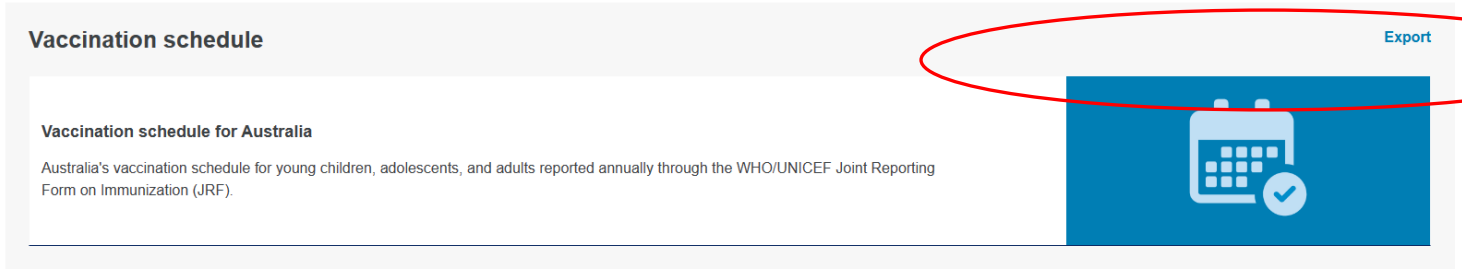
Principle 1

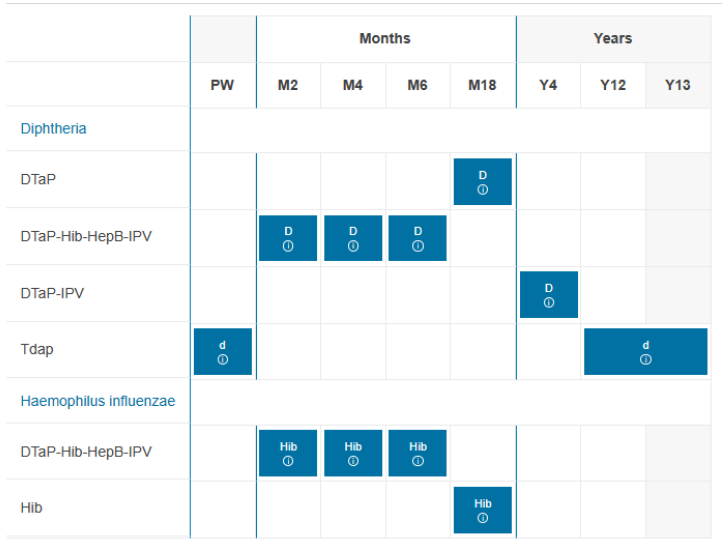
Unless there is a reliable vaccine history, individuals should be assumed to be **unimmunised and a full course of immunisations planned**

- If you leave the individual unimmunised they remain susceptible to a vaccine-preventable disease
- The immune system can cope with many different antigens

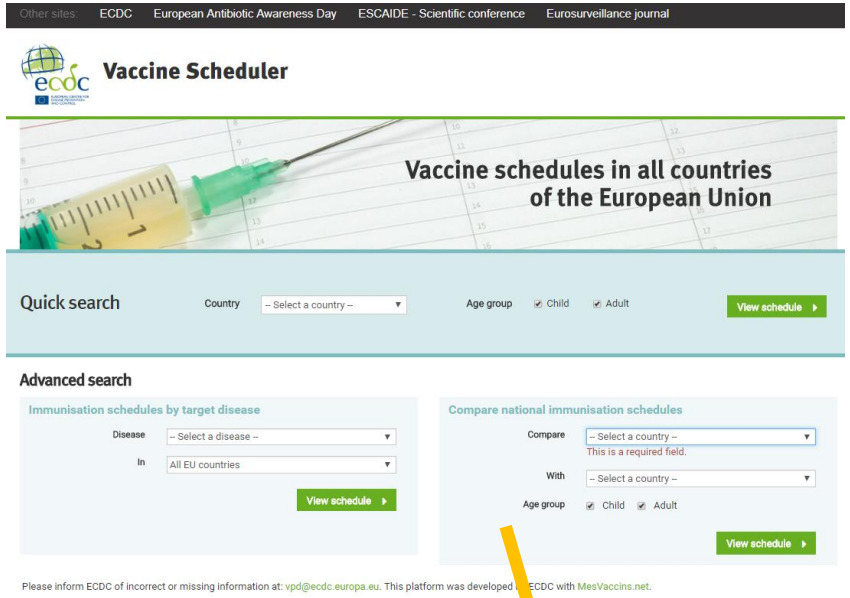
Resources to help interpret non UK schedules

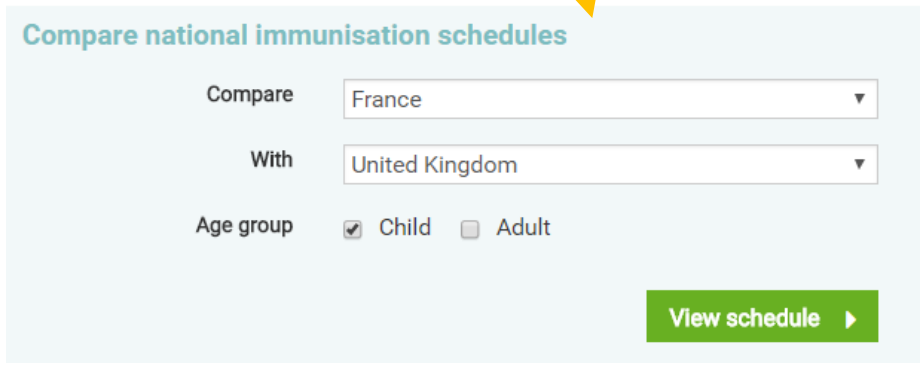


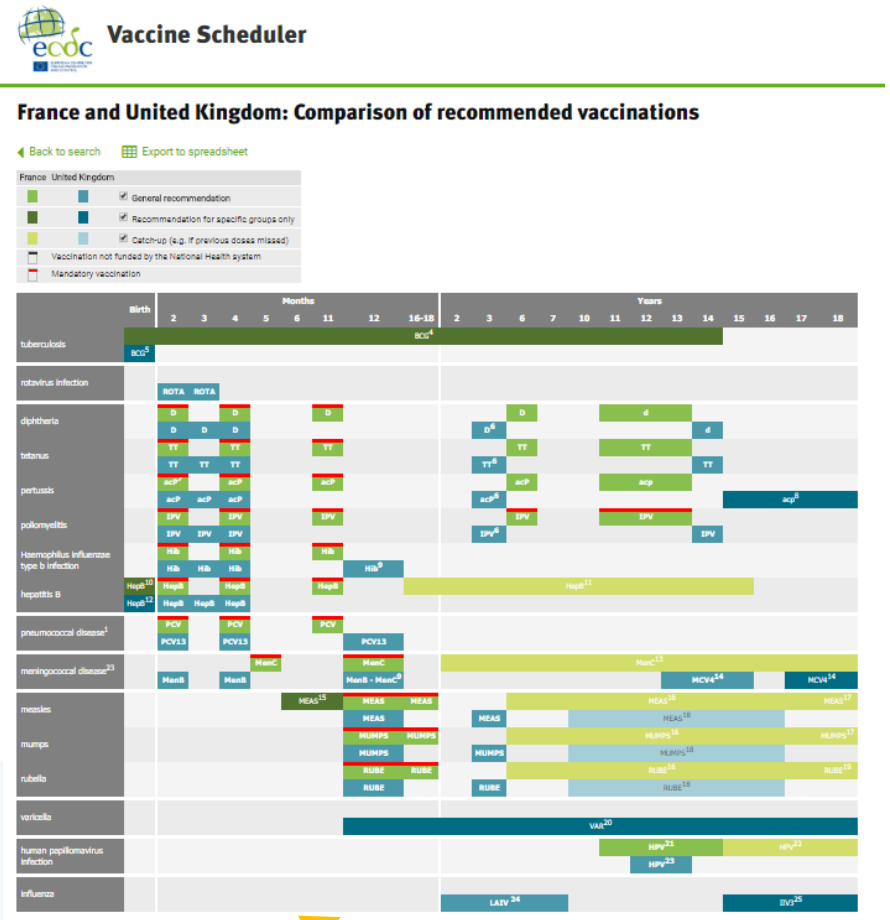




[WHO Immunization Data portal - All Data]







https://vaccine-schedule.ecdc.europa.eu/

European Centre for Disease Prevention and Control
An agency of the European Union

Guidance

UK and international immunisation schedules comparison tool

This tool is intended to help staff in general practice (i) ascertain what vaccines individuals moving to England from abroad have received and (ii) record those vaccines in their IT system. It contains, for each of the 20 countries individuals most commonly immigrate to the UK from, the vaccinations schedule, the name of the diseases/vaccines in the local language and, where available the vaccines used in the countries of origin. Please note that it should not be assumed that individuals have received all vaccines in their national schedule without a documented or reliable verbal history of immunisation.

Staff in general practice are strongly encouraged to code these vaccines using Read 2/CTV 3/SNOMED codes in order to ensure the patients can be identified as vaccinated for the purposes of call/recall and vaccine coverage calculations. Information and advice about vaccination for individuals with uncertain or incomplete immunisation status can be here

v1.1- June 2019

Australia
Bangladesh
China
France
Germany
India
Ireland
Italy
Kenya
Lithuania
Nigeria
Pakistan
Phillippines
Poland
Portugal
Romania
South Africa
Spain
Sri Lanka

UK and international immunisation schedules comparison tool - GOV.UK (www.gov.uk)

Poland

(return to list of countries)

General recommendation for Poland
Recommendation for specific groups only for Poland
Not funded by National Health system in Poland
General recommendation for United King
Recommendation for specific groups only

	Birth	2m	3m	4m	5m	6m	7m	9m	12m	13m	15m	16m	17m	18m	2 yrs	3 yrs
Rubella (Różyczka)									MMR							MMR
										MMR						
Varicella (Ospa)/Shingles (Półpasiec)									Varicella (3)							
							Varicella									
Human papillomavirus (Wirus brodawczaka ludzkiego (HPV))																
Influenza (Grypa)																

DTaP = Diptheria, tetanus and pertussis
PVC = Pneumococcal conjugate vaccine
PPV = Pneumococcal polysaccharide vaccine
IPV = inactivate polio vaccine
Hib = Haemophilus influenza B
MMR = Measles, mumps, rubella
LAIV = live attenuated influenza vaccine
aTIV = Adjuvanted trivalent influenza vaccine
QIV = Quadrivalent influenza vaccine
ZVL = Zoster vaccine live

Remember:

- All tools reflects what you could expect an individual to have received
- The immunisation schedule may have been different in the past

Identifying recommended vaccines

- What antigens have they already had?
- What antigens do they need?

Provides a summary of vaccines at key ages

Table 11.2 Routine immunisation schedule vaccination history at key ages

Key age	Vaccines child should have had or catch-up with
At the age of 12 months:	Three doses of diphtheria, tetanus, polio, pertussis, Hib and hepatitis B containing vaccine. A single dose of PCV vaccine. Two doses of MenB vaccine.
At the age of 24 months:	Three doses of diphtheria, tetanus, polio, pertussis (and hepatitis B) containing vaccines. A single dose of Hib/MenC and PCV13 vaccines after the age of one year. Either 2 doses of MenB under the age of one and one dose after the age of one year; or 2 doses of MenB after the age of one year. A single dose of MMR vaccine after the age of one year.
At school entry:	Four doses of diphtheria, tetanus, pertussis and polio containing vaccine. Two doses of MMR vaccine after the age of one year. A single dose of Hib/MenC conjugate vaccine after the age of one year.
At transfer to secondary school:	Four doses of diphtheria, tetanus and polio containing vaccine. Two doses of MMR vaccine after the age of one year. A single dose of Hib/MenC conjugate vaccine after the age of one year.
Before leaving school:	Five doses of diphtheria, tetanus, polio containing vaccine. A single dose of MenACWY vaccine after the age of 10 years. Two doses of MMR vaccine. Two doses of HPV vaccine (at least 6 months apart)[1]

1 All Females remain eligible for HPV vaccine up to their twenty-fifth birthday. All males born on/after 1 September 2006 are eligible up to their twenty-fifth birthday

You can use this table to see what vaccines a patient should of received according to their age

Remember to review adult's immunisation histories

Green book chapter 11 The UK immunisation schedule (publishing.service.gov.uk)

Principle 2

For individuals coming to UK part way through their immunisation schedule:

- They should be transferred onto the UK schedule and immunised as appropriate for age

NOTE:

- Ignore diphtheria/polio/pertussis/tetanus boosters given before 3 years as they do not count as a booster in the UK

Planning the schedule

UK Health Security Agency

Vaccination of individuals with uncertain or incomplete immunisation status

For online Green Book, see www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • For other countries' schedules, see immunizationdata.who.int/listing.html?topic=vaccine-schedule&location=

Infants from two months of age up to first birthday

DTaP/IPV/Hib/HepB[a#] + MenB[b] + rotavirus[c]
Four week gap
DTaP/IPV/Hib/HepB + PCV13[d] + rotavirus[c]
Four week gap
DTaP/IPV/Hib/HepB + MenB[b]

[a] A child who has already received 1 or more doses of primary diphtheria, tetanus, polio and pertussis should complete the 3 dose course with DTaP/IPV/Hib/HepB. Any missing doses of Hib and/or HepB can be given as Hib/MenC and/or, monovalent hepatitis B, at 4 week intervals

[b] Doses of MenB should ideally be given 8 weeks apart. They can be given 4 weeks apart in order for the primary MenB immunisation schedule to be completed before the first birthday if possible (i.e. if schedule started after 10m of age)

[c] First dose of rotavirus vaccine to be given **only** if infant is more than **6** weeks and under **15** weeks and second dose to be given **only** if infant is less than **24** weeks old

[d] Infants who are aged 12 weeks or over when starting their primary schedule can be given their single infant priming dose of PCV13 with their first set of primary immunisations. If a child has received PCV10 vaccine abroad, they should be offered 1 dose of PCV13 (at least 4 weeks after PCV10 was given)

Boosters + subsequent vaccination

As per UK schedule ensuring at least a 4 week interval between primary DTaP/IPV/Hib/HepB and the booster Hib/MenC dose, and a minimum 4 week interval between MenB and PCV13 priming and booster doses.

General principles

- unless there is a documented or reliable verbal vaccine history, individuals should be assumed to be unimmunised and a full course of immunisations planned
- individuals coming to UK part way through their immunisation schedule should be transferred onto the UK schedule and immunised as appropriate for age
- if the primary course has been started but not completed, resume the course – no need to repeat doses or restart course
- plan catch-up immunisation schedule with minimum number of visits and within a minimum possible timescale – aim to protect individual in shortest time possible

Children from first up to second birthday

DTaP/IPV/Hib/HepB[†#] + PCV13[††] + Hib/Men C[††] + MenB[†††] + MMR
Four week gap
DTaP/IPV/Hib/HepB[†]
Four week gap
DTaP/IPV/Hib/HepB[†] + MenB[†††]

[†] DTaP/IPV/Hib/HepB is now the only suitable vaccine containing high dose tetanus, diphtheria and pertussis antigen for priming children of this age. Children born from 01/08/17 who received primary vaccines without HepB should be opportunistically offered a 3 dose course of monovalent HepB vaccine. If they are in a high-risk group or are exposed to hepatitis B, they should be proactively offered a hepatitis B vaccine course

[††] All un- or incompletely immunised children only require 1 dose of Hib, Men C (until teenage booster) and PCV13 over the age of 1 year. It does not matter if 2 Hib-containing vaccines are given at the first appointment or if the child receives additional Hib at subsequent appointments if DTaP/IPV/Hib/HepB vaccine is given. If a child has received PCV10 vaccine abroad, they should be offered 1 dose of PCV13 (at least 4 weeks after PCV10 was given)

[†††] Children who received less than 2 doses of MenB in the first year of life should receive 2 doses of MenB in their second year of life at least 8 weeks apart. Doses of MenB can be given 4 weeks apart if necessary to ensure the 2 dose schedule is completed (i.e. if schedule started at 22m of age)

Boosters + subsequent vaccination

As per UK schedule

Children from second up to tenth birthday

DTaP/IPV/Hib/HepB[^#] + Hib/MenC[^^] + MMR
Four week gap
DTaP/IPV/Hib/HepB[^] + MMR
Four week gap
DTaP/IPV/Hib/HepB[^]

[^] DTaP/IPV/Hib/HepB is now the only suitable vaccine containing high dose tetanus, diphtheria and pertussis antigen for priming children of this age. Children born from 01/08/17 who received primary vaccines without HepB should be opportunistically offered a 3 dose course of monovalent HepB vaccine. If they are in a high-risk group or are exposed to hepatitis B, they should be proactively offered a hepatitis B vaccine course.

[^^] All un- or incompletely immunised children only require 1 dose of Hib and Men C (until teenage booster) over the age of 1 year. It does not matter if 2 Hib-containing vaccines are given at the first appointment or if the child receives additional Hib at subsequent appointments if DTaP/IPV/Hib/HepB vaccine is given

Boosters + subsequent vaccination

First booster of dTaP/IPV can be given as early as 1 year following completion of primary course to re-establish on routine schedule. Additional doses of DTaP-containing vaccines given under 3 years of age in some other countries do not count as a booster to the primary course in the UK and should be discounted. Subsequent vaccination – as per UK schedule

From tenth birthday onwards

Td/IPV[#] + MenACWY[*] + MMR
Four week gap
Td/IPV + MMR
Four week gap
Td/IPV

[*] Those aged from 10 years up to 25 years who have never received a MenC-containing vaccine should be offered MenACWY

Those aged 10 years up to 25 years may be eligible or may shortly become eligible for MenACWY usually given around 14y of age. Those born on/after 1/9/1996 remain eligible for MenACWY until their 25th birthday

Boosters + subsequent vaccination

First booster of Td/IPV: Preferably 5 years following completion of primary course
Second booster of Td/IPV: Ideally 10 years (minimum 5 years) following first booster

HPV vaccine

- all females (born on/after 01/09/91) and males (born on/after 01/09/06) remain eligible for HPV vaccine up to their 25th birthday on the adolescent programme
- eligible immunocompetent individuals aged 11 to 25 years only require a single dose of HPV vaccine
- eligible individuals who are HIV positive or immunosuppressed should be offered a 3 dose schedule at 0, 1, 4-6 months
- for details of GBMSM HPV vaccination programme, please see Green Book HPV chapter
- any dose of Cervarix, Gardasil or Gardasil 9 would be considered valid if previously vaccinated or vaccinated abroad

Shingles vaccine

- **severely immunosuppressed individuals** from 50 years of age (eligibility as defined in the Green Book Shingles chapter 28a): 2 doses of Shingrix vaccine 8 weeks to 6 months apart; no upper age limit to start or complete the course
- **immunocompetent individuals** from their 65th and 70th birthday (see Shingles: guidance and vaccination programme on GOV.UK website for eligibility): 2 doses of Shingrix vaccine 6 months to 12 months apart. Once these individuals have become eligible, they remain eligible until their 80th birthday. The second dose of Shingrix vaccine can be given up to 81st birthday to those who have commenced but not completed the course
- **immunocompetent individuals** aged from 70 years who were previously eligible for shingles vaccination before 01/09/23 should receive Zostavax (unless contraindicated) until stocks of this vaccine are exhausted, after which Shingrix should be offered

MMR – from first birthday onwards

- doses of measles-containing vaccine given prior to 12 months of age should not be counted
- 2 doses of MMR should be given irrespective of history of measles, mumps or rubella infection and/or age
- a minimum of 4 weeks should be left between 1st and 2nd dose MMR
- if child <3y4m, give 2nd dose MMR with pre-school dTaP/IPV unless particular reason to give earlier
- second dose of MMR should not be given <18m of age except where protection against measles is urgently required

Flu vaccine (during flu season)

- those aged 65yrs and older although recommendations may change annually so always check Annual Flu Letter
- children eligible for the current season's childhood influenza programme (see Annual Flu Letter for date of birth range)
- those aged 6 months and older in the defined clinical risk groups (see Green Book Influenza chapter)

Pneumococcal polysaccharide vaccine (PPV)

- those aged 65yrs and older
- those aged 2yrs and older in the defined clinical risk groups (see Green Book Pneumococcal chapter)

[#] If an individual has received any OPV in another country since April 2016, these doses should be discounted as it is unlikely that they will protect against all 3 polio types. Most countries who still use OPV have a mixed OPV and IPV schedule so if sufficient IPV doses have been received for age, no additional IPV doses are needed.
BCG and Hepatitis B vaccines for those at high risk should be given as per Green Book recommendations. Individuals in clinical risk groups may require additional vaccinations. Please check Green Book chapters.

Effective from 1 September 2023

OXFORD VACCINE GROUP

Make sure you are referring to the most up to date version

Vaccination of individuals with uncertain or incomplete immunisation status - GOV.UK (www.gov.uk)

Public Health England

Vaccination of individuals with uncertain or incomplete immunisation status

For online Green Book, see www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book • For other countries' schedules, see http://apps.who.int/immunization_monitoring/globalsummary/

Infants from two months of age up to first birthday	Children from first up to second birthday	Children from second up to tenth birthday	From tenth birthday onwards

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Step 1:

Decide which column to follow according to the child/patients age

Principles 3 & 4

- If the primary course has been started but not completed, continue where left off – **no need to repeat doses or restart course**

- Plan catch-up immunisation schedule with **minimum number of visits** and within a **minimum possible timescale** – aim to protect individual in shortest time possible

Factors that influence the schedule

The routine schedule adapts with the **age** to reflect:

- The age at which individuals are **most susceptible to severe disease**

  e.g. Men B and Pneumococcal conjugate vaccine (PCV) is not recommended over the age of 2 years in immunocompetent individuals

- The **safety profile** in accordance to age

  e.g. First dose of rotavirus vaccine to be given only if the infant is more than 6 weeks and under 15 weeks

  Second dose to be given only if the infant is less than 24 weeks old

- The required number of doses of a vaccine may change in accordance with the age at which the course is started
  - e.g. No previous doses and over the age of 12 months and under two years of age:
  - PCV one dose
  - Men B two doses

Factors that influence the schedule

The routine schedule adapts with the **age** to reflect:

- The most suitable vaccine product to use to provide protection
  - E.g. Td/IPV (low dose diphtheria) from tenth birthday
- The best timing and spacing of booster doses to fit an individual back into the routine schedule and processes to give immunisations
  - E.g. From **second to tenth birthday**:

  The first booster of dTaP/IPV can be given as early as 1 year following completion of the primary course to re-establish on the routine schedule.
  - E.g. **From the tenth** birthday

  First booster of Td/IPV: Preferably 5 years following completion of the primary course

  Second booster of Td/IPV: Ideally 10 years (minimum 5 years) following the first booster
- The age at which the vaccine is considered most beneficial in terms of providing the best immune response and cost-effectiveness
  - E.g. For immunocompetent individuals, there is an upper age limit of 80 years to be offered the shingles vaccine

UK Health Security Agency

Vaccination of individuals with uncertain or incomplete immunisation status

For online Green Book, see www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • For other countries' schedules, see immunizationdata.who.int/listing.html?topic=vaccine-schedule&location=

Infants from two months of age up to first birthday

DTaP/IPV/Hib/HepB[a#] + MenB[b] + rotavirus[c]
Four week gap
DTaP/IPV/Hib/HepB + PCV13[d] + rotavirus[c]
Four week gap
DTaP/IPV/Hib/HepB + MenB[b]

[a] A child who has already received 1 or more doses of primary diphtheria, tetanus, polio and pertussis should complete the 3 dose course with DTaP/IPV/Hib/HepB. Any missing doses of Hib and/or HepB can be given as Hib/MenC and/or, monovalent hepatitis B, at 4 week intervals

[b] Doses of MenB should ideally be given 8 weeks apart. They can be given 4 weeks apart in order for the primary MenB immunisation schedule to be completed before the first birthday if possible (i.e. if schedule started after 10m of age)

[c] First dose of rotavirus vaccine to be given **only** if infant is more than **6** weeks and under **15** weeks and second dose to be given **only** if infant is less than **24** weeks old

[d] Infants who are aged 12 weeks or over when starting their primary schedule can be given their single infant priming dose of PCV13 with their first set of primary immunisations. If a child has received PCV10 vaccine abroad, they should be offered 1 dose of PCV13 (at least 4 weeks after PCV10 was given)

Boosters + subsequent vaccination

As per UK schedule ensuring at least a 4 week interval between primary DTaP/IPV/Hib/HepB and the booster Hib/MenC dose, and a minimum 4 week interval between MenB and PCV13 priming and booster doses.

General principles

- unless there is a documented or reliable verbal vaccine history, individuals should be assumed to be unimmunised and a full course of immunisations planned
- individuals coming to UK part way through their immunisation schedule should be transferred onto the UK schedule and immunised as appropriate for age
- if the primary course has been started but not completed, resume the course – no need to repeat doses or restart course
- plan catch-up immunisation schedule with minimum number of visits and within a minimum possible timescale – aim to protect individual in shortest time possible

Children from first up to second birthday

DTaP/IPV/Hib/HepB[†#] + PCV13[††] + Hib/Men C[††] + MenB[†††] + MMR
Four week gap
DTaP/IPV/Hib/HepB[†]
Four week gap
DTaP/IPV/Hib/HepB[†] + MenB[†††]

[†] DTaP/IPV/Hib/HepB is now the only suitable vaccine containing high dose tetanus, diphtheria and pertussis antigen for priming children of this age. Children born from 01/08/17 who received primary vaccines without HepB should be opportunistically offered a 3 dose course of monovalent HepB vaccine. If they are in a high-risk group or are exposed to hepatitis B, they should be proactively offered a hepatitis B vaccine course

[††] All un- or incompletely immunised children only require 1 dose of Hib, Men C (until teenage booster) and PCV13 over the age of 1 year. It does not matter if 2 Hib-containing vaccines are given at the first appointment or if the child receives additional Hib at subsequent appointments if DTaP/IPV/Hib/HepB vaccine is given. If a child has received PCV10 vaccine abroad, they should be offered 1 dose of PCV13 (at least 4 weeks after PCV10 was given)

[†††] Children who received less than 2 doses of MenB in the first year of life should receive 2 doses of MenB in their second year of life at least 8 weeks apart. Doses of MenB can be given 4 weeks apart if necessary to ensure the 2 dose schedule is completed (i.e. if schedule started at 22m of age)

Boosters + subsequent vaccination

As per UK schedule

Children from second up to tenth birthday

DTaP/IPV/Hib/HepB[^#] + Hib/MenC[^^] + MMR
Four week gap
DTaP/IPV/Hib/HepB[^] + MMR
Four week gap
DTaP/IPV/Hib/HepB[^]

[^] DTaP/IPV/Hib/HepB is now the only suitable vaccine containing high dose tetanus, diphtheria and pertussis antigen for priming children of this age. Children born from 01/08/17 who received primary vaccines without HepB should be opportunistically offered a 3 dose course of monovalent HepB vaccine. If they are in a high-risk group or are exposed to hepatitis B, they should be proactively offered a hepatitis B vaccine course.

[^^] All un- or incompletely immunised children only require 1 dose of Hib and Men C (until teenage booster) over the age of 1 year. It does not matter if 2 Hib-containing vaccines are given at the first appointment or if the child receives additional Hib at subsequent appointments if DTaP/IPV/Hib/HepB vaccine is given

Boosters + subsequent vaccination

First booster of dTaP/IPV can be given as early as 1 year following completion of primary course to re-establish on routine schedule. Additional doses of DTaP-containing vaccines given under 3 years of age in some other countries do not count as a booster to the primary course in the UK and should be discounted. Subsequent vaccination – as per UK schedule

From tenth birthday onwards

Td/IPV[#] + MenACWY[*] + MMR
Four week gap
Td/IPV + MMR
Four week gap
Td/IPV

[*] Those aged from 10 years up to 25 years who have never received a MenC-containing vaccine should be offered MenACWY
Those aged 10 years up to 25 years may be eligible or may shortly become eligible for MenACWY usually given around 14y of age. Those born on/after 1/9/1996 remain eligible for MenACWY until their 25th birthday

Boosters + subsequent vaccination

First booster of Td/IPV: Preferably 5 years following completion of primary course
Second booster of Td/IPV: Ideally 10 years (minimum 5 years) following first booster

HPV vaccine

- all females (born on/after 01/09/91) and males (born on/after 01/09/06) remain eligible for HPV vaccine up to their 25th birthday on the adolescent programme
- eligible immunocompetent individuals aged 11 to 25 years only require a single dose of HPV vaccine
- eligible individuals who are HIV positive or immunosuppressed should be offered a 3 dose schedule at 0, 1, 4-6 months
- for details of GBMSM HPV vaccination programme, please see Green Book HPV chapter
- any dose of Cervarix, Gardasil or Gardasil 9 would be considered valid if previously vaccinated or vaccinated abroad

Shingles vaccine

- **severely immunosuppressed individuals** from 50 years of age (eligibility as defined in the Green Book Shingles chapter 28a): 2 doses of Shingrix vaccine 8 weeks to 6 months apart; no upper age limit to start or complete the course
- **immunocompetent individuals** from their 65th and 70th birthday (see Shingles: guidance and vaccination programme on GOV.UK website for eligibility): 2 doses of Shingrix vaccine 6 months to 12 months apart. Once these individuals have become eligible, they remain eligible until their 80th birthday. The second dose of Shingrix vaccine can be given up to 81st birthday to those who have commenced but not completed the course
- **immunocompetent individuals** aged from 70 years who were previously eligible for shingles vaccination before 01/09/23 should receive Zostavax (unless contraindicated) until stocks of this vaccine are exhausted, after which Shingrix should be offered

MMR – from first birthday onwards

- doses of measles-containing vaccine given prior to 12 months of age should not be counted
- 2 doses of MMR should be given irrespective of history of measles, mumps or rubella infection and/or age
- a minimum of 4 weeks should be left between 1st and 2nd dose MMR
- if child <3y4m, give 2nd dose MMR with pre-school dTaP/IPV unless particular reason to give earlier
- second dose of MMR should not be given <18m of age except where protection against measles is urgently required

Flu vaccine (during flu season)

- those aged 65yrs and older although recommendations may change annually so always check Annual Flu Letter
- children eligible for the current season's childhood influenza programme (see Annual Flu Letter for date of birth range)
- those aged 6 months and older in the defined clinical risk groups (see Green Book Influenza chapter)

Pneumococcal polysaccharide vaccine (PPV)

- those aged 65yrs and older
- those aged 2yrs and older in the defined clinical risk groups (see Green Book Pneumococcal chapter)

[#] If an individual has received any OPV in another country since April 2016, these doses should be discounted as it is unlikely that they will protect against all 3 polio types. Most countries who still use OPV have a mixed OPV and IPV schedule so if sufficient IPV doses have been received for age, no additional IPV doses are needed.
BCG and Hepatitis B vaccines for those at high risk should be given as per Green Book recommendations. Individuals in clinical risk groups may require additional vaccinations. Please check Green Book chapters.

Effective from 1 September 2023

OXFORD VACCINE GROUP

All the influencing factors to the schedule are applied and explained on this flow chart

Vaccination of individuals with uncertain or incomplete immunisation status - GOV.UK (www.gov.uk)

It takes practice…

- Ask for support when responding to incomplete and uncertain immunisation schedules
- Two heads better than one
- Contact your local screening and immunisation team with what you think an individual needs and ask for their advice
- It gets easier with practice (like most things)
- You could give the obvious missing immunisations and reschedule another appointment to give yourself time to work out the more complicated scenarios
- Make use of the resources that are there to help you

Some people may need extra vaccines

Some people are **more likely to suffer serious illness** from infections and should be offered extra vaccinations to help protect them. This includes people living with a chronic illness that affects their major organs or their immune system.

Hepatitis A The vaccine is needed for people at high risk of hepatitis A, including those with liver disease and families where a case has been reported.

Hepatitis B Extra hepatitis B vaccine is also available for people with liver disease or those with a high chance of catching the infection (e.g. babies born to women with hepatitis B or people who have a partner or family member with the infection). Ask your GP practice if you or your baby should receive hepatitis B vaccination.

Tuberculosis The BCG vaccine is needed by children and adults living in areas with high rates of TB. People with close family members with TB also need the BCG vaccine.

For information on the current NHSE registration guidance (the Primary Medical Care Policy and Guidance Manual) and the BMA's rough guide to migrant health needs please visit: https://bit.ly/2hv37zc

NHS

I have a right to register and receive treatment from a GP practice

Are you or someone you care about ill?

Call 111

Call NHS 111 if you urgently need medical help or advice but it's not a life-threatening situation. You can also call NHS 111 if you're not sure which NHS service you need.

Ask your local Pharmacist for advice – your pharmacist can give you advice for many common minor illnesses, such as diarrhoea, minor infections, headache, travel advice or sore throat.

Make an appointment with your GP if you are feeling unwell and it is not an emergency.

Visit a walk-in centre, minor injuries unit or urgent care centre if you have a minor illness or injury (cuts, sprains or rashes) and it can't wait until your GP surgery opens.

999

Call 999 if someone is seriously ill or injured and their life is at risk.

A&E

An A&E department (also known as emergency department or casualty) deals with genuine life-threatening emergencies. People are seen and treated in order of need.

UK Health Security Agency

UK Health Security Agency gateway number: 2019206

UK Health Security Agency

NHS

Moved to the UK:

Get up-to-date with your vaccinations

Vaccines are the safest way to protect you and your family from serious infections – they help you stay healthy

In England, most vaccinations are offered free on the NHS. Vaccinations can protect you throughout your life. To protect children as early as possible many vaccines are offered to babies and toddlers before they start school. As vaccinations are so well accepted in England, they are not mandatory.

Vaccinations are usually given by practice nurses at your GP practice. Practice nurses are specially trained to give advice and offer vaccines. The nurse will carefully check the medical history but, as long as you or your child is well, an examination by a doctor is not needed.

Older children are offered some vaccinations in school. Vaccinations for adults are normally offered at your GP practice or pharmacy.

If you are unsure if you or your child has had all the recommended vaccinations in England – check with your GP practice. It is never too late to catch-up on the vaccinations recommended in England.

Registering with a GP practice

Anyone in England can register with a GP practice and see a primary care doctor or nurse for FREE. You do not need to provide proof of identity or of immigration status in order to register with a GP practice.

This also applies if you are an asylum seeker, refugee, a homeless patient or an overseas visitor, whether lawfully in the UK or not.

You should register even if you are fit and well. You never know when you may need health care and the practice can offer preventive services to keep you healthy.

If you need a chaperone or an interpreter, ask your GP practice.

Everyone in England should register with a GP. You can see them for free and you do not need proof of address

You can find details on how to register with a GP in this leaflet and at **www.nhs.uk/using-the-nhs/nhs-services/gps/how-to-register-with-a-gp-practice**

You may have to pay for some treatment on the NHS, but routine vaccinations are free.

What to do if you have problems accessing health care?

If you are still having problems dial 111.

Different countries offer different vaccines

It is good to check with your GP practice and make sure you have had all of the vaccines we offer for free here in England. It does not matter why you have missed them, it is important to catch up and get protected.

Some infections can be more common in other countries, so it is also important to check if you need any extra vaccines before you travel overseas to visit family and friends – some travel vaccines are not free on the NHS.

When and what vaccines are given routinely in England?

Vaccinations are offered to new-born babies, young children, teenagers, pregnant women and older people. You can find out more about the vaccination schedule here www.nhs.uk/conditions/vaccinations. If you have missed any of the vaccines in the UK schedule, you may still need protection, even at an older age. Ask your GP or nurse to check if you need a catch-up dose.

Babies and toddlers need vaccinations to protect them from childhood infections including measles, mumps, rubella (MMR), rotavirus, diphtheria, whooping cough, meningitis, polio, tetanus, hepatitis B, TB and more.

Pre-school children need booster vaccinations for some of the diseases listed above. This helps to protect children better and for longer. Primary school children are offered flu vaccination every year.

Teenagers need another top up (booster) vaccination for some of these infections, including meningitis, to give longer lasting protection into adulthood. They are also offered the HPV vaccine which can prevent some cancers.

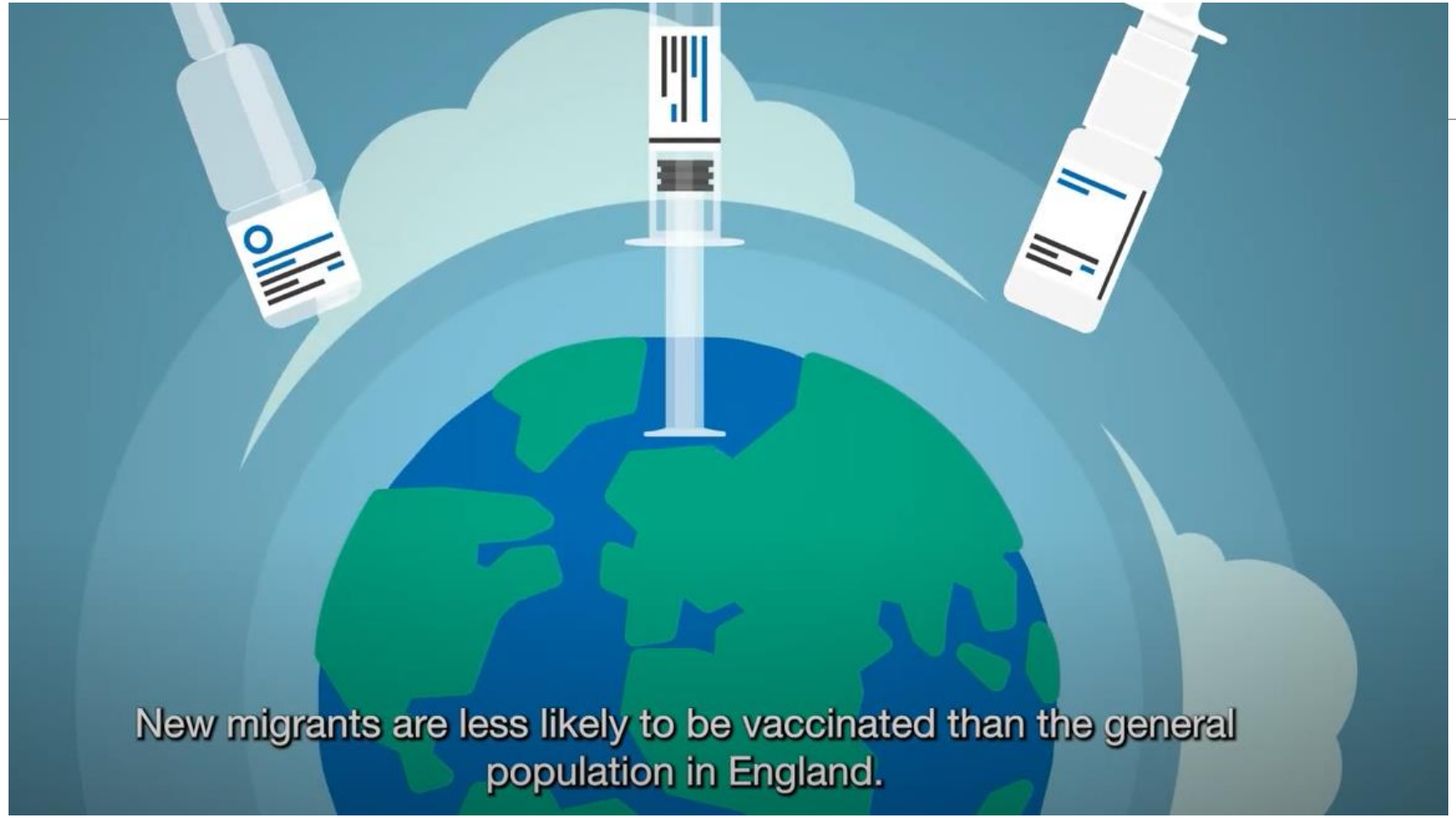
If you are planning a baby then you should check you have received all of your vaccinations – especially two doses of MMR – before you get pregnant.

If you are pregnant you need vaccinations to protect you and your baby from whooping cough and flu. You should also be screened (have a blood test) for infections such as hepatitis B which can pass from mother to child. Some babies may need an extra hepatitis B vaccination at birth.

Older people need vaccinations to protect them against flu, pneumonia and shingles.

Talk to your GP or practice nurse to check if you or your child need any routine or extra vaccines.

[Moved to the UK: Get up-to-date with your vaccinations_2019206_English (publishing.service.gov.uk)]



Keeping up to date with vaccinations for migrants - YouTube

Reminder - General principles

Unless there is a documented or reliable verbal vaccine history, individuals should be assumed to be unimmunised and a full course of immunisations planned

Individuals coming to the UK part way through their immunisation schedule should be transferred onto the UK schedule and immunised as appropriate for age

If the primary course has been started but not completed, resume the course – no need to repeat doses or restart course

Plan catch-up immunisation schedule with minimum number of visits and within a minimum possible timescale – aim to protect the individual in the shortest time possible

Vaccination of individuals with uncertain or incomplete immunisation status: from 1 September 2023 - GOV.UK (www.gov.uk)

DEPARTMENT OF
PAEDIATRICS

An Overview of the Vaccine Research Trials

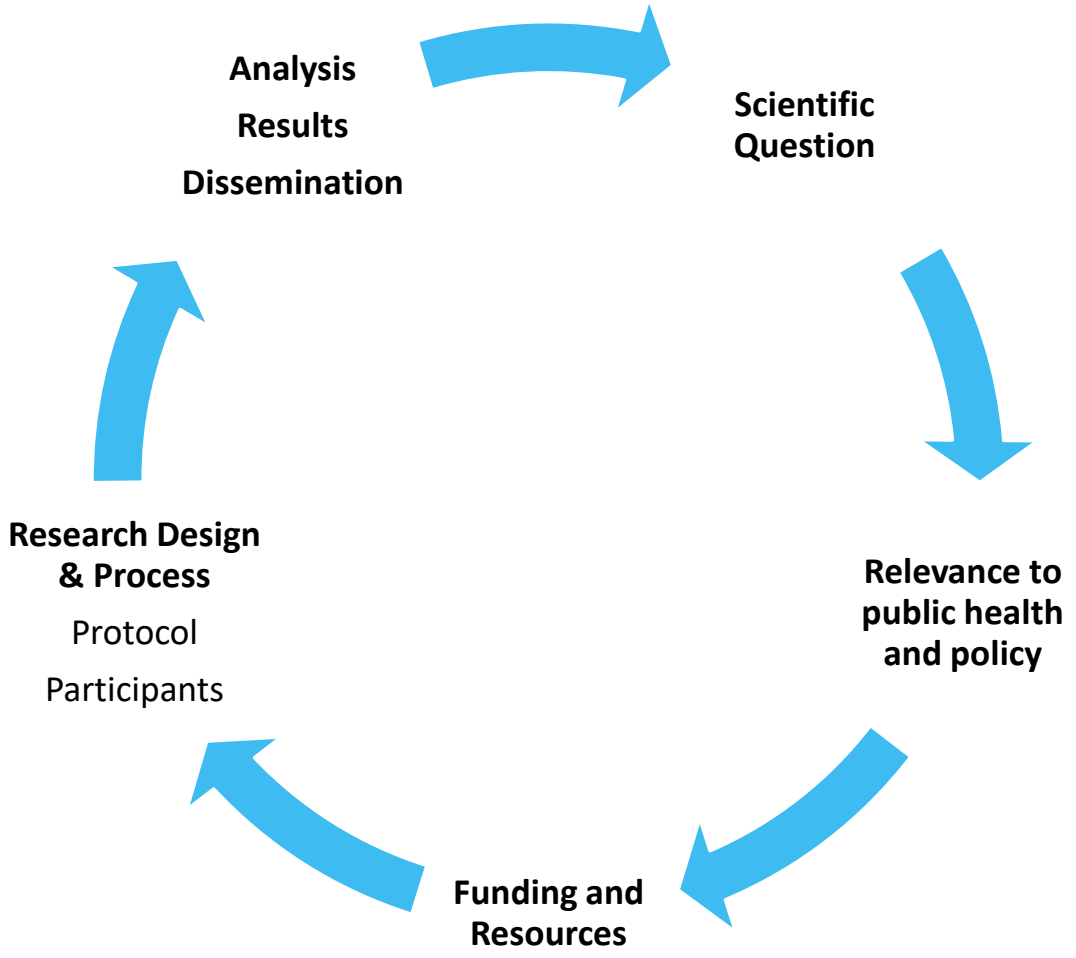
Karen Ford, Immunisation Specialist and Senior Research Nurse

OXFORD
VACCINE GROUP

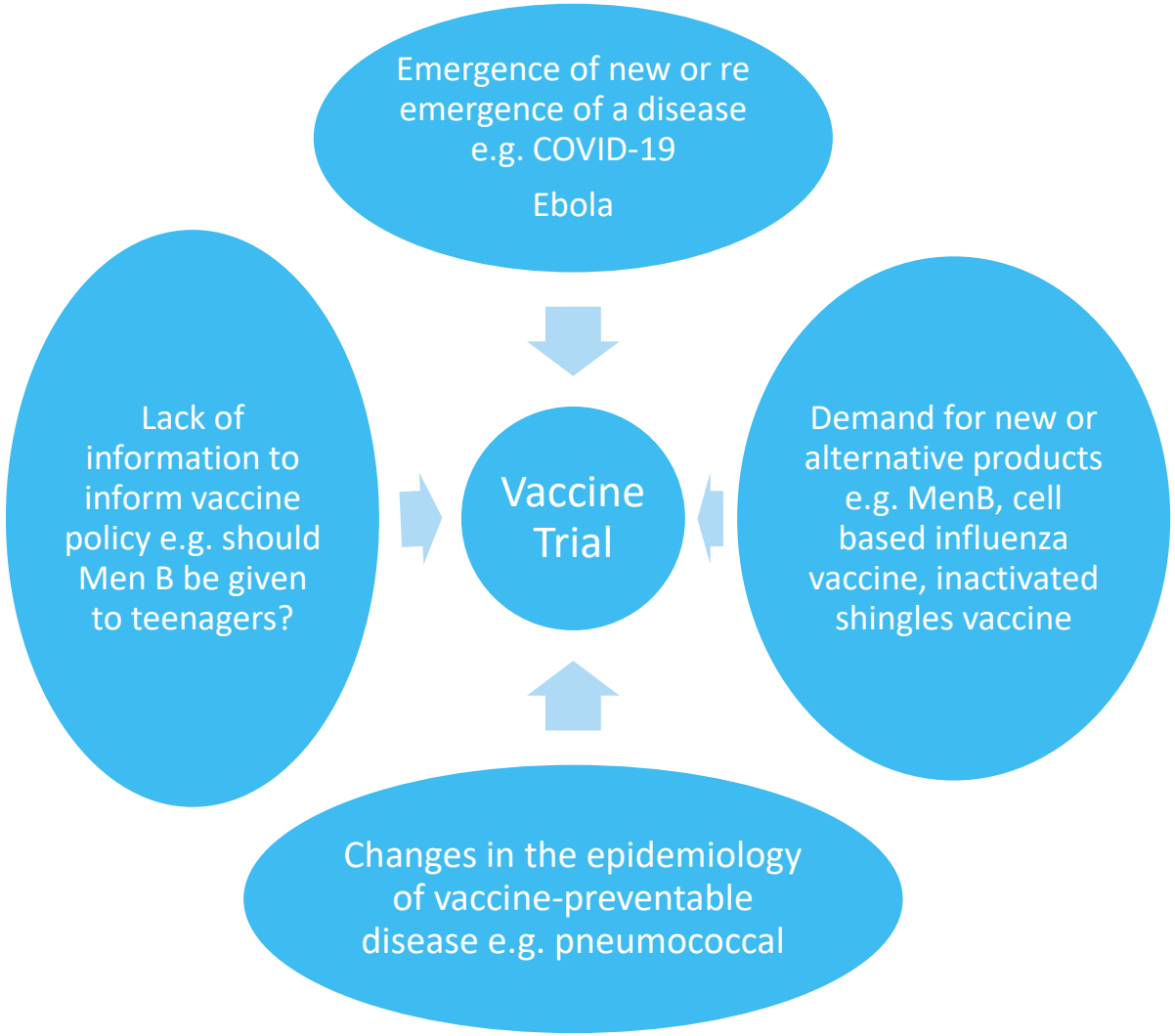
Vaccine trials in terms of…

- Focus on the UK vaccine schedule
- How the process can reassure parents/patients regarding vaccine safety
- How they inform the UK national immunisation policy

Clinical vaccine trial



Factors that can initiate vaccine trials



e.g. lack of information to inform vaccine policy

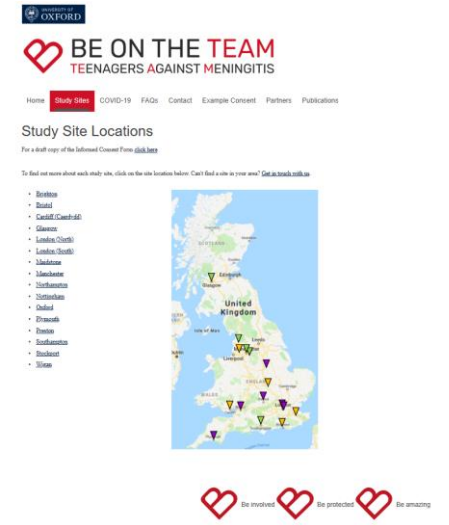
Trial carried out as lack of information to inform vaccine policy

Be on the TEAM: TEenagers Against Meningitis

28 March 2018

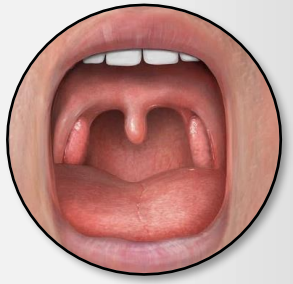
Public Engagement | Research

The Oxford Vaccine Group are inviting students in school year 12 to take part in a research project to understand whether immunising teenagers with vaccines against 'Meningitis B' could protect them and the rest of the community against these potentially deadly bacteria. This is a national study involving 24 000 year 12 students across the United Kingdom. Teenagers at participating schools are being asked to take part by local research teams involved.



https://www.ovg.ox.ac.uk/news

What is The BE ON THE TEAM Study about?



REDUCE

CARRIAGE

Do MenB vaccines reduce the amount of MenB bacteria at the back of teenagers throats?

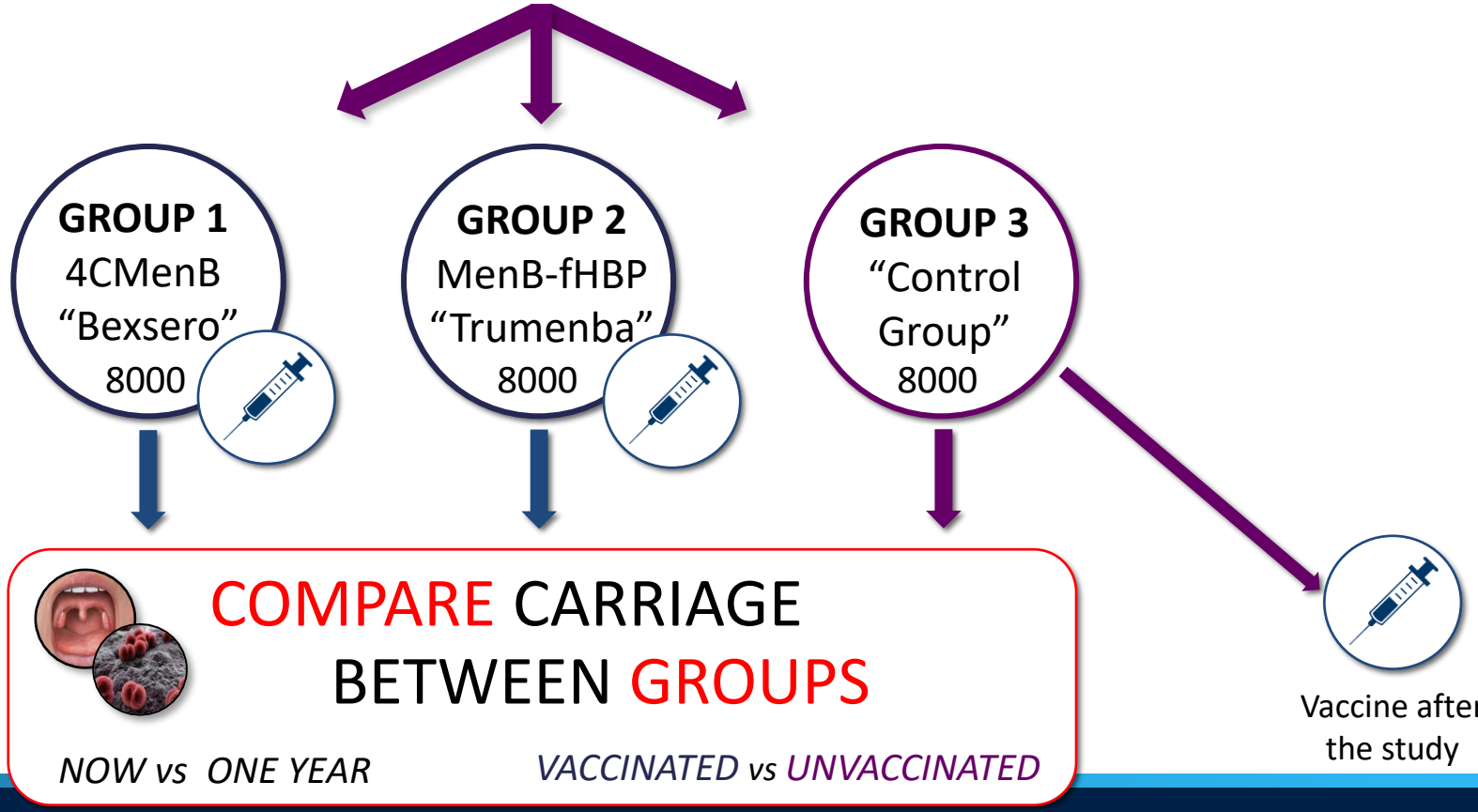
If you reduce teenage carriage, can you reduce the spread of MenB throughout the community?

BROAD COMMUNITY

PROTECTION

Study Overview

24000 16-19yr olds - Yr 12 students from across the UK

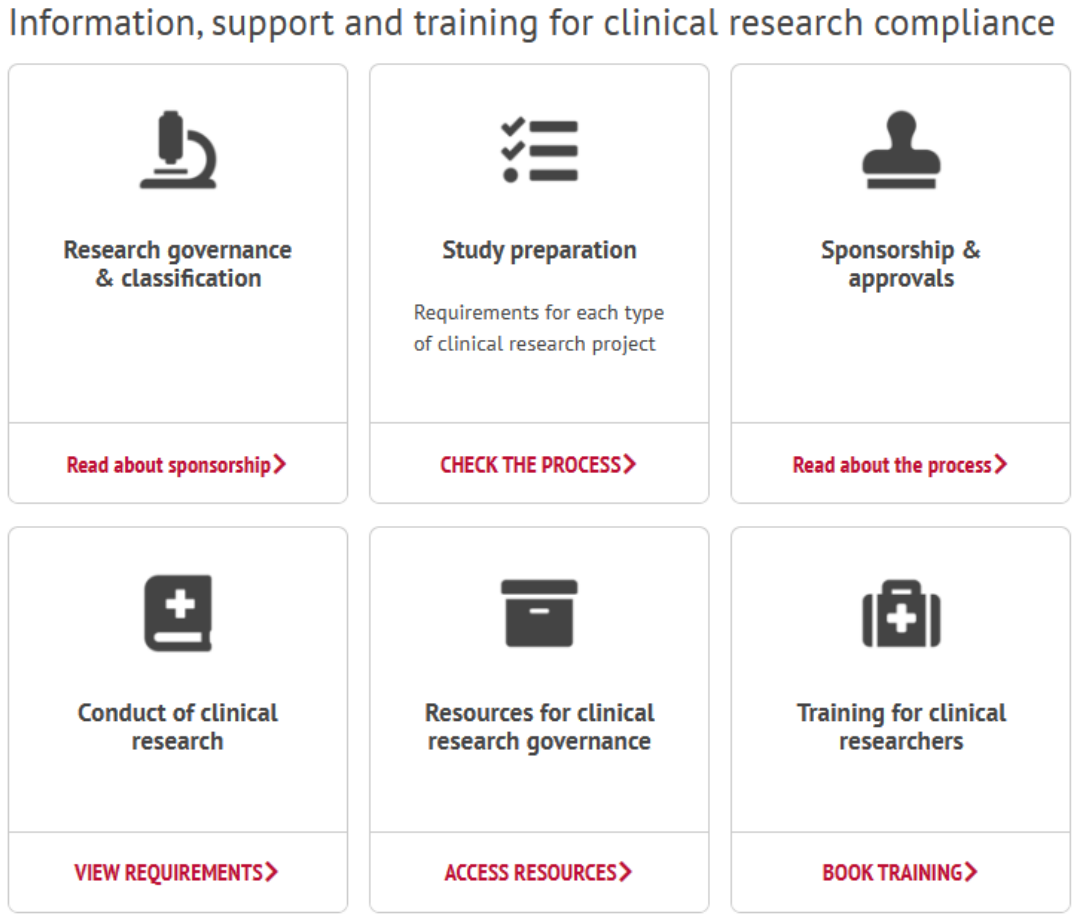


Study was modified due to COVID-19 and school/college closures in March 2020
Laboratory work in progress on samples collected

Research governance and approvals

Regulatory Requirements

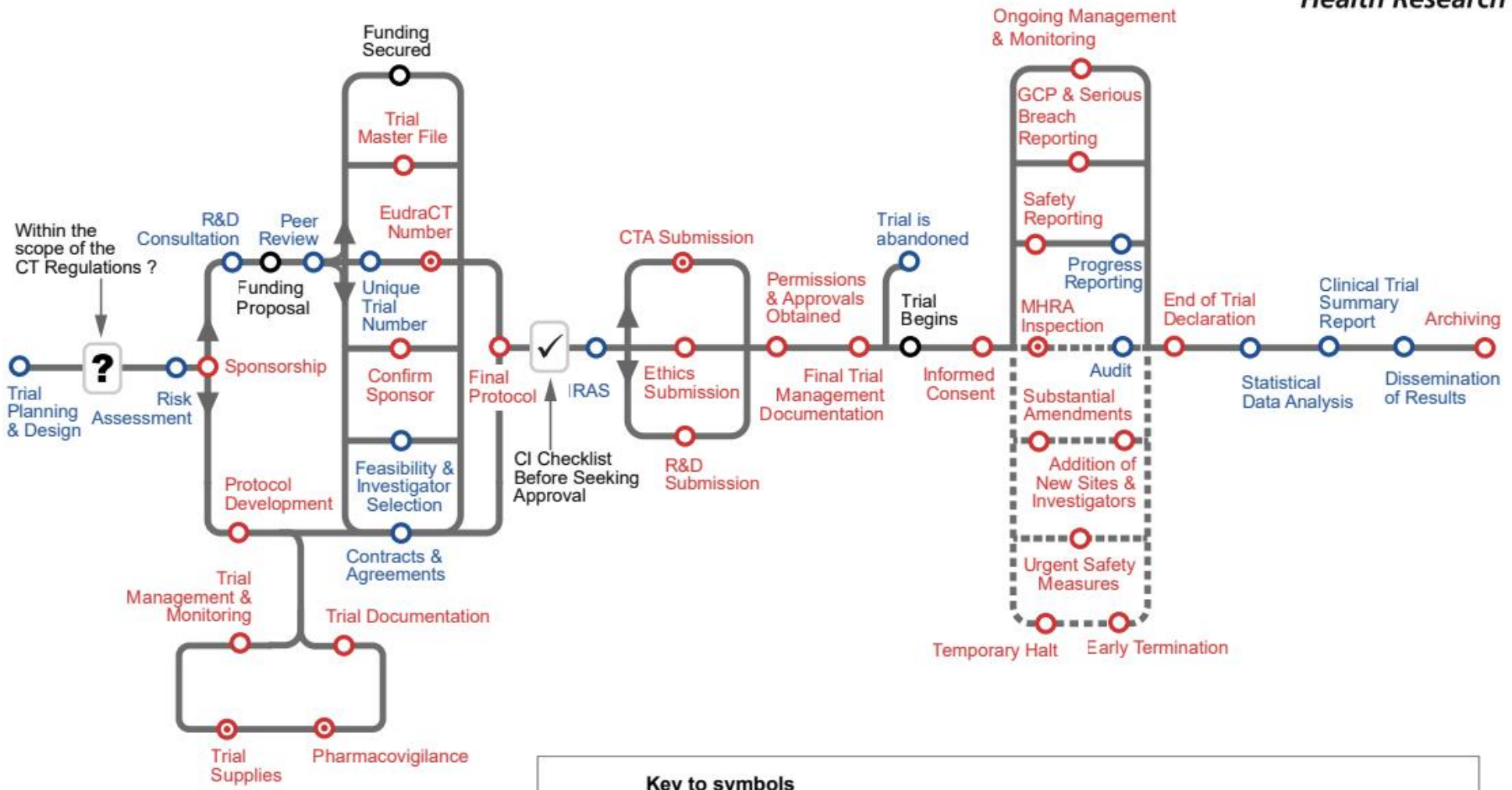
For every stage of research there are regulatory requirements that must be followed



https://researchsupport.admin.ox.ac.uk/ctrg

The Clinical Trials Toolkit Routemap

NHS National Institute for Health Research



Routemap (ct-toolkit.ac.uk)

Research governance

Research governance applies to everyone connected to clinical research, whether as a chief investigator, care professional, researcher, their employer(s) or support staff.

Clinical research is any health-related research that involves humans, their tissue and/or data

Why do we need it?

- safeguard participants in research
- protect researchers/investigators (by providing a clear framework within which to work)
- enhance ethical and scientific quality
- mitigate risk
- monitor practice and performance
- promote good practice and ensure that lessons are learned

Regulatory Requirements

UNIVERSITY OF OXFORD
Research Support
Facilitating world-class research

Key documents & regulations

Research governance is made up of regulations, principles and standards of good practice designed to achieve and continuously improve research quality.

Key documents, regulations and other resources relevant to clinical research

+ Expand All

- UK policy framework for health and social care research
- Good Clinical Practice (GCP)
- EU directives
- Medicines for Human Use (Clinical Trials) Regulations
- Human Tissue Act
- Declaration of Helsinki
- General Data Protection Regulation (GDPR)
- Mental Capacity Act
- Risk-adapted approach
- Genetically modified organisms (GMOs)

https://researchsupport.admin.ox.ac.uk/ctrg

Regulation leads to standards.
The significance of which are …

- The outcomes of research inform clinical decisions and guidance
- If the research process is flawed, the information becomes unreliable
- Quality standards for the conduct of clinical research are, therefore, essential to ensure we conduct safe and meaningful studies
- The international standard for the conduct of clinical research is Good Clinical Practice (GCP)

Regulatory Requirements e.g.

Good Clinical Practice (GCP)

GCP is a set of internationally recognised ethical and scientific quality requirements for designing, conducting, recording and reporting research that involves human participation. Compliance provides public assurance that the rights, safety and wellbeing of participants are respected and protected, and that the data generated are credible and accurate.

Compliance with GCP is a legal obligation in Europe for all trials of investigational medicinal products.

https://researchsupport.admin.ox.ac.uk/ctrg

The Principles of GCP

The Principles of Good Clinical Practice (GCP) are at the heart of the guidance and legislation which governs the conduct of any clinical research carried out

There are 13 core principles of GCP including...

- *The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society*
- *Freely given informed consent should be obtained from every subject before clinical trial participation*

The principles of GCP are the foundation of high-quality, ethical research practice. Developed in response to bad practice e.g.

NUREMBURG TRIALS

- During World War 2, Nazis performed many experiments on concentration camp prisoners without their consent to 'advance science'
- 'Nuremberg Code' was drafted as a set of standards against which physicians and scientists who had conducted the experiments could be judged
- Code became the foundation of many later codes intended to assure that research involving human subjects would be carried out ethically.

RONALD MADDISON

- 21yr Royal Air Force engineer who was unlawfully killed as the result of exposure to a nerve agent (Sarin) in 1953 at Porton Down (then War Department Experiment Station)
- One of 6 subjects offered 15 shillings and a three-day leave pass for taking part in the experiments
- Highlighted the importance of freely given informed consent without coercion

Health Research Authority (HRA)

They are one of several organisations that work together in the UK to regulate different aspects of health and social care research.

'Our vision is for high-quality health and social care research that improves people's health and wellbeing, and our core purpose is to protect and promote the interests of patients and the public in health and social care research.'

To achieve this they:

- make sure that research is ethically reviewed and approved
- promote transparency in research
- oversee a range of committees and services
- coordinate and standardise research regulatory practice

Research Ethics Committee (REC)

- Managing the Research Ethics Committees in England is one of the **Health Research Authority's core functions**.
- There are more than **80 NHS Research Ethics Committees** across the UK. **They exist to safeguard the rights, safety, dignity and well-being of research participants.**
- RECs consist of up to **15 members**, a third of whom are 'lay' - their main professional interest is not in a research area, nor are they registered healthcare professionals.
- RECs review research proposals and give an opinion about **whether the research is ethical.**

Medicines and Healthcare Regulatory Agency

- In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices by ensuring they work well and are acceptably safe. They also make sure that, for most people, the product's advantages far outweigh the disadvantages.
- In the UK, a Clinical Trial Authorisation (CTA) from the Medicine and Healthcare Products Regulatory Agency (MHRA) is required for a Clinical Trial of an Investigational Medicinal Product (CTIMP)
- They review the IMP manufacturing, safety profile and release, the background and rationale of the trial and the scientific integrity.
- **Ensuring trials comply with Good Clinical Practice standards.**

Clinical Trials of Investigational Medicinal Products (CTIMPs)

- **Safety, quality and efficacy** of vaccines must be demonstrated before they are authorised for use

- Vaccines which are being investigated through a clinical trial are known as **Investigational Medicinal Products (IMPs)**

- **Clinical Trials** of Investigational Medicinal Products **(CTIMPs)** are conducted to gather the evidence for a licence (marketing authorisation) to be granted, or to find out more about vaccines which already have a marketing authorisation.

Design and logistics

Phases of Clinical Trials

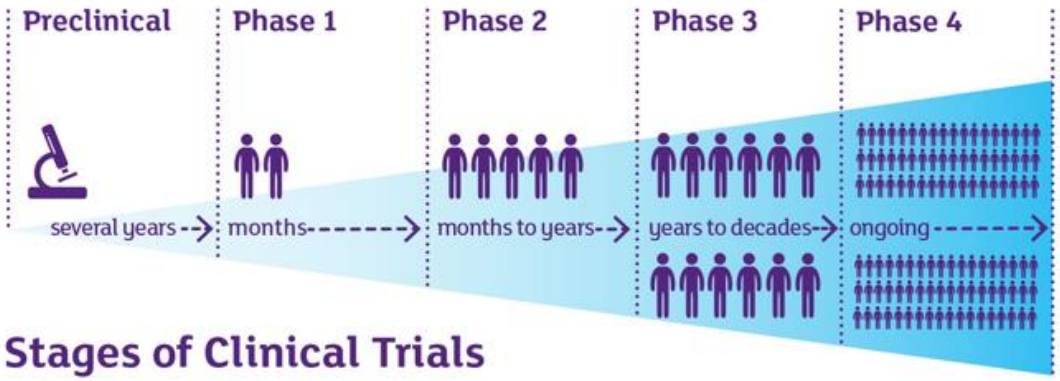


Image from:
https://www.cancer.nsw.gov.au/data-research/clinical-trials/how-do-clinical-trials-progress

- Normally several years to decades to develop vaccines
- COVID-19 vaccines developed within a shorter time frame – less than 12 months but
  - based upon years of previous research of the vaccine platforms
  - priority for this research by all organisations
  - lots of volunteers to participate

Pre clinical

Laboratory testing and development – vaccine has to pass rigorous safety tests and demonstrate that it works in animals

Phase I:

Small group of people (20-80)

Safety – safe dose and identifying side effects

Phase II:

Large group (100-300)

Effectiveness & Safety

Phase III:

Larger group (1,000-3,000)

Effectiveness, monitor side effects

Compare to commonly used treatment

Phase IV:

Post marketing
Vaccine effectiveness – reduction in disease, herd immunity

Adverse events (phase 4 surveillance) through:

Larger number and diverse range of people vaccinated – identify very rare adverse events

Vaccine trials

Design considerations

Sample size and characteristics

Placebo controlled trial – will the placebo be an alternative vaccine or sterile water? – consider ethics

Blinded to participant or double-blind

Containment of pathogens and GMO

What will the outcome measurements be?

- immunogenicity and reactogenicity
- disease prevention – challenge model of vaccine trials

Logistics

How will the participants be recruited?

How long will it take to recruit?

Will the trial be multicentred?

Is there space, staff, and facilities to carry out the study visits including laboratory analysis/storage of samples collected?

How will the vaccine of interest be procured?

Research outcomes

GENERATION OF SAFETY DATA

Safety monitoring within vaccine trials

A key feature of vaccine trials is to ensure safety and identify expected adverse events following vaccination

Achieved through:

- Diary card completion by participant/parent – local and systemic reactions e.g. redness, swelling, tenderness, temperature, change in eating habits

- Safety markers checked through out study and prior to enrolment e.g. full blood count, liver function tests, CRP
- 24 hour contact to a study doctor to report adverse events

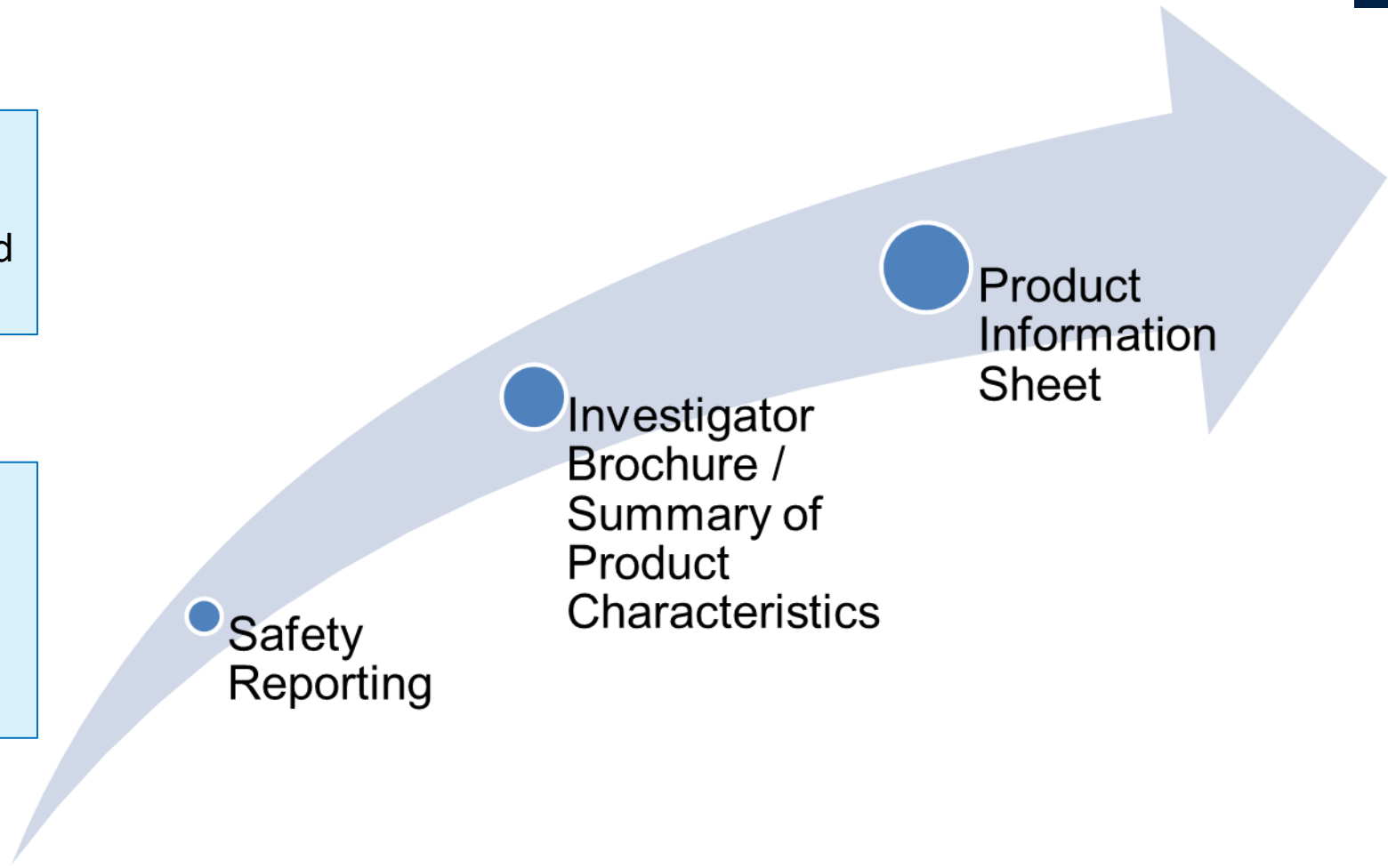
- Follow – up of participants -visits or phone call - may last for years

Safety Reporting – Why?

Key principle of GCP – the rights, safety and wellbeing of trial subjects will be maintained at all times

Collation of safety data

- Collect
  - Validate
    - Assess
      - Report

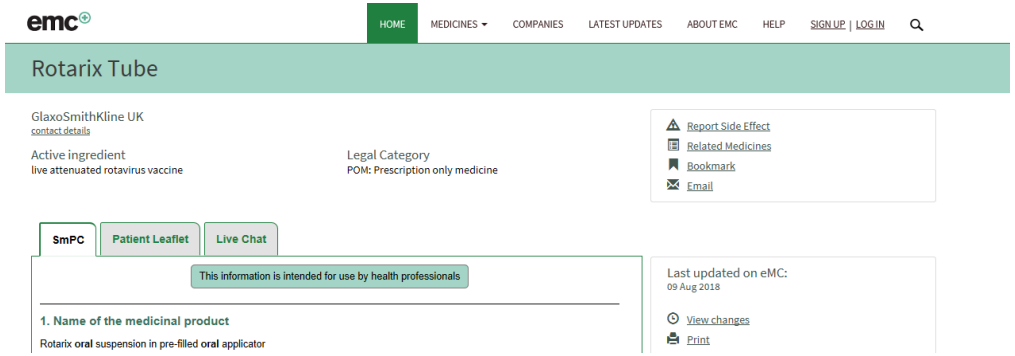


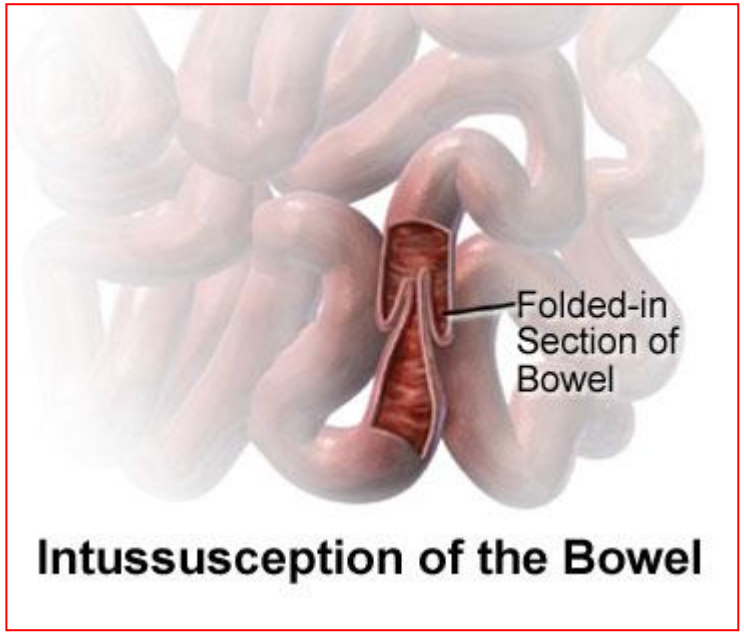
Safety monitoring within vaccine trials

- Generates data contained within the Summary of Product Characteristics
- Guides recommendations made within the routine national immunisation schedule
- Informing parents/patients of possible adverse events empowers them to be prepared if they do occur

Safety data collected within vaccine trials influence on national schedule

E.G Rotavirus vaccine - Rotarix





Intussusception

Data from observational safety studies performed in several countries indicate that rotavirus vaccines carry an increased risk of intussusception, mostly within 7 days of vaccination. Up to 6 additional cases per 100,000 infants have been observed in these countries against a background incidence of 25 to 101 per 100,000 infants (less than one year of age) per year, respectively.

There is limited evidence of a smaller increased risk following the second dose.

Up to 6 additional cases of intussusception per 100,000 infants

https://www.medicines.org.uk/emc/product/2739/smpc

Safety data collected within vaccine trials influence on national schedule

Rotavirus: the green book, chapter 27b

PDF, 269KB, 14 pages

Background risk of intussusception in the UK increases to peak at around 5 months of age

The benefits of vaccination in preventing the consequences of rotavirus infection outweigh this small potential risk of intussusception in young children.

Because of the potential risk, and to reduce the likelihood of a temporal association with rotavirus vaccine, the first dose of vaccine should not be given after 15 weeks of age

https://www.gov.uk/government/publications/rotavirus-the-green-book-chapter-27b

Safety data collected within vaccine trials influence the national schedule e.g Infant MenB vaccine

In clinical studies in infants vaccinated at 2, 4 and 6 months of age, fever (≥ 38°C) was reported by 69% to 79% of subjects when Bexsero was co-administered with routine vaccines (containing the following antigens: pneumococcal 7-valent conjugate, diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliomyelitis and *Haemophilus influenzae* type b) compared with 44% to 59% of subjects receiving the routine vaccines alone. Higher rates of antipyretic use were also reported for infants vaccinated with Bexsero and routine vaccines. When Bexsero was given alone, the frequency of fever was similar to that associated with routine infant vaccines administered during clinical trials. When fever occurred, it generally followed a predictable pattern, with the majority resolving by the day after vaccination.

4CMenB at 2, 4 and 6 months,
fever > 38 degrees in 69%-79% of infants

Around 2 out of 3 infants

https://www.medicines.org.uk/emc/product/5168

Safety data collected within vaccine trials influence the national schedule e.g Infant MenB vaccine

Meningococcal: the green book, chapter 22

PDF, 623KB, 24 pages

This file may not be suitable for users of assistive technology. Request an accessible format.

Prophylactic paracetamol reduced fever rates without affecting the immune response to 4CMenB or the other routine infant immunisations when given together

Dosage and timing of infant paracetamol suspension (120mg/5ml) for use after primary MenB vaccinations (usually at two and four months of age)

Age of baby	Up to 6 months (usually at 2 and 4 months)
Dose 1	One 2.5ml (60mg) dose as soon as possible after vaccination
Dose 2	One 2.5ml (60mg) dose 4-6 hours after first dose
Dose 3	One 2.5ml (60mg) dose 4-6 hours after second dose

https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22

Research outcomes

GENERATION OF NEW VACCINES

Vaccine Trails - new products licensed e.g. Men B

Vaccine trials in infants commenced 2006

Clinical Trial > JAMA. 2012 Feb 8;307(6):573-82. doi: 10.1001/jama.2012.85.

Immunogenicity and tolerability of recombinant serogroup B meningococcal vaccine administered with or without routine infant vaccinations according to different immunization schedules: a randomized controlled trial

Nicoletta Gossger [1], Matthew D Snape, Ly-Mee Yu, Adam Finn, Gianni Bona, Susanna Esposito, Nicola Principi, Javier Diez-Domingo, Etienne Sokal, Birgitta Becker, Dorothee Kieninger, Roman Prymula, Peter Dull, Ellen Ypma, Daniela Toneatto, Alan Kimura, Andrew J Pollard, European MenB Vaccine Study Group

Collaborators, Affiliations + expand

PMID: 22318278 DOI: 10.1001/jama.2012.85

Immunogenicity and tolerability of recombinant serogroup B meningococcal vaccine administered with or without routine infant vaccinations according to different immunization schedules: a randomized controlled trial - PubMed (nih.gov)

+ 7 yrs

January 2013 – UK licence

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Health

Meningitis B vaccine gets European licence

By Michelle Roberts
Health editor, BBC News online

22 January 2013 Share

A vaccine to protect children against one of the most common and deadly forms of meningitis has been licensed for use in Europe.

The Bexsero vaccine licensed by the European Commission is the first to cover meningococcal B meningitis - until now vaccines had protected against only some of the bacterial types involved.

The vaccine is not currently recommended in the UK

https://www.bbc.co.uk/news/health-21140285

+2 yrs

MenB vaccination: introduction from September 2015

Published 22 June 2015
From: Public Health England

Documents

Introduction of MenB vaccination for infants

Ref: PHE Gateway Number: 2015116
PDF, 164KB, 15 pages

This file may not be suitable for users of assistive technology. Request an accessible format.

https://www.gov.uk/government/publications/menb-vaccination-introduction-from-1-september-2015

Vaccine Trails - new products licensed
COVID-19 vaccine development

- scientists, industry and other organisations have worked collaboratively across the globe to complete the **different phases of vaccine development in parallel, rather than sequentially,** to make a safe and effective vaccine available as soon as possible
- by knowing the genetic code for the SARS-CoV-2 virus, various methods to create vaccines can be used such as using the code itself (mRNA vaccines) or inserting part of this code into existing viruses (viral vector vaccines)
- hundreds of different COVID-19 vaccines are/were in development, in trials or in use
- some vaccines have been made using currently used vaccine technology, others have been made using new approaches or methods used during previous emergencies such as the SARS pandemic and west African Ebola

THE LANCET
Global Health

CORRESPONDENCE | VOLUME 9, ISSUE 5, E590-E592, MAY 2021

An interactive website tracking COVID-19 vaccine development

Madhumita Shrotri • Tui Swinnen • Beate Kampmann • Edward P K Parker

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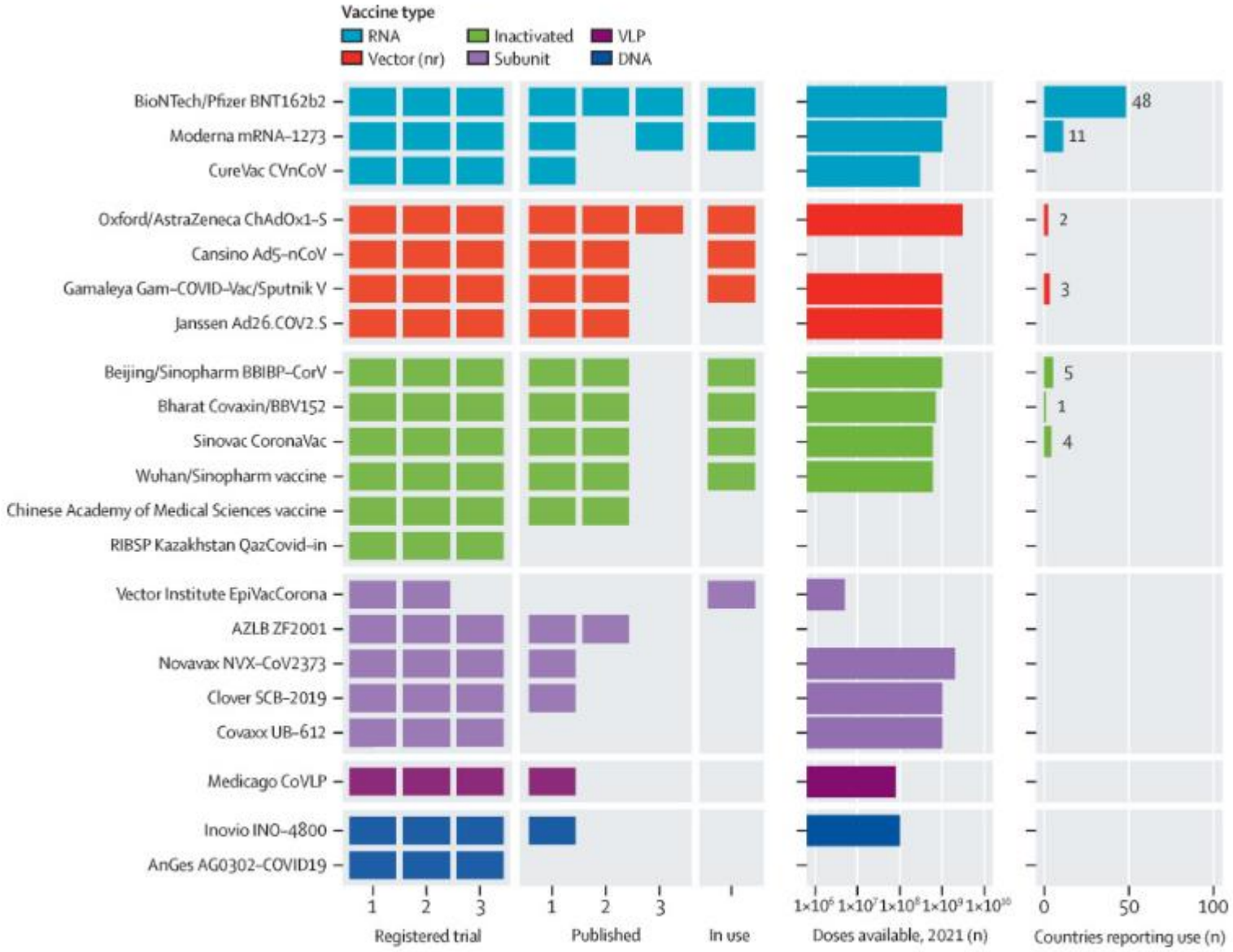
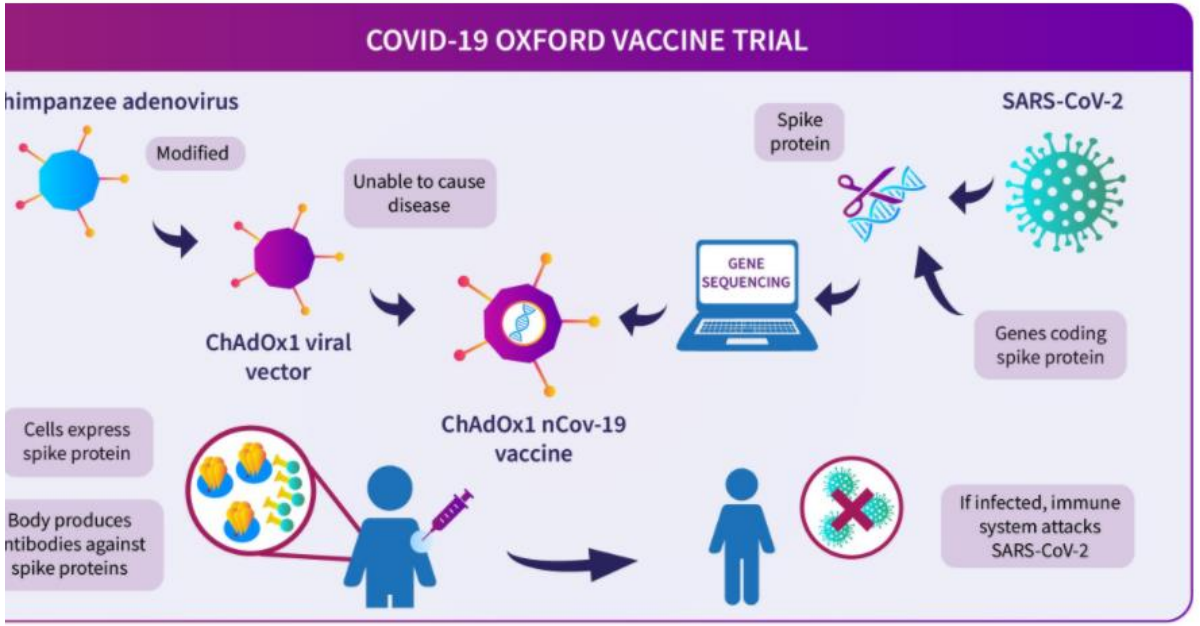


Figure Status of the COVID-19 vaccine landscape

Time line of Oxford COVID-19 Vaccine development

- **Phase I:** The phase I trial in healthy adult volunteers began in April 2020. More than 1,000 immunisations were given in the UK.
- **Phase II:** The phase II part of the study expands the age range of people the vaccine is assessed in, to include a small number of older adults and children. Researchers will be assessing the immune response to the vaccine in people of different ages, to find out if there is variation in how well the immune system responds in older people or children. The results of the Phase I/II trial were published in July 2020. Children's trials are now underway.
- **Phase III:** The phase III part of the study involves assessing how the vaccine works in a large number of people over the age of 18. This group will assess how well the vaccine works to prevent people from becoming infected and unwell with COVID-19. It involves multiple locations, including other countries. Initial Phase III results were published in December 2020.



A diagram showing how the Oxford COVID-19 vaccine works. A chimpanzee adenovirus is used in the ChAdOx1 viral vector, engineered to match the SARS-CoV-2 spike protein.

About **the Oxford COVID-19 vaccine | Research | University of Oxford**


Press release

Oxford University/AstraZeneca COVID-19 vaccine approved

The new vaccine has been approved after meeting the required safety, quality and effectiveness standards.

From: Medicines and Healthcare products Regulatory Agency

Published 30 December 2020

The COVID-19 vaccine developed by Oxford University/AstraZeneca has today been given regulatory approval by the Medicines and Healthcare products Regulatory Agency (MHRA) after meeting required safety, quality and effectiveness standards.

Approved 30th Dec 2020

4th January 2021 – first individuals vaccinated with COVID-19 Vaccine AstraZeneca

9th May 2024

AstraZeneca to withdraw Covid vaccine

Its vaccine was estimated to have saved millions of lives during the pandemic.

AstraZeneca to withdraw Covid vaccine - BBC News

Oxford University/AstraZeneca COVID-19 vaccine approved - GOV.UK (www.gov.uk)

Video: Professor Andrew Pollard receives vaccine he helped to create | Daily Mail Online

Research outcomes

CHANGES IN THE EPIDEMIOLOGY OF VACCINE PREVENTABLE DISEASE LEAD TO RESEARCH INTO POSSIBLE CHANGES TO TIMINGS/DOSES OF VACCINE

Research outcomes - changes to timings/doses of vaccine

Pneumococcal conjugate vaccine 13 delivered as one primary and one booster dose (1 + 1) compared with two primary doses and a booster (2 + 1) in UK infants: a multicentre, parallel group randomised controlled trial

David Goldblatt, Jo Southern*, Nick J Andrews, Polly Burbidge, Jo Partington, Lucy Roalfe, Marta Valente Pinto, Vasilli Thalasselis, Emma Plested, Hayley Richardson, Matthew D Snape, Elizabeth Miller*

https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(17)30654-0.pdf

	2 months	3 months	4 months	12 months
Group 1	PCV13		PCV13	PCV13
Group 2		PCV13		PCV13

All other routine vaccines received in both groups

Findings:

Nine of 13 serotypes in PCV13, post-booster responses in infants primed with a single dose are equivalent or superior to those seen following the standard UK 2+1 schedule

1+ 1 schedule in countries with mature PCV programme and established herd immunity is likely to maintain population control of vaccine type pneumococcal disease

Changes to timings/doses of vaccine

JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

Minute of the meeting on 04 October 2017

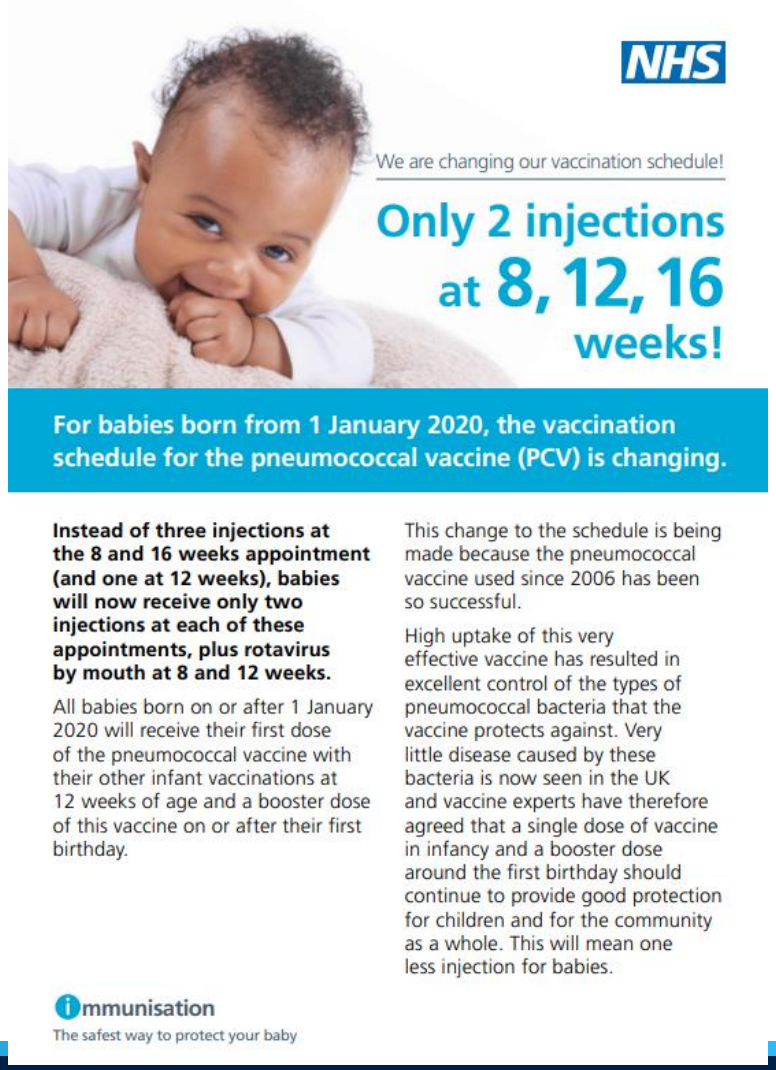
Wellington House, Waterloo Road, London

JCVI minutes 4th October 2017

- PCV programme in UK highly successful
- Sustained decrease in PCV13 serotype disease
- High vaccine uptake and good vaccine effectiveness
- 1+1 schedule appropriate for UK
- PCV13 at 3m and 12m

https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/247634612957

From 1st Jan 2020



The PCV vaccination schedule change flyer for parents and healthcare professionals (publishing.service.gov.uk)

Research outcomes

CHANGES TO SUPPLY OF A VACCINE LEAD TO RESEARCH INTO POSSIBLE CHANGES TO TIMINGS & COMBINATIONS OF DOSES OF VACCINE

Menitorix© discontinuation

Independent report

Joint Committee on Vaccination and Immunisation (JCVI) interim statement on the immunisation schedule for children

Published 5 August 2022

The Joint Committee on Vaccination and Immunisation (JCVI) has been notified of the discontinuation of Menitorix© (Hib/MenC). This necessitates a change to the routine infant schedule as this vaccine is currently given at 12 months.

JCVI interim statement on changes to the childhood immunisation schedule - GOV.UK (www.gov.uk)

After careful consideration of options, JCVI advises

An additional Hib-containing vaccine (12 or 18 months)

Second MMR at 18 months to improve coverage

MenC containing vaccine in infant schedule not recommended

To evaluate: 6 in 1 vaccine study part 2

What was 6 in 1 part 1?

Part 1 separate study started in 2019:

What: Compare the ***immunogenicity*** of the ***Hib component*** of 6 in 1 (IH) and 6 in 1 (V) when ***co-administered*** with ***4CMenB*** (Bexsero) in the UK routine immunisation schedule at ***5 months*** of age

How: Measurement of anti-PRP (Hib) IgG concentrations at 5 months of age (Vaxelis uses a meningococcal outer membrane protein complex as a carrier protein for *Hemophilus influenza* type b (Hib), creating potential interactions with the meningococcal vaccine 4CMenB

Publication:

A Randomized Trial Assessing the Immunogenicity and Reactoge... : The Pediatric Infectious Disease Journal (lww.com)

Both these brands of vaccines are now distributed for routine use in the national immunisation schedule as part of the primary infant course of DTaP/IPV/Hib

Availability of Vaxelis® vaccine as an alternative to Infanrix hexa®

Since 31 January 2022, as part of the current vaccination programme, Vaxelis® has been available to order via ImmForm. Vaxelis® is an alternative hexavalent vaccine to Infanrix hexa® (DTaP/IPV/Hib/HepB) for routine infant primary immunisations scheduled at 8, 12 and 16 weeks of age. Vaxelis protects against the same 6 diseases as Infanrix hexa® and has been licensed in Europe for more than 5 years.

Vaccine update: Issue 325, April 2022 (publishing.service.gov.uk)

Aim of 6 in 1 part 2 vaccine study

This study will address the question of whether the two 6-in-1 vaccines may be used interchangeably for the booster dose by randomising participants with an equal chance to receive either the same vaccine for a booster, as received in the initial course, or the alternative vaccine.

The second dose of MMR being brought forward to 18 months

The 6-in-1 Part 2 Vaccine Study

Study Visit Overview

	Hex-I primed (Infanrix hexa) N= 264		Hex-V primed (Vaxelis) N= 264	
	Homologous Hex-I N = 132 (INFANRIX HEXA)	**Heterologous Hex-V** N = 132 (VAXELIS)	**Homologous Hex-V** N = 132 (VAXELIS)	**Heterologous Hex-I** N = 132 (INFANRIX HEXA)
12 Months – Visit 1	PCV13 4CMenB MMR (Optional: Varicella)	PCV13 4CMenB MMR (Optional: Varicella)	PCV13 4CMenB MMR (Optional: Varicella)	PCV13 4CMenB MMR (Optional: Varicella)
18 Months – Visit 2	Hex-I MMR (Optional: Varicella) Blood Test	Hex-V MMR (Optional: Varicella) Blood Test	Hex-V MMR (Optional: Varicella) Blood Test	Hex-I MMR (Optional: Varicella) Blood Test
19 Months – Visit 3	Blood Test	Blood Test	Blood Test	Blood Test

National Immunisation Schedule Evaluation Consortium

Home | About | Membership | Studies | Outputs & Policy Impact

Welcome to NISEC

Welcome to the website of the National Immunisation Schedule Evaluation Consortium (NISEC). NISEC is a collaboration between a network of Academic Clinical Research groups and the UK Health Security Agency, with a brief of conducting clinical research relevant to UK immunisation policy. NISEC is funded by the National Institute for Health Research Policy Research Programme (PR-R17-0916-22001), with additional funding for COVID-19 studies from the NIHR and Vaccine Task Force. On these pages you will find out more about who we are, our past and present studies, and these are influencing the UK Immunisation programme.

Home | National Immunisation Schedule (nisec.ac.uk)

Studies

Com-COV 3

Comparing COVID-19 Vaccine Schedule Combinations in Adolescents

Com-COV3 aims to find out how well young people (aged 12-16 years) respond to two doses of COVID-19 vaccine, comparing three different vaccines at different doses.

Visit Study Website >

Preg-CoV

Evaluating COVID-19 Vaccines in Pregnancy

Ongoing global studies so far have found that pregnant women are more likely to develop severe COVID-19 disease compared to non-pregnant women of the same age. The trial will compare vaccines that are currently being used for the UK vaccination programme, as well as new vaccines as they are approved.

Visit Study Website >

COV-Boost

Comparing COVID-19 Booster Vaccinations

University Hospital Southampton NHS Foundation Trust's COV-Boost vaccine trial is studying the use of seven different COVID-19 vaccines when given as a third dose.

Visit Study Website >

Com-COV

Comparing COVID-19 Vaccine Schedule Combinations

The Oxford Vaccine Group's Com-Cov vaccine trial is studying the use of different combinations of approved COVID-19 vaccines for the first and second immunisation doses.

Visit Study Website >

ComFluCOV

Combining influenza and COVID-19 vaccination

The study will look at the safety, as well as the immune responses, when giving currently approved COVID-19 vaccines at the same time as the recommended influenza (flu) vaccines from the 2020/21 flu season programme.

Visit Study Website >

Com-COV 2

Comparing COVID-19 Vaccine Schedule Combinations

The Oxford Vaccine Group's Com-Cov vaccine trial is studying the use of different combinations of approved COVID-19 vaccines for the first and second immunisation doses.

Visit Study Website >

What's the STORY?

Serum Testing Of Representative Youngsters

The Oxford Vaccine Group is researching a new way of surveying how well protected we are from infectious diseases by collecting blood samples from people who represent different groups across society.

Visit Study Website >

OpTIMUM

Optimising the Timing of Whooping Cough Immunisation in MUMs

A multicentre study to evaluate the impact of timing of whooping cough (pertussis) vaccination in pregnancy, with participants randomised to receive whooping cough vaccination at one of three time points in pregnancy.

Visit Study Website >

iMAP3

Immunising Mums Against Pertussis 3

A multi-centre observational cohort study comparing children whose mothers were randomised to one of two pertussis-containing vaccines in pregnancy as part of the IMAP2 study (REPEVAX or BOOSTRIX-IPV) or who received no pertussis- containing vaccine in pregnancy

Visit Study Website >

Studies | National Immunisation Schedule (nisec.ac.uk)

Key learning points

- There are different stages of clinical vaccine trials starting with very few participants increasing to thousands

- Vaccine trials are conducted following many regulatory requirements to ensure ethical, safe and meaningful studies producing quality data

- Vaccine schedules are dynamic being influenced in part by data generated from vaccine trials

Vaccines and Society Unit

The Vaccines and Society Unit (VAS) is a multidisciplinary research centre that aims to improve understanding of the roles played by individuals and groups in their interaction with healthcare practice and medical research.

The unit aims to produce theoretical and empirical research in social sciences and create a bridge to public health issues through policy advice, interventions, and public engagement. We draw on a variety of disciplines from sociology, history, behavioural science, health economics, and public policy to combine a wide set of tools and literatures. Being hosted by the Oxford Vaccine Group, benefits from the unique opportunity to interact with vaccinologists, epidemiologists, immunologists, and clinicians.

A particular focus is on studying actors' attitudes and behaviour towards vaccination in society, policy, and media, across time and geographies. More broadly, our interests are also in a wide range of public health topics, including issue prioritisation, disease history, and social mobilisation.

The research unit runs regular research seminars, has ongoing collaborative writing groups on a wide range of topics, and frequently hosts visiting researchers.

Visit the **Vaccines and Society Unit**

How vaccines are tested, licensed and monitored | Vaccine Knowledge Project (ox.ac.uk)