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BRIEFING PAPER

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UK Vaccination Policy

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Summary

Vaccines are a type of prescription-only medicine. Their purpose is to stimulate a person's immune system to produce antibodies that fight a specific disease, so that the person develops 'immunological memory'. If the body is later exposed to the same natural infection, immunological memory enables the immune system to recognise and respond to it rapidly, thereby preventing or modifying the severity of the disease.

Vaccines are a key part of preventative medicine and are described by the NHS as "the most effective way to prevent infectious diseases."

What is in vaccines?

Vaccines are designed to trigger an immune response without making the person experience symptoms of the disease they are protecting against.

The main ingredient of a vaccine is a "small amount of bacteria, virus or toxin that has been weakened or destroyed in a laboratory first." Vaccines containing bacteria or viruses that have been weakened are known as 'live attenuated vaccines'.

Vaccines containing whole bacteria or viruses which have been killed, or small parts of bacteria or viruses, such as proteins or sugars, are called 'inactived vaccines.'

Vaccines that rely on nucleic acid-based vectors (DNA or RNA – the genetic code of a virus) are also under development, including for Covid-19: one such vaccine has recently received a temporary authorisation for use from the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK.

Vaccination programmes

Vaccination programmes against specific diseases began in the UK in the nineteenth century, though modern, nationwide programmes took off following the establishment of the NHS in 1948. The UK's current routine immunisation schedule provides protection against 14 vaccine-preventable infections, including measles, meningococcal disease and polio. The majority of vaccinations are given during childhood though some, such as vaccination against shingles, are aimed at those aged 70+.

Recommendations for vaccination coverage (the percentage of people from the target population who have received a specific vaccine) are made by the World Health Organization (WHO). It suggests that, at a national level, at least 95% of children are immunised against vaccine-preventable diseases and these targets have been adopted by the Department of Health and Social Care (DHSC).

For the year 2019-20, with the exception of DTaP/IPV/Hib vaccine at age five (diphtheria, tetanus, pertussis, polio and Haemophilus influenzae type b), none of the routine vaccinations met the 95% target at the national, UK level. There is also geographical variation. The National Audit Office, for example, highlighted lower levels of uptake in pre-school vaccinations in London, compared to the rest of England.

Factors identified by NHS England and Public Health England (PHE) which affect uptake of childhood vaccines include:

- inconsistent call/recall (direct communication between health care providers and parents or carers to arrange their child's vaccinations);
- difficulties in timely access to healthcare professionals;

- incomplete data on vaccination uptake (NHS England and PHE identified a range of potential inaccuracies in the reported data and do not know the extent to which these affect information on rates of uptake);
- 'under-served' populations;
- anti-vaccination messages; and
- vaccine hesitancy among a small minority of parents.

Vaccination policy in England

Health is a devolved matter. National strategic oversight of vaccination policy in England is provided by the DHSC. The department is advised by the Joint Committee on Vaccination and Immunization (JCVI), an independent expert advisory committee, and the Commission on Human Medicines.

Responsibility for commissioning national immunisation programmes in England rests with NHS England. The DHSC sets performance targets and Public Health England provides oversight and surveillance of vaccine-preventable diseases.

Pre-school and adult vaccinations are usually delivered by GP surgeries and commissioned through the NHS GP contract. School-age services are commissioned by seven regional NHS England teams and delivered through School Immunisation Teams.

Additional support has been put in place specifically for a Covid-19 vaccine programme, such as the establishment of the UK Vaccine Taskforce, which aims to "drive forward the development and production of a coronavirus vaccine". Further information on the Covid-19 vaccine programme can be found in the Parliamentary Office of Science and Technology publication *Regulatory approval of COVID-19 vaccines in the UK* (December 2020).

In August 2019, the WHO's European Regional Verification Commission for Measles and Rubella Elimination (RVC) determined the UK had lost its measles elimination status. The Government responded by setting out measures aimed at increasing immunisation rates for the MMR (measles, mumps and rubella) vaccination, such as promoting 'catch-up' vaccination programmes for 10-11-year-olds.

The DHSC is also due to publish a 10-year vaccination strategy, to increase uptake of all recommended vaccinations across all communities and areas, but it has been delayed by the Covid-19 pandemic.

Mandatory vaccination

Vaccines offered through the national immunisation programme in the UK are not mandatory. Vaccinations are also not currently mandatory in the UK during a pandemic.

Medical and ethical opinion is divided on the introduction of immunisation policies that involve some degree of coercion (such as fines). Some countries, such as Italy and France, have mandatory vaccination policies in place, an overview of which is provided on pages 43-48. In response to falling vaccination rates, some countries, including Italy, have extended existing mandatory vaccination programmes, or introduced them for the first time, such as in Germany. Certain policies criminalise vaccine refusal, such as by fining parents, or make access to services – such as state-run schools – contingent on immunisation status.

The effectiveness of mandatory vaccination policies is not clear, partly because attitudes to immunisation vary between countries and there can be several factors contributing to declining or poor immunisation coverage.

Other resources

The Parliamentary Office of Science and Technology (POST) has published several related articles on Covid-19 vaccines, as has the House of Lords Library:

POST, Regulatory approval of COVID-19 vaccines in the UK, 2 December 2020

POST, COVID-19 vaccines November update: progress of clinical trials, 6 November 2020

House of Lords Library, Covid-19 vaccine: Winter update, 10 November 2020

1. What is a vaccine?

1.1 Vaccination and immunity

A vaccine is a prescription-only preparation that stimulates a person's immune system to enable them to develop immunity to a particular infectious disease. Immunity can be long-lasting; 'immunological memory' enables the immune system to recognise and respond rapidly when the body is subsequently exposed to the same natural infection, thereby preventing – or modifying the severity of – the disease.[1] Unlike other drugs that treat or cure disease, the purpose of a vaccine is to stop a person contracting a disease in the first place.[2] Vaccines are thus an important part of preventative medicine; they are described by the NHS as the "most effective way to prevent infectious diseases".[3]

Detailed information on vaccines and vaccination procedures is published by Public Health England in *Immunisation against infectious disease* (commonly known as the 'Green Book') which is regularly updated. In November 2020, for example, Chapter 14a was added to the Green Book on COVID-19 - SARS-Cov-2 which covers guidance on the storage, dosing and schedule of Covid-19 vaccines, as well as advice on vaccinating high risk groups.

The World Health Organization (WHO) has estimated that, globally, around two to three million deaths are prevented each year through vaccination programmes.[4] The WHO also notes that vaccines can help reduce the spread of antibiotic resistance on the grounds that "vaccinating humans and animals is a very effective way to stop them from getting infected and thereby preventing the need for antibiotics".[5]

Precursors to modern-day vaccination date back to approximately 1000CE when societies in Asia, Africa and the Middle East used a method called 'variolation' to protect people against smallpox:

> material from smallpox sores (pustules) was given to people who had never had smallpox. This was done either by scratching the material into the arm or inhaling it through the nose.[6]

In 1796, the doctor Edward Jenner successfully inoculated cowpox material into the arm of a boy to create immunity to smallpox. By the end of the 19th century, through the work of people such as Louis Pasteur, the fundamental principles of vaccination had been established.

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1 Public Health England, The Green Book, Chapter 1: Immunity and how vaccines work, December 2018

2 Therapeutic vaccines for those with certain cancers are being researched and, at this stage, are mainly available as part of clinical trials, see R E Hollingsworth & K Jansen, Turning the corner on therapeutic cancer vaccines, *npj Vaccines,* volume 4(7) (2019)

3 NHS, Why vaccination is safe and important, 30 July 2020

4 World Health Organization, Immunization, December 2019

5 Why is vaccination important for addressing antibiotic resistance?, World Health Organization, November 2016

6 Centers for Disease Control and Prevention, History of Smallpox, August 2016

We now know that immunity is achieved through the person producing 'antibodies' that work to neutralise or destroy a disease. There are two different types of immunity: passive and active.

An antibody is a protein produced by 'B Cells' (a type of white blood cell) in response to a foreign substance known as an antigen.

Passive and active immunity

'Passive immunity' is a process whereby a person is given specific antibodies to protect against infection, such as antibodies transferred across the placenta from a mother to her baby. 'Active immunity' is protection against infection that is produced by an individual's own immune system. It involves exposing the body to an antigen – a toxin. This generates a response by the person's immune system to produce antibodies to the specific disease. It is usually classified as 'natural' (infection with an actual disease) or 'acquired', whereby immunity is purposefully introduced through vaccination, using a killed or weakened form of the disease organism (vaccines that rely on nucleic acid-based vectors (DNA or RNA – the genetic code of the virus) are also under development, such as for Covid-19) . Immunisation is thus the process by which a person becomes protected against a disease through vaccination.

Herd/population immunity

Many bacterial and viral infections are spread from person to person. When a large proportion of the population have immunity to a particular disease, those people are unlikely to contribute to its transmission and chains of infection are more likely to be disrupted. This may either stop, or slow, the spread of the disease (and in some instances can eradicate it, such as Polio), thereby providing 'herd immunity' (or indirect protection) to those who are not immune.

Herd immunity helps to protect those who are unable to build up immunity, such a people with immunodeficiency disorders, or whose immune systems are being suppressed for medical reasons (eg those undergoing chemotherapy). It can also help those who do not produce an effective immune response to a vaccine[7] or who cannot be immunised with a particular vaccine.

Further information about instances where vaccination is contraindicated can be found in Chapter 6 of the Green Book - *Contraindications and special considerations*, August 2017.

The vaccine alliance, Gavi, notes that the more infectious a disease, the greater the population immunity needed to ensure herd immunity. In the case of measles, for example, one person with measles can infect up to 18 other people which means that around 94-95% of people need to be immune for the wider group to have herd immunity.[8]

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7 For example, the effectiveness of vaccination in the elderly has been found to be "strongly reduced" compared to younger adults, see A Ciabattini et al, Vaccination in the elderly: The challenge of immune changes with aging, *Seminars in Immunology*, Volume 40, December 2018, Pages 83-94

8 Gavi, What is herd immunity?, 26 March 2020

Herd immunity does not protect against all vaccine-preventable diseases; tetanus for example is caught from bacteria in the environment, not from other people who have the disease.[9]

1.2 What is in a vaccine?

Active ingredients

The NHS explains that the main ingredient of a vaccine is a "small amount of bacteria, virus or toxin that's been weakened or destroyed in a laboratory first".[10]

Live attenuated vaccines

Vaccines containing bacteria or viruses that have been weakened are known as "live attenuated vaccines". This type of vaccine tends to create a strong and lasting immune response because they are similar to the natural infection that they help to prevent. Live attenuated vaccines used in the UK immunisation schedule include:

- Rotavirus vaccine
- Measles, Mumps, and Rubella (MMR) vaccine
- Nasal influenza vaccine (used in children)
- Shingles vaccine

The Oxford Vaccine Project, based at the University of Oxford, notes that live vaccines are not suitable for everyone, particularly those "whose immune system does not work, either due to drug treatment or underlying illness. This is because the weakened viruses or bacteria can multiply too much and might cause disease in these people".[11]

Inactivated vaccines

Inactivated vaccines use whole bacteria or viruses which have been killed or "small parts of bacteria or viruses, such as proteins or sugars, which cannot cause disease".[12] The NHS provides the following table comparing vaccines made from live and killed pathogens:

Live (weakened) vaccines	Killed (destroyed) vaccines
Contain viruses or bacteria that have been weakened	Contain viruses or bacteria that have been destroyed
Cannot be given to people with a weakened immune system	Can still be given to people with a weakened immune system
Gives long-term protection	Often needs several doses or a booster vaccine for full protection

Source: NHS, Why vaccination is safe and important, July 2019

9 L Gordis, Epidemiology, Elsevier Health Sciences, 2013 pp. 26–27.
10 NHS, Why vaccination is safe and important, 30 July 2019
11 Oxford Vaccine Project, Types of vaccine, January 2019
12 ibid

There are multiple types of inactivated vaccines:

- **Subunit** - these vaccines rely on using a specific part from the surface of the virus or bacteria, such as proteins, sugars (polysaccharides), or capsids (the protein shell of a virus).[13]
- **Toxoid** - certain pathogens cause disease by secreting toxins. Some vaccines are made with inactivated versions of these toxins. They are called 'toxoids' because they look like toxins but are not poisonous.[14]

  Toxoid vaccines used in the UK schedule include:

  — Diphtheria vaccine (in the 6-in-1 vaccine, pre-school booster, teenage booster and pertussis (whooping cough) vaccine in pregnancy).

  — Tetanus vaccine (in the 6-in-1 vaccine, pre-school booster, teenage booster and pertussis vaccine in pregnancy).

  — Pertussis vaccine (in the 6-in-1 vaccine, pre-school booster and pertussis vaccine in pregnancy). This contains pertussis toxoid, together with proteins from the surface of the pertussis bacteria. It is often called an 'acellular' vaccine.[15]
- **Conjugate** - while these vaccines also use sugars from the surface of bacteria, they are bound to protein molecules, to enhance the strength and effectiveness of the immune response. The Oxford Vaccine Project notes that, in most conjugate vaccines, the polysaccharide is attached to diphtheria or tetanus toxoid protein.

  Conjugate vaccines used in the UK schedule include:

  — Hib vaccine (Haemophilus influenzae type b in the 6-in-1 vaccine and Hib/MenC vaccine), which contains a polysaccharide joined to tetanus toxoid.

  — MenC vaccine (Meningococcal C in the Hib/MenC vaccine), which contains a polysaccharide joined to tetanus toxoid.

  — PCV (children's pneumococcal vaccine), which contains polysaccharides from the surface of 13 types of the bacteria which causes pneumococcal disease joined to diphtheria toxoid.

  — MenACWY (Meningococcal group A, C, W-135 and Y conjugate vaccine), which contains polysaccharides from the surface of four types of the bacteria which causes meningococcal disease joined to diphtheria or tetanus toxoid.[16]
- **Recombinant** - these vaccines rely on recombinant DNA technology (genetic material brought together from multiple sources). The Oxford Vaccine Project gives the example of how the hepatitis B vaccine is made, whereby part of the DNA from

13 D Baxter, Active and passive immunity, vaccine types, excipients and licensing, *Occupational Medicine*, 57(8) December 2007, Pages 552–556
14 Centers for Disease Control and Prevention, Understanding How Vaccines Work, August 2018
15 Oxford Vaccine Project, Types of vaccine, January 2019
16 Oxford Vaccine Project, Types of vaccine, January 2019

the hepatitis B virus is inserted into the DNA of yeast cells. These yeast cells are then able to produce one of the surface proteins from the hepatitis B virus, and this is purified and used as the active ingredient in the vaccine.

Recombinant vaccines used in the UK schedule include:

- Hepatitis B vaccine (in the 6-in-1 vaccine and as the separate hepatitis B vaccine)
- Human Papillomavirus (HPV) vaccine
- MenB vaccine which provides protection against infection with meningococcal group B bacteria. This contains proteins from the surface of meningococcal bacteria. Three of the proteins are made using recombinant technology.[17]

RNA Vaccines

RNA vaccines are under development and are the subject of ongoing clinical trials. The Imperial College Covid-19 Vaccine Trial, for example, seeks to establish a self-amplifying RNA vaccine for the first time in humans, while the Pfizer and BioNTech mRNA Covid-19 vaccine has recently received a temporary authorisation for use from the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The active ingredient in the latter is 'messenger RNA' (mRNA) which the *New Scientist* describes as "synthetic" (i.e. not extracted from actual viruses) and which, when injected into muscle tissue in the arm, is:

> taken up by specialist immune cells, which follow its instructions to make the [virus's] spike protein, just as they would do if they had become infected with the actual virus.[18]

A briefing published by the PHG Foundation explains the overall approach:

> RNA vaccines [...] take advantage of the process that cells use to make proteins: cells use DNA as the template to make messenger RNA (mRNA) molecules, which are then translated to build proteins. An RNA vaccine consists of an mRNA strand that codes for a disease-specific antigen. Once the mRNA strand in the vaccine is inside the body's cells, the cells use the genetic information to produce the antigen. This antigen is then displayed on the cell surface, where it is recognised by the immune system.[19]

Additional vaccine ingredients

The main ingredient in any vaccine is the 'active ingredient', as set out in the section above. Vaccines also contain very small amounts of added ingredients, usually no more than a few milligrams. Certain added ingredients are called "**adjuvants**". The purpose of an adjuvant is to improve the immune response of a vaccine; they can, for example, enhance the speed of the immune response and its duration (thereby reducing or eliminating the need for 'booster' vaccines in the future).[20]

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17 ibid

18 Everything you need to know about the Pfizer/BioNTech covid-19 vaccine, *New Scientist*, 3 December 2020

19 phg foundation, RNA vaccines: an introduction, October 2018

20 Adjuvants: Introduction, British Society for Immunology, not dated [last accessed 29 June 2020]

They can also decrease the dose of antigen required which can help to reduce costs.[21] **Stabilisers** are also added to a vaccine to help ensure that the vaccine remains effective after it is manufactured. They can prevent components of the vaccine from separating or from adhering to the vaccine vial during transportation and storage.[22]

Products used in the manufacture of vaccines (which may not remain in the finished vaccine) include **antibiotics**, which are used "to prevent bacterial contamination of the tissue culture cells in which the viruses are grown", **preservatives** which are used to inactivate toxins from the bacteria used in vaccines and **acidity regulators** which are "used in very small quantities to help keep the pH balance right while vaccines are being manufactured".[23]

Further details about common additional ingredients in vaccines can be found in the 'other vaccine ingredients' section on the NHS vaccines page.

A full list of any vaccine's ingredients is available on the electronic medicines compendium (emc) website.

1.3 Vaccine testing and licensing in the UK

Vaccines must be tested through a series of clinical trials to establish their efficacy and safety, and have a product licence, known as a "marketing authorisation", before they can be made available for widespread use in humans.

Clinical trials

The conduct of clinical trials in the EU is currently governed by the EU Clinical Trials Directive. This was transposed into UK law through the Medicines for Human Use (Clinical Trials) Regulations (2004). The current EU regulatory framework is due to be replaced by a new EU Clinical Trial Regulation; at the time of writing, this new Regulation will not be applied until after the end of the UK's Transition Period.

The conduct of a clinical trial must also meet the standards set out by the International Conference on Harmonisation of Good Clinical Practice. These are a set of ethical and scientific guidelines agreed in 1997 between the US, EU and Japan for designing, recording and reporting results from trials that involve human subjects to get a drug registered for human use.

In the UK, the clinical trial must be approved by the UK regulator – the Medicines and Healthcare products Regulatory Agency (MHRA).[24] Detailed information on the authorisation of clinical trials in the UK is published by MHRA, see Clinical trials for medicines: apply for authorisation in the UK (October 2020) and Registration of clinical trials

21 ibid
22 World Health Organization, Components of a vaccine, Vaccine Safety Basics, not dated
23 Oxford Vaccine Project, Vaccine ingredients, August 2019
24 Prior approval for the trial must also have been sought through the Health Research Authority in England (and devolved administration equivalents)

for investigational medicinal products and publication of summary results from 1 January 2021 (September 2020).

Clinical trials are divided into three main stages:

- Phase I trials involve a small group of healthy people (<100) and aim to make sure that there are no safety concerns, to see how well it stimulates an immune response and to work out an effective dose.
- Phase II trials involve several hundred people and aim to see whether the vaccine works consistently, to assess the immune response and to look for side effects.
- Phase III trials involve several thousand people under natural disease conditions. This produces enough data to identify rare side effects and to evaluate whether the vaccine produces enough immunity to prevent and/or reduce the disease.[25]

Marketing authorisation

After successfully completing each stage of the clinical trial, the vaccine manufacturer (usually a pharmaceutical company) will apply for a licence for the vaccine – a "marketing authorisation" – in order to market the vaccine, and make it available, to patients. In the UK, there are currently two licensing authorities, the European Medicines Agency (EMA) and the MHRA. Both authorities are responsible for the scientific evaluation of applications for a marketing authorisation. This includes examining whether the medicine / vaccine is effective, safe and of good quality. For further information see:

- European Medicines Agency, How EMA evaluates medicines for human use, not dated

The regime for the authorisation of medicinal products for human use – including their manufacture, distribution, sale, supply, labelling and advertising – is based on EU legislation, notably Directive 2001/83/EC (medicinal products for human use), much of which was implemented in the UK through the Human Medicines Regulations 2012.

The licensing of certain medicines (such as those used to treat viral disease) currently has to be undertaken by the EMA. The EMA's centralised process allows the marketing-authorisation holder to "market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorisation".[26] From January 2021, the MHRA will be solely responsible for licensing procedures in the UK. It has published a suite of guidance on how national licensing procedures will operate.[27] The MHRA has also stated that, for two years from 1 January 2021:

> Great Britain will adopt decisions taken by the European Commission on the approval of new marketing authorisations in the community marketing authorisation procedure [the centralised process].

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25 POST, COVID-19 vaccines November update: progress of clinical trials, November 2020

26 EMA Authorisation of medicines, December 2017.

27 MHRA, MHRA post-transition period information, last updated 25 November 2020

> [...]
>
> The UK will also have the power to take into account marketing authorisation decisions of EU Member States when considering applications for marketing authorisations for products that have been approved in decentralised or mutual recognition procedures.[28]

Box 1: Licensing a Covid-19 vaccine

Between the 28 August and 18 September 2020, the Government held a public consultation on proposed changes to the Human Medicines Regulations (HMRs) which aimed to support the rollout of Covid-19 vaccines. The consultation covered a number of issues, including the temporary supply of unlicensed medical products, the civil liability of the manufacturers of medical products that are supplied without a marketing authorisation, and the healthcare professionals that can give vaccinations.

A Government press release on the draft regulations stated that the measures were particularly necessary if a Covid-19 vaccine was discovered before the end of the Transition Period:

> If a vaccine is discovered before 2021, the proposals will bolster existing powers that allow the MHRA to consider approving its use, before a full product licence is granted, provided it is proven to be safe and effective during robust and extensive clinical trials.
>
> The measures are necessary because during the transition period, a new potential COVID-19 vaccine must be granted a licence by the European Medicines Agency (EMA).
>
> The regulations will permit the MHRA to consider giving temporary authorisation allowing patients to benefit while it undergoes the full licensing process, with reinforced conditions attached to ensure safety, quality and efficacy.
>
> This is a precautionary measure and will be used as a last resort if there is a strong public health justification for widespread use of a vaccine before it has been granted a product licence.

The Government published its response to the consultation on 16 October 2020. The changes to the HMRs were laid on the same day as the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020. The consultation response explains that the Government has proceeded "with the changes to the Human Medicines Regulations (HMRs) proposed in [the] consultation" but that three "key changes" were made to the original proposals:

1. Ensure robust scrutiny of the impact of regulation 174 takes place by making it a requirement that the impact of this regulation will be formally reviewed within a year of any first use. Regulation 174 is the existing mechanism which allows for the temporary authorisation of an unlicensed medicine or vaccine.
2. Promote objectivity by changing the 'objective bystander' test that relates to loss of immunity from civil liability where conditions are breached to make this a person who has 'relevant expertise in the subject matter of the breach', in place of the original reference to pharmaceutical companies.
3. Create an additional level of reassurance in relation to the expanded workforce by making it clear that the new national protocol should include, where appropriate, the requirements for the supervision of an additional experienced vaccinator.

1.4 World Health Organization immunisation initiatives

The World Health Organization (WHO) has described vaccines as one of "the biggest success stories of modern medicine", with at least "10 million deaths [...] prevented between 2010 and 2015" due to

[28] MHRA, Guidance: Guidance note on new assessment routes from 1 January 2021, 27 October 2020

"vaccinations delivered around the world".[29] In 2010, the Decade of Vaccines was launched at the World Economic Forum as a means to extend the full benefits of immunization globally by 2020. To support this goal, the World Health Assembly approved the Global Vaccine Action Plan as the framework for delivering universal access to vaccines. The GVAP is a framework to promote equitable access to existing vaccines through six strategic objectives:

- All countries commit to immunisation as a priority.
- Individual and communities understand the value of vaccines and demand immunisation as both their right and their responsibility.
- The benefits of immunisation are equitably extended to all people.
- Strong immunisation systems are an integral part of a well-functioning health system.
- Immunisation programmes have sustainable access to predictable funding, quality supply and innovative technologies.
- Country, regional and global research and development innovations maximise the benefits of immunisations.[30]

In 2014, the Member States of the WHO European Region unanimously adopted the European Vaccine Action Plan (EVAP) 2015-2020, developed to facilitate the implementation of the GVAP in the European Region. The EVAP defined six goals:

- Sustain polio-free status.
- Eliminate measles and rubella.
- Control hepatitis B infection.
- Meet regional vaccination coverage targets at all administrative levels throughout the Region.
- Make evidence-based decisions on introduction of new vaccines.
- Achieve financial sustainability of national immunization programmes.[31]

Progress towards meeting the goals of the GVAP and EVAP has been limited. Writing in 2017, the then Director-General of the WHO, Dr Margaret Chan, described the overall progress towards meeting the GVAPs targets as both "sluggish" and "woefully inadequate to meet the soaring ambitions of the action plan".[32] In Europe, the EVAP mid-term report highlighted that only 3 of the goals were on track. The

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29 World Health Organization, The power of vaccines: still not fully utilized in *Ten Years in Public Health 2007-2017*, Dr Margaret Chan, Director-General, World Health Organization, 2017, p82

30 World Health Organization, Global Vaccine Action Plan 2011-2020, published 2013, p30-31

31 Regional Office for Europe of the World Health Organization, European Vaccine Action Plan (EVAP) 2015-2020, published 2014, p18

32 World Health Organization, The power of vaccines: still not fully utilized in *Ten Years in Public Health 2007-2017*, Dr Margaret Chan, Director-General, World Health Organization, 2017, p87

report identified periodic outbreaks of measles and rubella, together with suboptimal surveillance levels, as an impediment to disease elimination.[33] Similarly, it reported that the goal to meet regional vaccination coverage targets was at risk.

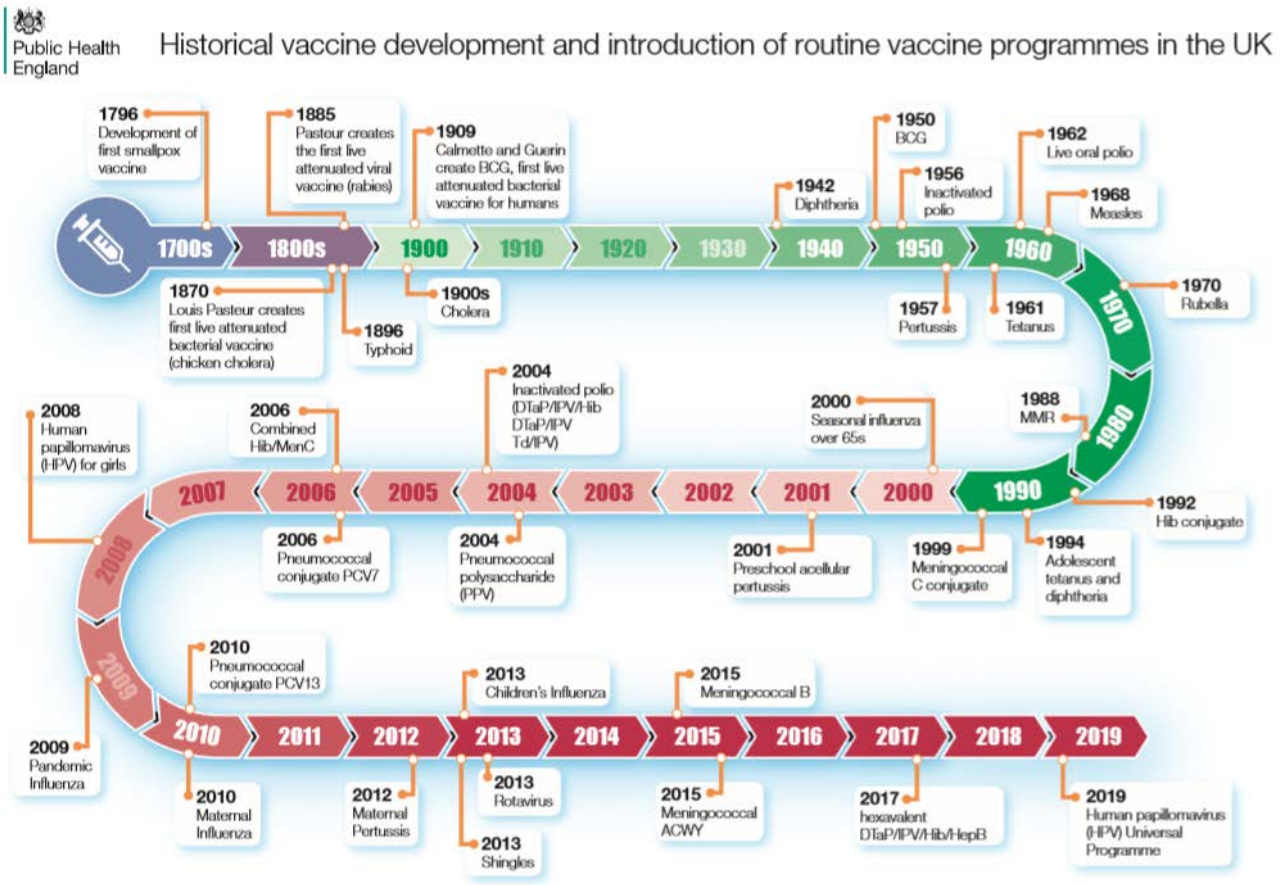
The World Health Organization's Tailoring Immunisation Programmes Model guidance sets out best practice for countries seeking to improve vaccine take up, particularly by groups that are least likely to engage with immunisation services. This has been used by Public Health England to improve immunisation coverage in communities in which outbreaks of vaccine preventable infectious disease have been reported. UK vaccination programmes are discussed in detail below, together with commentary on PHE's tailored immunisation programmes.

[33] Regional Office for Europe of the World Health Organization, European Vaccine Action Plan 2015-2020 Midterm report, 2018

2. UK vaccination programmes

Vaccination programmes against specific diseases began in the UK in the nineteenth century, though modern, nationwide programmes took off following the establishment of the National Health Service in 1948. The timeline below, produced by Public Health England (PHE), sets out both the history of vaccine development and the introduction of routine vaccine programmes in the UK.

Multiple *Vaccination Acts* were passed during the nineteenth century which placed a duty on local authorities to provide vaccination free of charge. Vaccination against smallpox was made compulsory under the *Vaccination Act of 1853* for all infants under three months old in England and Wales.[34] All the nineteenth century Vaccination Acts (including the 1853 Act) were subsequently repealed by the National Health Service Acts of 1946 and 1947.[35] Vaccination is not compulsory in the UK, see section 4 for further discussion.



Source: Public Health England, Vaccination timeline infographic from 1796 to present, last updated July 2019

[34] The Health Foundation, United Kingdom Vaccination Act 1853, not dated
[35] G Milward, Vaccinating Britain: Mass vaccination and the public since the Second World War, Manchester University Press, January 2019

2.1 UK immunisation schedule

The overall aim of the UK's current immunisation schedule is to provide protection against the following vaccine-preventable infections:

- Haemophilus influenzae type b (Hib)
- hepatitis B
- human papillomavirus
- influenza
- measles
- meningococcal disease
- mumps
- pertussis (whooping cough)
- pneumococcal disease
- polio
- rotavirus
- rubella
- shingles
- tetanus

Copied below is the UK routine immunisation schedule, as set out in 'The Green Book'; a publication by Public Health England containing all the latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK.

Age due	Vaccine given	How it is given[1]
Eight weeks old	Diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type b (Hib) and hepatitis B (DTaP/IPV/Hib/HepB)	One injection
	Meningococcal B (MenB)	One injection
	Rotavirus	One oral application
Twelve weeks old	Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (DTaP/IPV/Hib/HepB)	One injection
	Rotavirus	One oral application
	Pneumococcal conjugate vaccine (PCV13)	One injection
Sixteen weeks old	Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (DTaP/IPV/Hib/HepB)	One injection
	Meningococcal B (MenB)	One injection
One year old (on or after the child's first birthday)	Hib/MenC	One injection[2]
	Pneumococcal conjugate vaccine (PCV13)	One injection[2]
	Meningococcal B (MenB)	One injection[2]
	Measles, mumps and rubella (MMR)	One injection[2]
Primary school age children (school years reception to six) Chapter 19)	Live attenuated influenza vaccine (LAIV)	Nasal spray, single application in each nostril (if LAIV is contraindicated and child is in a clinical risk group, give inactivated flu vaccine; see Chapter 19)
Three years four months old or soon after	Diphtheria, tetanus, pertussis and polio (dTaP/IPV)	One injection
	Measles, mumps and rubella (MMR)	One injection
Twelve to thirteen years old	Human papillomavirus (HPV)	Course of two injections at least six months apart
Fourteen years old (school year 9)	Tetanus, diphtheria and polio (Td/IPV) Meningococcal ACWY conjugate (MenACWY)	One injection One injection
65 years old	Pneumococcal polysaccharide vaccine (PPV)	One injection
65 years of age and older	Inactivated influenza vaccine	One injection annually
70 years old	Shingles vaccine	One injection

Source: Public Health England, The schedule for routine immunisations, The Green Book, Chapter 11, p2, December 2019

All vaccinations offered on the national routine immunisation schedule are available free of charge. No immunisations are compulsory (see discussion in section 4 on mandatory vaccination). For childhood immunisations, parents or guardians make the decisions about whether a child is immunised and consent on their behalf. In the UK, sixteen- and seventeen-year olds are presumed in law to be able to consent to medical treatment. Some children aged under sixteen many also have the capacity to consent to medical treatment themselves – this is called Gillick competence.[36]

The majority of vaccinations listed above are given during childhood. While newborn babies initially have immunity to some diseases due to antibodies passed to the child from its mother, this immunity is temporary and declines during the child's first year. The childhood immunisation schedule is thus "designed to provide early protection against infections that are most dangerous for the very young".[37]

Additional vaccinations that are not on the routine immunisation schedule are offered to babies and children in specific high-risk groups. For example, the BCG vaccine, which protects against tuberculosis (TB) is targeted at those babies up to age 1 who;

- are born in areas of the UK where the rates of TB are high;
- have a parent or grandparent who was born in a country where there's a high rate of TB.[38]

Similarly, the chickenpox vaccine is not part of the routine childhood vaccination schedule but it is recommended for certain individuals, such as:

- non-immune healthcare workers;
- people who come into close contact with someone who has a weakened immune system.[39]

Non-immune children of those patients undergoing chemotherapy are thus advised to have the chickenpox vaccine. Chapter 12 of the Green Book also identifies those working in occupations where additional vaccines may be required, see:

- Public Health England, Immunisation against infectious disease - Chapter 12, Immunisation of healthcare and laboratory staff, March 2013;
- Health and Safety Executive, Immunisation, not dated

In addition, travel outside of the UK may require vaccination against diseases that are found in other parts of the world. Information can be found on the NHS webpage on travel vaccinations and on www.travelhealthpro.org.uk (a website provided by the National Travel Health Network and Centre and commissioned by Public Health England). Certain travel immunisations can be provided free of charge

36 NHS, Children and young people, Consent to treatment, 29 March 2019
37 Public Health England, The Green Book, Chapter 11:The UK immunisation schedule, December 2019, p3,
38 Who should have the BCG (TB) vaccine?, NHS, April 2019
39 Chickenpox vaccine overview, NHS, January 2019

through the NHS, such as hepatitis A and typhoid. Others may be provided privately through a travel vaccination clinic.

Some vaccination strategies are designed to reduce transmission of a disease in the group that is vulnerable by immunising another group. One example is influenza, which is largely transmitted by children. While children bear some risk from influenza infection, older people and others in high risk groups are more vulnerable to severe disease. Therefore, in addition to vaccinating those aged 65+, the UK programme also aims to immunise all children aged 2-10 years. From autumn/winter 2020, all those starting secondary school (aged 11 in September) are also eligible for the nasal spray flu vaccine.[40] This not only protects them individually but also confers indirect protection to older adults and babies by reducing overall levels of viral transmission in the population.[41]

The following websites provide further patient-facing information about the immunisation schedules and the diseases that they target:

- NHS vaccinations and when to have them, NHS, July 2019
- The UK Immunisation Schedule, Vaccine Knowledge Project, University of Oxford, July 2019
- Complete routine immunisation schedule, Public Health England, December 2019

Box 2: Vaccines for Covid-19

The Government has committed to establishing a programme to vaccinate people against Covid-19, once a vaccine (or vaccines) have been authorised by the regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). There are multiple Covid-19 vaccine candidates, each at different stages of development / clinical trials. To date, several candidate vaccines have shown promising interim results from Phase III clinical trials. The Parliamentary Office of Science and Technology (POST) has published an overview of the progress to date: COVID-19 vaccines November update: progress of clinical trials (6 November 2020).

At the time of writing, the MHRA was reviewing clinical trials data from several candidate Covid-19 vaccines to determine whether they meet quality, safety, and effectiveness standards.[42] On 2 December 2020, the MHRA issued a temporary authorisation for use of the Pfizer/BioNTech vaccine.

The UK Government's Vaccine Taskforce has been responsible for establishing access to a "diverse portfolio"[43] of Covid-19 vaccines and is reported to have secured early access to over 355 million doses of seven vaccine candidates, including:

1. BioNTech/Pfizer for 40 million doses
2. Oxford/AstraZeneca for 100 million doses
3. Moderna for 5 million doses
4. GlaxoSmithKline and Sanofi Pasteur for 60 million doses

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40 NHS, Children's flu vaccine overview, 8 July 2019

41 Joint Committee on Vaccination and Immuization, JCVI statement on the annual influenza vaccination programme – extension of the programme to children, 25 July 2012, para 3

42 Press release: Government welcomes the MHRA review into Pfizer and BioNTech vaccine, Department of Health and Social Care, Department for Business, Energy & Industrial Strategy, 23 November 2020

43 Kate Bingham, The UK Government's Vaccine Taskforce: strategy for protecting the UK and the world, *The Lancet*, 27 October 2020

5. Novavax for 60 million doses
6. Janssen for 30 million doses
7. Valneva for 60 million doses.[44]

Information on the deployment of a Covid-19 vaccine is being regularly updated by NHS England and NHS Improvement – for the most recent guidance see: NHS, COVID-19 vaccination programme, (not dated).

2.2 Vaccine policy in England

Joint Committee on Vaccination and Immunization

National strategic oversight of vaccination policy in England is provided by the Department of Health and Social Care (DHSC). The DHSC is advised by the Joint Committee on Vaccination and Immunization (JCVI), an independent expert advisory committee. It provides advice on the introduction of new programmes, as well as major changes to, or the discontinuation of, an existing immunisation programme. The JCVI states that it formulates advice and recommendations based on "appraisal of the best scientific and other evidence available and reflecting current good practice and/or expert opinion".[45] The process followed by the JCVI is outlined in the flow diagram below.

Since 1 April 2009, the Health Protection (Vaccination) Regulations 2009 (SI 2009/38) place a duty on the Secretary of State for Health in England to ensure, so far as is reasonably practicable, that the recommendations of JCVI are implemented, where those recommendations:

a) relate to new provision for vaccination under a national vaccination programme or to changes to existing provision under such a programme and;

b) are made by JCVI (and not therefore a Sub-committee of JCVI) and;

c) are in response to a question referred to the JCVI by the Secretary of State and;

d) are based on an assessment which demonstrates cost-effectiveness and;

e) do not relate to vaccination in respect of travel or occupational health.

While the JCVI has no statutory basis for providing advice to Ministers in Scotland or Northern Ireland, health departments from these countries may choose to accept the Committee's advice or recommendations.

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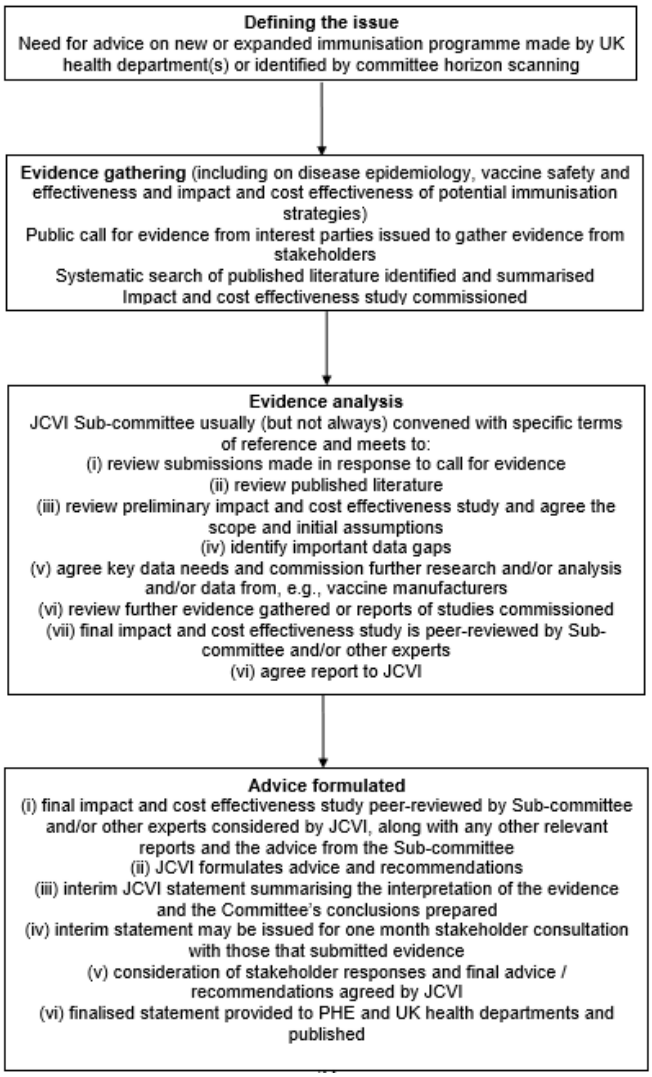
44 Press release: Government welcomes the MHRA review into Pfizer and BioNTech vaccine, Department of Health and Social Care, Department for Business, Energy & Industrial Strategy, 23 November 2020

45 Joint Committee on Vaccination and Immunisation, Code of Practice, June 2013

General schematic for the evaluation of a new immunisation programme or major changes to, or discontinuation of, an existing immunisation programme



Source: Joint Committee on Vaccination and Immunization, Code of Practice, June 2013, p24

Box 3: JCVI and priority groups for Covid-19 vaccination

The JCVI published an independent report on 2 December 2020 providing advice on priority groups for COVID-19 vaccination. The Committee explained that the information / data that it had considered when developing its advice included:

> a review of UK epidemiological data on the impact of the COVID-19 pandemic so far, data on demographic and clinical risk factors for mortality and hospitalisation from COVID-19, data on occupational exposure, a review on inequalities associated with COVID-19, Phase I, II and III data on the Pfizer-BioNTech mRNA vaccine and headline phase III results on the AstraZeneca vaccine, Phase I and II data on other developmental COVID19 vaccines, and mathematical modelling on the potential impact of different vaccination programmes.

Based on the "current epidemiological situation in the UK" and the available evidence, the JCVI recommended that the "best option for preventing morbidity and mortality in the initial phase of the [vaccination] programme is to directly protect persons most at risk of morbidity and mortality". It added that "maintenance of the health and social care systems should also be a priority" and that, as the risk of mortality from Covid-19 increases with age, "prioritisation is primarily based on age".

An "age-based programme" is thus envisaged by the JCVI to optimise both delivery and uptake of any Covid-19 vaccine. The prioritisation, as of 2 December 2020, is set out below:

1. Residents in a care home for older adults and their carers
2. All those 80 years of age and over. Frontline health and social care workers
3. All those 75 years of age and over
4. All those 70 years of age and over Clinically extremely vulnerable individuals*
5. All those 65 years of age and over
6. All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
7. All those 60 years of age and over
8. All those 55 years of age and over
9. All those 50 years of age and over

The JCVI stated that, as more Phase III trial data becomes available, the Committee will be able to prepare further advice for policy makers in the UK.

Commission on human medicines

The Commission on Human Medicines (CHM) is an advisory non-departmental public body, sponsored by the Department of Health and Social Care. It was established in 2005 and advises ministers on the safety, efficacy and quality of medicinal products, including vaccines. Further details about its functions are set out in regulation 10 of the Human Medicines Regulations 2012 (SI 2012/1916). The Commission is supported in its work by Expert Advisory Groups (EAGs), covering various areas of medicine, including the *Clinical Trials, Biologicals and Vaccines EAG.*

Responsibility for monitoring the safety of all marketed medicines (including vaccines) rests with the Medicines and Healthcare products Regulatory Agency (MHRA). Its 'Yellow Card' scheme is a voluntary reporting system for suspected adverse reactions (ADRs) to medicines including vaccines.[46] See: https://yellowcard.mhra.gov.uk/

Delivering vaccination services

The DHSC does not deliver vaccination programmes. Under the NHS Public Health Functions Agreement (the Section 7A Agreement), the DHSC delegates responsibility for delivering national immunisation programmes to NHS England. The DHSC, however, sets performance standards for each vaccination: for example, the standard for population vaccination coverage for one dose of MMR at 2 years old is 95%, whereas the shingles vaccination coverage (for the routine cohort of 70+ year olds) is 60%.[47] The performance of vaccination programmes and other public health services are discussed every three months at Section 7A accountability meetings between the DHSC, NHS England and Public Health England.[48]

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46 Public Health England, The Green Book, Chapter 9:Surveillance and monitoring for vaccine safety, December 2019,

47 Department of Health and Social Care and NHS England, NHS public health functions agreement 2018-19 Public health functions to be exercised by NHS England, March 2018, p20-21

48 National Audit Office, Investigation into pre-school vaccinations, October 2019, p15

NHS England is responsible for commissioning vaccination services. Pre-school and adult vaccinations are usually delivered by GP surgeries and are commissioned through the GP contract, whereas school-age services are commissioned by seven regional NHS England teams and delivered through School Immunisation Teams.

Public Health England (PHE) is responsible for public health oversight of vaccination programmes and surveillance of vaccine-preventable diseases, including providing data on the number of vaccines undertaken. It published its Infectious Diseases Strategy Framework for 2020-2025 in September 2019 and made optimising vaccine provision and reducing vaccine preventable diseases in England its "strategic priority 1".[49] Other PHE vaccine responsibilities include:

- providing clinical advice to commissioners on delivery
- central procurement and distribution of specific vaccines for the national programme
- public messaging and guidance for parents and healthcare professionals.[50]

Further information on vaccination policy in the devolved nations is available:

- Public Health Scotland, Overview of immunisations, last updated, 15 September 2020
- Public Health Wales, Immunisation and Vaccines, not dated
- HSC Public Health Agency Northern Ireland, Immunisation/vaccine preventable diseases, not dated

2.3 Vaccine coverage (England)

Childhood vaccination coverage

Vaccination coverage is the percentage of people from the target population who have received a specific vaccine. The WHO recommends that, on a national level, at least 95% of children are immunised against vaccine-preventable diseases (specifically, diphtheria, neonatal tetanus, pertussis, polio, Haemophilus influenzae type b (Hib), Hepatitis B, measles, mumps and congenital rubella).[51] In the England, under the NHS Public Health Functions Agreement, the standard for routine childhood immunisations up to five years of age is set at 95% coverage, in line with the WHO target.

For the year 2019-20, with the exception of DTaP/IPV/Hib vaccine at age 5 (diphtheria, tetanus, pertussis, polio and Haemophilus influenzae type b), none of the routine vaccinations met the 95% target at the national, UK level.[52] PHE reported, however, that coverage did increase in most

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49 Public Health England, PHE Infectious Diseases Strategy 2020-2025, Addressing urgent threats in the 21st century, September 2019, p9
50 Ibid pp14-15
51 WHO Europe, Health21, the health for all policy framework for the WHO European Region, 1999
52 Public Health England and NHS Digital, Childhood Vaccination Coverage Statistics England, 2019-20, September 2020

routine vaccinations, with the increases ranging in size from 0.2 to 0.9 percentage points.[53]

There is also geographical variation in coverage. Detailed information about Childhood Immunisation Statistics can be found in the Library briefing paper, published 5 August 2020.

Adolescent vaccination coverage

The **Human papillomavirus (HPV)** programme for girls in years 8 and 9 (aged 12-14 years) began in 2008. The HPV vaccines helps protect against genital warts and cancers caused by HPV, including cervical cancer.

In September 2019 the programme was extended to boys in year 8 (aged 12-13 years). The table below sets out PHE's HPV vaccination coverage data in adolescent females in England since 2015-16.[54]

HPV vaccination rates
Year 9 females, England

Year	Coverage
2015-16	85.1%
2016-17	83.1%
2017-18	83.8%
2018-19	83.9%
DHSC Target	*90%*

The 2019-20 programme has been affected by the closure of schools during the Covid-19 pandemic, with 64.7% of Year 9 females completing the 2-dose HPV vaccination course in 2019/20. HPV vaccine coverage for the "priming dose in 2019/20 was 59.2% in Year 8 females (compared with 88.0% in 2018/19) and 54.4% in Year 8 males.[55]

The **school-based tetanus, diphtheria and polio (Td/IPV)** adolescent programme is for students in years 9 and 10 (13-15 years old). This "school leaver booster" is the fifth dose of Td/IPV vaccine in the routine immunisation schedule which, Public Health England (PHE) states, provides long-term protection against all three diseases.[56] The table below sets out PHE's Td/IPV average vaccination coverage data since 2015-16.[57] Please note that some areas give the Td/IPV vaccine in year

53 Ibid p2
54 Public Health England, Human papillomavirus (HPV) vaccination coverage in adolescent females in England: 2018/19 Report for England, December 2019, p4
55 Public Health England, Human papillomavirus (HPV) vaccination coverage in adolescent females and males in England: academic year 2019 to 2020, October 2020, p2
56 Public Health England, Vaccine coverage estimates for the school based tetanus, diphtheria and polio (Td/IPV, 'school leaver booster') adolescent vaccination programme in England, to end of August 2019, January 2020, p3
57 Public Health England, Vaccine coverage estimates for the school based tetanus, diphtheria and polio (Td/IPV, 'school leaver booster') adolescent vaccination programme in England, to end of August 2019, January 2020, p2

10 (14-15yrs), though Local Authorities are transitioning towards delivering the programme in year 9 (13-14yrs).[58]

Td/IPV vaccine coverage
England

Year	Year 9	Year 10
2015-16	83.5%	74.9%
2016-17	83.0%	81.7%
2017-18	85.5%	82.9%
2018-19	87.6%	86.0%

Adult vaccination coverage

The **shingles** (herpes zoster) vaccination programme began on 1 September 2013. All those aged 70 years old are eligible for the vaccine and catch-up programmes for older cohorts have been offered. Data published by Public Health England in August 2019 shows that, in England, of those who have been eligible since 2013, 76.6% have been vaccinated whereas, among those who have been eligible since 2018, 48.2% have been vaccinated.[59] The standard set by the DHSC is 60% coverage.[60]

The **pneumococcal polysaccharide vaccine** (PPV) programme in England began in 2004, with adults aged 65 years and over eligible for the vaccine. PPV coverage was 69.0% in all patients aged 65 and over, immunised at any time up to 31 March 2019 in England, rising to 82.4% for those aged 75 and over.[61] The standard set by the DHSC is 75% coverage.[62]

In 2003, the World Health Assembly urged member states to increase **influenza** vaccination coverage of all people at high risk and to attain a coverage of 75% among older people and persons with chronic illnesses by 2010.[63] This has been adopted by the DHSC as its coverage standard. Public Health England reported in June 2020 that the cumulative influenza vaccine uptake in GP registered patients from 1 September 2019 to 29 February 2020 in England was 72.4% for patients aged 65 years and over compared to 72.0% in 2018 to 2019. It

58 For further information about the figures, see Public Health England, Vaccine coverage estimates for the school based tetanus, diphtheria and polio (Td/IPV, 'school leaver booster') adolescent vaccination programme in England, to end of August 2019, January 2020, p4-7
59 Public Health England, Cumulative shingles vaccine coverage report to end of June 2020 (quarter 4) and annual 2019 to 2020 coverage: England, August 2020, p8
60 Department of Health and Social Care and NHS England, NHS public health functions agreement 2018-19 Public health functions to be exercised by NHS England, March 2018, p21
61 Public Health England, Pneumococcal Polysaccharide Vaccine (PPV) coverage report, England, April 2019 to March 2020, 2020, p7
62 Department of Health and Social Care and NHS England, NHS public health functions agreement 2018-19 Public health functions to be exercised by NHS England, March 2018, p21
63 World Health Organization, Prevention and control of influenza pandemics and annual epidemics. Geneva; 2003.

noted that 40 of the 191 Clinical Commissioning Groups (CCGs) met the 75% target.[64]

Factors affecting vaccine coverage

In its investigation into pre-school vaccination in 2019, the National Audit Office (NAO) reported that NHS England had missed the DHSC's performance standard for uptake of nearly all routine pre-school vaccinations in England since 2012-13.[65]

The statistics outlined above indicate that DHSC performance standards are also not being met in England for some adolescent and adult vaccinations on the routine immunisation schedule.

The NAO report highlights regional variations in the uptake of pre-school vaccinations, with lower levels in London compared to the rest of England. The report gives the following examples:

- 4-in-1 [*pre-school booster*] from 96.2% in County Durham and Cumbria to 63.9% in Westminster
- Hib/MenC (24 months) from 97.5% in County Durham to 71.2% in Hackney and City of London; and
- MMR (2nd dose) from 96.4% in County Durham to 64.1% in Westminster.[66]

Factors identified by NHS England and PHE as affecting uptake of vaccines include:

- inconsistent call/recall (direct communication with parents or carers to arrange their child's vaccinations);
- difficulties in timely access to healthcare professionals;
- incomplete data on vaccination uptake (NHS England and PHE have identified a range of potential inaccuracies in the reported data and do not know the extent to which these affect information on the rates of vaccination uptake);
- 'under-served' populations;
- anti-vaccination messages; and
- vaccine hesitancy among a small minority of parents.[67]

Further commentary on these points is set out below.

Access to, and awareness of, routine vaccinations

Call and recall system

Sending out reminders to schedule a routine vaccination appear to have been affected by the reorganisation of the NHS under the *Health and Social Care Act 2012*. The NAO report concluded that, following the reorganisation of responsibility for vaccine policy and delivery away from primary care trusts and to NHS England in 2013, communication with parents and carers about routine immunisations (known as the call/recall

64 Public Health England, Seasonal influenza vaccine uptake in GP patients: winter season 2019 to 2020. Final data for 1 September 2019 to 29 February 2020, June 2020, p5
65 National Audit Office, Investigation into pre-school vaccinations, October 2019, p7
66 Ibid p8
67 Ibid p30

system) had been "done inconsistently". It said there was "no coherent system" and that NHS England had "not set out requirements of GPs for call/recall under the changed arrangements."[68]

Other studies have also pointed to the reorganisation affecting uptake. One 2018 study described the reorganisation as "extremely disruptive to the delivery of the vaccination programme."[69] Another study concluded that the "April 2013 health system reorganisation in England resulted in significant fragmentation in the way the immunisation programme was delivered".[70]

Timely access

Problems with timely access to immunisations were highlighted in a survey of 2,000 adults, conducted on behalf of the Royal Society of Public Health (RSPH). It examined barriers to vaccination across course of a person's life.

The survey results, published in 2019, indicated that the most common barriers to vaccination were:

- timing of appointments (49%);
- availability of appointments (46%);
- childcare duties (29%).[71]

One general practice nurse was quoted in the RSPH report as saying:

> We tend to do immunisation appointments in the afternoon… I do find this is quite difficult for parents, especially when clinics don't start until half past 2, and they have then got other children to pick up from school. I think that is a massive barrier.[72]

Certain populations have also been identified as experiencing particular challenges associated with accessing immunisation services. These "under-served" populations are defined in the NAO's report as those "communities who do not access healthcare in the usual ways" and therefore can have lower vaccination uptake, such as "travellers, recent migrants and some religious faiths."[73]

The NAO points to a report by PHE on the importance of tailoring immunisation programmes to meet the needs of these communities and highlights PHE's work with the Charedi Orthodox Jewish community in north east London, where there have been outbreaks of vaccine-preventable diseases, such as measles. Delivery models to address low vaccine uptake in the community included: "the introduction of community immunisation clinics, the employment of a Charedi outreach

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68 Ibid p31

69 T Crocker-Buque and S Mounier-Jack, Vaccination in England: a review of why business as usual is not enough to maintain coverage, *BMC Public Health*, 2018; 18: 1351.

70 T Chantler et al "It's a complex mesh"- how large-scale health system reorganisation affected the delivery of the immunisation programme in England: a qualitative study, *BMC Health Service Research* 2016; 16: 489.

71 Royal Society for Public Health, Moving the Needle, Promoting vaccination uptake across the life course, January 2019, p10

72 Royal Society for Public Health, Moving the Needle, Promoting vaccination uptake across the life course, January 2019, p10

73 National Audit Office, Investigation into pre-school vaccinations, October 2019, p32

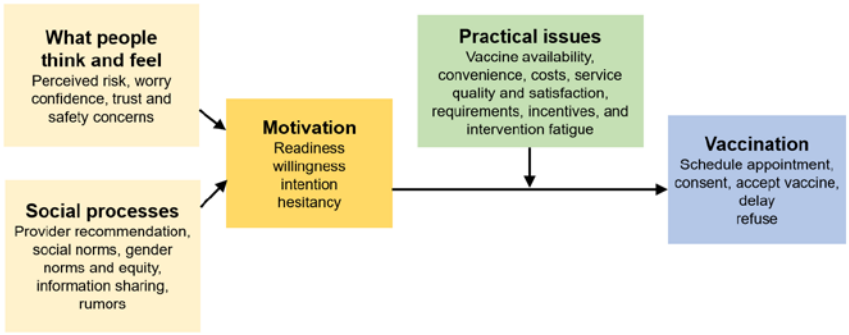
nurse, home immunisation (restricted) and school based clinics during a measles outbreak."[74]

Vaccine hesitancy

The World Health Organization (WHO) defines vaccine hesitancy as:

> …delay in acceptance or refusal of vaccines despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines […][75]
>
> [It is] influenced by a number of factors including issues of confidence (level of trust in vaccine or provider), complacency (do not perceive a need for a vaccine, do not value the vaccine), and convenience (access). Vaccine hesitant individuals are a heterogeneous group who hold varying degrees of indecision about specific vaccines or vaccination in general. Vaccine hesitant individuals may accept all vaccines but remain concerned about vaccines, some may refuse or delay some vaccines, but accept others; some individuals may refuse all vaccines […][76]

The WHO's definition is also known as the "3Cs" model of hesitancy – confidence, complacency and convenience. In 2019, the WHO also identified "vaccine hesitancy" as one of the "ten threats to global health in 2019." Its resources on addressing vaccine hesitancy include the following model on increasing vaccination.



Source: The WHO Measuring Behavioural and Social Drivers of Vaccination (BeSD) expert working group. Based on: Brewer NT, Chapman GB, Rothman AJ, Leask J, and Kempe A (2017). Increasing vaccination: Putting psychological science into action. *Psychological Science for the Public Interest* 18(3): 149-207

Attitudes towards vaccination and anti-vaccine messages

Identifying "what people think and feel" about vaccination, as set out in the WHO's model above, has tended to be examined through surveys.

PHE conducts an annual survey on the public's and parents' attitudes to vaccinations. In 2019, it was based on 1,674 interviews with parents of

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74 Public Health England, Tailoring Immunisation Programmes Charedi community, north London, October 2018, p8

75 WHO, Report of the SAGE (Strategic Advisory Group of Experts On Immunization) Working Group on Vaccine Hesitancy, 1 October 2014, p7

76 WHO, The SAGE Vaccine Hesitancy Working Group, What influences vaccine acceptance: A model of determinants of vaccine hesitancy, 18 March 2013, p1

children aged 0 to 4 years.[77] The survey found that parents had a high level of confidence in vaccinations, with 95% of parents reporting feeling confident or very confident in vaccinations, compared to 93% in 2017. The percentage of parents refusing or postponing vaccination fell from 11% in 2015 to 8% in 2019.[78]

Health professionals remained the "most trusted source of advice on immunisation," with 93% of parents agreeing with this statement.[79] The survey did not find that anti-vaccination messages on social media had a major impact on vaccine uptake:

> Of the small number of parents (n=143) who had seen information to make them doubt having their child immunised, 35% had seen this on the internet and 14% mentioned social media as the main source. Information relating to side effects of vaccines was the main topic parents cited that might have persuaded them not to immunise their child.[80]

The Royal Society for Public Health (RSPH) conducted several surveys in 2018 on vaccination. One of these was with 2,622 UK parents which aimed to "explore their attitudes and views on vaccinating their child(ren)." The RSPH found that two in five parents with children under the age of 18 said they were:

> exposed to negative messages about vaccinations online 'often or sometimes': 41% on social media and 38% on online forums. This rose to one in two among parents with children under five years old (50% and 47% respectively).[81]

It is not clear from the RSPH report whether these negative messages affected behaviour towards vaccination. In April 2019, the Health Secretary, Matt Hancock, said that the rise of social media "now makes it easier to spread lies about vaccination," and highlighted "problems in America and on the continent" regarding misinformation on vaccines via social media which "are worse than here." He said the Government was "determined to get ahead of the problem, because failure to vaccinate has real and devastating consequences."[82]

In line with PHE's work, the RSPH found that 91% of parents agreed that "vaccines are important for their children's health."[83] Parents also identified scientific experts, and doctors and nurses, as the "most trusted sources of advice, with 94% and 92% respectively saying they were valued sources of information."[84]

Global findings

Aside from national surveys, there have been recent pan-European and global surveys examining "vaccine confidence", namely "trust in the effectiveness and safety of vaccines and trust in the healthcare system

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77 Press release: PHE offers support to UK vaccine heroes, Public Health England, 24 April 2019
78 National Audit Office, Investigation into pre-school vaccinations, October 2019, p33
79 Public Health England, PHE offers support to UK vaccine heroes, 24 April 2019
80 ibid
81 Royal Society for Public Health, Moving the Needle, Promoting vaccination uptake across the life course, January 2019, p12
82 HC Deb 30 April 2019 c136
83 Ibid, p3
84 Ibid, p12

that delivers them."[85] Part of the Wellcome Global Monitor 2018 survey, for example, examined attitudes towards vaccines and particularly how "people around the world feel about the safety, effectiveness and importance of vaccines." Overall, the survey found that most people around the world 'agree' that vaccines are safe:

> Eight in ten people (79%) 'strongly' or 'somewhat agree' that they are safe, while 7% 'strongly' or 'somewhat disagree', 11% 'neither agree nor disagree' and 3% say they don't know or have no opinion.[86]

Regional differences, however, were found:

> people in several higher-income regions are among the least certain about vaccine safety. Only 72% of people in Northern America and 73% in Northern Europe 'agree' that vaccines are safe, and the figure is as low as 59% in Western Europe, and 50% in Eastern Europe. By contrast, an overwhelming majority of people in lower-income areas 'agree' ('somewhat' or 'strongly') that vaccines are safe. The highest such proportions are in South Asia, where 95% of people said they 'agree' that vaccines are safe, and in Eastern Africa, where the figure stands at 92%.[87]

Perceptions of the effectiveness of vaccines were found to vary less by region than views about vaccine safety – globally "63% of people 'strongly agree' and 21% 'somewhat agree' that vaccines are effective". The survey also found that scepticism about vaccine safety did not always translate into scepticism about vaccine effectiveness:

> In several regions where people are least likely to agree that vaccines are safe, the percentage who agree that they are effective is significantly higher; the biggest gaps are seen in Western Europe (59% safe, 77% effective) and Eastern Europe (50% safe, 65% effective). This gap suggests that some people accept that they are effective at preventing certain diseases, even if they also believe some vaccines may have negative side-effects.

Commenting on Wellcome's findings, a comment piece in the journal *Nature* noted that opinions on vaccination may change where widespread immunisation has made outbreaks of infectious disease much less common:

> As cases become rarer, the number of people with first-hand experience of the seriousness of the diseases diminishes. Belief in the need for vaccinations weakens, as more people calculate that the safer course is to go without them, says Helen Bedford, a children's health specialist at Great Ormond Street Institute of Child Health, London. "When the disease isn't around," she says, "half the equation has been removed — all the risk is focused on the vaccine."[88]

In the EU, the London School of Hygiene and Tropical Medicine conducted a survey on behalf of the European Commission, as part of

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85 London School of Hygiene and Tropical Medicine, State of vaccine confidence in the EU 2018, produced for the European Commission in 2018, p8

86 Wellcome Trust, Wellcome Global Monitor 2018 - Chapter 5: Attitudes to Vaccines, June 2019

87 Wellcome Trust, Wellcome Global Monitor 2018 - Chapter 5: Attitudes to Vaccines, June 2019

88 L Drew, The case for mandatory vaccination, *Nature 'Outlook'*, 27 November 2019

the 'Vaccine Confidence Project', in 2018. It found that across the EU public perceptions towards vaccines were largely positive, with:

> the majority of the EU public agreeing (strongly or tend to agree) that vaccines are important (90.0%), safe (82.8%), effective (87.8%), and compatible with religious beliefs (78.5%).[89]

Variation between EU Member States was identified. Portugal had the "highest percentage of respondents agreeing that vaccines generally are safe (95.1%), effective (96.6%), and important for children to have (98.0%)" whereas respondents from Bulgaria were "least likely to agree that vaccines are safe, with only 66.3% agreeing" with the statement.[90]

Standard medical opinion, and that of national and international health organisations (for example the WHO) is that, like all medicines, there are some risks associated with the use of vaccines, but these risks are small, serious adverse events are rare and are outweighed by the risks of the serious diseases that they prevent.[91] Public-facing information on vaccine safety can be found on the following websites:

- NHS, Why vaccination is safe and important, July 2019
- Vaccine Knowledge Project, University of Oxford, General vaccine safety and science, September 2018
- World Health Organization, Vaccine Safety Net (this is a search tool, provided by the WHO, that enables people to search for reliable information on vaccines, in different languages, from one place).

Information about *Vaccine safety and adverse events following immunisation* can also be found in Chapter 8 of the 'Green Book' (PHE's 'Immunisation against infectious disease' publication, March 2013).

Box 4: Government statements on Covid-19 vaccine safety

Vaccine safety has recently been discussed in the context of the development of vaccines for Covid-19. The Health Secretary, Matt Hancock, stressed on several occasions that any such vaccine will not be deployed unless it has been shown to be both effective and safe.[92]

Speaking to *Times Radio* on 16 November 2020, the Health Secretary said the UK did not "propose, and allow vaccines in this country, unless they pass some of the most stringent safety requirements in the world."[93] Similarly, the Government's Covid-19 Winter Plan stated that the:

> safety of the public will always come first. A Covid-19 vaccine will only be approved for use if it has met robust standards on safety, effectiveness and quality through clinical trials. The MHRA [Medicines and Healthcare products Regulatory Agency] will apply the key criteria of safety, quality and efficacy before authorising the use of a vaccine. This means that, once the data is submitted, MHRA scientists and clinicians will carefully and scientifically review the safety, quality

89 London School of Hygiene and Tropical Medicine, State of vaccine confidence in the EU 2018, produced for the European Commission in 2018, p15

90 London School of Hygiene and Tropical Medicine, State of vaccine confidence in the EU 2018, produced for the European Commission in 2018, p16

91 WHO, Vaccine Safety Basics learning manual, 2013, p16; Australian Academy of Science, The science of immunisation: questions and answers: Chapter 4 Are vaccines safe?, 2017, p13; Royal College of Paediatrics and Child Health, Vaccination in the UK - position statement, 24 August 2020; International Coalition of Medicines Regulatory Authorities (ICMRA), ICMRA statement about confidence in vaccine safety and effectiveness (for healthcare professionals), June 2020

92 HC Deb 17 September 2020 c515; HC Deb 10 November 2020 c755

93 Matt Hancock refuses to rule out making Covid-19 vaccine mandatory, *msn news*, 16 November 2020

and effectiveness data, how it protects people from COVID-19 and the level of protection it provides. The data will include:

a. results from the lab and clinical trials in humans;

b. manufacturing and quality controls;

c. product sampling; and

d. testing of the final product.[94]

Public health specialists have also voiced concerns that anti-vaccination messages, particularly those circulated on social media, could have a negative impact on the effectiveness of a mass roll-out of Covid-19 vaccines.[95] On the 8 November 2020, the Government agreed a package of measures with social media companies to address vaccine disinformation, while the Opposition has suggested that further, legislative steps need to be taken in this area.[96]

94 HM Government, Covid-19 Winter Plan, November 2020, CP 324, p31

95 How anti-vaxxers are threatening the UK's Covid programme, *Financial Times*, 30 November 2020

96 Social media giants agree package of measures with UK Government to tackle vaccine disinformation, Department for Digital, Culture, Media & Sport, Department of Health and Social Care, 8 November 2020; Covid-19: Stop anti-vaccination fake news online with new law says Labour, *BBC News Online*, 15 November 2020

3. Responses to the UK's loss of WHO measles elimination status

In August 2019, the World Health Organization's European Regional Verification Commission for Measles and Rubella Elimination (RVC) determined that, for the first time since the verification process began in the Region in 2012, four countries had lost their measles elimination status; Albania, the Czech Republic, Greece and the UK.[97] The WHO had previously declared in 2017 that the UK had eliminated measles, based on data from 2014-16.[98]

Public Health England gave the following explanation as to why the UK had lost its measles elimination status:

> in 2018, there was a marked increase in the number of confirmed measles cases, with 991 confirmed cases in England and Wales, compared with 284 cases in 2017. Furthermore, the same strain of measles virus (called B3 Dublin) was detected for more than 12 months across 2017 and 2018. Based on this, WHO determined that the UK could no longer be consider as 'eliminated' and that transmission of measles had been re-established [...] While coverage of the first dose in the UK has reached the WHO target of 95% for children aged five, coverage of the second dose is at 87.4%. As measles is highly infectious, even small declines in uptake can have an impact, and anyone who has not received 2 doses of MMR vaccine is at risk, particularly those travelling to countries affected by the ongoing, large outbreaks.[99]

3.1 Government response

Following the UK's loss of its measles-free status, the Prime Minister set out measures aimed at increasing immunisation rates for the MMR vaccination. They included:

- NHS England writing to GPs urging them to promote 'catch up' vaccination programmes for MMR for 10-11 year olds, as well as all those 5-25 year olds who have not had two doses of the jab;
- Strengthening the role of local immunisation coordinators – healthcare professionals that promote vaccines particularly with hard-to-reach families. This includes supporting areas with low uptake and tailoring specific local interventions to under-vaccinated communities;
- Addressing parents' concerns about vaccines by updating the advice on NHS.uk specifically to address misleading information about the dangers of vaccines, by giving people NHS-approved, evidence-based and trusted advice on vaccines including through a new website;

97 Press release: European Region loses ground in effort to eliminate measles, World Health Organization, Regional Office for Europe, 29 August 2019
98 Public Health England, Measles in England, 19 August 2019
99 ibid

- Calling a summit of social media companies to discuss how they can play their part in promoting accurate information about vaccination; and
- The Department for Health and Social Care – working with Public Health England and NHS England – delivering a comprehensive strategy to address the issue in the Autumn.[100]

During the 2019 General Election campaign, the Conservative Party also announced that it would introduce "a national vaccination reminder system to boost childhood vaccination rates" so that "every family will receive a reminder from their GP practice that it is time for their child's next vaccination".[101] It added that the move would:

> come as part of a wider Vaccination Strategy, which the next Conservative Government will launch within the first 30 days of the new administration as part of a bid to regain the UK's 'measles-free' status.[102]

Vaccination strategy

At the time of writing a 'Vaccination Strategy' had not been published. In response to a Parliamentary Question on the matter in January 2020, the Junior Health Minister, Jo Churchill, stated:

> The Department is working closely with NHS England, NHS Improvement and Public Health England to develop a 10 year vaccine strategy to be published early in 2020. This will include a focus on improving immunisation uptake rates across the life course including through better use of call/recall.[103]

The Government's Green Paper, Advancing our health: prevention in the 2020s, published in July 2019, gave more detail on the issues that the Strategy would cover, including:

- Operational work to increase uptake of all recommended vaccinations across all communities and areas, to include the medium-term aim of reaching over 95% uptake for childhood vaccinations and continuing to increase uptake of the seasonal influenza vaccine. This includes implementing the UK measles and rubella elimination strategy to increase uptake of the second dose of the MMR vaccine to at least 95%, to match the aspiration for the first dose.
- Enhanced use of local immunisation co-ordinators and primary care networks, ensuring the right mechanisms are in place to increase uptake (through the GP Vaccines review) including consistent application of call and recall, and improved data services.
- Continued evolution of our immunisation programme, incorporating new, more effective and cost-effective vaccines and new uses for existing vaccines across the life

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100 Press release: Prime Minister orders urgent action to improve vaccination uptake, Department of Health and Social Care &, Prime Minister's Office, 10 Downing Street, 18 August 2019

101 New national vaccination reminder system to boost childhood vaccination rates, Conservative Party, 27 November 2019

102 ibid

103 PQ 291 [on Shingles: Vaccination], 13 January 2020

> course, as advised by our expert group, the Joint Committee on Vaccination and Immunisation.[104]

Further information on the strategy is outlined in the October 2019 minutes of the JCVI meeting. The minutes noted that the strategy was being developed by the DHSC:

> who were writing to stakeholders, including JCVI, to seek views on issues to be considered in the strategy. The idea was to set out a clear vision for maintaining the UK's world-leading position over the next decade, with a shorter-term focus on improving vaccine coverage, including for MMR.[105]

The Government's response to the Green Paper consultation, which closed on 14 October 2019, has been delayed due to the Covid-19 pandemic.[106] Similarly, in response to a Parliamentary Question in May 2020 about the publication of the vaccination strategy, the junior health Minister, Jo Churchill, stated:

> The forthcoming vaccine strategy, as announced in the Green Paper 'Advancing our health: prevention in the 2020s', will consider all vaccination programmes over the life-course. Due to re-prioritisation necessary as part of the health and care system's response to the COVID-19 pandemic, publication has been delayed, but is expected in due course.[107]

3.2 NHS England Vaccinations and Immunisations Review – interim findings

GP's have an important role to play in delivering vaccination programmes and ensuring that uptake remains high (see section 2.2). Prior to the UK losing its measles free status, a "small but steady decline" in childhood immunisation coverage was apparent, with NHS England and others taking steps to address it.[108] In January 2019, for example, the NHS Long Term Plan committed to reviewing "GP vaccinations and immunisation standards, funding, and procurement".[109] According to the Long Term Plan, the overall aim of the review was to improve "immunisation coverage […] and improve groups and areas with low vaccines uptake".[110]

Interim review findings were published in October 2019. The review considered vaccinations in the context of the GP contract, focusing on how GPs are reimbursed for vaccinations and what incentives are in place to encourage increased uptake rates. A second stage of the review was due to focus on travel vaccinations and catch-up programmes.

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104 Cabinet Office, Department of Health and Social Care, Advancing our health: prevention in the 2020s – consultation document, 22 July 2019
105 Joint Committee on Vaccination and Immunisation, Minute of the meeting held on 2 October 2019
106 PQ 64355 [on Health], 7 July 2020
107 PQ 37683 [on Coronavirus: Vaccination], 6 May 2020
108 NHS England & NHS Improvement, Interim findings of the Vaccinations and Immunisations Review – September 2019, October 2019, p3
109 NHS, NHS Long Term Plan, January 2019, p15
110 ibid

The interim review findings made several recommendations and identified opportunities to:

- Simplify payment structures wherever possible and align payment mechanisms with their intended impact.
- Reform the current childhood immunisation target incentive scheme to help increase uptake.
- Consider broadening the range of vaccines included in any incentive scheme to support uptake.
- Consider widening the range of health professionals who deliver convenient MMR vaccinations.[111]

The review went on to state that the detail of the recommendations and "how they could be operationalised will be discussed in the contract discussions with GPC England".[112] No further review details or findings have been published.

[111] NHS England & NHS Improvement, Interim findings of the Vaccinations and Immunisations Review – September 2019, October 2019, p12
[112] ibid, p13

4. Mandatory vaccination

Summary

Vaccines offered through the national immunisation programme in the UK are not mandatory. Vaccinations are also not currently mandatory in the UK during a pandemic.

Medical and ethical opinion is divided on the introduction of immunisation policies that involve some degree of coercion (such as fines). Some countries, such as Italy and France, have mandatory vaccination policies in place, an overview of which is provided on pages 43-48. In response to falling vaccination rates, some countries (including Italy) have extended existing mandatory vaccination programmes, or introduced them for the first time, such as in Germany. Some policies criminalise vaccine refusal, such as by fining parents, or make access to services – like state-run schools – contingent on immunisation status.

The effectiveness of mandatory vaccination policies is not clear, partly because attitudes to immunisation vary between countries and there can be several factors contributing to declining or poor immunisation coverage.

Introduction

The UK does not make any vaccination offered through the national immunisation programme mandatory. NHS guidance notes that you should be "asked for your consent before each vaccination."[113] In September 2019, at the Conservative Party Conference, Health Secretary Matt Hancock reportedly said he was "looking very seriously" at making vaccinations mandatory for all children going to school in England:

> When the state provide service to people then it's a two-way street […] You have to take your responsibilities too […] I have received advice from inside government this week on how we would go about it and I am looking into it very seriously.[114]

The former Chief Medical Officer for England, Dame Sally Davies, has also commented on mandatory vaccination. Speaking on *BBC Radio 4's The Today Programme* in October 2019 about childhood vaccinations, Dame Sally said: "We need to up our vaccination rates. I hope we can do it by other means, but if we can't, we might well end up with mandatory."[115]

A spokesperson for the Prime Minister, however, said there were no plans to make childhood vaccinations compulsory for those attending state schools, adding: "we're not at the stage of refusing admission. Our priority is on increasing vaccination numbers."[116]

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113 NHS, Booking your child's vaccination appointment, July 2019
114 Health secretary 'looking seriously' at compulsory vaccines for schoolchildren, *BBC News Online*, 29 September 2019
115 Mandatory vaccines could be introduced in England if officials fail to tackle falling immunisation rates, says Dame Sally Davies, *Daily Mail*, 10 October 2019
116 No plan to require vaccinations at state schools, says No 10, *The Guardian*, 30 September 2019

4.1 Vaccination during a pandemic

Vaccinations are not currently mandatory during a pandemic. The *Public Health (Control of Disease) Act 1984* (as amended by the *Health and Social Care Act 2008*) contains regulation making powers that allow a number of public health measures to be taken in situations such as the Covid-19 outbreak. Under section 45C of the 1984 Act (*Health protection regulations: domestic*) the appropriate minister:

> may by regulations make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in England and Wales (whether from risks originating there or elsewhere).

Section 45E (*Medical treatment*), however, is clear that any health protection regulations put in place under s.45C "may not include provision requiring a person to undergo medical treatment." 'Medical treatment' is defined in s.45E to include "vaccination and other prophylactic treatment." There is equivalent legislation in Scotland and Northern Ireland.

Speaking at the Downing Street daily coronavirus briefing on 4 May 2020, the Health Secretary said he did not think any future Covid-19 vaccine would be made mandatory:

> I think the extent of the public's reaction following the lockdown shows we will be able to achieve very, very high levels of vaccination without taking that step […] We are proceeding on the basis that just such a huge proportion of the population are going to take this up because of the obvious benefits to individuals and their families and their communities and indeed the whole nation, that there will be enormous demand for it as and when the science is safe to proceed.[117]

In November 2020, the Health Secretary again stated that the Government was not proposing to make any vaccination for Covid-19 mandatory, but added that he had "learnt not to rule things out during this pandemic because we have to watch what happens and you have to make judgments accordingly."[118]

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117 Coronavirus: Health secretary doesn't think future COVID-19 vaccine will need to be made compulsory, *Sky News* [online], 4 May 2020

118 Matt Hancock refuses to rule out making Covid-19 vaccine mandatory, *msn news*, 16 November 2020

4.2 Medical and ethical perspectives on coercive vaccination policies

There is a body of research on the ethical perspectives relating to coercive childhood immunisation policies to reduce the risk to populations from infectious diseases. In some research a distinction is drawn between types of coercive immunisation policies:

- compulsory – refers to the criminalisation of vaccine refusal;
- mandatory – social goods or services offered by the State may be withheld from families that choose not to vaccinate their children.

The research referred to here was published before the current Covid-19 pandemic and mainly refers to childhood vaccination.

Medical and ethical opinion is divided on the introduction of immunisation policies that involve some degree of coercion. An opinion piece published in *The Lancet* in 2015, suggested: "the problem of vaccine hesitancy is far more complex than can be addressed with a simple elimination of non-medical exemptions" for vaccination. It went on to question whether mandatory vaccination could "result in more harm than good, and might even backfire by driving hesitant parents to accept antivaccination arguments".[119]

Others have suggested the focus should be on improving a country's immunisation "infrastructure" (such as vaccination call/recall systems and the availability and accessibility of appointments) before considering mandatory vaccination. An article in the *British Medical Journal (BMJ)* noted that, even if such improvements are made, introducing mandatory vaccination could still have "unintended consequences" and risk "alienating parents unnecessarily".[120] The article adds: "evidence that mandatory vaccination has been effective in other countries is not conclusive, and no evidence exists in relation to the UK".[121]

The Ethics and Vaccination working groups of the European Academy of Paediatrics published a joint statement on mandatory vaccination in November 2019. It notes that the benefits of vaccination "are not only accumulated by an individual child but also by children as a population".[122] It went on to conclude that mandatory vaccination could be considered but that other options, such as educating parents and doctors about vaccinations, should be pursued first:

> It would be preferable to achieve high rates of vaccination coverage by educating both parents and physicians without adopting any legislation for mandatory vaccination. However, in countries where vaccination uptake is low and/or outbreaks of vaccine-preventable diseases occur, the implementation of mandatory vaccination will most probably save children's lives.

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119 D Salmon et al, Making mandatory vaccination truly compulsory: well intentioned but ill conceived, *The Lancet* vol 15, August 2015, p872-873

120 H E Bedford, D A C Elliman, Should measles vaccination be compulsory? No, *BMJ* 2019;365:l2359 (5 June 2019)

121 ibid

122 A Hadjipanayis et al, Mandatory vaccination: a joint statement of the Ethics and Vaccination working groups of the European Academy of Paediatrics, *European Journal of Pediatrics*, volume 179, pages 683–687(2020)

> EAP calls for action to make all scheduled childhood vaccinations a matter of fact for all European children.[123]

A subsequent commentary by two of the authors of the Academy's statement suggested the following questions need to be considered before any move towards mandatory vaccination:

- Under what conditions is it justifiable?
- What is the risk of harm and the impact of removing choice from personal decision-making?
- Might selective or partial vaccine mandates might be harmful for a comprehensive vaccination program?
- What are the limits of parents' decision-making over their children's healthcare?[124]

Elsewhere in the literature it has been noted that attempts to make vaccinations mandatory have prompted opposition from those who emphasise an:

> individual's [right] to refuse any medical intervention. Any form of coercion in this context can be interpreted as a restriction of freedom, autonomy and the granted rights.[125]

Others have highlighted the importance of considering an individual's medical history as well as their beliefs. A report produced for the European Commission on a proposed mandatory childhood vaccination law in Romania stated that the law must allow for "customised [health] protection for each child in his or her particular circumstances".[126] In the United States, for example, there is a system of medical, religious, and/or philosophical exemptions, operated at the state level, where childhood vaccination is otherwise mandatory.[127] Reasons for a medical exemption include:

- They have a disease or take medicine that weakens their immune system.
- They have a severe allergy to a vaccine or an ingredient in it.
- They had a serious reaction to a vaccine in the past.[128]

'The intervention ladder'

A similar approach to that outlined by the European Academy of Paediatrics was proposed by the Nuffield Council on Bioethics; an independent advisory organisation in the UK that considers the ethical dimensions of biological and medical research and policy. In 2007, it published Public Health: Ethical Issues. The report considered the

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123 A Hadjipanayis et al, Mandatory vaccination: a joint statement of the Ethics and Vaccination working groups of the European Academy of Paediatrics, *European Journal of Pediatrics*, volume 179, pages 683–687(2020)

124 A Hadjipanayis, E Efstathiou, Editorial Commentary on the paper "Mandatory vaccination in Europe", *Translational Pediatrics*, Vol 9, No 3 (June 2020)

125 Rafał K. Patryna and Anna Zagajaa, Vaccinations—Between free will and coercion, *Human Vaccines & Immunotherapeutics*, 12(8): 2204–2205 (August 2016)

126 Luana Pop, Mandatory vaccination: an individual choice or a matter of public health?, *European Social Policy Network*, ESPN Flash Report 2017/47, June 2017

127 Roland Pierik, On religious and secular exemptions: A case study of childhood vaccination waivers, *Ethnicities,* 2017, Vol. 17(2) 220–241

128 What Are the Rules on Vaccine Exemptions?, *WebMD*, April 2019

approaches that government, industry and other organisations should take to enable people to live healthy lives. It also reflected on what degree of government intervention is acceptable. It proposed a model of interventions ('the intervention ladder') based on their intrusiveness into personal autonomy and decision making.

The least intrusive step is defined in the report as 'do nothing', whereas the most intrusive is to legislate in a way that restricts the liberty of individuals, specific groups or the whole population. The report states that policies that are most intrusive are likely to be acceptable by the public only if the benefits of the outcomes are favourably weighted against any loss of liberty.[129]

In between these steps are levels of intervention which enable, guide or restrict choices that are most likely to result in the desired outcome. Therefore, according to this model, a government would have to clearly demonstrate that the benefits of mandating immunisations outweigh any infringement of personal liberty.

The Nuffield Council on Bioethics considered prevention of disease through vaccination in its report and concluded:

> In general, public health policies should use the least intrusive means to achieve the required public health benefit. Directive vaccination approaches that go further than simply providing information and encouragement to take up the vaccine may, however, be justified on the basis of minimising risks of harm to others, or protecting the health of children and other vulnerable people. A case-by-case assessment will always be required. When assessing whether more directive policies are acceptable, the following factors should be taken into account: the risks associated with the vaccination and with the disease itself, and the seriousness of the threat of the disease to the population. In the case of incentivised policies, the size of the incentive involved should be appropriate so that it would not unduly compromise the voluntariness of consent.[130]

It added that "quasi-mandatory" approaches can be ethically justified for highly contagious and serious disease and if eradication is within reach.[131] The Council's overall view, in 2007, was that there was "not sufficient justification in the UK for moving beyond the current voluntary system and implementing incentivised or quasi-mandatory policies for routine childhood vaccinations."[132] In August 2019, following the Prime Minister's statement about improving vaccination coverage, the Council wrote to the Health Secretary, restating its ethical arguments against compulsory vaccination made in the 2007 report which, it added, had "not changed."[133]

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129 Nuffield Council on Bioethics, Public Health: Ethical Issues, November 2007, page xviii
130 Ibid para 4.26
131 Ibid para 4.27
132 Ibid para 4.32
133 Nuffield Council on Bioethics, Letter to the Health Secretary on action to increase vaccination uptake, 29 August 2019

Ethical and moral arguments for compulsory immunisations for some vaccines

More recent studies have been published by ethicists at the Uehiro Centre for Practical Ethics at Oxford University. This work considers the ethical and moral arguments for compulsory immunisations for some vaccines. It argues that individuals who refuse vaccines are failing to contribute to the public good. In a research article published in 2019, two academics at the Uehiro Centre argued that coercive vaccination policies were analogous to seat belt use in vehicles and can be ethically justified[134]:

> If you fail to buckle up yourself or your child, you are putting yourself and your child at unnecessary risk, and perhaps other people at some small risk too (for instance, those who are not buckled up in the back seat are more likely to kill or injure those in the front seat in case of accident). But if you fail to vaccinate yourself or your children there is a much larger risk of harming other people who are not vaccinated (for example those who are immunosuppressed, young children or those whose immunity has waned over time), besides imposing an easily preventable risk on you and your children.[135]

Thus, while decisions over the health care of children are traditionally considered a matter of parental discretion, the authors argue this is not the case with vaccination. This is on the grounds that vaccination benefits not only the individual child but the wider population, particularly those who cannot be vaccinated for medical reasons. The authors go on to argue that vaccination:

> should be legally coerced […] at least if the objections that are raised against coercive vaccination are the same as the ones that are raised against coercive seat belt laws: risks and liberty infringement.[136]

Elsewhere, ethicists have proposed practical approaches to increase immunisation coverage in children. One suggestion, published in the research paper Nudging Immunity: The Case for Vaccinating Children in School and Day Care by Default, is to use guided choices in an opt-out system. In this example, children attending day-care or school would be immunised by default, but parents would retain the right to opt their children out.[137] A group of doctors wrote to the Health Secretary in 2019, proposing that the immunisation status of children should be checked at school entry and that parents declining immunisations must register a conscientious objection.[138]

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134 A Giubilini & J Savulescu, Vaccination, Risks, and Freedom: The Seat Belt Analogy, *Public Health Ethics*, Volume 12, Issue 3, November 2019, Pages 237–249; see also A Giubilini & J Savulescu, Why vaccines should be compulsory, Oxford University Press blog, 4 April 2020

135 A Giubilini & J Savulescu, Why vaccines should be compulsory, Oxford University Press blog, 4 April 2020

136 A Giubilini & J Savulescu, Vaccination, Risks, and Freedom: The Seat Belt Analogy, *Public Health Ethics*, Volume 12, Issue 3, November 2019, Pages 237–249;

137 A Giubilini et al, Nudging Immunity: The Case for Vaccinating Children in School and Day Care by Default, *HEC Forum*, volume 31, pages 325–344 (2019)

138 Stop return of measles by making MMR jab compulsory, say GPs, *The Guardian*, 8 September 2019; L Drew, The case for mandatory vaccination, *Nature 'Outlook'*, 27 November 2019

4.3 Coercive vaccination programmes in other countries

Countries have taken different approaches in the face of decreasing vaccination coverage in children, which risks outbreaks of infectious disease that can have serious consequences for the whole population. Policies can incorporate incentives or penalties with different levels of enforcement.

It is not clear which are the most effective, partly because attitudes to immunisation vary between countries and there can be several factors contributing to declining or poor immunisation coverage. Some policies criminalise vaccine refusal, such as by fining parents, or make access to services – such as state-run schools – contingent on immunisation status.

In Australia, for example, under the national "no jab, no pay" legislation, a child must meet the immunisation requirements set out in the National Immunisation Program Schedule in order receive child care fee assistance and Family Tax Benefit Part A (a type of child benefit).[139] Certain states in Australia, including New South Wales and South Australia, have also introduced "no jab, no play" legislation, whereby children must be fully immunised in order to attend child care.

In Europe, there have been high profile instances in both Italy and France whereby new legislation has been introduced to extend existing mandatory vaccination programmes. These were in response to declining vaccination coverage and outbreaks of measles. Further details about these cases are provided below.

Information on how the immunisation schedules compare across Europe is provided by the European Centre for Disease Prevention and Control. WHO provides a similar tool to compare schedules globally, see:

- European Centre for Disease Prevention and Control, Vaccine schedules in all countries of the European Union
- World Health Organization, WHO vaccine-preventable diseases: monitoring system. 2020 global summary (data as of 30 June 2020)

Italy

Please note that references starred (*) are published in Italian and have been reviewed using a translation tool.

The first mandatory vaccination to be introduced in Italy (from 1888 to 1977) was against smallpox, a deadly disease that was eradicated in 1980 as a result of vaccination campaigns at a global scale, combined with surveillance and prevention measures.[140] Until 2017, four vaccinations were mandatory for children in Italy: against diphtheria

[139] National Centre for Immunisation Research and Surveillance (Australia), No Jab No Play, No Jab No Pay, last updated July 2020
[140] World Health Organization, The Smallpox Eradication Programme - SEP (1966-1980), May 2020

(introduced in 1939), against polio (introduced in 1966), against tetanus (introduced in 1968) and against hepatitis B (introduced in 1991).[141]

In the early 2010s, declining vaccination coverage* was reported in Italy caused by an increase in vaccine hesitancy. Vaccines were incorrectly associated with autism in two court cases (in 2012 in Rimini* and in 2014 in Milan*) and some deaths were incorrectly linked with the influenza vaccine in 2014 (the Fluad case).

In 2015, Italy had 28% of all measles cases in Europe and was warned by WHO* for the decrease in mandatory immunisation coverage in children. A 67-country survey published in 2016 reported that, in Italy, 15% of responders disagreed that vaccines were important, while 21% and 18% disagreed that they were safe and effective respectively.

After a two-year long administrative process, the Italian Government developed the National Immunization Prevention Plan* 2017-2019, which introduced new free and voluntary vaccinations (including vaccinations against meningococcus B, meningococcus C, pneumococcus and rotavirus), and a new vaccination schedule*.

In January 2017, following a large measles outbreak* which led to almost 5,000 cases (including four deaths), Italy introduced a new vaccine law*, adopted in July 2017. The Government added vaccinations against pertussis, Haemophilus influenzae type b (Hib), measles, mumps, rubella and chickenpox to the list of mandatory vaccinations (taking the number to ten in total). The law applies to children born from 2017. Children born between 2001 and 2016 must receive all vaccinations in the list, except the one against chickenpox.

Mandatory vaccinations against measles, mumps, rubella and chickenpox are subject to revision every three years. This is based on epidemiological data and vaccination coverage. The next revision was due on 7 August 2020, but the National Immunization Technical Advisory Group, a committee to evaluate the impacts of mandatory vaccinations, highlighted the lack of data* necessary to take any decisions.

The approval of the new vaccine law in 2017 triggered several protests* in Italy, including one where three MPs were reportedly attacked* by anti-vaccine activists. Some members of the Five Star Movement and the League are opposed to mandatory vaccinations.

Mandatory vaccinations and schools

For children aged 0 to 6 years, vaccinations are a requirement for kindergarten and nursery school admission* and parents need to provide vaccination certificates. From primary school onwards, non-vaccinated children and adolescents can access school and take exams, but the Local Health Authority will liaise with them to provide the missing vaccinations, or parents can be sanctioned between 100-500 Euros. Children who are already immune because they have had the

[141] https://www.epicentro.iss.it/vaccini/ObbligoVaccinaleStoria (in Italian)
*Original reference in Italian

infection, or have conditions which mean vaccinations present a risk, are exempted.

Consequences of legislative changes in Italy

Several studies reported an increase in vaccination coverage following the introduction of compulsory vaccinations, at both regional (Emilia Romagna[142], Lombardy and Sicily)[143] and national level.[144] For example, a study on childhood vaccine coverage reported that the 2017 national-level vaccine coverage at 24 months of age was 94.5% for polio and 91.7% for measles. This was a 1.2% and 4.4% increase respectively in comparison to 2016.[145]

According to WHO monitoring data, there was almost a two-thirds decrease in measles cases between 2017 and 2019 in Italy. Reported rubella cases decreased as well, but to a smaller extent (from 31 to 23 cases).[146]

A 2018 survey reported a very small reduction[147] in vaccine hesitancy following the change in the law, but no significant differences in the number of those opposed to vaccination in comparison to 2016 data.[148] In late 2018, the Ministry of Health launched a campaign 'Let's team up for our health*' to promote the importance of vaccinations and to address the concerns of parents who are vaccine hesitant.

In August 2018, the new Italian Government presented a bill to revise vaccination legislation and make the mandatory vaccinations 'flexible'[149], depending on regional vaccination coverage data*. This would depend on the data monitored from the national vaccine registry*, that was established in September 2018. According to the Senate website, the bill was still under examination* in August 2019.

France

In 2017 the French Government announced a new policy to increase coverage of childhood immunisation. This was in response to declining levels of childhood immunisation coverage and outbreaks of vaccine-preventable disease. The World Health Organization (WHO) collates international data on disease outbreaks and childhood immunisation coverage. Data for France show that measles outbreaks are an ongoing problem, with France in the top ten countries for the highest increase in

142 D Gori et al, Vaccine Hesitancy and Mandatory Immunizations in Emilia-Romagna Region: the case of MMR vaccine, *Acta Bio-medica: Atenei Parmensis*, 19 Sep 2019, 90(3):394-397

143 D Gori et al, The Impact of Mandatory Vaccination Law in Italy on MMR Coverage Rates in Two of the Largest Italian Regions (Emilia-Romagna and Sicily): An Effective Strategy to Contrast Vaccine Hesitancy, *Vaccines* 2020, 8(1), 57

144 Fortunato D'Ancona et al, The law on compulsory vaccination in Italy: an update 2 years after the introduction, Euro Surveillance 24(26) June 2019

145 C Signorelli et al, Childhood vaccine coverage in Italy after the new law on mandatory immunization, *Annali di igiene: medicina preventiva e di comunita*, Jul-Aug 2018; 30 p1-10

146 World Health Organization, WHO vaccine-preventable diseases: monitoring system. 2020 global summary - Italy, 12 October 2020

147 Fortunato D'Ancona et al, The law on compulsory vaccination in Italy: an update 2 years after the introduction, *Euro Surveillance*, 24(26), 27 Jun 2019

148 Cristina Giambia et al, Parental vaccine hesitancy in Italy – Results from a national survey, *Vaccine*, Volume 36, Issue 6, 1 February 2018, Pages 779-787

149 Flexible vaccine obligation plan - Grillo, *ANSA*, 9 August 2018

measles cases between 2017 and 2018.[150] This is a direct result of immunisation coverage in France being below the WHO 95% target required for herd immunity to prevent infectious diseases, notably measles, mumps and rubella, as well as hepatitis, and booster immunisations against pneumococcal disease.[151]

Immunisation coverage levels have been linked to attitudes to vaccination, with levels of trust in vaccines reported to be lower in France than all other countries that have been surveyed. An academic report of vaccine confidence in 67 countries, published in 2016, found that 41% of respondents in France disagreed that vaccines are safe.[152]

More recent data reports that confidence has marginally increased. The Wellcome Trust's Global Monitor study collects information about people's thoughts and attitudes about science and health. The latest report, published in 2019, highlighted that France had the highest proportion of people (one in three of those surveyed in 2018) who think vaccines are not safe.[153]

The causes of this negative sentiment towards vaccines are thought to be linked to specific reports related to vaccine controversies in France and vaccine hesitancy demonstrated by general practitioners, all of which have combined to erode trust in vaccines in France in the last twenty years.[154] The level of negative sentiment, however, is not matched by rates of childhood immunisation.

Legislative changes

Diphtheria, tetanus and polio vaccinations have been mandatory in France for decades.[155] The Government held extensive citizen consultation in 2016 following a recommendation by parliamentarians in 2015 to extend the policy to improve immunisation coverage in children.[156]

New legislation to mandate a further eight immunisations (eleven in total) was introduced on 30 December 2017. It applies to all children born on or after 1 January 2018, requiring them to be immunised by the time they begin school at age three. The vaccines included are:

- diphtheria

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150 World Health Organization, WHO vaccine-preventable diseases: monitoring system. 2020 global summary - France, data as of 12 October 2020; Wellcome, Wellcome Global Monitor 2018: Chapter 5: Attitudes to vaccines, June 2019

151 World Health Organization, WHO vaccine-preventable diseases: monitoring system. 2020 global summary - France, data as of 12 October 2020

152 Heidi J Larson et al, The State of Vaccine Confidence 2016: Global Insights Through a 67-Country Survey, *EBioMedicine*, 13 September 2016

153 Wellcome, Wellcome Global Monitor How does the world feel about science and health?, June 2019

154 How France is persuading its citizens to get vaccinated amid high levels of scepticism, *The Independent,* 8 July 2020; Santé publique, France, Vaccine Hesitancy Among General Practitioners and Its Determinants During Controversies: A National Cross-sectional Survey in France, last updated 9 September 2019

155 Pourquoi la France impose la vaccination depuis plus d'un siècle? (Why has France imposed vaccination for over a century?) *National Geographic, France*, (not dated)

156 See, for example, Santé publique, France, Présentation de la concertation citoyenne sur la vaccination (Presentation of the citizen consultation on vaccination), December 2016 (video)

- tetanus
- polio
- Haemophilus influenzae B
- pertussis (whooping cough)
- hepatitis B
- measles
- mumps
- rubella
- meningitis C
- pneumococcus[157]

There are medical exemptions in some circumstances, such as immunocompromised children, for whom some vaccines are not suitable. No exemptions other than medical exemptions are permitted, such as on religious or other grounds. Such exemptions do apply in other countries with coercive immunisation policies, notably in a number of US states.

Parents are personally responsible for complying with the law and must have documentation certifying their child's immunisation status in order to access childcare (childminders and creches), the state education system (nurseries and schools) and other provision for children, such as summer camps. If immunisation status is incomplete, children are enrolled in education provisionally and parents have three months to have the missing immunisations carried out. The sanction for not complying is that children cannot access state education or other provision for children such as childminders or summer camps. There are no fines or criminal sanctions levied against parents or guardians.

The law obliges health professionals who must offer the vaccines, to explain the consequences of refusal, and record refusals.[158] Health professionals can face criminal sanctions if they supply false immunisation certifications. This can be a fine of 45,000 Euros or a three-year prison sentence.[159]

The French Government launched information campaigns using a range of methods (health promotional materials, web resources, targeted text messages) to give people more information about immunisation and the vaccines.[160] French health insurance companies (through which most medical treatment is administered in France) were also involved in dissemination of information.

The legislative change is intended to be temporary until it is judged that public confidence has improved. Provisions in the legislation require an

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157 Ministère des Solidarités et de la Santé, Vaccins obligatoires, 14 January 2020
158 Vaccination Info Service, France, Non-respect des obligations vaccinales, last updated 12 April 2018
159 Ministère des Solidarités et de la Santé, Vaccins obligatoires, Questions-Réponses, 14 January 2020
160 Ministère des Solidarités et de la Santé, Vaccins obligatoires, Questions-Réponses, 14 January 2020

annual review of the impacts of the changes (vaccine coverage, public attitudes and vaccine safety monitoring), which is also made public.

Consequences of legislative change

In December 2019, the French Health Ministry published a review of vaccine coverage and attitudes, a year after the reforms to make childhood immunisations mandatory (in French). Coverage increased for all vaccines for children born in 2018 compared with children born in 2017. For example, hepatitis B coverage increased from 90.5% to 96.3%, the first does of meningitis C coverage increased from 35.5% to 75.8% and the first dose of measles, mumps and rubella (MMR) increased from 86.2% to 87.6%.[161]

Immunisation coverage increased in infants to whom the new law applied. This was accompanied by an increase in booster and other immunisations for older children, that are not covered by the changes to the mandatory childhood list, such as the Human Papilloma Virus vaccine which is offered to 15-year-old girls in France to protect from cervical cancer. This vaccine increased from 29.4% in 2018 to 34.1% in 2019.[162]

The review also notes general changes to public attitudes to immunisation as well as specific legislative changes. It reported the proportion of the French population in favour of mandatory vaccination increased from 49% in 2017 to 63% in 2019. For those people who were less in favour of the changes three general attitudes were expressed:

- an opposition to the principle of obligation rather than the specific measure itself
- concerns about side effects of vaccines
- a view that compulsory vaccination is being promoted by the pharmaceutical industry.

[161] Ministère des Solidarités et de la Santé, Synthèse du premier bilan annuel des obligations vaccinales du nourrisson, Décembre 2019

[162] Ministère des Solidarités et de la Santé, Synthèse du premier bilan annuel des obligations vaccinales du nourrisson, Décembre 2019

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