

THE ART OF CONVERSATION

LET'S TALK ABOUT VACCINATION



This guide was commissioned by the European Patients' Forum (EPF) and developed by #PersonBeforePatient, a health storytelling charity based in Amsterdam, The Netherlands, and EPF.

In May 2019, we brought together a group of committed patient representatives in a workshop held in Amsterdam. In that workshop, participants representing a variety of chronic conditions and from across Europe explored the topic of vaccination, what people living with chronic conditions need to know in order to make an informed decision about vaccination, and what is needed to have constructive conversations about vaccination.

The result is this guide: a tool, patient advocates can use to support them in having conversations about vaccination, whether they are individual patients, family members, friends, or patient organisation representatives. We hope it will be useful to anyone who wishes to strengthen their knowledge on vaccination and their confidence in having meaningful conversations about vaccination.

THANKS AND ACKNOWLEDGEMENTS

EPF would like to thank our committed group of patients and patient advocates for their engagement and insights that helped shape this guide:

Saskya Angevare, Autoinflammatory Alliance, the Netherlands; Konstantina Brousa, Panhellenic Association for Patients with Autoimmune Rheumatic Disease, Greece; Ovidiu Covaciu, independent patient advocate, Romania; Ricardo Fonseca, National Association Against Fibromyalgia and Chronic Fatigue Syndrome, Portugal; Vera Gomes, Inflammatory Bowel Diseases, Portugal/Belgium; Tunde Koltai, HAPO the Hungarian National Patient Coalition, Hungary; Filipa Monteiro, Portuguese Multiple Sclerosis Society, Portugal; Helga Ovens, Lupus Europe, UK; Annemarie Sluijmers, Lupus Europe, the Netherlands; Thomas Smith, independent patient advocate, UK; Plamen Taushanov/Reneta Ilieva, Bulgarian Association for Patients' Defence, Bulgaria.

We would also like to thank Dr Hanne Nøkleby (MD), Chief Scientific Adviser, Norwegian Institute of Public Health for kindly undertaking an independent scientific review of this publication.

Finally, we would like to thank Vaccines Europe for providing the necessary funding for the EPF initiative on vaccination for patients with chronic conditions, of which this guide forms an important part. Vaccines Europe provided technical clarifications where needed but had no influence on the process of developing this guide, or any editorial control over its content.



WHAT'S INSIDE

Get answers to your questions

1. What is a vaccine?
2. How do vaccines work?
3. What is herd immunity?
4. How are vaccines made?
5. How are vaccines approved in Europe?
6. How is the safety of new vaccines ensured?
7. What is a vaccination schedule?
8. Development of Vaccines for COVID-19
9. What are the possible side effects of vaccines?
10. Why is it important for people with chronic health conditions to be vaccinated?
11. How to have better conversations about vaccines?

DEAR READER,

Equitable access to vaccination across the life-course is a key health policy [priority](#) of the European Commission. In response to concerns about falling rates of vaccination coverage, the spread of hesitancy, and the re-emergence of vaccine-preventable disease in some parts of Europe, the Commission is taking a range of actions to strengthen EU cooperation on vaccination.

The current COVID-19 pandemic has made this priority a matter of urgency: health systems across Europe have seen disruption in the provision of healthcare services, including routine vaccination in several countries, while simultaneously, safe and effective vaccines against the new coronavirus are needed to bring the pandemic under control in the long term. The picture is further complicated by the need to address hesitancy and misinformation about vaccines, and fostering public trust.

Infectious diseases are particularly dangerous for people living with a chronic condition, putting them at increased risk from complications and adverse effects. In addition, some patients cannot be vaccinated and are more vulnerable to the falling rates of vaccination in the general population.

Nevertheless, even though patients are at risk and specific vaccination recommendations exist for many chronic diseases, up-take amongst patients is thought to be lower than it could be. One of the reasons for this is lack of awareness, linked to a lack of high-quality, evidence-based information in patient-friendly language and accessible format targeted specifically at patients.

EPF has been advocating for the importance of vaccination for patients with chronic conditions since 2018 and has developed an [information toolkit](#) to support patient advocacy. We also organised three workshops with our national member organisations in Romania and Germany on the topic and in 2019 launched our [Manifesto](#) on the importance of vaccination.

This Patient Guide is the next step in filling the awareness and information gap. The Guide complements and expands on our other available information materials and gives guidance on having conversations around vaccination. The idea to make such a guide was based on requests from several patient advocates who attended our events. True to our philosophy, we developed this guide in collaboration with patient advocates.

Although Europe is estimated to have the lowest confidence in vaccination worldwide and coverage rates have been falling, recent reversals of this trend in some countries prove that it is possible to change the conversation. The patient voice can be very powerful, and we hope this Guide will help amplify it.

Marco Greco
President, EPF



This Guide gives you up-to-date, fact-based, and credible information so that you can engage confidently in a conversation about vaccination whether you are a patient, family member, friend or patient advocate.

With facts at your fingertips, you are ready to start talking. Please note that this Guide does not contain medical advice. You should always speak to your healthcare professional for personal medical advice.

DEFINITIONS AND TERMINOLOGY

Vaccination:

The use of vaccines to protect from infectious illnesses.

Vaccine:

Medicinal products that produce immunity, thus protecting the body from disease. Vaccines contain dead or weakened forms of the disease-causing micro-organism (pathogen) or immunologically important parts of the micro-organism.

Childhood vaccines are developed and/or administered specially to children, to give long-lasting or even lifelong protection against a preventable childhood disease, such as measles.

Live attenuated vaccines are produced by weakening a disease-producing ('wild-type') virus or bacterium in the laboratory. The modified strains are able to multiply within the body and trigger a strong immune response. Live attenuated vaccines are generally given in one or two doses.

Inactivated (or killed) vaccines consist of virus particles, bacteria, or other pathogens that have been grown in a lab and then killed. Inactivated vaccines often need adjuvants and/or multiple "booster" injections to provide an effective immune response.

Subunit vaccines do not use the actual microbe but only the important parts of it: the antigens that best stimulate the immune system – polysaccharides (sugars) or proteins from the surface of the microbe that our immune system recognises as 'foreign'. There are several different types of subunit vaccines such recombinant, polysaccharide, conjugate or toxoid vaccines.

Recombinant vaccines are vaccines whose antigens were produced by genetic engineering technology. A small piece of DNA from the virus or bacterium is inserted into other cells to make them produce large quantities of active ingredient for the vaccine (usually just a single protein or sugar).

Toxoid vaccines are made with inactivated versions of the toxins produced by the microbe. They are called 'toxoids' because they look like toxins but are not poisonous.

Conjugate vaccines are improvements on polysaccharide vaccines where the polysaccharide is attached to something else, usually a protein. The immune system recognises these proteins very easily and this helps to generate a stronger immune response than polysaccharide vaccines.

Combination vaccine:

Combination vaccines include two or more vaccines against different diseases.

So, at a doctor's visit, your or your child may only get two or three vaccinations to protect you or them from five diseases, instead of five individual ones.

Several vaccines are so common that they are generally known by their initials: MMR (measles, mumps, and rubella) and DTaP (diphtheria, tetanus, and pertussis). Each of these protects against three diseases.

Vaccine delivery:

The method of administering a vaccine. Most people think of an injection, but some vaccines can also be delivered orally and/or via nasal administration.

Vaccination schedule:

A full list of the routine vaccinations offered by a national health system and when they should be given.

Adjuvant:

Adjuvants help the body to produce an immune response that is strong enough to protect the person from the disease they are being vaccinated against.

An adjuvant is an ingredient that is added to the vaccine. Most common adjuvants used are aluminium salts.

Adverse reaction:

An unintended, negative reaction to a drug or vaccine.

Herd protection:

When a large enough majority of people are vaccinated, they do not transmit the disease, therefore indirectly protecting those people who are not vaccinated. Sometimes this is referred to as *herd or community protection*.

Immune system:

The organs and processes of the body that provide immunity, through innate immunity (general defences) and adaptive immunity (defence against specific attackers, like viruses). Adaptive immunity is acquired by having the infection or by vaccination.

Immunity:

The body's ability to resist disease caused by an infection with a microorganism or a toxin made by a microorganism. The immune system is responsible for immunity. Immunity can be provoked by a vaccine or by having previously had the disease.

Immunisation:

The process of becoming immune to (i.e., protected against) a disease through vaccination.

HOW VACCINATION CHANGED HISTORY

Life in the eighteenth century was precarious: for every 1,000 babies born, 140 would be dead before their first birthday, largely because of infectious diseases. The impact of infectious diseases was huge for children and adults alike. Smallpox in particular ravaged communities, infecting as many as one in five people in towns and cities. This was just one of many – cholera, tuberculosis, influenza, pneumonia, measles, and polio threatened people everywhere. Parents were constantly worried about losing their children to diseases – and, sadly, many did: an estimated three in ten did not make it to adulthood.

Before vaccination, variolation or inoculation was the method first used to immunize an individual against smallpox (Variola) with material taken from a patient or a recently variolated individual, in the hope that a mild, but protective, infection would occur. The procedure was most commonly carried out by inserting/rubbing powdered smallpox scabs or fluid from pustules into superficial scratches made in the skin.

The earliest described example of vaccination occurred in 1796, when an eight-year-old boy called James Phipps went to physician Edward Jenner's surgery in the UK to trial the physician's smallpox vaccine. Jenner took matter from a cowpox pustule and transferred it to Phipps through cuts on his arms. Smallpox and cowpox were similar enough that Phipps was protected against smallpox infection.

This trial led to the replacement of variolation with vaccination, a safer alternative which in turn led to the development of the many vaccines now available against other diseases. The word vaccination comes from the Latin word "vacca", meaning cow, because the material was taken from a cowpox pustule.

Back then, the effects of disease were visible everywhere: the trailing limbs of polio survivors, the scars of smallpox and measles survivors. These signs continued to show all the way to the 20th century, slowly fading but still common.

Scientists have since then developed vaccines for a range of diseases, making life steadily less precarious, especially for babies and young children. Today, we can protect ourselves and our families from many serious infectious diseases with vaccines, and many of the diseases that plagued our ancestors are on their way to being eliminated.

Jenner's smallpox vaccination was rolled out in the UK, reducing the number of deaths from smallpox from 18,447 in 1791-1800 – the last decade before vaccination – to 7,858 in 1810-1820. James Phipps lived to the age of 66.

WHERE ARE WE TODAY?

Vaccination has had a significant positive impact towards the eradication of many diseases.¹

Disease ²	Before vaccine introduced (per million per year)	After vaccine introduced (per million per year)	% reduction
Diphtheria	158 (1936-45)	0.96 (2016)	99.4
Measles	3044 (1953-62)	47 (2018-19)	98.5
Mumps	830 (1963-68)	22 (2006)	97.3
Pertussis	1534 (1934-43)	20 (2018)	98.7
Poliomyelitis	68.63 (1988)	0.01 (2015)	99.99
Smallpox	2500 (1900-49)	0 (2006)	100
Hepatitis A	465 (1986-95)	187 (2018)	59.8
Haemophilus influenza type b	84 (1980s)	0.17 (2006)	99.8
Pneumococcal disease	233 (1997-99)	139 (2006)	40.5

To maintain these signification levels of community protection and reduction of disease, it is important to reach and maintain 95% coverage rates. The recent epidemics of measles in various regions of the world show how, when coverage rates fall, diseases can easily come back.

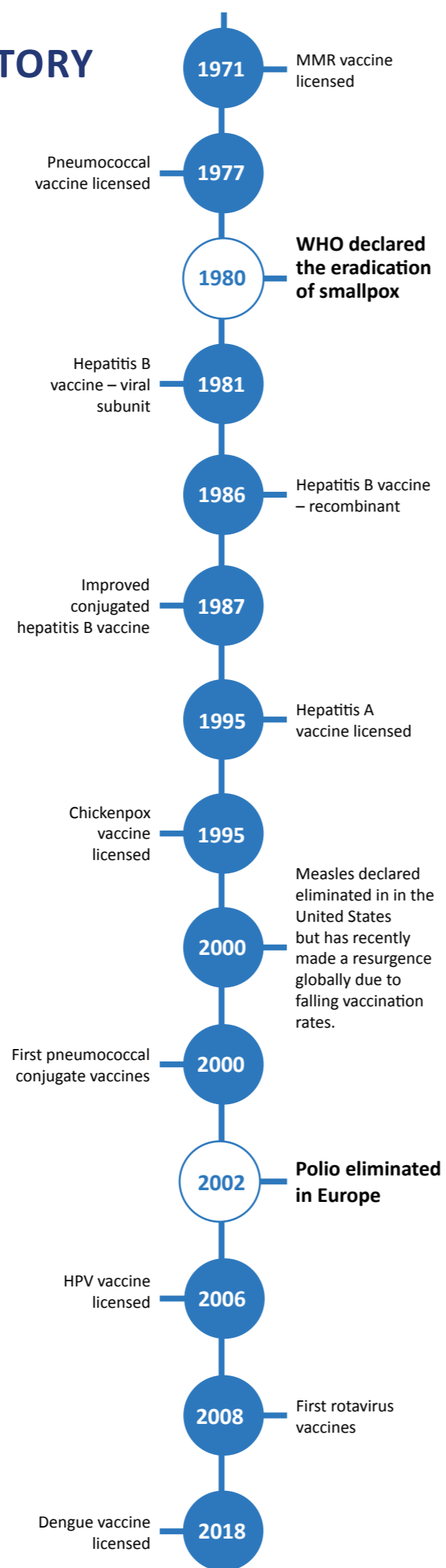
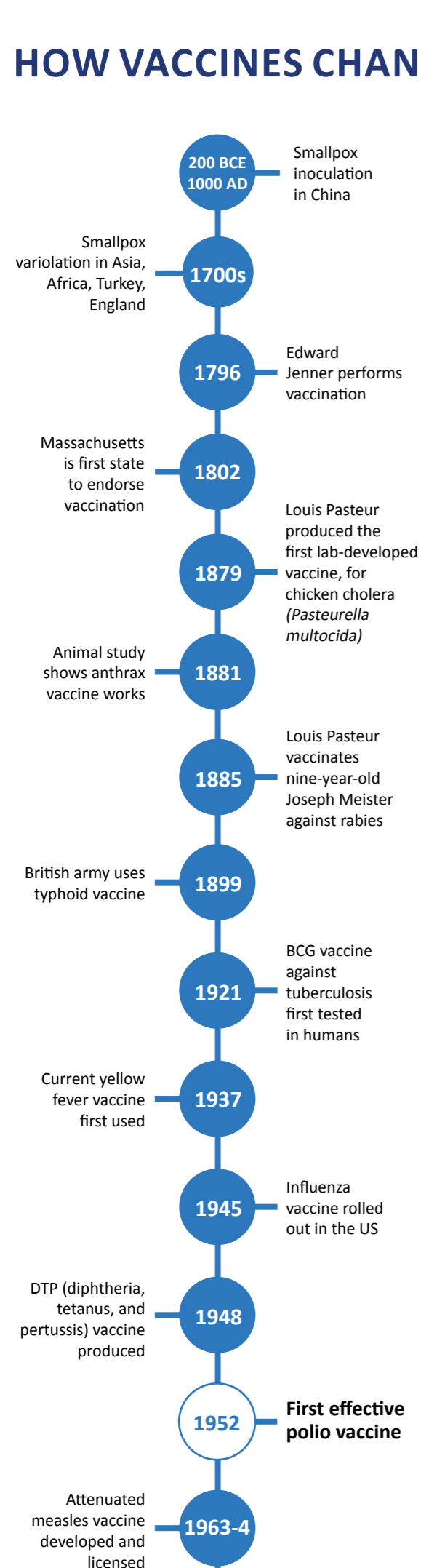
There are also vaccines currently in development for many diseases and pathogens, including:

Campylobacter jejuni, Chagas Disease, Chikungunya, Enterotoxigenic *Escherichia coli*, Enterovirus 71 (EV71), Group B Streptococcus (GBS), Herpes Simplex Virus, HIV-1, Human Hookworm Dis- ease, Leishmaniasis Disease, Malaria, Nipah Virus, Nontyphoidal Salmonella Disease, Norovirus, Paratyphoid fever, Respiratory Syncytial Virus (RSV), Schistosomiasis Disease, Shigella, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Streptococcus pyrogenes*, Tuberculosis and the Universal Influenza Vaccine.

¹ https://ourworldindata.org/uploads/2013/05/Vaccine_Reduction-of-Cases-and-Deaths-1.png

² For a full list of vaccines for specific diseases, both currently available and in development, please refer to the World Health Organization web-site on immunisation: <https://www.who.int/immunization/diseases/en/>

HOW VACCINES CHANGED HISTORY



HOW VACCINES WORK

Vaccination currently saves an estimated 2-3 million lives a year globally.³ They work by helping people acquire immunity – build defences – against particular pathogens, like the flu (influenza) virus, measles or polio without having to be infected.

The immune system is layered, giving us a structure for defending against pathogens like viruses and bacteria that can cause disease. The two major layers of defence are the innate immune system and the adaptive immune system.

The **innate immune system** is our first line of defence against harmful intruders. It is made up of physical barriers, such as the skin and mucous surfaces, and immune cells that repel and attack anything they think is harmful.

The **adaptive immune system** is made up of white blood cells that recognise and remember pathogens. They develop weapons against pathogens that get through our barriers and innate immune defences. These white blood cells are called lymphocytes and they include B cells and T cells. There are about 2 trillion lymphocytes in the body. These are the cells we can teach to recognise pathogens, by vaccinating. This allows the immune system to develop a “memory”.

The underlying science is simple: expose a person to a (part of a) pathogen or a toxin, often by injecting it, and their immune cells will develop specific weapons against those pathogens or toxins. If they are infected in the future, their immune system will recognise them and its response will be fast and strong, preventing them from getting the disease.

There are **two main types of vaccines**:

- Live attenuated – containing a weakened form of the pathogen. Immunocompromised people may not be able to have these. Examples of these vaccines include MMR, rotavirus, varicella and yellow fever.
- Inactivated – containing killed pathogens, parts of pathogens, like proteins, or toxins that pathogens produce. These are safer for immunocompromised people, though sometimes the immune response is not as good. Such vaccines include influenza, Hepatitis A and B, polio, and HPV.

Some vaccines include an adjuvant – an extra ingredient that makes the immune system react more strongly, to act and develop immunity. Adjuvants go through rigorous safety testing with the vaccines themselves. For more information on adjuvants, see page 15.

³ <https://www.who.int/news-room/facts-in-pictures/detail/immunization>



VACCINES: FROM LAB TO PERSON

On average, it takes 12-15 years to develop a vaccine. In general, vaccines are tested very thoroughly for safety following the highest standards and involving trials in large numbers of people. The aim of the testing, and the following approval process, is to make sure the vaccine is safe, of high quality, and that it works.

The schema below refers to the usual development process; the COVID-19 pandemic has led to the adoption of emergency processes that made it possible to accelerate vaccine development while still ensuring the same high standards of safety and efficacy. Please refer to page 16 for more details.

PRE-CLINICAL DEVELOPMENT

1. Scientists identify a potential target for a vaccine – this could be a protein or process that is critical for the virus or bacterium to survive or replicate, for example.
2. Researchers test the vaccine's efficacy and safety in the lab, studying it using living cells and animals.

Did you know?

There are a huge number of potential vaccine targets and limited funding, so only the most promising are pursued. Only about 7% of vaccine development projects that reach the preclinical development phase result in a licensed vaccine.



CLINICAL DEVELOPMENT

3. Phase I clinical trial: researchers test the vaccine to see if it is safe and can generate an immune response in people.

Phase I Studies are designed to answer two questions.

- Is the vaccine safe?
- Does it induce an immune response?

If the answer is 'NO' to either question, the vaccine cannot be developed further.

Did you know?

People who enrol in a Phase I study are usually healthy people with low risk of infection. The study usually includes less than 100 participants.

4. Phase II clinical trial: tests aim to further confirm its safety and find out if the vaccine consistently gives a good immune response and therefore probably protects people against disease. It also tests what is the best (optimal) dose to be given.

Phase II Studies usually include people representing the (part of) the population the vaccine is targeted at.

Typically, the studies enrol a few hundred participants. If the vaccine is determined to be unsafe or does not consistently induce an immune response, it will not be developed further.

5. Phase III clinical trial: this phase provides the conclusive evidence needed to authorise the vaccine and make it widely available; it is a much larger trial to test whether the vaccine is sufficiently effective.

Phase III Studies determine whether the vaccine is effective enough and can include thousands, to tens of thousands of people.

They also look for rare side effects, not seen in smaller studies. In many cases, more than one Phase III Study will be undertaken across a large geographic area to test it in wider, more diverse groups of people.

APPROVAL

In the EU, vaccines go through a rigorous approval process, like other medicinal products.

6. Marketing authorisation: the vaccine is evaluated against a number of product properties, such as quality, safety and efficacy. The European Medicines Agency (EMA) has scientific guidelines specifically for vaccines development.
7. Registration or licensing: this can be done centrally for the whole of the EU, via the EMA, or nationally.

MANUFACTURE

8. Once approved, the vaccine is manufactured in a process that can take between 1-3 or more years depending on the complexity of the vaccine.
9. About 70% of manufacturing time is spent on quality control.
10. There are many quality checks along the way, with several hundred tests carried out by the manufacturer, the exporting and importing countries and an official European control laboratory.

NATIONAL IMMUNISATION PROGRAMMES

11. Each country develops their own national immunisation programme, which includes the recommended vaccines and the targeted population. Governments take various factors into account when choosing vaccines, including epidemiology, cost, and efficacy. It takes about 6.5 years on average for a vaccine to be added to the schedule after marketing approval, but the time may differ between countries.
12. Costs differ depending on the country, but in general, childhood vaccines and many others are covered by the health service.

Did you know?

The costs of vaccination in Europe can vary from country to country, and vaccine to vaccine.

However, studies show that it costs – on average – less than €4,000 to protect one person against 17 infectious diseases for a lifetime of 80 years.

Vaccination programs represent less than 0.5% of the healthcare budget.⁴

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4994732/>

SAFETY MONITORING AND FOLLOW-UP

13. Vaccines are continuously monitored for adverse reactions.
14. Once the vaccine is distributed, additional studies take place. These are called Phase IV Studies and post-commitment studies included in the Risk Management Plan. Phase IV Studies are important because it ensures that the safety of the vaccine continues to be monitored and any side effects are being reported.
15. Licenses can require follow-ups like stability studies and reporting of changes since approval.
16. Vaccine licenses must be renewed every five years in Europe.

SAFETY SIGNALS

If someone has a suspected adverse reaction to a vaccine, they can report it through a healthcare professional or directly to their country's national authority. That reaction gives a 'safety signal'.

Safety signals are collected from reports, clinical studies and published scientific research. The European Medicines Agency (EMA) works with national authorities and the vaccine manufacturers to investigate these signals and take action if necessary.

A list of national authorities is available online at https://www.hma.eu/nationalcontacts_hum.html

VACCINATION AS PART OF A LIFE-COURSE APPROACH TO HEALTHCARE

Vaccination is not just for children; it benefits people of all ages. Because we are living longer, across Europe people have started to talk about a life-course approach to vaccination. This aims at increasing and maintaining health throughout a person's life, from childhood into old age, and targeting people's health needs at different periods throughout their lives. Access to vaccination at the appropriate times is now seen as an important part of *universal health coverage*.

For example, many vaccines are given to babies and small children, to protect them from childhood diseases like measles, mumps, whooping cough, and diphtheria. Depending on the vaccine, you might get one, two or more doses to make sure you are protected for life. A 'booster' dose many years after the initial vaccination can remind the immune system what the pathogen looks like, so it can be kept up the protection in case of future infection.⁵

⁵ Most live inactivated vaccines require only one dose, as they mimic the immune system by replicating in the body. Inactivated vaccines often require more than one dose to reach protection, and often a booster later on life. See glossary for different types of vaccines.

⁶ See EPF report (2018) "Vaccination for patients with chronic conditions". Available at <https://www.eu-patient.eu/globalassets/policy/vaccination/resources/background-report--vaccination-and-patients-with-chronic-conditions.pdf>

Adults are also recommended to receive vaccinations, depending on their age, underlying medical conditions, lifestyle, prior vaccinations, and other considerations. Some vaccinations recommended for adults:

- **Flu (influenza):** Every year a new flu vaccine is available, to protect people from the strain of flu that's expected to circulate that year.
- **Pneumococcal:** The pneumococcal vaccine protects against serious and potentially fatal pneumococcal infections. It is also known as the pneumonia vaccine. Pneumococcal infections are caused by the bacterium *Streptococcus pneumoniae* and can lead to pneumonia, septicaemia (a kind of blood poisoning) and meningitis.
- **Hepatitis A, yellow fever, typhoid:** if you are planning to travel and live in a country where these vaccines aren't routinely given to babies, you might need to get them as an adult.

PROTECTING YOUR HEALTH AS A PATIENT

Vaccination is particularly important for patients with chronic health conditions.⁶ Infectious diseases can be more dangerous and difficult to manage, and patients can be at increased risk of complications and adverse effects. Some patients, for example people with autoimmune conditions or who have had organ transplants, or those undergoing cancer treatment are more vulnerable to infections in general. While others, cannot be vaccinated at all.

For people with chronic conditions, this can raise questions. Which vaccines are most important to protect me? Are they safe for me? What are the benefits and risks for me?

WHAT VACCINES SHOULD I HAVE?

There are specific vaccination recommendations for different chronic conditions in national vaccination programmes. Vaccination schedules differ across Europe, and although there are similarities, the age ranges and included conditions are not the same everywhere.

It is important for patients to know the recommendations for their condition, and to discuss their individual situation and health needs with a healthcare professional.

Some examples of vaccinations:

Vaccine	Protects against	How often?	Recommended for people with...
Influenza	Influenza (flu)	Every year	Asthma, neurological and developmental conditions, chronic lung disease, heart disease, endocrine disorders (including diabetes), blood disorders, kidney, liver or metabolic disorders, weakened immune systems (including due to cancer or HIV/AIDS), long-term aspirin therapy (aged 18 or under), obesity, pregnancy, age of 65 or over
Td	Tetanus and diphtheria	Every 10 years	Everyone, including any chronic condition
Tdap	Tetanus, diphtheria and pertussis (whooping cough)	Once, instead of Td vaccine, and during pregnancy	Everyone, including any chronic condition
Pneumococcal	Pneumococcus	Once	Age of over 60-65, chronic heart, kidney, liver or lung disease, diabetes, alcoholism, conditions that weaken the immune systems (including cancer and HIV/AIDS, people without spleen function either due to operation to remove it (splenectomy) or otherwise lack of function
Hepatitis B series	Hepatitis B	Once (full series)	Haemodialysis, dialysis treatment, end-stage kidney (renal) disease, HIV infection, chronic liver disease, diabetes and are aged under 60

Certain vaccines are not recommended for people with compromised immune systems. If you are concerned whether your immune system is strong enough for a vaccine, you can talk to a healthcare professional, such as your doctor, a nurse, or a pharmacist.

HERD IMMUNITY PROTECTS THE VULNERABLE

Not everyone can be vaccinated. This is why it is so important that the people around the vulnerable patients are vaccinated, and that the population as a whole has sufficient coverage.

Vaccines work on two levels: they protect the individual person, and they also protect whole communities. When a big enough majority of people in a community is immune – either through vaccination or having been previously infected with the disease, the disease is unable to spread, so people who are vulnerable are protected. This is called **herd immunity**.⁷

The vaccination coverage rate – or, more accurately, the percentage of the population that needs to be immune – to achieve herd immunity depends on how infectious a disease is. For mumps, which is very infectious, you need a coverage rate of 92%. For COVID-19 based on current knowledge it is expected that you need a coverage rate of about 70% as it is less infectious.

VACCINES: BENEFITS VS. RISKS

Vaccines are designed to save lives by preventing disease, and vaccination greatly reduces the burden of disease worldwide.

Misguided safety concerns, often perpetuated by misinformation, have resulted in a fall in vaccination rates, putting vulnerable people – particularly patients with chronic health conditions and the immunocompromised – at risk of vaccine-preventable disease.

THE BENEFITS

- Vaccination saves lives. Since the first smallpox vaccination, millions of people have been saved from deadly diseases.
- Vaccination eradicates diseases. Thanks to vaccination efforts, smallpox was completely eradicated, and polio is close to being eradicated.
- Vaccination protects communities. When enough people are vaccinated, vulnerable people – the young, or those who are unable to be vaccinated – are protected too, because the disease can no longer spread.
- Vaccination is safe. Often, there are greater benefits to prevent disease rather than treat them after developed.
- Vaccination is cost-effective. It is more cost-effective to prevent a disease than to treat it.

Other benefits include avoiding hospitalization, reducing GP visits, reducing sick leave and increasing quality of life.

⁷ For more about herd protection see <https://vk.ovg.ox.ac.uk/vk/herd-immunity>

THE RISKS IN CONTEXT

As with any medicine that has a therapeutic effect on the human body, there can be side effects.

It is important to be aware that for most people, these are mild, such as redness, pain and swelling at the site of the injection, and sometimes a few days of fever and fatigue.

According to the US Centers for Disease Control and Prevention (CDC), only one in every million people vaccinated has a serious reaction.

You may have some questions about the rare and more serious adverse reactions.

- What is anaphylaxis and how often does it occur?
 - Anaphylaxis is a serious and rapid allergic reaction that occurs in less than two cases per million people vaccinated; a 2003 study showed that after more than 7.6 million vaccinations, there were five possible cases of anaphylaxis, but no deaths.
- What is Guillain–Barré syndrome?
 - Guillain–Barré syndrome is a rapid onset muscle weakness caused by the immune system damaging the nervous system. It is rare, and to provide some wider context, it has been indicated in possibly one or two cases per million doses of influenza vaccine, though some studies suggest the vaccine may actually protect against the condition. The syndrome occurs spontaneously after influenza in about 1 in 40 000-80 000 cases, and more often after some other infectious diseases.



- I am immunocompromised, what does a vaccine mean to me?
 - If you are immunocompromised, you may not be able to have all vaccines and you should talk to your healthcare professional about the impact of vaccination and any other medical treatment.

There have also been reports of concern over the additional ingredients in vaccines, including adjuvants, which are included to make the vaccines work better.

These ingredients added to vaccines are in tiny amounts, and we consume more of them from the environment than from vaccines. However, they have often been made a focus for anti-vaccination campaigns and made to sound unnatural and even dangerous.

Here are some of the ingredients used in vaccines and what they do:

- Adjuvants, such as aluminium salts – help boost the body’s response to the vaccine.
- Stabilizers, such as gelatin and monosodium glutamate (MSG) – help make sure the vaccine works after it is produced.
- Antibiotics or formaldehyde – prevent contamination with bacteria during manufacturing.
- Thimerosal (ethylmercury) – a preservative. Despite concerns about its safety, there is no scientific evidence of adverse reactions. Today only one type of influenza vaccine contains this, and alternatives are available.

Did you know?

Formaldehyde is always present in the human body as part of our natural metabolic process. The amount used in vaccines is tiny and most of it diluted to residual amounts during the manufacturing process.

The highest amount of formaldehyde present in any vaccine is .02 mg per dose.

An average two-month-old baby would have around 1.1 mg of formaldehyde circulating in their body, with higher naturally occurring amounts for older children.⁸

⁸ <https://www.publichealth.org/public-awareness/understanding-vaccines/goes-vaccine/>

⁹ <https://www.publichealth.org/public-awareness/understanding-vaccines/goes-vaccine/>

ADJUVANTS

There are a few different adjuvants in vaccines. Because they are designed to boost the body’s response to a vaccine, they can also cause adverse reactions, such as redness and swelling at the injection site, as well as symptoms like fever and fatigue.

Adjuvant	What is it?	Example vaccines
Aluminum based mineral salts (Alum)	E.g. Aluminum phosphate	Hepatitis A, DTP, HPV
MF59	An emulsion of natural liver oil (squalene) and water	Influenza
Monophosphoryl lipid A (MPL)	A molecule from bacteria that has been made safe	Hepatitis B
Virosomes	Microscopic bubbles that have virus proteins in their skin	Hepatitis A, influenza

Did you know?

- Aluminium is the third most common naturally occurring element, after oxygen and silicon. It is found in plants, soil, air, and water. It may harm people if absorbed in very high amounts and when a person’s kidneys are not working properly.
- A breast-fed infant gets around 7 milligrams of aluminium through diet throughout the first six months of life. The standard vaccines given in the first six months contain an average of just 4.4 milligrams of aluminium.
- The quantity of aluminium in a vaccine is so small – less than we ordinarily consume in our daily lives – that it does not cause any noticeable raise in this base amount found in the blood, even immediately after an injection.⁹

DEVELOPMENT OF VACCINES FOR COVID-19

The COVID-19 pandemic has led to the development and approval of new vaccines in a much shorter time-frame than usual. How was this possible?

There are several reasons, including:

- The availability of immediate funding and human resources,
- Quick authorisation of clinical trials,
- Many volunteers which means getting large amounts of data more quickly,
- International collaboration and pooling of expertise, and
- Making the EU regulatory process more efficient through a dedicated COVID-19 Task Force with multidisciplinary experts to focus and support the work of scientific committees.

All of these factors make evaluation and final approval much quicker.

The process described here is more efficient and therefore faster, but it still ensures the same high standards of safety, quality and efficacy as for any other vaccines or medicinal products approved in the EU.



For up-to-date information, please click on the bullet points below of the European Medicines Agency:

- Key Facts about COVID-19
- COVID-19 vaccines: development, evaluation, approval and monitoring

WHAT ARE mRNA VACCINES AND HOW DO THEY WORK?



mRNA vaccines (messenger RNA vaccines) are new types of vaccine that, instead of introducing weakened or killed germs into the body, give instructions for cells to make a protein that triggers an immune response to the virus causing COVID-19. The vaccines approved thus far protect individuals from developing symptomatic COVID-19 disease. For more details, please [visit this EMA section](#).

Certain vaccines developed for COVID-19 use this mRNA technology to give the body's immune cells instructions to make a "spike protein" that is found on the surface of the coronavirus. The immune system then recognises that this protein doesn't belong in the body, and builds an immune response protecting itself against future infection from the real virus.

Important to know

mRNA used in COVID-19 vaccines never enters the nucleus of the human cell, which is where DNA (genetic material) is located. It does not interfere in any way with human DNA. The body rapidly breaks down the mRNA material once it has taken the "instructions" to build immunity to the virus. (Source: CDC)

One of the advantages of this technology is that there is no virus at all in the vaccine. The human body gets rid of the mRNA soon after it is finished using the instructions. The downside is that mRNA vaccines are very fragile, and currently used vaccines must be stored in extremely cold temperatures. mRNA technology is relatively new in vaccines, but not unknown – it has been studied for a long time in different contexts.

For more details, see <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>

WHY CAN TALKING ABOUT VACCINATION BE SOMETIMES SO DIFFICULT?

In recent years, there has been increasing concern about vaccine hesitancy. The reasons why some people choose not to get vaccinated are complex, with false information being a contributing factor. The proliferation of misinformation about vaccination – false information made to look convincing – has undoubtedly contributed to the concerns that some people have about vaccination. This is coupled with wider trends, such as growing distrust in science, experts, and industry, perpetuated by some public figures who question broadly accepted scientific knowledge.¹⁰

It is easy to feel fearful, distrustful and confused by the information being provided. This has led to the topic of vaccination becoming an emotionally charged debate. The data shows that the anti-vaccination phenomenon is relatively small, though vocal, and the majority of people do trust science and facts.

We believe that asking questions is a powerful and positive tool. Anyone living with a chronic health condition should ask their healthcare professional questions before making any decision about a vaccine or any other medical treatment.

WHAT MAKES VACCINATION A CONTROVERSIAL TOPIC?

- *Misinformation is confusing* – there is so much false information out there that is designed to look like real science, how do you know what is true? People want certainty, and taking a side is easier than navigating the space in between.
- *We do not know the facts* – despite the scientific evidence being available, there's a lack of knowledge among the general public about vaccination, immunity and how it all works.
- *The media loves an argument* – in the fight for an audience, media outlets embrace false balance – they show the vaccination debate as a story with two equal sides, when in reality the vast majority of scientists and other experts support vaccination. This is widespread across science, and it is a matter of media ethics.
- *It is not fun* – holding your baby still while they are given a vaccine is tough for any parent, and without access to the facts about risks and benefits, it can seem unnecessary. This can make it difficult to talk about rationally.
- *We are not listening* – the discussion has become a procession of broadcasts – rather than having conversations, people are just sharing their views and hoping they can shout the loudest.
- *It is a scapegoat* – many conditions are diagnosed in childhood, such as autism, at the time of many vaccinations. People often make a connection between the vaccines and different conditions because they can happen at the same time, when in reality they are not related. Anecdote takes over, and people's stories seem to stand alongside studies with equal weight.
- *A falsified study lives on* – a fraudulent study falsely linking the MMR vaccine and autism that was published in 1998 – and finally retracted a decade later – is still being used to mislead people.
- *There is a lot of judgment* – with emotionally charged views, people can be quick to judge others' decisions.
- *Echo chambers do not help* – we surround ourselves with people who share our views, making different views seem wrong. We either stick to our own groups or get angry with others.
- *But it is not new* – anti-vaccination arguments have been around as long as vaccines have. In 1882, the Anti-Vaccination League of America held its first meeting in New York, claiming smallpox was not an infectious disease, but a condition spread by filth.

FINDING THE FACTS YOU CAN TRUST

How do you know if the information you find about vaccination is reliable?

- Is it from an official source? Check the URL – is it secure (https://)? Is it official, such as a governmental website (e.g. .gov.uk)
- Look at the context – who is publishing the information, and why? Is it a university, funding body or peer-reviewed journal?
- Check references – do the claims come with sources? Can you trace them back to reliable information?
- Google it – does the information appear on a trustworthy site or in a scientific journal?

REFRAMING THE CONVERSATION

The topic of vaccination is important, and we need to be talking about it. However, many people struggle with how to discuss vaccination when confronted with a friend, relative or acquaintance who expresses hesitancy. Dismissing their views is not effective, and facts alone are not effective in changing behaviour.

Applying the 'art of conversation' to a discussion about vaccination.

What is a conversation?

- Conversation is a form of communication that is usually more spontaneous and less formal. We enter conversations for purposes of pleasant engagement in order to meet new people, to find out information and to enjoy social interactions.
- Conversations can vary in type, from intellectual conversations and information exchanges to friendly debate and witty banter.

You do not need to be more gregarious, animated, or outgoing to have good conversational skills, nor do you need to be a great storyteller, actor or comedian... you need to have the ability to listen attentively, ask fitting questions and pay attention to the answers.

- Listen to what is being said;
- Be curious as to why it is being said;
- Know your facts, and trust your sources;
- Know when to step back from the conversation – sometimes it takes more than one conversation.

¹⁰ See for example the discussion on hesitancy in EPF's 2018 Background report on vaccination: <https://www.eu-patient.eu/globalassets/policy/vaccination/resources/background-report--vaccination-and-patients-with-chronic-conditions.pdf>



We all know that often this is ‘easier said than done’ and it is hard to hear opinions and perspectives that are wildly different to our own. In a good conversation, each person needs to express themselves; otherwise the conversation turns into a monologue. So always remember to ‘check in with yourself’ to understand how you are feeling in any conversation about vaccination.

You are likely to have this guide because you live with a chronic health condition and/or are a member of a patient advocacy group, so it is likely that you are already genuinely interested in others and are open about learning and understanding new things, even if the perspective being shared is different to your own.

Try to:

- Ask open questions (who, why, when, what, how, where?) that encourage people to elaborate on their perspectives. Showing interest also encourages the other person to be relaxed and share information more freely. Display attentiveness by keeping good eye contact and listening actively.
- Ensure there is a balance of give and take. A conversation can get boring quickly if one person is doing all the talking while the other is trying to get a word in edgewise. When that happens, whoever is not talking begins to tune out and there is no conversation!
 - There can be many reasons for a lack of give and take. If this happens, just take a deep breath, smile and reflect on what you want to say.
 - If you have tried several times to interject, it's ok to excuse yourself and move away from the conversation.
- Know your facts, and trust your sources.



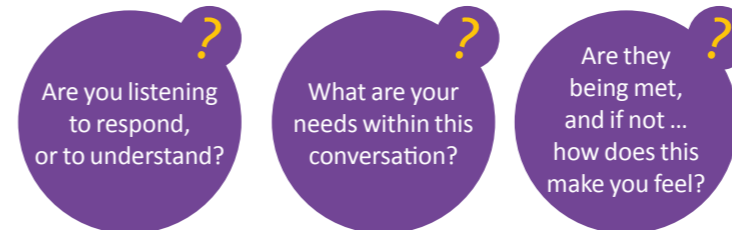
FIGHTING TO BE HEARD

Individuals who hold alternative perspectives often feel that they have to ‘fight to be heard’. For this reason, and a number of others, they might not be able to recognise that a conversation is not purely just about informing others of an opinion or perspective. Likewise, you might feel unheard.

Likewise, you might feel unheard.

In any conversation ‘check in with yourself’.

Ask yourself:



You can also ask the person you are talking to:



You can share with them that your intention is curiosity about what they feel and need: “I want to feel sure that I fully understand what you mean.”

And check again: “Are you okay with this? That I am trying to understand you?”

Be prepared for the fact that some people are not used to being asked how they are feeling, maybe no one has ever asked about their feelings and their needs before, especially if they are more used to having to ‘fight to be heard’ because they express an alternative perspective to vaccination.

Being respectful to another human being important; respecting their need (and your own) to have the space to reflect on what is being said and come back to the conversation is also important.

Key Tips

Ask about, and listen to, people's concerns

Acknowledge their concerns

Provide information to respond to their concerns

Share personal stories

Do not pass judgement

SHARE PERSONAL PERSPECTIVES

The patient voice can be powerful. As a patient with a chronic health condition, you have a unique perspective regarding vaccines and the benefits of being vaccinated. If you are comfortable to share your story then introduce it as a personal perspective, it *is* about you – a patient with a chronic health condition.

You need to explain why the topic of vaccination is important to you and your community, and what the impact is for those who cannot be vaccinated or need to avoid (certain) vaccines.

Helping others see the wider picture using facts highlighted in this Guide to outline the benefits of vaccinations may help a shift in the perspective of others.

Patient Voices

Organ transplantation: I need your protection. A young patient who has had an organ transplant explains why the entire community must contribute to stopping infections from spreading.

<https://www.vaccinestoday.eu/stories/organ-transplantation-i-need-your-protection/>

A mother of three boys with a hereditary immunodeficiency explains the importance of herd immunity
<https://www.voicesforvaccines.org/please-help-me-keep-my-children-healthy/>

Testimonial video with a patient with diabetes
<https://www.eu-patient.eu/whatwedo/Policy/vaccination/>

A teenager's story of contracting measles encephalitis
<https://www.ecdc.europa.eu/en/publications-data/patient-story-nastasias-story-ecdceuronews-video>

Laura Brennan – A Tribute. Laura Brennan died of cervical cancer in 2019 at age 26. Her powerful voice helped reverse the trend on HPV vaccination uptake in Ireland. <https://www.youtube.com/watch?v=UeVdgSWv28s>

If you would like to share your voice and experience as a patient with chronic disease on the importance of vaccination, please get in touch with EPF! We would love to hear from you.

Email: info@eu-patient.eu

WANT TO KNOW MORE ABOUT VACCINATION?

Check out some of these trustworthy sources (mainly in English, apart from national government websites) with evidence-based information and some amazing free resources which you can download and use in your patient advocacy work and discussions about vaccination.

European Vaccination Information Portal
A joint initiative of the European Commission,
the EMA and the ECDC
<https://vaccination-info.eu/en>

National public health organisations
A list of official national websites for EU and EEA
countries is available at
<https://vaccination-info.eu/en/trusted-sources>

European Centre of Disease Control and Prevention (ECDC)
<https://www.ecdc.europa.eu/en>

European Medicines Agency (EMA)
<https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/multidisciplinary/multidisciplinary-vaccines>

World Health Organization (WHO) vaccination web-pages
<https://www.who.int/topics/vaccines/en/>
https://www.who.int/vaccine_safety/en/

The Vaccine Safety Net
A global network of websites established by WHO that
provides reliable information on vaccine safety
<https://www.vaccinesafetynet.org>

Centre of Diseases Control and Prevention, USA (CDC)
<https://www.cdc.gov/>

Vaccine Knowledge Project at the University of Oxford
<https://vk.ovg.ox.ac.uk/vk/>

British Society for Immunology
<https://www.immunology.org/public-information/all-about-vaccines>

History of Vaccines
<https://www.historyofvaccines.org/timeline/all>



European Patients' Forum
Chaussée d'Etterbeek 180
B-1040 Brussels

www.eu-patient.eu
[@eupatientsforum](https://twitter.com/eupatientsforum)