

Promoting an EU Lifecourse for:

An Immunisation Strategy

Vaccinate – A Forgotten Public Health Protection Measure

Infectious diseases have posed and continue to pose serious threats to public health, especially in the developing world. Worldwide, smallpox has been eradicated and polio has been almost eliminated. However, there are a number of infectious diseases that continue to plague society worldwide such as malaria, Ebola, Zika, HIV/AIDS, and tuberculosis. Developing effective vaccines for those diseases and more would greatly benefit both society and individuals. Despite past successes, if and when immunisation is considered today, it is primarily discussed in the context of childhood vaccination—preventing common diseases, such as diphtheria, measles, pertussis, rubella, mumps, and poliomyelitis (polio)—or if there is a disease scare.

Many Europeans seem to lack awareness of the threats of infectious disease and the importance of immunisation as an effective societal public health measure. Vaccines protect society broadly and vulnerable individuals who cannot be vaccinated for medical reasons specifically. Immunisation also protects opponents of vaccination who will not be immunised due to beliefs. Apart from protecting individuals, vaccination also prevents infectious diseases from spreading to vulnerable groups, such as people with underlying chronic conditions (like asthma or diabetes), pregnant women, and older people. Public health stakeholders, healthcare professionals, and policymakers must weigh up societal and human rights – the rights of the individual versus the needs of the community – with regard to vaccination. A balance must be struck between various social, cultural, and religious norms, beliefs, rights, and the need to prevent future crisis.

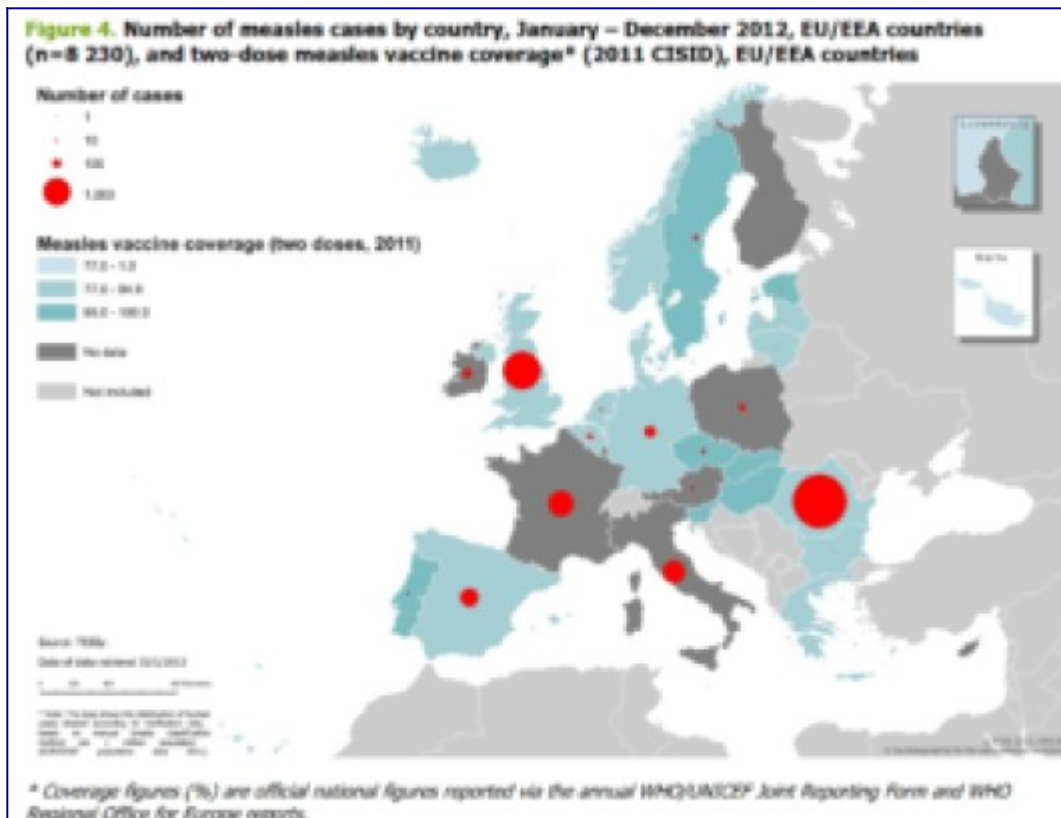
Vaccines: The Basics

Currently, there are about twenty vaccines in use worldwide for diseases such as diphtheria, haemophilus influenza type b (Hib), hepatitis B, human papilloma virus (HPV), influenza, measles and rubella, mumps, pertussis, poliomyelitis (polio), rotavirus, tetanus, tuberculosis, meningococcal disease (meningitis and septicaemia), and invasive pneumococcal disease (pneumonia and meningitis). About twenty new or improved vaccines are anticipated in the near future.¹ According to the World Health Organization, immunisations save more than three million lives annually. A further three million more deaths of both children and adults could be prevented by vaccination.²

How Vaccines and Immunisation Programmes Work

Vaccines cause the immune system to develop antibodies (a blood protein that combats infection) against a specific pathogen (disease -causing virus or

bacteria) without infecting the individual with that disease; this process is called “active immunity.” If a person then encounters the disease after having been vaccinated, the body will respond quickly by developing antibodies to combat it.³ Vaccines are developed by altering the pathogen to trigger an immune response without infecting the individual with the disease itself. The antigens within an effective vaccine can be created by using the live but inactivated pathogen, part of the pathogen, or a toxin produced by the pathogen. Vaccines may last for a period of time or a lifetime, depending on the vaccine itself.⁴



Immunisation programmes aim to protect the at-risk population from specific diseases by offering vaccines to large groups.

If a sufficient percentage of the population is vaccinated, it is difficult for the disease to spread, even among those who have not been vaccinated. Those who have not received or have refused to be vaccinated are protected by this phenomenon called “**herd immunity**” or “**community immunity**.”⁵

For example, in the case of measles, everyone is protected—including the vulnerable, frail and those who cannot be vaccinated for various reasons—if 95% of the population is vaccinated against this infection. Society must commit to immunisation programmes to effectively, efficiently, and equitably combat infectious disease.

Infectious Disease: A Threat in Europe?

Infectious diseases and their pathogens easily cross borders. Yet, many Europeans have become “vaccination shy,” and no longer consider such diseases a problem. Vaccination seems to have become the victim of its own success. Few remember the serious bodily damage, disability, and death caused by polio before the Salk vaccine became readily available.

With many major infectious disease outbreaks safely kept under control in recent years, chronic diseases have become the major focus of European prevention and health promotion policy. Although a laudable priority, chronic disease prevention and management is often reliant on the personal commitment of people to make lifestyle changes, such as smoking cessation, healthy diet and adequate physical exercise. Whenever possible, vaccines should be also included as an effective prevention measure throughout the lifespan. For example, bacterial meningitis and septicaemia kill children and adults; survivors often become life-long patients, suffering from a variety of life-changing expensive conditions, such as amputations and kidney failure.

Alarmingly, vaccination coverage rates and trust in vaccination are decreasing across all EU Member States, placing them **below vaccination targets**, leading to **avoidable and costly outbreaks** of communicable diseases in many countries.

Notably, recent measles outbreaks have occurred throughout Europe, which should mobilise the public health community into action. Europe has a target of 95% protection against measles, but did not meet the WHO measles-eliminating target in 2014.

The Need for Vaccination Advocacy

Today, patient advocacy groups are active in many disease areas, including cardiovascular disease, cancer, rare diseases, Alzheimer’s, Parkinson’s, Multiple Sclerosis, and diabetes. These groups advocate for the best treatment for their patients. Yet, advocacy for immunisation is lacking. Instead, scientifically refuted scare stories, such as those linking the measles vaccine with autism in children, still circulate. These stories stubbornly prevail, propagated by social media.

Moreover, some young parents take their children to playgroups to catch measles “naturally” rather than following the recommended vaccination schedule supported by their national health authorities. Such schedules can be found on the *European Centre of Disease Prevention and Control’s website*.⁷

This lack of health literacy and the perpetuation of scare stories that misrepresent and exaggerate the dangers of vaccines have led to neglect, distrust, and fear of immunisation among the general public.

Consequently, vaccination as a primary prevention tool is not placed high on society's agenda. The current measles upsurge in some European countries is a warning to both policymakers and to society. Unless **positive advocacy for immunisation** is combined with the political will to support robust, consistent, coherent, and evidence-based communication and dialogue by health authorities, trust in vaccination will not be restored, and society will be unable to count on a vaccine- and health-literate public in the case of a health emergency and epidemic.

The European Dimension

The European Union (EU) guarantees the free movement of goods, capital, services, and people. As a result, an increasing number of Europeans are living, working, and retiring in other Member States, bringing their pathogens with them. The European treaties assure citizens a high level of health protection. The European Commission supports Member States in maintaining and increasing rates of immunisation.

National health authorities and the European institutions share responsibility for preventing the transmission of emerging pathogens and the resurgence of others as well as orchestrating a rapid and coordinated response to infectious disease threats. Yet, there is no a comprehensive strategy covering the role of immunisation employing a life-course approach. Vaccination policies and schedules vary greatly across the twenty-eight Member States, which adds additional confusion and uncertainty during a time of declining population immunisation coverage.⁸

Council Conclusions on Childhood Immunisation

The **Council conclusions on childhood immunisation** were adopted in June 2011. The Council acknowledges that childhood vaccination falls under the purview of individual Member States, but recognises the benefit of addressing childhood vaccination across the EU in a coordinated fashion. The Council invites the European Commission, the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) in collaboration with the World Health Organization (WHO) to improve and monitor vaccination coverage. Moreover, the Council Conclusions encourage the monitoring of public support and development of effective communication messages, including addressing sceptics.⁹

Council Conclusions on Vaccinations as an Effective Tool in Public Health

The **Council conclusions on vaccinations as an effective tool in public health** were adopted in December 2014 under the Italian Presidency of the Council of the European Union. The Conclusions state that immunisation programmes are an essential aspect of the health system. They highlight the

recent outbreaks of vaccine preventable diseases in Europe, outbreaks of diseases that were nearly eliminated through effective immunisation programmes in the past. The Conclusions call on the Commission and Member States to conduct more research on vaccines, including the effectiveness of new vaccines and immunisation programmes, particularly for studies on vaccine programmes and the effectiveness of new vaccines. With a population in Europe that is ageing ever more rapidly, the Conclusions also discuss the importance of life-long vaccinations, not only childhood immunisation.¹⁰

The Conclusions call on the European Commission, ECDC, and the EMA to provide support and guidance on the strengthening of national immunisation programmes, including the provision of research methods to aid in the improvement of Member State uptake strategies. They commend the ECDC communication toolkits on vaccination and call for more health literacy efforts on immunisation to enable European citizens to make informed decisions.¹¹

Covering Vulnerable Population Groups—The Measles Outbreak Case

In recent years, measles outbreaks have occurred in various regions of the EU. From 2007 to 2010, outbreaks took place in Austria, Bulgaria, France, Germany, Ireland, Italy, the Netherlands, the United Kingdom, and Switzerland. In Bulgaria, there were 24,000 cases of measles and 24 resulting deaths in 2009 and 2010. In a study of Western Europe, measles treatment cost averaged €209-480 per person while vaccination cost €0.17-0.97 per person. In 2009, 95% of the reported measles cases in the European Region were in the EU, with 65% of cases occurring in Western Europe.¹²

Life-Course Approach to Vaccination

Infectious diseases are not only a danger to children but also pose a serious health challenge for older individuals. One of the big challenges in public health is to reach “well” people who would benefit from vaccination, but who do not regularly interact with the healthcare system. There is a lack of awareness on the benefit of immunisation across the life-course and gaps persist in policy, communication, and supportive programmes. As Europe ages, a life-course approach — spanning from childhood, adolescence, the middle years, and older age — is necessary to achieve effective immunisation programmes that reach all.¹³

Why Are There so Few Advocates for Vaccination?

Chronic disease patient organisations laudably focus on the best treatment and care for their patients, but they are not always aware of the interaction between chronic and infectious diseases. Patients must understand that bacterial and viral infections can worsen pre-existing chronic condition. Shielding older and vulnerable people with chronic diseases from further

infection can prevent unneeded hospital care. For example, patients with asthma and respiratory diseases are at an elevated risk of contracting pneumonia and pneumococcal disease. Diabetes patients should be regularly reminded by their health professionals to keep up-to-date with their vaccination schedule. Many groups who advocate for immunisation are orientated towards one specific infection; however, in order to effect change, they should join forces to raise awareness.

The Role of Healthcare Professionals

Awareness and **support** for vaccination across the life-course should start with General Practitioners (GPs), who typically are the closest to patients, their families, and the community. There is an urgent need for strengthening the GP's role in supporting, facilitating and implementing a comprehensive immunisation policy across the lifespan. Healthcare professionals, medical/nursing students, GPs, paediatricians, and geriatricians would all benefit from training programmes on advising patients. Pharmacists should also be mobilised to reach out to the general public, "the well", and patients. Practice nurses and midwives can also reach additional population groups. Moreover, healthcare professionals and hospital workers must be encouraged to keep up-to-date with their own vaccinations.

Biological (Sex) Variations in Vaccination

Differences exist between men and women with regard to their immune systems, though these differences need to be further explored. Immune response to infectious disease, and consequently vaccination reaction, varies. Often, women have a stronger reaction than do men, but the reason for this variation is not fully understood or exploited by the research and healthcare community. Researchers are beginning to study biological and gender differences with regard to vaccines. Some speculate that evolutionary differences with respect to trauma exposure may account for some varied immune response. Research continues to explore higher rates of certain diseases in women than in men, and why some diseases go into remission during pregnancy.¹⁴

For example, researchers looking at influenza and immunisation have found that immune response to the vaccine is affected by male testosterone. While the exact mechanism for the biological sex difference is unclear, testosterone appears to play an important role. The female immune system tends to have a stronger reaction to the influenza vaccine than does the male system. Moreover, men with the highest levels of testosterone appear to have the weakest antibody response to the vaccine.¹⁵ In future, it may be useful to look at gender-based differences in the reaction by the immune system. Dosages may also vary between men and women, which could be a vital vaccine-saving tool during times of outbreak and shortage.

Gender Differences and Access to Vaccination

In addition to the biological variation in vaccine response, sex and gender-based social and cultural norms affect access to vaccination. Women, due to their reproductive and caring roles, often hold responsibility for the health of children, older family members, and those with disabilities. Yet, in many countries throughout the world, especially in male-dominated societies, women lack the empowerment, financial resources, autonomy, and independence to access immunisation programmes for themselves and for their children.¹⁶

The Global Alliance for Vaccines and Immunisation (GAVI), which primarily focuses on immunisation in poor and developing countries, makes gender equity an overarching principle in their work. Equal access is crucial to expanding vaccine coverage and making immunisation more equitable. GAVI works together with countries to overcome gender inequities. To qualify for GAVI support, countries are requested to separate data based on gender, income, and geographic location to help identify reasons for low immunisation coverage rates. Importantly, GAVI argues that **empowering women is of utmost importance in order to protect children through vaccination.**

Sex and gender differences in vaccination rates are particularly pronounced in developing countries where women are of lower socio-economic status. As a result, children are less likely to be vaccinated in these countries than in those where women are empowered. Coverage can and should be improved by reducing barriers that women face accessing health services and immunisation for their children.¹⁷

Women's Role in Vaccination

Traditionally, women have played an important role in childhood vaccination. It is primarily mothers who take their offspring to be vaccinated and ensure that the schedule is kept up-to-date. With the introduction of the HPV vaccines for the prevention of many forms of cervical cancer, mothers and their daughters face the issue together of vaccination past childhood into teenage years.

Women are the main carers of children and ageing parents; therefore, they are more likely to recognise the importance of preventing disease. As European women outlive men by an average of six years, **women are an obvious group** for public health experts to engage in a meaningful dialogue about vaccination across the lifespan. Women are often involved in or targeted by the anti-vaccination lobby with negative information on vaccine safety and effectiveness despite robust evidence on the benefit of immunisation. Additionally, health authorities primarily communicate immunisation information during times of a crisis, missing out vital opportunities to build trust and understanding of vaccination in the general public. Consequently, the lack of **effective, consistent, evidence-based public health messages**

about the benefits of immunisation has allowed misinformation and alarm to fall on fertile ground.

HPV Vaccination – Preventing Cervical Cancer

Three different vaccines have been developed to protect against two of the most common high- risk cervical- cancer causing strains of Human Papillomavirus (HPV) that are responsible for 73% of cervical cancer in Europe (HPV-16 and HPV-18). Some vaccinations include protection from cancer-causing HPV types 16, 18, 31, 33, 45, 52, and 58 as well as the prevention of genital warts caused by HPV types 6 and 11. The vaccines also provide lower levels of protection against other HPV strains. HPV vaccines are aimed at adolescent girls prior to sexual activity.^{18,19}

Cervical cancer is the second most common type of cancer in women in Europe. In 2008, the ECDC issued the *Guidance document for the introduction of the HPV vaccines in Europe*. In its September 2012 report, the ECDC summarised the experience gained from the HPV vaccination programmes during the last four years, including evidence gathered from research studies.^{20,21} The ECDC recommends that routine HPV vaccination should target girls between the ages of 10 and 14 before the onset of sexual activity and that it be administered in three doses within six months. The vaccination of young girls requires the support of parents.

To date, all but three EU Member States have recommended immunisations for human papillomavirus infection in adolescent girls.²² Many countries have integrated HPV vaccination into their national immunisation schedules. However, coverage is sometimes low, ranging from less than 20% to over 80%, with only Portugal and the UK achieving coverage above 80% of the target groups.²³

HPV vaccine affordability is a major implementation hurdle across Europe. The ECDC stresses that national screening programmes must be maintained, as HPV vaccination does not eliminate the need for screening, even among immunised women. However, existing screening guidelines will have to be adjusted for vaccinated women. Randomised trials and observations demonstrate the safety and efficacy of the HPV vaccine against cervical cancer precursors. The ECDC also examined the immunisation of boys, concluding that "*vaccinating boys and men is beneficial.*"²⁴ However, "*vaccinating girls is shown to be more cost-effective than vaccinating boys,*" so public health initiatives should continue to focus on vaccinating girls.

- In the future, HPV vaccination policy should be reviewed as the evidence base grows. In the EU, only Austria recommends HPV vaccination of boys, which is provided at the individual's expense.²⁶

Vaccines During the Reproductive Years

Some infectious diseases can seriously harm pregnant women and their unborn children. During pregnancy, a woman's immune system is altered, so women are at elevated risk of contracting certain infectious diseases. In addition, the foetus is particularly vulnerable to certain infections that can be prevented through immunisation.²⁷ As pregnant women are

- vulnerable population group, their immunisation schedules should be up-to-date, ideally before a woman becomes pregnant **to protect the health of both mother and child.**

Vaccines prevent pregnant women from contracting certain infectious diseases. If a mother has been vaccinated against infections, such as measles, mumps and rubella, her protective antibodies pass through the placenta to her infant; this is referred to as "**passive immunity.**"²⁸ Antibodies are transferred to the foetus, primarily during the third trimester. Antibodies from the mother persist in newborns for three to four weeks and then decline over the next six to twelve months. As antibodies decline over time, newborns should be immunised in order to develop their own antibodies to help combat disease.²⁹

The NHS choices website recommends that all pregnant women have the flu vaccine at any stage of pregnancy.³⁰ **Historically, studies on immunisation in pregnant and breastfeeding women remain limited. Inactivated vaccines** can be given during pregnancy as studies have shown vaccination against tetanus toxoid and the use of the inactivated polio vaccine to be effective and safe. However, **active vaccines** are generally not recommended to pregnant women due to concerns that they could affect the foetus. Additionally, women are advised **not** to receive active vaccines less than twenty-eight days **before** becoming pregnant.^{31,32}

Many European public health websites are surprisingly silent on vaccination during women's reproductive years. For example, in the case of the influenza vaccination, European data is urgently needed as most advice is based on non-European data. The Health Canada website explains that pregnancy provides an opportunity for evaluating a woman's immunisation status.³³ The ECDC has a **European vaccination schedule finder** on its website; however, this does not seem to allow searching for pregnancy status.³⁴ By contrast the New York State Department, the U.S. Centers for Disease Control and Prevention, and Health Canada provide information on vaccination before and during pregnancy, as well as when breastfeeding.

Routine inactive vaccines appear to be safe to administer during breastfeeding. The period after delivery and before discharge from hospital offers an opportunity to vaccinate women for their own protection and for the protection

of their infants. ^{35,36} If the mother is breastfeeding, active vaccines are not recommended as they may be passed on through the milk to the infant. ^{37,38}

The Ageing Challenge—Immunisation Across the Lifespan

Generally, vaccination programmes in Europe focus on the childhood years. An ageing population brings an increasing burden of chronic disease. By 2025, nearly 50% of Europeans will be over 50. Infections will be a major cause of illness and incapacity for this age group, particularly if they have underlying chronic conditions. Pneumonia remains a sizeable killer of older people; together with influenza, it accounts for approximately 8% of all deaths of older people. Infectious disease is the fourth leading cause of death following cancer, cardiovascular disease, and stroke. Mortality from infectious disease peaks during influenza outbreaks.

Vaccination provides cost-effective protection against a number of diseases throughout the lifespan, yet it remains an underused public-health strategy for the promotion of healthy ageing. Life-course immunisation programmes reduce preventable infectious disease and lighten the chronic diseases burden. Several geriatric societies, therefore, recommend immunisation of older adults as part of active and healthy ageing. ³⁹

To raise awareness of the health and socio-economic benefits of a life-course approach to immunisation, an informal group of healthcare professionals, academics, industry partners, age think tanks, geriatricians, patients, and health advocates commissioned a report to support their argument for vaccination across the lifespan. The report, entitled *Adult vaccination: a key component of healthy ageing—Benefits of life-course immunisation in Europe*, provides an overview of the state of adult immunisation in the EU Member States and highlights the value of the implementation of robust policies and programmes.

- Reviewing various EU countries' healthy ageing strategy and examining the rates of the main vaccine-preventable diseases in Europe, the report reveals gaps in adult immunisation policies and a general lack of public awareness of the health and economic benefits of adult vaccination. Moreover, the group's report identifies key elements for the successful implementation of adult vaccination and provides practical recommendations for improving immunisation rates in older adults. ⁴¹

The body's ability to respond effectively to vaccines diminishes with age, which may affect the benefits of vaccination in frail older people, particularly in those over the age of eighty. The British Geriatrics Society recommends developing more effective vaccines and better forms of delivery for the elderly (for example, adjuvants and intradermal injections) and advises that more

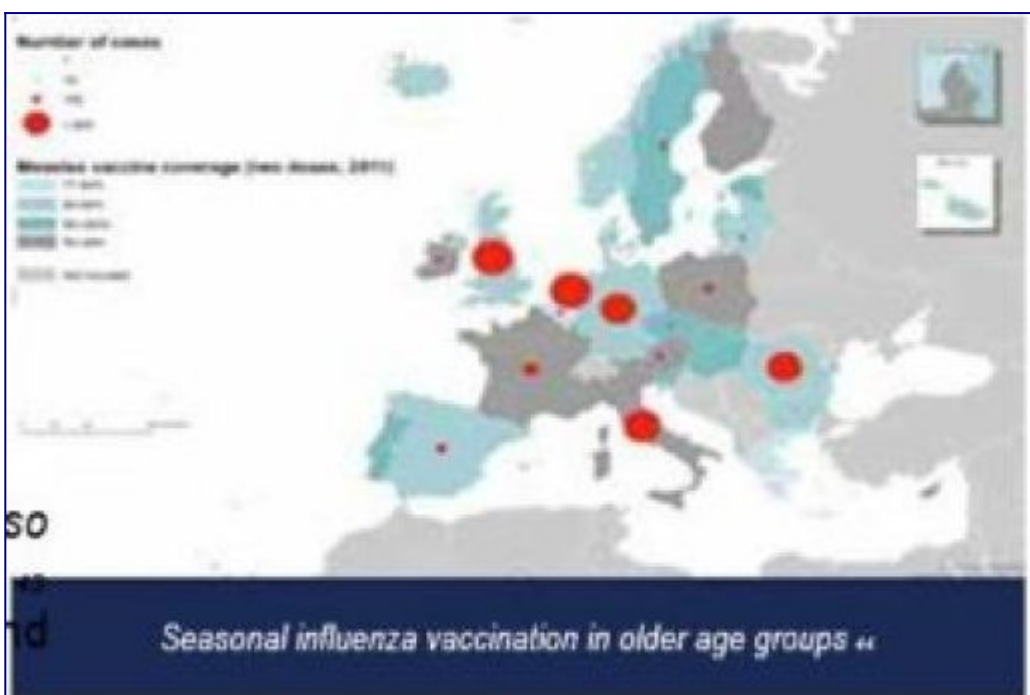
healthcare workers and carers who come into contact with vulnerable older people be vaccinated against influenza. ⁴²

Vaccine Inequities and Variation

General rates of vaccination vary across Europe and within countries. There have been some notable successes with regard to immunisation programmes. With regard to childhood vaccination in the European Region, the average vaccination coverage is 94% for measles; 90% for polio; and over 90% for diphtheria, pertussis (whooping cough), and tetanus (DPT).

However, large inequities exist across Europe. Studies indicate that lower socio-economic groups have reduced access to healthcare services and have lower vaccination coverage than do higher socio-economic groups. Coverage also differs between rural and urban settings. Coverage is lower in minority groups, such as members of the Roma community and migrant workers, than it is in the general population. There is a gap between Eastern and Western Europe due to the cost of vaccination and affordability for health systems.

It is important to note that the reasons for being unvaccinated globally differ significantly from those of being under- vaccinated in Europe. Many in Europe take access to vaccination for granted. Yet, in many developing countries due to huge barriers including high costs and lacking infrastructure, routine vaccinations access remains a key public health challenge. Large delays often exist between the introduction of vaccines in developed countries and in the developing world. The **WHO considers immunisation a basic right and a strategic component for reducing poverty** arguing that *"immunisation is not only an effective intervention to reduce disease and death, but it can also strategically reduce inequalities in the delivery of primary health care."* ⁴³



Efforts must be made to reduce inequities in immunisation access and use, both throughout Europe and globally.

Steps for Action

1. **The Commission together with EU Member States must adopt a coordinated and comprehensive life-course immunisation strategy to tackle infectious diseases among all citizens, from children to older people, including vulnerable people such as pregnant women.**

Infectious diseases easily cross borders. With the prevention focus of European health policy, the adoption of the Cross Border Healthcare Directive and more recently, the Joint Procurement Initiative, the Commission and EU Member States have a solid base to strengthen collaboration and coordination for a common vaccination strategy that protects all of Europe's population from infectious diseases.

2. **The Commission, together with Member States, should develop robust pro-active communication programmes to create a health- and vaccine-literate public that understands the benefit of vaccination for protecting both individuals and society from infectious diseases.**

Currently, there is a lack of positive information on the benefit of vaccination aimed at the general public. Once a disease outbreak occurs, scare stories and rumour easily spread. Therefore, public authorities must invest in consistent, proactive communication prior to outbreak. Robust programmes that provide balanced evidence-based information on vaccine-preventable diseases and immunisation programmes. Key stakeholders such as government officials, regulatory agencies, academic institutions, NGOs, industry professionals and healthcare providers must be engaged to develop effective, efficient and equitable communication programmes.

3. **Programming and policies that target the immunisation of older people as part of healthy active ageing must be developed.**

Infectious disease is the fourth leading cause of death of older individuals. In Europe, women make up the majority of older individuals and comprise most of the group of individuals eighty and older, individuals who often become frail and need care. Preventing infectious disease through immunisation can help to reduce the disability and disease burden facing older people across Europe.

4. **Positive vaccination advocacy initiatives based on evidence must be supported so that immunisation is made the norm for society.**

The Commission and Member States should engage and collaborate with civil society, government officials, health authorities, healthcare professionals,

NGOs, patient organisations, industry, and other key stakeholders to develop jointly a robust and appropriate European vaccination strategy based on best practice. Support for public health vaccination advocacy is urgently needed as communicable disease health advocacy is virtually non-existent.

5. **Research that explores gender as well as age differences in immunisation and provides advice based on robust European data must be encouraged and funded.**

Differences exist between men and women with regard to their immune systems and their reaction to infectious disease. Mechanisms behind variation in immune response should be further studied and more targeted vaccines developed. Gendered socio-cultural differences are important considerations for implementing effective vaccination programmes that reach out to and address different population groups.

6. **Research exploring the safety and effectiveness of vaccines during pregnancy and breastfeeding must be encouraged.**

Currently, most recommendations on vaccinations during pregnancy and breastfeeding are based on theoretical predictions and data reported from physicians. Research should be funded to better understand the relationship between female reproduction and immunisation to improve the health of mother and child for the protection of future generation.

7. **HPV vaccination should be included in all cervical cancer prevention programmes.**

It is important to revise the Cervical Cancer Prevention Guidelines to adjust for and integrate HPV vaccination. This may potentially bring cost savings to screening programmes and a different screening timetable for already vaccinated women. Women's groups and health NGOs should be involved in the process to improve communication and increase uptake of vaccination and cost effective screening programmes.

8. **The role of the ECDC in collecting and sharing consistent and comparable epidemiologic data, disaggregated by age and gender, should be improved, and surveillance must be more visible.**

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Daphne Holt: *Ph.D., Vice President, Confederation of Meningitis Organisation*

Contributors: Hildrun Sundseth, Peggy Maguire, Kristin Semancik and Lisa Keenan, *December 2017*

European Institute of Women's Health, CLG

33 Pearse Street, Dublin 2, Ireland

Telephone: +353-1-671 5691

Email: info@eurohealth.ie

Website: <https://www.eurohealth.ie>

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