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IFMSA Policy Document Vaccination

Proposed by Team of Officials

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Policy Statement

Introduction:

Vaccination is a successful public health measure to prevent infectious diseases and improve health of individuals and communities. It is therefore closely linked to the Sustainable Development Goal (SDG) Agenda, especially SDG 3 (health and wellbeing) but can also be seen as a prerequisite for further SDGs, as SDG 5 (gender equality), SDG 8 (work and economic growth) and SDG 13 (climate action). A growing movement against vaccination and immunization is spreading amongst several regions worldwide.

IFMSA position:

The IFMSA, as future health professionals, believes that our duty of care not only includes the future of our individual patients, but also that of communities locally, nationally and globally. IFMSA acknowledges that holistic, transversal and interprofessionality tackle is a mandatory requirement when addressing this global health problem. IFMSA therefore stresses the importance of improving the vaccination coverage worldwide, by increasing the research, distribution as well as education and awareness.

Call to Action:

Therefore, the IFMSA calls on:

Governments and Ministries of Health to:

- Ensure access, availability, equity to quality, and proper population adherence for the established National Immunization programs, expanding its coverage towards vulnerable populations;
- Invest in R&D resources and funds in order to gain knowledge and insight in the development;
- Invest in mass education strategies on vaccination to improve population adherence to the vaccination plan and to address vaccine hesitancy (e.g. Social Media);
- Implement vaccine production and price data transparency policies to establish a stricter control on Good Manufacturing Practices (GMP) regulations compliance and allow the country to conduct reasonably priced licitations;
- Urge all parents and caretakers to let their children follow their country's national immunization programme;
- Establish a national immunization program and a national vaccine regulation interdisciplinary entity, to ensure the quality of the products and the correct administration of the resources;
- Establish a national immunization programme built on functional, end-to-end supply chain, and logistics systems such as, but not limited to, an effective health surveillance to appropriately weigh the national burden of communicable disease to adequate the administrative response;
- Consider the introduction of temperature-stable vaccines into the national immunization plan, so the immune coverage's diversity is expanded and the established scheme is strengthened.

The WHO and other relevant international organizations to:



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- Ensure the access to immunization programmes for everyone, with a focus on disadvantaged groups within countries and refugees as well as Low and Middle Income Countries (LMICs)
- Actively encourage innovation and research of new and improved vaccines are accessible and affordable to everyone.
- Insist on vaccine price transparency from governments and other philanthropic entities, especially the ones who are actively involved in vaccine price negotiations.
- Consult countries on the development of immunisation strategies that are tailored to their needs
- Continue making annual progress reports and reviewing existing programmatic policies and implement new ones according to potential changes in world politics, scientific advancement, etc.
- Continue collaborating with various NGO's and CSO's to improve vaccination coverage

Universities and other educational/professional bodies to:

- Provide both practical and theoretical training on vaccination. Enhance the communication skills of health careers so they can better address the population's needs and hesitancies.
- Introduce 'vaccination drives' in the universities where students from all disciplines are enlightened about vaccines, the legislature of their country and international laws; as well as learn about their personal vaccination records and schedules by first hand interactions with experts, thus developing the skills to become a positive ambassador for vaccines in their community.
- Provide free access to data as well as copious funding to encourage research and development of vaccines.
- Facilitate means of networking between LMIC and HIC educational institutes and research facilities, to allow for better communication and coordination.
- Allocate the funds and resources received to sustainable research of new vaccines or the improvement of the ones already created.
- Support the immunization programs in both HIC and LMIC.
- Ensure an accurate and evidence-based breakthroughs in an One Health approach.

Healthcare NGOs and professional associations to:

- Advocate for the universal vaccination coverage and vaccine price transparency, especially for the LMICs, as well as migrants and refugees
- Support the research that reflects the global burden of infectious diseases
- Promote active provision of objective knowledge about vaccination to the public

IFMSA members and NMOs to:

- Provide healthcare students in different NMOs with efficient advocacy tools to approach the different stakeholders and policy makers in the field.
- Advocate and promote local and national campaigns to raise awareness among healthcare students as well as the general population.
- Collaborate with governments and other organizations to promote importance of immunization in a proper legal framework.
- Promote research exchanges in vaccination research and development through SCORE.

One Health partners to:

- Veterinarians need to establish a vaccine program that caters to the needs of the animals being treated within their region, as well as educate pet owners of the importance of vaccination and risk of disease transmission.
- Support vaccine manufacturers with developing modified methods of vaccine waste disposal procedures
- Develop safety protocols related to development of vaccines, specifically vaccines that are obtained from animals and wildlife
- Establish new or fortify existing regulations for the rational use of vaccines on livestock following rigorous research.



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Position Paper

Background information:

What is Vaccination?

Vaccination, is a simple yet efficient method of preventing and managing deadly diseases since the early 17th century but still remains a topic of debate to the date. Vaccine is defined by the WHO as “a biological preparation that improves immunity to a particular disease” [1]. In simple terminology, a vaccine is a drug that is made to resemble a specific disease causing agent that once injected into the human body the immune system spontaneously identifies, destroys, and memorizes it so as to destroy such organisms in future encounters.

There are four types of vaccines: live attenuated, inactivated, subunit, and toxoid. Live-attenuated vaccines utilize a weakened form of the specific agent, which in turn creates a long lasting immune response and requires either one or two doses, i.e. tuberculosis, oral polio vaccine, etc. Inactivated vaccines utilize the killed version of the agent and in turn the immunity aspect requires several booster shots over a period of time, ie whole-cell pertussis, inactivated poliovirus, hepatitis A, ect. Subunit vaccines also known as recombinant, polysaccharide, and conjugate vaccines utilize a specific part of the agent and like the inactivated vaccines they too require booster shots, ie pneumococcal, hepatitis B, haemophilus influenzae, ect. Toxoid vaccines are based on toxins produced by certain bacteria, but are rendered harmless. These toxoids cannot cause disease and elicit a strong immune response that is reinforced with booster shots over time, ie tetanus and diphtheria [2].

According to the Centers for Disease Control and Prevention (CDC) vaccines are needed because “it is always better to prevent a disease than to treat it after it occurs” [3]. Throughout time a large number of disorders have been discovered that arise from various agents that over a span of decades science has been able to develop a preventative measure for each. This has made it so that we have been able to eliminate various diseases from certain regions and even entirely eradicate others such as smallpox. In the 17th century the practice of vaccination was first adopted by Edward Jenner following the inoculation of a young patient with vaccinia virus, cowpox, in order to create immunity to smallpox. Following this breakthrough various scientists have began the development of vaccines for diseases such as cholera in 1897, the plague in the late 19th century, tetanus in 1923, polio in 1957 as an injectable vaccine and 1962 as an oral vaccine, and have been very successful in their endeavours [4].

Following the development of these vaccines, countries have introduced vaccination programs to reach the goal of eradication of vaccine-preventable diseases worldwide. With the implementation of such programs countries around the world have been able to document reduction in the prevalence of various diseases and total elimination in various countries. The Global Polio Eradication Initiative is an example of a global collaborative effort to eradicate polio worldwide. Since its launch in 1988 there has been a 99% fall in newly reported cases of polio worldwide. The WHO Region of the Americas, Western Pacific Region, European Region, and South-East Asia Region have all been certified polio-free meaning that 80% of the world population is living within a polio free region [5].

Discussion:

Global and Regional Vaccination Coverage

- According to the WHO, Vaccination coverage is defined as the proportion of the children who receive recommended vaccines. This proportion has been stable for a few years now and despite the fact that in 2017, around



- 85% of infants globally received the DTP vaccine in its 3 doses, around 19.9 million children under the age of one never received it in different countries and regions of the world [6].
- Vaccination coverage in 2017 according to different regions based on WHO-UNICEF estimates published in September 2018 has been varying;
 - in the African region (47 countries), 79% received first dose of DTP but only 72% received the three doses [7].
 - In the Americas (35 countries), 96% received first dose of DTP but only 91% received the three doses [8].
 - In the Eastern Mediterranean region (21 countries), 86% received first dose of DTP but only 81% received the three doses [9].
 - In the European region (53 countries), 97% received first dose of DTP but only 94% received the three doses [10].
 - In the South-East Asia region (11 countries), 93% received first dose of DTP but only 88% received the three doses [11].
 - In the Western-Pacific region (27 countries), 97% received first dose of DTP and 97% received the three doses [12].
 - Global Vaccination coverage summary in 2017 is :
 - Haemophilus influenzae type b (Hib) has been introduced in 191 countries, with an estimated coverage to be 72%, highest in the Americas region and lowest in the Western-Pacific region.
 - Hepatitis B Vaccine introduced in 187 countries estimated coverage being at 84%, also 105 countries supplied the children with the first dose of the vaccine in the first 24 hours in life estimated at 43%, highest in the Western-Pacific region.
 - Measles vaccine (2 doses) has been introduced in 167 countries as routine vaccine where 67% of children received the vaccine.
 - Polio has been stopped in all countries targeting its eradication after 85% of children around the world have received the vaccine except for three countries; Afghanistan, Pakistan and Nigeria where the disease is still endemic. [6]
 - The Global Vaccine Action Plan (GVAP) 2011-2020 has been called and endorsed by the WHO to reach a global vaccination coverage of 90% for every vaccine in a country's routine immunization plan by 2020 and to reach that goal, it's necessary to improve the different policies and program performance for each country according to its situation [13].

Access to vaccines and availability to certain groups

The access to affordable, high-quality vaccines is an important prerequisite for universal immunisation coverage. Unstable political and economic situations, as well as lack of primary health care, show a negative impact on access. Geopolitical and natural disasters are threatening the universal vaccination coverage, as shown in the unvaccinated population worldwide, mainly migrants, refugees and vulnerable groups such as First Nations People within the country.

Refugees play a central role in this for several reasons. According to the United Nations High Commissioner for Refugees (UNHCR), 68.5 million people, accounting for almost 1% of the global population, had to be displaced as a result of conflicts, violence and persecution in 2017 [13]. Unstable geopolitical situations also cause destruction of health systems, intimidation to national immunization systems, and a burden for countries taking in migrants and refugees.

Migrants and refugees lose the governmental protection and access to healthcare and the immunization program in many cases. Vulnerable groups within a country are not always protected by the government either, which leads to the unintended exception from vaccination due to a lack of resources. A recent study from Europe shows that immunization rates were lower in migrants and refugees than European-born individuals, mainly because of the short vaccination coverage from their homelands, appended by



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several risk factors owing to migration [14]. These risk factors include frequent changes in locations, overcrowding, lack of water, poor sanitation, and limited access to health care [15].

It is important to aim for a reduction of vaccine-preventable diseases (VPDs) with provision of highly required vaccines for maintenance of high immunization rates even for migrants, refugees, and other vulnerable groups. This applies especially to children with an immune system still in development and thus more susceptible for infectious diseases [16]. It was reported that 33.5% and 40.1% of Syrian refugees residing respectively in Jordan and Lebanon had difficulties in getting childhood vaccinations [17]. Venezuela experienced diphtheria outbreaks after 24 years of no case and is close to losing its measles elimination status due to the country's unstable socioeconomic situation [13]. Nevertheless, there are successful cases as well; Global support, provided by the Global Alliance for Vaccines and Immunization (GAVI), has helped Syria increase the DTP3 coverage from 6% to 48% in spite of having 60% of Syrian hospitals being rendered closed or non-functional [18]. Gavi is a public-private global health partnership that works on broader vaccination coverage for children in poor countries.

It is called for consistent global policies, securing public health even in emergency situations, and partnerships for the equitable access to immunization goods and services, tracking the immunization status with various, tailored models and appropriate vaccination education.

Vaccine hesitancy movement and education

Vaccine hesitancy is a complex term, defined by WHO as a “*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. It includes factors such as complacency, convenience and confidence.*” [19].

It shows that there are many reasons why certain people refuse or delay vaccination of themselves or their children. Vaccine hesitancy describes the middle ground of a “*continuum ranging from active demand for vaccines to complete refusal of all vaccines*” [20].

Vaccine hesitancy can be traced all the way back to the first discovery of vaccination. Motives for opposing vaccination were most often religious [21] in nature or rooted in distrust in physicians and medicine. Identical reasons can also be seen today.

WHO lists three main factors for vaccine hesitancy: complacency, convenience and confidence. People who reject vaccination due to complacency are thought to have a low perceived risk of vaccine-preventable diseases and deem vaccination not necessary. For them, other life/health issues are of a greater priority. Those whose main problem is lack of confidence have low levels of trust in vaccine efficacy and/or safety, the delivery system and health authorities in general. Convenience is a factor that mainly refers to those who suffer from inadequate accessibility, affordability, availability, and acceptability of services [19].

Reasons for vaccine hesitancy vary greatly and depend on time, region and type of vaccine. That is exactly why there is no single intervention that addresses all instances of vaccine hesitancy. Interventional methods such as dialogue and directly targeting specific under vaccinated groups, whose reasons for vaccine hesitancy are unified, has been proven to be most efficient [19].

The lack of confidence in vaccines is driven by a large spread of misinformation – for example out of 100 websites only 51% provided the correct information about the fact that no association has ever been demonstrated between MMR vaccination and autism [22] – and various socio-cultural characteristics [20]. Some people also have a complete misunderstanding of the immune system which can also result in vaccine hesitancy [20].

Education was proven to be an effective intervention since “*health workers remain the most trusted advisor and influencer of vaccination decisions*” [19]. This is a great responsibility that healthcare



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workers need to be conscious of. That is why special thought needs to be put into training them to communicate their message efficiently. Medical and epidemiological education should be evidence based, with a special focus on the delivery of the information as proper communication techniques are crucial for a physician to maintain their patients' trust [23].

While talking about dissatisfactory vaccination coverage we must not forget those who do not reject vaccination but still add to this statistic – those, who should have received their booster shots but have not due to a lack of information. It is important to note that some researchers found that “vaccine hesitancy was significantly associated with a higher level of education irrespective of the population sub-group” [24]. It was also suggested that modern ways of communication such as reminders via smartphones or tablets could be used to inform people of their waning immunity. Future vaccination strategies should therefore include regular and well-documented booster shots, e.g. against tetanus and diphtheria, throughout adulthood [25].

Regarding communication it has been, however, suggested for public health communicators to move beyond the information deficit model of communication and use new tools of communication, such as the use of social media, and to move from a reactive to a proactive stance [26].

Education is a crucial method for improving the public's perception of vaccination but it should be tailored specifically to the audience. Since reasons for vaccine hesitancy vary greatly, different tactics should be used – preferably such that address complacency, convenience and confidence and that take socio-cultural, historical and political context into consideration. An unlimited access to high quality vaccines is a major prerequisite.

Compulsory and Consigned vaccination

The recent measles outbreaks in developed countries have shed an alarming light on the coverage gaps in the vaccination programs [27]. A decreased coverage becomes a major problem, when the herd immunity threshold cannot be reached anymore and vulnerable populations are left unprotected.

Mandatory vaccination has been a well known public health measure in the past and is still used in several countries today [28]. It is defined as a vaccination that must be received by law, without giving the individual the possibility to choose and linked to law enforcement and legal consequences [29]. There is no standard approach for compulsory vaccination, it could be a highly flexible mandate to a rigid law changing from country to country with certain factors like the socioeconomic status and literacy ratios impacting these laws [30].

For some countries with rigid mandates like Australia and State of California penalties of financial kind have been set for vaccine exempted individuals [30]. Others have a relatively less rigid mandate with room to opt out of vaccination on conscientious grounds of ethical or philosophical nature, without any penalties. Whereas in some other countries only a proof of participation in an education program regarding immunization is required for exemption from vaccination programs, without any penalties or social restrictions

Although implemented in several countries, mandatory vaccination is discussed controversially in public health as the impact on vaccine coverage is not clear yet. First of all, mandatory vaccination seems to be an easy option to increase vaccine coverage short-term in order to protect vulnerable populations, who cannot get vaccinated themselves and are relying on herd immunity. With regard to the concept of vaccine hesitancy, mandatory is a strong measure to break complacency.[30]

On the other hand, mandatory vaccination provides no guarantees of achieving high uptake rates. In a European study no relationship between mandatory vaccination and rates of childhood immunization in the EU/EEA countries could be found. [29] Furthermore, mandates do not improve vaccine confidence,



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but they make opposition to vaccines even stronger. [30] The resulting anger can even lead to lower vaccine coverage rates. [31] This indicates that while being effective in decreasing complacency, mandates are not the right measure to increase trust in vaccination, as broader determinants of vaccine hesitancy are not addressed.

Many countries have systems where only some, but not all vaccines are compulsory. This bears the risk of a decrease in the vaccination coverage of the non-compulsory vaccine. Reasons are a reactance to the mandate [32] and the perception that non-compulsory vaccines might be less important.

Finally, mandatory vaccination are a very restrictive public health measure from a human rights perspective, limiting freedom of choice and autonomy. [33] A clear and strong indication should be present, when such measures are taken. Considering all these perspectives, it becomes apparent, that there is no universal solution. But any decision about a proposal for vaccines strategies, whether recommendations or mandates, should be elaborated in agreement with local contextual habits, the size of the problem the urgency of the situation and ethical considerations. A transparent decision-making process should be encouraged to ensure that the right measures for the situation are taken.

Quality of vaccines and handling process

Assuring the quality of vaccine production

While having access to vaccines themselves is important, this access is rendered futile unless the product inoculated has the adequate quality for the physiological response to arise as expected, and thus providing the desirable immunity. In order to assure this, we must focus on strengthening two areas: Good Manufacturing Practices (GMP) and Quality Control.

GMP encompasses the disposition of an appropriate facility compliant with all the established regulations and guidelines, have qualified and trained staff to perform the job, components and product tested through previous clinical trials, transparency on production methods and records. From the side of the quality control aspect, this is directed towards the more technical aspects of the chain of production [34,35].

However, both processes are not a responsibility exclusive to the vaccine manufacturers, but as well of the national authorities, who must establish a control entity for these kind of products. This entity should be suitable to perform auditing duties for all the previously mentioned components. Meaning that the personnel working in such a group must be equally qualified to understand and properly evaluate the suitability of a production process, while at the same time being interdisciplinary enough to integrally evaluate the process from different angles. On the other hand, this national regulation organism must be in charge of running audits on these manufacturers, while also serving as database of all the documentation regarding the production of a vaccine, that might serve to empower action for or against a product to safeguard the consumers [36].

Good vaccine handling practices

We have two main types of vaccines when it comes down to handling them: those that remain stable in heat but are affected by cold, and those resistant to cold but affected by heat. For these last ones when we think of their handling, we think immediately of the famed "Cold chain". According to the resources of every country, the problems that might arise in this sense are diverse. Let it be because of administrative or technological issues, or both. We have to keep in mind that when we think of vaccine cold chain issues we might be tempted to solely focus on what's lacking or missing within that national system, yet to be able to properly evaluate and offer solutions, we have an integral view, by example, by also searching for issues regarding misuse or faulty protocol [37].

This said, issues do Cold chains face that we must attend to include [37]:

1. Increasing knowledge on vaccine stability to find the most reliable temperature parameters.



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2. Developing vaccines that are more stable and thus preserve their effectiveness in a wider temperature range.
3. Open access to vaccine temperature sensibility research.
4. Periodic international and national vaccine handling protocol/guideline review.
5. Improve temperature control in transport units. Specially, attempting to avoid extreme cold temperatures for vaccine storage, as freezing can also rend vaccines ineffective.
6. Appropriate capacity building for all the staff that is involved in the vaccine transport chain.
7. Continued use of ice instead of cool-water packs for vaccine in-country transport in LMIC.
8. Adoption of out-of-chain vaccine use policies for mass immunization events.
9. Reducing human error through staff training.

This allows us to realize that the improvement of this situation focuses mainly in two areas: propulse innovative vaccine development in their R&D stage, and establish a solid national network of vaccine services management. Integrated, they both empower the effort to provide products that are of easier distribution and handling. By letting themselves to be transported easier across the different environments, an augment of vaccine coverage by being able to bring them to the door of new communities.

Research in the field of vaccination

Investigation and research have a crucial role in raising knowledge of the microorganisms' cycle and their progression. The understanding of infectious agents and their interaction with the host immune system are aspects of the biological development that support the vaccines' enhancement. This knowledge leads to a more efficient and faster identification and, consequently, to a proper evaluation of the innovative measures that we ought to use and perform in order to ensure an acceptable coverage regarding vaccines and immunization [13].

Currently, R&D resources are focused on those vaccine-preventable diseases, that reflect a significant global burden including TB, malaria or HIV/AIDS. Apart from the vaccines themselves, there are active studies found on the circulation of the vaccines, such as an earlier diagnostic tools, delivery system, and broader technological uses. These high-tech innovations offer the prospect of "more convenient, safer and people-friendly" on the delivery process. As a matter of fact, WHO's lately Assessment Report of the Global Vaccines Action Plan, stated that the "R&D indicators that are mostly on track are HIV/AIDS, TB, Malaria, Universal Influenza, New Vaccines for Priority Infections and Platform Delivery Technology" [13]. Concreterly, pilot runs for malaria vaccine have shown encouraging results [38], whereas RV144 trials in HIV have afforded us with some semblance of efficacious protection against the disease [39].

Another point worth taking into consideration is emerging growth of R&D industry and manufacturing capacity in low- and middle- income countries thereby contributing to their economic and financial development and also promoting research leadership [13]. Without leaving this apart, performing research in partnership with representative and minority populations who are disproportionately affected is crucial for the healthy development of the industry. Immunization it's one of the most profitable prevention measure and the settlement of vaccine trials being conducted in these countries is challenging but worthwhile as these vaccines could be directly used there leading to a great impact because of its implementation [40].

In addition, vaccines function as a preventive measure to antimicrobial resistance (AMR). Indeed, an increased coverage of vaccines could reduce antibiotic usage, a 47% of reduction, to be precise [41]. Concretely, a 2011 study performed in the US reported that "the use of such vaccines led to a 64 percent reduction in antibiotic-resistant pneumococcal infections among children and a 45 percent decrease among adults over 65 years of age" [42].



Although the cost of the vaccines vary and oscillate depending on the quality and quantity of the availability of those products needed, vaccines programmes have been, historically, the most cost-effective health intervention. The Review Antimicrobial Resistance suggests that vaccines saved more than 100 million childhood lives and shown effects 10 times more than what they originally cost. However, those relevant vaccines regarding AMR are more complex and expensive to develop and their target population is smaller [41].

Cooperatively, the approaches mentioned above ensure and confirm the accurate and meticulous evidence-based of the immunization discipline taking into account the study design considerations in order to reveal which mechanisms are to play and how investigation and research can be boosted [41,43].

Interprofessional collaboration

For the elimination of vaccine-preventable diseases, the focus should not only be on human vaccination. Diseases with animal-reservoirs may require a more inclusive “one health” approach. Rabies, for example, is a disease responsible for about 59,000 human deaths and over 3.7 millions DALYs lost per year [44]. Up to 99% of human cases are transmitted by dogs. Therefore mass vaccination campaigns targeting dogs are the main strategy of rabies control nowadays [45]. However, it is not sufficient on its own and human vaccination is still required. This shows the huge need for collaboration between medical and veterinary sectors in order to prevent the unnecessary burden of rabies, as well as other infectious diseases transmitted by animals.

Interprofessional collaboration may also be needed to push back vaccine hesitancy and complacency. Offering pharmacists the option to deliver adult vaccination has shown an increase in vaccine uptake in several countries [46]. The effect is notable through reaching under-vaccinated populations [47], as well as greater engagement with public health messaging and immunisation advocacy [46]. Increased collaboration with pharmacists and pharmaceutical students, including adequate training, may help to increase vaccination coverage and public trust.

Finally, to maximise the success of vaccination programmes a joint effort between different disciplines including clinicians, public health doctors, epidemiologists and policy makers is inevitable [49].

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