

**HUMANITARIAN &
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VACCINES: QUESTIONING OUR SUPER HEROES

By

Dr Anne SENEQUIER

ASSOCIATE RESEARCH FELLOW AT IRIS

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« GLOBAL HEALTH » THINK TANK



To ask ourselves of the legitimacy of vaccines is a problem of the rich. We are 'rich' because our children are no longer paralysed by polio, because they no longer die of pertussis, diphtheria or measles. We have forgotten all of these childhood diseases. Society has forgotten them. One no longer knows what it is to have a child who died of diarrhea, another from a scratch on a rusty nail. We have forgotten what it is to have five, six or even seven children and to only see two survive by the age of five years. In the West, we have forgotten because our children have been vaccinated for several decades. This is not the case for everyone. Today and every year, 1.7 million children die from diseases that could have been prevented had they been vaccinated¹.

Testaments of 'children ill after being vaccinated' that we've all read, seen and heard. Stories that force out a tear from each parent's eye and fuel the initial doubts. Who of us isn't worried about our children? However, nothing in these testimonies would allow me take a stand and confirm the link between vaccines and illness. There is nothing else to say on the topic. We must start from the idea that in 2017 - and for a long time - our medical knowledge is far from exhaustive and nothing is set in stone. Questioning and questioning is necessary to enable us to move forward, to understand that bleeding in order to balance our mood does not make us healthy, or more recently that the 'Mediator' was not the miracle drug that it claimed to be. But we must be careful - the debate that hangs over an adjuvant should not call into question the very principle of vaccination.

WHAT IS VACCINATION, AND HOW DOES IT WORK?

Immunisation is essentially educating the immune system, a first encounter with a 'diminished' version of the infectious agent so that our white blood cells know how to react when they encounter the actual virus/bacteria for which we have been vaccinated.

Physiologically speaking, there are two types of vaccines²:

- 'Live attenuated vaccines', which are live organisms, but 'diminished'. It is most often a version that does not know how to defend itself against our immune system.
- 'Inactivated vaccines' (such as tetanus) that do not contain live infectious agents, but rather a piece of its cell wall. This will allow our immune system to know the infectious agent without really having encountered it.

¹ UNICEF accessed on 4th July 2017: 'Know how to save' 4th edition.
<https://www.unicef.org/french/ffl/pdf/factsforlife-fr-part7.pdf>

² <http://vaccination-info-service.fr>

IMMUNISATION: THE PILLAR OF PUBLIC HEALTH, THE PRINCIPLE OF HERD IMMUNITY AND ITS LIMITATIONS

The primary purpose of vaccination is to protect the individual however vaccination also has a positive effect on the community as it reduces the number of potential carriers and thus protects vulnerable people who cannot be vaccinated - children who are too young or those who are too fragile. Vaccinated persons form a rampart preventing the spread of the disease among the population. However, the greater the number of those unvaccinated, the less effective the rampart.

In the case of measles and considering its contagiousness (one patient can contaminate up to 15 people), the immunisation coverage in the population must be at least 95% to confer immunity to groups who can not get vaccinated or those for whom it did not work (5% of those vaccinated). This explains why, by refusing to vaccinate, you endanger yourself (in terms of your health), but also that of others. This is what happened in the late 2000s in Europe, notably in France. 75% vaccination coverage resulted in 20,000 cases of measles, 5000 hospitalisations, 1023 pulmonary complications, 27 neurological cases and 10 deaths (9 of which were under the age of 30), while only 40 cases had been reported in the previous year.

On the other hand, there are illnesses that are not contagious, and yet they are endemic in our environment - tetanus for example. In this case, herd immunity is pointless and therefore will not protect you from a possible *Clostridium tetani* infection. Thus, the need for vaccination is even greater.

WHY ARE SOME VACCINES 'MANDATORY' WHILST OTHERS ARE ONLY 'RECOMMENDED'?

The distinction between 'mandatory/recommended' vaccines instils doubt and confusion in people's minds. 'Recommended' was mistakenly understood as 'optional' when they are actually indispensable.

In France, the diphtheria vaccine has been mandatory since 1938, tetanus since 1940 and poliomyelitis since 1964, three decisions made in order to definitively eradicate these disabling or even fatal diseases, considered at the time as health-related plagues. The requirement made it possible to make these vaccines accessible to all, and thus to disallow social considerations that impede access to health for all. ('Access to health', by the way, is the challenge of global health in the 21st century).

In recent years, the Ministry of Health has considered extending this immunisation requirement to other vaccines. The new French Minister Dr. Buzyn is considering a number of compulsory vaccines - DTP, pertussis, measles, mumps, rubella, hepatitis B, Haemophilus influenzae bacteria, pneumococcus, meningococcus C. Today the 3 compulsory vaccines (DTP: Diphtheria, Tetanus, Polio) are no longer available on the French market. DTP is now part of a penta or hexavalent vaccine, which means that it is combined with other vaccines. This avoids increasing numbers of plasters stuck on children, and improves the stability of the DTP vaccine which was unstable in its trivalent form. However, this also leads to some inconsistencies insofar as under the obligation of DTP vaccination, the vaccine against Haemophilus influenzae, hepatitis B and pertussis is imposed. It should be noted that this semantic confusion (mandatory/recommended) leads mainly to legal problems, insofar as any adverse events following immunisation (AEFI) are managed and recognised for mandatory vaccinations. However this is not the case for recommended vaccinations. The result becomes legal battles to determine responsibility for these AEFIs in the case of combined/mandatory/recommended vaccinations.

With regards to this list of 11 vaccines selected to become mandatory, it should be noted that, with one exception, it includes the list of vaccinations that are 'recommended by the WHO'³ revised in March 2017.

But why such force? Because of the distrust of vaccination. The high-cost vaccination campaigns, hepatitis B vaccine failures that are largely out-of-target, excessive costs and profits, long-term eradication (polio). In short, we no longer trust in them.

The estimate for the additional vaccines in the list of compulsory vaccines in France is between 10 and 20 million euros per year for social security. But how much would the care of patients cost having contracted measles, pertussis, mumps, Hepatitis B, Haemophilus influenzae, meningococcus in the same time interval? Undoubtedly well over 20 million euros per year. The problem of vaccination is not a problem of money, it will always be more cost-effective to vaccinate than to pay for the price of healthcare. A hepatitis B vaccine for an adult is at €17.01 whilst the price of a 'liver transplant' package is €86,896.94 at the APHP - hospitals of Paris.

PROBLEMS, FALSE RUMORS OR A REAL DEBATE

False rumors and erroneous beliefs are real barriers to public and individual health. During the last Ebola epidemic, false beliefs (amongst others things) were at the root of the outbreak that brought the number of cases to around 20,000 whilst the previous ones

³ WHO website accessed on 7th July 2017 http://www.who.int/immunization/policy/immunization_tables/en/

didn't even get to 400. In 2003, a rumour spread in Nigeria that the polio vaccine was causing HIV and making girls infertile⁴. The vaccination campaign couldn't reach its goal due to the reluctance of the population and the authorities. In the years that followed, polio cases have exploded in Nigeria, when Africa was about to be declared polio-free by WHO.

Today more than 40% of French people have an unfavourable opinion towards vaccination. As noted above, some health policy decisions have not helped. As a result of this, and catalysed by certain questions, especially about adjuvants, our vaccination coverage remains poor.

The adjuvant is a facilitator of the immune response to vaccination. It presents the pathogen to the immune system, it is the support to the vaccine. Each vaccine has a specific adjuvant. The question today is about Aluminium (an adjuvant in certain vaccines) and its implication in the appearance of MMF: 'macrophagic myofasciitis', a histological lesion found at the injection site of the vaccine in the deltoid muscle that could cause other illnesses.

On searching for 'macrophagic myofasciitis' (MMF) on PubMed (the search engine for scientific papers) there are 98 results including 34 papers of one particular French group at the origin of the debate on the aluminium adjuvants, which cite their own work in their references. Among the 64 other published research, numerous papers cite in their references the work of this same French group. Whether the injection of a vaccine containing an aluminium adjuvant causes a granuloma is not a fact contested by the scientific community and by the health authorities. This has been looked at by the WHO Advisory Committee on Vaccine Safety (GACVS), but nothing in this data has led to the conclusion that there is an association between the histological lesion and a specific illness. In the face of doubt, a 'case-control' study by the French Health Products Safety Agency (AFSSAPS) and the French Institute for Public Health Surveillance (InVs) was carried out a few years later to come to the same conclusion. In 2015, a HAS⁵ report again came to recognise the link between vaccinations and the presence of granulomas in muscles containing aluminium (the histological lesion), whilst highlighting several shortcomings in the methodology of the studies, which confirms causality between the clinical signs reported by the patients and the presence of MMF - this de facto invalidates the conclusion of these same studies. All the more so because the fascinating thing about macrophagic myofasciitis that it is apparently a purely French disease, since France makes up almost all the cases listed.

⁴ WHO website (World Health Organization) accessed 04 July 2017
http://www.who.int/vaccine_safety/committee/reports/october_1999/en/

⁵ Health authority 'Aluminum and vaccines'

The debate is blown up when discussing the cerebral toxicity of aluminium (Al). The neurological toxicity of aluminium has been a known fact (for a long time), prompting the WHO and FDA (Food and Drug Association) to establish an acceptable toxicological threshold set at 1mg/kg/day. A vaccine contains 0.85 mg of Al per dose. Moreover, the neurological toxicity of aluminium is responsible for clinical manifestations distinct from those described as associated with MMF. The same controversy about aluminium is now found in the debate about the use of it in of antiperspirants (containing aluminium salts) in the onset of breast cancer.

Ultimately, the debate between vaccinations/illnesses caused by vaccination is not so much in the medical world, but on the Internet where the hounds are released. Let us remember: 98 results on PubMed compared to 19,500 results on Google. More and more results from 'Round-up in Vaccines' stories, websites that lie about the WHO recommendations, which, to date, recommend that vaccine practices should not be changed⁶ if they contain aluminium, or some people who, in order to remain in good health, propose to close borders to immigration rather than make vaccines mandatory. Let us recall, in this vein, what happened to the Andean civilizations when they first met the conquistadors/smallpox. It is a safe bet that prior sharing of a small-dose pathogen would have changed the course of history.

MMF is not the only burden of immunization today; we are talking about multiple sclerosis (MS), autism, and infertility. What is it about really?

Autism and the MMR (Measles-Mumps-Rubella) vaccine? The physician author of this 'cause-effect relationship' discovery was found guilty of falsifying his data. His article published by The Lancet (the world's leading medical journal) was removed from the publication after the release of several independent studies proving opposite results. However, the rate of MMR vaccination has dropped, leading to an outbreak of measles/mumps/rubella cases in the 2000s, the epidemic of measles in Europe in the late 2000s.

As for autism, two things to clarify:

- Its incidence did not decline following the decrease in vaccination via the MMR
- As of 2017, the actual causes of autism are still unexplained.

The link between multiple sclerosis and hepatitis B has been established by a study on a 'population at risk', with very little included in the study. General population studies found 5 reported cases of MS among the 270,000 vaccinated between 1992 and 1998, and

⁶ WHO website (World Health Organization) accessed 04 July 2017
http://www.who.int/vaccine_safety/committee/reports/october_1999/en/

nine out of the unvaccinated 290,000. It is true that some studies find an increase in the number of MS diagnostics in the 1990s. However, the arrival of the MRI in the therapeutic arsenal in the mid-1990s, as well as the advent of interferon will bias any argument of temporality.

However, adverse events following immunisation that can harm the health of a healthy individual should not be taken lightly. At an international level, WHO has set up a Global Advisory Committee on Vaccine Safety, an entity that is also present at national level. The stories of problems with vaccines are not limited to adjuvants, MS, autism or mercury poisoning. To tell the truth, in the history of vaccination, the biggest tragedies occurred after poor vaccine manufacture. Polio vaccines that have resulted in hundreds of cases of paralysis in the US in the 20th century, and other aberrations of the same level. Despite all this, the doubts shared by some, the mistakes made by others - and while it is true that only one case of serious damage due to a vaccine is always one case too many, the risk-benefit analysis is always in favour of vaccination.

WHY DO WE NOT DO CAUSE AND EFFECT STUDIES?

The team supporting the issue of the AI-MMF causal link reported in an interview with France Culture that the number of adverse events following immunisation (AEFI) accounted for 0.5% of the vaccines, having also complained of their lack of funding for research. And whilst it is true that 0.5% AEFI is still something, the trouble is that this is not the only problem. And it has been understood that the funds allocated to research and health in general are limited. Public health at the international level is setting priorities. It is necessary to manage the multiple and varied problems with a limited budget, such as (amongst others of course):

- Tobacco kills 6 million people a year,
- Non-communicable diseases (diabetes, cardiovascular disease, cancer, chronic respiratory disease), which account for 63% of deaths worldwide,
- The fight against parasitic diseases (half of the world is exposed to malaria, with 212 million cases each year and nearly 430,000 deaths);
- The fight against neonatal and infant mortality
- To create an amended and comprehensive care of the elderly population
- The HIV epidemic (36.7 million people are currently living with HIV, only 18.2 million are on antiretroviral therapy),
- More than one and a half billion overweight adults
- Depression: 300 million people affected.

- Suicide, 1 death every 40 seconds worldwide (suicide causes more deaths than wars and homicides combined),
- Road accidents that cost most countries, 3% of their GDP,
- Abortion: 22 million unsafe abortions per year worldwide. Not everyone has the chance to have a Mrs. Veil in their country.
- Antibiotic resistance which forces us to think of a post-ATB (antibiotic) era and urgently pushes us to find an alternative to ATB (wherein lies the interest of vaccination)
- Influenza that recurs regularly...

In an ideal world, we would stop making and buying weapons and then maybe we would have the money to carry out all these studies and research. But even in these cases, funding would be allocated to studies that answer to certain methodological criteria, avoiding the biases of selection and interpretation, based on verified, verifiable and reproducible facts, which have so far missed the studies affirming a link between MMF and illness. However, it would be wise to finance these studies anyway, simply because Paris is well worth a Mass...

HOW IS IT ELSEWHERE?

Elsewhere, the systems differ. Some have no required vaccination; others do as a result of the history of their healthcare and recently political movements. However, all of them are simply trying to reduce infant mortality. This is the third Sustainable Development Goal: 'good health and well-being' led by the United Nations. By 2030, eliminate preventable deaths of newborns and children under the age of 5.

- Seek to reduce neonatal mortality to no more than 12 per 1,000 live births and under-5 mortality to 25 per 1,000 live births at most.
- Two regions of the world have not yet achieved this objective. Asia with 34% is close to the target, especially since it had an infant mortality rate of 87% in 1990. The African region starts higher, with a mortality rate of 164% in 1990s reduced to 76% by 2015.

To support each health actor (professional and government) with this common goal, WHO and UNICEF through the IMCI (Integrated Management of Childhood Illness) propose simple and effective methods to prevent and the major causes of serious illness and mortality in young children. Three pillars support this initiative: hygiene, proper use of

medicines and immunisation which alone would give a chance at life to 1.7 million children each year.

In order for a vaccination campaign to work, a functioning health system is needed and a budgetary priority issue is brought into play. In many states, even today, health is considered a cost that one cannot afford. No budget, no medicines, no cold chain, no professional trained correctly, no awareness of the population to health, which brings about insufficient vaccination coverage. In view of globalisation, and the movement of people, we can no longer consider health as a personal concept, it is time to embrace also its more global notion: public health, herd health in order to protect individual health. To take but one example: measles has been eradicated from the Americas, should they stop vaccinating after all that effort? How many tourists/students/professionals from the Americas come to Europe each year where measles is still present? How many foreigners embark upon the American continent each year? Suffice to say that maintaining this eradication is utopian and we do not make any effort on this side of the pond.

WHAT ABOUT THE FUTURE?

The recurrence of known and recognised epidemics of diseases (measles in Europe, poliomyelitis in Syria in May 2017), the geographical spread of certain viruses and the appearance of new viruses (influenza A) re-emphasise the case for vaccination in the fight against infectious diseases.

In addition to this traditional purpose, and indirect purposes, vaccination also plays an important role in the prevention of many public health problems such as antibiotic resistance (ATB), infertility, and some cancers. Additionally, the vaccination of respiratory pathologies (pneumococcus) de facto avoids the use of ATBs, which increase the resistance of bacteria to ATB. The human papillomavirus HPV vaccine avoids the cancerous lesions of the genital tract and some of the fertility disorders that may result. Same for cirrhosis and liver cancer resulting from hepatitis B.

The vaccine of tomorrow needs to be therapeutic, and could eventually teach the immune system, that we've already reached, to get rid of certain cancers (melanomas) or AIDS.

'OBLIGATION TO VACCINATE' - WILL THIS BE ENOUGH?

What can be done to lessen the French (and other nations citizens') mistrust of vaccination? The obligation is a measure designed to respond to an emergency. Yes, we are in an emergency situation, as it is because of immunisation coverage of measles, the

current rate is the same⁷ as the 2008 rate at the beginning of the epidemic, which caused 20,000 cases. This requirement is a short-term solution and has the disadvantage of increasing the suspicion of the populations as much towards the health authorities as the vaccine industry in general.

Focusing on the prices of so-called 'essential/indispensable' vaccines is good, sometimes essential, but also to understand that even if the estimated turnover of the vaccine industry in 2016 is €42.3 billion, it is not adequate to say that 'these compulsory vaccinations are a gift for the pharmaceutical industries'. The global market for the drug is estimated at €800 billion. Ultimately, vaccine sales represent only 5.2% of the total turnover of the drug industry, not enough to make it a spearhead of an industry, unlike diabetes and anti-cholesterol medications, which rank among the ten best-selling products in the world. Perhaps it is us who gives this 'gift' to the pharmaceutical industries.

In terms of this suspicion towards vaccines, and from a strictly epidemiological point of view, the extension of the mandatory vaccination is coherent insofar as it will prevent the recurrence of an epidemic due to immunisation coverage that is currently too low. It is therefore to protect the population (sometimes in spite of itself), which is the main message of this measure. An understandable arrangement, which acceptable only on the condition that we do not stop here. This obligation must be the cornerstone of a larger, longer-term building that aims to regain the trust of the population and health workers (not spared by doubt). A multi-sectorial and comprehensive approach involving government, media, health actors and civil society. Health is not a due, it is not a cost either, it is a common goal or individual and collective must work hand in hand.

In order to ensure that in a few years this obligation can be lifted without the vaccination rate suffering, it would only be right to rely on a better health awareness so that subsequent communications are welcomed and above all understood.

- First and foremost, there is now an urgent need to respond to the public's concerns about vaccines, adjuvants, AEFIs, success rates, persistent questions and vaccine failures, so as not to let the doubt settle in. We must go further than three posters and a postcard on the vaccination calendar⁸. Restore mutual trust, and not let Google answer questions that first should be addressed to health authorities and which often remain unanswered. Why not set up a seat for representatives of civil society in the various health committees, so that the communication routes are twofold and transparent.

⁷ at around 1%

⁸ "Let's mobilise for vaccination" <http://inpes.santepubliquefrance.fr/70000/dp/11/dp110422-b.pdf>

- Communication on the how health authorities function at national level would also be interesting - how are the decisions made? On what criteria? Who finances the health authorities? How are research and development funded? What is epidemiology?
- Strengthen the knowledge of primary care physicians. Communicate on a regular basis with a clear and simple message about investigations and investigative findings about adverse events such as aluminium adjuvant, autism and MMR vaccine, MS, Hepatitis B and all other problems. Even today, a large majority of them are not able to answer questions from patients about vaccination.
- Restore health education to the population through schooling. Modern and age-appropriate communication using social media and traditional media. A 'medical adventure' (TV show) on vaccines would not be inappropriate, a realistic medical television series (miniseries after the 8 'clock news/others programmes) that is 'made in France'. It is time to think of innovative communications.

Many ideas are to be put in place; the national critical thinking is a good thing and allows everyone to move forward. It is time to use this same spirit to foresee a new dynamic for our common goal: To live in good health until old age. The path is still long. We are still waiting for a vaccine against malaria, tuberculosis and AIDS (among others) which would avoid nearly 4 million child deaths each year. ■

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« GLOBAL HEALTH » THINK TANK

Directed by Nathalie ERNOULT and Dr Anne SÉNÉQUIER
ernoult@iris-france.org – senequier@iris-france.org

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Directed by Michel MAIETTA, Senior Research Fellow at IRIS
maietta@iris-france.org

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INSTITUT DE RELATIONS INTERNATIONALES ET STRATÉGIQUES
2 bis rue Mercoeur
75011 PARIS / France

T. + 33 (0) 1 53 27 60 60
contact@iris-france.org
@InstitutIRIS

www.iris-france.org