

## REPORT DIPHTHERIA IN SPAIN DURING THE PERIOD 1901 – 2015

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### Introduction

The tragic incident that took place in June 2015 at Olot (Gerona) concerning the regrettable death of a child diagnosed with diphtheria, makes necessary a professional update of the epidemiologic situation of diphtheria in Spain by the medical professionals of LLV .

In this article the microbiological characteristics of the *Corynebacterium Diphthericum* will be held against the light of the most recent information.

First of all and based on the available official data it the evolution of the epidemic of diphtheria in Spain during 113 years will be shown, before and after the introduction of the vaccine.

Secondly the composition of the anti-diphtheria vaccine is described according to the information given by the Pharmaceutical Industry after 2011.

Finally a calculation is done of the population that has suffered and still suffers the detrimental effects of the anti-diphtheria vaccine. This calculation is based on official publications of the Agency of Pharmacy Vigilance of Spain and other countries.

### *Microbiology of Corynebacterium and life circumstances of the population.*

*Corynebacterium*, from the Greek 'koriné' club and 'bacterium' stick (1), is an extremely divers Group of bacteria Gram +, pleomorph living in aerobic as well as anaerobic environments depending on the surrounding circumstances.

This means that it can live in an environment that is rich in oxygen as well as in an environment without oxygen and it has the capacity to change its shape according to its needs, transforming the bacillus into other microorganisms.

It belongs to the kingdom of Eubacteria and is related to *Clostridium*, *Streptococcus*, *Lactobacillus*, *Staphylococcus*, *Microplasm*, *Actinomycetes*, *Streptomyces*, *Bifid bacterium*, *Nocardia mycobacterium*. It inhabits the earth, air, mucous membranes and skin.

Together with other bacteria, fungus and viruses it constitutes the so called saprophytic flora (2) that inhabits the human organism, performing functions as interesting as the synthesis of vitamins K, B12, B9, B3, Lactic and acetic acid and microbicides substances (bacteriocins). It prevents the colonization of other germs and stimulates immunity (3). There are many families of *Corynebacterium* inhabiting our body such as *bovis*, *mutissim*, *hoffami*, *striatum*, *jeikeim*, *xerosis*, *renalis*, *pseudodiphthericum*, *diphtheria*, etc., and this happens without causing any infection.

Its pleomorphic (4) capacity allows it to pass from being a stick bacillus to a coccoid bacterium (*staphylococcus*, *streptococcus*, *meningococcus*, *pneumococcus*, etc) depending on the life conditions of every person.

Its presence does not mean that the persons are carriers of the diphtheria disease but that it lives in symbiosis where it has a cooperative function.

Corynebacterium and specifically the diphtheria can only become parasitary or pathogenic if they undergo a modification in their DNA or genetic material. This happens through a phage (new DNA information is incorporated to the genetic material of the bacillus) and as a reaction to this phenomenon the bacterium synthesizes the exotoxin. Any extreme situation stimulates the bacillus to change its genetic material and generate new bacterial activity, in this case lethal.

This change often occurs in life situations such as famine, the presence of some amount of iron, antibiotics, radiations, indiscriminate vaccination campaigns, the use of corticoids and immuno-supresors, surgery, stress (5).

When one of these special life conditions occur, Corynebacterium manufactures a protein or exotoxin with 535 aminoacids which stick to the cells of the organism interfering with the RNA activity and the capacity of protein synthesis of the own bodily cell.

This toxin is only produced when the bacillus changes its genetic information. If this does not happen the Corynebacterium diphtheria will not product such a toxin and just inhabit the body in a symbiotic manner without harming our organism.

#### EPIDEMIOLOGY OF DIPHTERIA IN SPAIN

It is very important that the reader will not believe anything said in this rapport, or others by the matter, if the information cannot be verified by himself. We encourage you to follow the links we offer and check for yourself the truth of our statements.

If you get in your hands an official study but cannot verify the data it is based on, most probably the study has been manipulated. It is advisable not to believe it until you can check the presented data.

To avoid the slight suspicion we base ourselves on official data.

In fact the same data theoretically used to defend the goodness of this vaccine.

#### MORTALITY AND MORBILITY OF DIPHTERIA IN SPAIN 1901-2015

In 1901 the number of mortalities was 6.299,

In 1937 = 1773.

In 1940 = 3.169,

In 1945 = 642

In 1950 = 587

In 1952 = 297

In 1964 = 81

In 1965 = 56

In 1972 = 6

In 1973 = 3

In 1974 = 4

In 1975 = 1

In 1976 = 5

In 1977 = 3

In 1978 = 2=

**In 1979= 1**

**In 1981-82 = 0**

**In 1983-84 = 1**

**In 1987 = 1**

In 1940 we observe an important increment of diphtheria casualties due to post-war conditions such as famine, economical blockade and stress.

There had not been casualties from diphtheria in Spain since 28 years.

According to the data available on the region of Catalonia we see that during the period 1951 – 1988 there were 20 casualties, 2 in 1972 and none in 1973.

In June 2015 there was 1 casualty.

Regarding the morbidity (cases in which the disease fully develops) of diphtheria in Spain these are the numbers:

In 1901 = 60000 persons

In 1950 = 4.741

In 1960 = 1.841

In 1964 = 1.700

In 1980 = 7

In 1983 = 0

In 1997 = 3

In 1998 = 2

In 2015 = 1

Regarding the mortality due to diphtheria in Spain, we have the following chart of the Ministry of Health:

<http://gesdoc.isciii.es/gesdoccontroller?action=download&id=19/10/2012-3c0cfd4ca3> page 116.

The graphics, published in the same document (the red arrow marking the start of massive vaccination in 1965 is by us).

Observe the tendency. It is difficult to say that the disease decreased thanks to the vaccine but.....they say it and repeat it a thousand times.

Since in 1965 the number of cases was so low that it seems it is 0, we will amplify it with a graphic after 1950:

The arrow indicates the beginning of the massive vaccination. The mortality tendency, even after the introduction of DTP continued to descend.

Check all the data.

It seems too little, we can see the coverage of the vaccine or the real percentages of vaccination in the period 1945-1973.

The reference is the before mentioned document.

The diphtheria vaccine was firstly introduced in Spain in 1945.

At that time and without the vaccine, the mortality rate from diphtheria between the Spanish population had gone down by a 98, 7% and morbidity to a 97, 2%.

In 1950 a number of 104.616 single doses of the diphtheria vaccine were introduced in Spain to children aged between 0-3 years. At that time the children population was 1.350.000 approximately.

The introduction of the vaccine, according to the calculations done covered **7, 7% of** the population. This figure is not sufficient to be considered a good degree of protection.

The official vaccinology considers a sufficient vaccinal coverage to be found between 50-80%.

In the year 1965 a number of 1.500.000 doses of diphtheria combined with DTP

(diphtheria, tetanus and pertussis) were given in 2 doses to children aged 0-3 years.

Taking into consideration that the complete vaccination at that time consisted of 2 doses and that the infantile population was 1.500.000, the results are that the number of vaccinated persons was 750.000.

This meant vaccination coverage of around 50% of the population. After 1945 the vaccination coverage for diphtheria was progressively increasing from the initial 7,7% to 50% in 1965 to 80% in 1984 and to 94% in 2015.

These days it is being repetitively said that there had not been cases of diphtheria in Spain since 1987. You may find it here for instance:

[http://ccaa.elpais.com/ccaa/2015/06/02/catalunya/1433255972\\_743084.html](http://ccaa.elpais.com/ccaa/2015/06/02/catalunya/1433255972_743084.html)

But on the webpage of the WHO to whom this and other diseases in the world have to be declared it is revealed that in 1997 there were 3 cases of diphtheria, and 2 other in 1998.

Look it up here:

[http://apps.who.int/immunization\\_monitoring/globalsummary/incidences?c=ESP](http://apps.who.int/immunization_monitoring/globalsummary/incidences?c=ESP)

The Spanish health administration did not make them public, unlike the case in Olot, we wonder why? On June 22<sup>nd</sup>, 2015 we asked to the Ministry of Health by electronic mail if the cases of 1997 and 1998 were of vaccinated persons or not but until now, July 12<sup>th</sup> no answer has been received.

One could think that the reason to not make it public was that they were vaccinated. We hope it is only an error of the health system of this country and not a manipulation of data due to the necessity of not making public data that could bring any doubt to the infallibility of the recommended vaccines. Needless to say vaccines that in occasions can produce unwanted effects, like provoking the infection it is meant to fight.

## HISTORY OF THE DIPHTHERIA VACCINATION

During the 17<sup>th</sup> and 18<sup>th</sup> century numerous authors made descriptions more or less detailed of the disease, but it was Bretonneau who in 1826 accomplished the final description of diphtheria.

Klebs was the first to describe the diphtheric bacillus in 1883 and associated it to the disease.

Löeffler was the first to achieve the cultivation of the bacillus and to differentiate it from others.

In 1901 Behring was awarded the Nobel Prize for the discovery of the antidiphtheric serum. Already in 1860 the serum disease had been described as a consequence of the use of the smallpox serum.

During the decade of the 1920's Ramon and Glenny found an effective method to detoxify the diphtheria toxin with formaldehyde and heat, opening up the pathway of the antidiphtheric vaccination by way of toxoids or anatoxines.

In 1930 the reaction of Arthur caused by serums and vaccines was described.

In 1951 Freeman described the bacteriophage role and toxigenicity of the diphtheric bacillus and it was in 1973 when Pappenheim described the mechanisms by which the toxin inhibits the protein synthesis.

Germany begins to use the vaccination in 1929, France between 1930-1931 and Spain in 1945.

During the pre-vaccination era, before 1929, immunity was acquired through a natural way by suffering the infection, subclinical or clinic, during periods of high incidence of the disease. This immunity was lasting and it applied to all countries, industrialized or not.

At that time the majority of newborns, about 80%, were already protected with passive antibodies that were passed on through the mother. This passive immunity would

decrease in time to give way to the immunity actively acquired after exposure to the bacillus. This way the natural protection ascended from 15% to 80%.

This happened not only in European countries but also Americans, Asians, Australian and African.

It is curious to observe that in African countries the manifestation of the infection with diphtheria was not in the respiratory system but on the skin, specifically shown as impetigo (staphylococcus).

After 1929 when the diphtheria vaccination was massively implemented and the epidemics descended the pattern of acquisition of immunity was progressively changing. With the descent of the diphtheritic infection the presence of the bacillus in our body Diminished but the natural immunity within the world population lasted.

When studying the natural seroprotection it is common to find a minimum of 20% of the population to be positive to the diphtheria bacillus.

With the massively amplified vaccination programmes it was observed, contrary than expected, that the artificial immunity produced by the vaccine descended.

And so the population aged between 25-54 of Spain, Germany, Japan, Poland, Italy, Australia and the USA presented a postvaccinal protection inferior to 30%.

This was due to the short memory induced by the vaccine.

Now days it is considered that this memory can last between 1-8 years (6).

That means that to consider a population with an excellent protection or immunity the group should be vaccinated every 8 years.

#### THE DIPHTHERIA VACCINE

It is a vaccine on a base of toxoids or anatoxines, not containing the Corynebacterium and with the purpose to avoid the bacillus will **not** synthesize harmful toxins for the organism (7).

From the start in 1929 the purpose with this vaccine was not to neutralize the circulating vines or to act on the supposed carriers.

Already since it began to be used Dr. Sala Ginabreda in his publication on the prophylaxis of diphtheria in 1942 stated that it is possible the presence of diphtheria in vaccinated.

In the beginning Spain started between 1945-1950 to employ the monovaccine diphtheria.

In its composition we distinguish the presence of flocculation units (Lf) of diphtheritic toxoids, formaldehyde and aluminium.

We do not have date on the exact composition or the real quantities employed at that time.

From 1965 on the Tri-vaccine was continued (Diphtheria, Tetanus, Pertussis complete/acellular). Posteriorly it went to a composition of 4, 5 and 6. In 2015 Infanrix Hexa is being used (Diphtheria, Tetanus, Pertussis acellular, Polio, Hib and Hepatitis B) in infants and DT (Diphtheria and Tetanus) in adults.

Common to all in its composition we distinguish the following components:

30-50 units of toxoid flocculation (Lf) in the infants' vaccines and of 2-20 Lf in the adults' vaccine (8). One can observe that the infant vaccine contains more than double of LF than the one for adults.

We also find Aluminium Hydroxide/Aluminium Phosphate (200-1500 micrograms), thiomersal (ethylmercury + acetylsalicylic acid) between 25-50 micrograms, formaldehyde (12,5 micrograms), glutaraldehyde, 2 - phenoxyethanol (2,5 milligrams)

Polysorbate 20 and 80 (25 micrograms), sodium chlorate (4,5 milligrams), potash chlorate, disodium phosphate, sodium carbonate, lactose (12,5 micrograms), sodiumbicarbonate, glycine, phenylalanine, trometamol (600 micrograms), saccharose, gelatine, Medium 199, neomycin, polymyxin, streptomycin (9).

The antigen component of the Hepatitis B recombinant of the Infanrix Hexa is produced from genetically modified yeast cells *sacharomyces cerevisiae*.

The polio component of the Hexa vaccine is produced through cultivation of Vero cells, Continuous cell lines or tumoral growth derived from ape kidneys.

According to the Environmental Protection Agency (EPA) the mercury protection limits in our diet should be 0,1 microgram/kg/day (10).

In the diphtheria vaccine the presence of mercury is between 25-50 micrograms in each dose. If in the first dose, with an average weight of the nursling of 5 kg, we can bear 0,5 micrograms but receive between 25-50 micrograms we are clearly surpassing the exposition limits accepted by EPA (11).

According to the standards established in 1990 by the American Society for Parenteral and Enteral Nutrition (ASPEN) the limits tolerated for aluminium would oscillate between 1-30 micrograms/kg/day (12).

In the diphtheria vaccine the presence of aluminium salts oscillates between 200-1500 micrograms in each inoculate doses.

If the first dose, with an average weight of the nursling of 5kg and we can bear between 5-150 micrograms/day but receive between 200-1500 in a single dose, we are clearly surpassing the allowed limits (13).

You could look at: // [www.youtube.com/watch?v=ICQD9wuQmSc](http://www.youtube.com/watch?v=ICQD9wuQmSc)

Not only the diphtheria monovaccines and combined contain units of diphtheritic toxoids also the conjugated Hib, Meningitis C and Pneumococcus –in the market since 1996,200 and 2003 respectively, contain in its composition 10 micrograms of diphtheritic toxoids.

Since the protection or memory of the vaccine decreases exponentially since the first to the 8<sup>th</sup> year after administration, the recommendation of the official vaccinology is to frequently inoculate until puberty. To extend the vaccination of diphtheria among adults between 25 and 54 years due to this lack of protection has not been decided yet. The Spanish Vaccination Calendar in force recommends to vaccinate against diphtheria before the age of 14 in 6 occasions: at 2,4,6, 15-18 months and at 5-6 and 12-14 years. Also when injecting the Meningitis C, Hib and Pneumococcus vaccine an extra 10 micrograms of diphtheritic toxoids is given in each of them.

Therefore the diphtheria vaccines given in the first 14<sup>th</sup> years of life amounts to 9 times. The manufacturers of the diphtheria vaccine are presently Sanofi Pasteur, GlaxoSmithKline, Pasteur Mirieux, Aventis Pasteur and Chiron.

The before mentioned components when directly injected to the bloodstream can produce in the organism neurological lesions, autoimmune allergic reactions, endocrine alterations and metabolic bone alterations (14).

Already in 2013 the Autoimmune Syndrome of Adjuvants (ASIA) was defined as a reaction to the aluminium salts and other components of the vaccines that can appear within 6 weeks after the vaccination which is observed after exposition of the organism to high doses of the aluminium salts present in the vaccines (15).

**Adverse Effects of the Anti-diphtheritic Vaccine**

Both the diphtheria mono and conjugated can provoke serious adverse effects.

One of every 2.200.000 can lead to sudden death in a nursing, the adult and the old.  
One of every 1.000 – 10.000 doses (16) can affect a person of postvaccinal encephalopathy (convulsion, epilepsy, paresis or paralysis, autism, ADHD, Asperger syndrome, sleep disorders, disorders in the wake-sleep rhythm, apnoea and changes in the muscular tonus).

Also 1 person affected by postvaccinal allergy (urticaria, anaphylactic shock, anaphylactic reaction, Arthur's reaction, serum sickness, bronchiolitis and digestive intolerances).

One person affected with kidney problems (nephrosis of renal insufficiency);

One person affected of blood and lymph organs (Thrombocytopenia, alteration in coagulation and lymphadenopathy).

One person affected autoimmune (vasculitis cerebral, cutaneous, glandular, renal and pulmonary).

One person with muscular affections (myalgia,, artralgya, chronic fatigue and myopathy).

One person cardiovascular affected (change in the cardiac rhythm, arterial hypotension).

One person affected in the locomotor apparatus (osteitis, artralgya and multiple fractures).

One person affected in the digestive system (diarrhoea, vomit and intolerances).

One person affected on the endocrine and metabolic system (disruption on the calcium metabolism, thyroid, parathyroid and pancreas affections).

Throughout 28 years of massive and indiscriminate vaccinations (1987 – May 2015) in Spain we can assess a large number of persons that has suffered postvaccinale lesions. 99% of the affected has not been acknowledged and continuously the Administration refuses any relation between the lesion and the vaccination of diphtheria.

Taking into account that every year since 1987 2.000.000 of doses of diphtheria have been spread in Spain if we apply the calculation of 1 person affected every 2.200.000 the number of deaths in Spain in these 28 years due to the diphtheria vaccine is of 25 persons.

The number of persons affected by the vaccine in Spain in the last 28 years, if we apply the calculus of 1 person of each 10.000 doses, is of 5.600.

Within the 5.600 persons affected by the vaccines the most frequent lesion is postvaccinal encephalitis (50%), followed by allergic reactions (30%) and the remaining 20% distributed between renal, blood, cardiovascular, digestive and endocrine alterations.

#### Conclusions:

In light of the exposed data we observe that between 1901 and 1945 the mortality and morbidity from diphtheria descended respectively 98% and 97% without intervention of the diphtheria vaccine.

- Between 1945-1964 the descent continued with a vaccinal coverage of 7,7% en 50%, insufficient to interfere in the descent of the diphtheric epidemic.
- Between 1965-1984 the sustained descent in mortality and morbidity from diphtheria overlapped an ascendant vaccinal coverage (50-80%).
- Between 1987 and May 2015 there were no deaths and practically no diphtheric infections. The vaccinal coverage ascended from 80% to the present 94%.
- It started in 1945 with 1 dose, in 1964 with 2 doses of DTP and in 2015 with 9 doses of diphtheria combined and conjugated.



- The amounts of thiomersal and aluminium salts present in the diphtheria vaccines surpass the bearable levels for the organism.
- The 25 persons deceased in the period 1987-2015 are superior to the number of deaths produced by natural diphtheria during said period.
- Similarly the 5.600 persons affected by the diphtheria vaccine surpass the 5 persons affected by diphtheria during the period 1987-2015.

Recommendations of the Liga por la Libertad de Vacunacion on the diphtheria vaccine  
As we can see on the conclusions of the report the effectiveness of the diphtheria vaccine is not evident, but on the contrary strongly disputable.

The patient that is going to be vaccinated or wants to be vaccinated with diphtheria has to be well informed on the epidemiology of the disease, the history of the vaccine, the components of the vaccine and the adverse effects it can cause.

To be vaccinated of diphtheria is subjected to the Informed Consent to Medical Treatment.

The option to not vaccinate of diphtheria in the light of the actual knowledge, if taken as adequate information while assessing risks and benefits and particularly the personal situation of each individual, is a legally possible decision and medically advisable.

#### Bibliographic references.

1. Navarro-Beltrán, E. Diccionario Terminológico de Ciencias Médicas. Editorial Salvat. 12ª Edición. 1985.
2. Santos LS. Diphtheria ontbuak in Maranhão, Brazil, microbiological, clinical and epidemiological aspects. *Epidemiol Infect* 2015 Mar;143(4):791-8.
3. Rusch, K. Terapia Microbiológica. Instituto de Ecomicrobiología Madrid. 2006.
4. D. Brock, Th. Microbiología. Prentice Hall Hispanoamericana SA. 6ª Edición. 1993.
5. Dubos, R. El Hombre en Adaptación. Fondo de Cultura Económica. Primera Edición. 1975.
6. Salleras, L. Vacunaciones Preventivas. Editorial Masson. 1998.
7. Campins, M. y Moraga, F. Vacunas 2000-2009. Editorial Wyeth (la editorial pertenece al laboratorio Pfizer). 2010.
8. Prospecto Información para el usuario. Infanrix Hexa. Laboratorio GlaxoSmithKline group of companies. 2012.
- Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)  
<http://www.aemps.gob.es/>
9. Pilette, J. Constituants des Vaccins. Nouvelle édition du 7 octobre 2009.  
Liga por la Libertad de Vacunación (LLV)  
<http://www.vacunacionlibre.org>  
European Forum for Vaccine Vigilance (EFVV)  
<http://www.efvv.eu>
10. Segura, M. Evaluación de la seguridad de las vacunas por su contenido en timerosal. *Pharm Care Esp*. 2000;2: 432-439.
11. Mark, R. Thimerosal in Childhood Vaccines, Neurodevelopment Disorders, and Heart Disease in the United States. *Journal of American Physicians and Surgeons*, Vol. 8, Number 1. Spring 2003.
12. Belle, V. Quand l'aluminium nous empoisonne. Enquête sur un scandale



sanitaire. p. 103. Ed. Max Milo, 2010.

13. Bishop NJ. et al. Aluminium Neurotoxicity in Preterm infants Receiving Intravenous- Feeding Solutions. The New England Journal of Medicine. 1997;336( 22): 1557-61.

14. Aristegui, J. Vacunaciones en el niño. De la teoría a la práctica. Ed. Ciclo. 2004.

15. Batista-Duharte, A. Vacunas y Autoinmunidad una rara asociación bajo debate. Rev. Perú. Med Exp Salud Publica. 2012;29(2):265-71.

16. Contraindicaciones y Posibles Efectos Adversos Vacuna Infanrix Hexa.

Resolución de autorización de comercialización excepcional de medicamentos.

Prospecto Información para el usuario.

AEMPS. Ministerio de Sanidad. Noviembre 2013.