EXCELLENCE IN PEDIATRICS INSTITUTE

Improving Child Health Globally

MEETING REPORT

# THE PATH TOWARDS UNIVERSAL VARICELLA VACCINATION

## Policy Focus Group Meeting on Varicella Vaccinations

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### Initiative History, Purpose and Work Within the EU Coalition on Vaccination

Since 2015 the Excellence in Pediatrics Institute (EIP) has worked with European and global partners to help overcome the many remaining barriers to vaccination uptake. By connecting and working with colleagues across Adolescent Medicine, General Practice, Pharmacy and Nursing, and uniting behind the **EU Commission's Coalition on Vaccination**, EIP's goals is to promote a LifeCourse approach to vaccines.

Most notably, EIP believes that the following barriers remain: 1) **Policy discrepancies** - Heterogeneous national vaccination policies. Differences in approach, prioritisation and decision making processes. 2) **Overarching barriers** - Lack of policies to increase vaccines confidence, counteract misinformation, increase awareness and mobilise medical communities, and 3) **Failure to adopt a LifeCourse approach** - Prevention Policies not adapted to demographic changes and an increasingly ageing population. Disease prevention in all stages of life is not yet a priority.

As part of EIP's work within the **EU Coalition on Vaccination**, 8 Stakeholder Working Groups, as well as a joint EU Commission and WHO plenary briefing, took place at 11th EIP Annual Conference in Copenhagen in December 2019. During the Working Groups, speakers were asked to share their opinions on ways to increase vaccination uptake in both general public and healthcare professionals, on the current state and progress made in increasing vaccination coverage rates in different countries and to mention the obstacles faced in the process of doing so.

The **Varicella Working Group** was convened to explore the latest available data on varicella vaccination across Europe and debate the need for the implementation of a universal vaccination program. The Group was tasked with looking at the two-dose strategy, which is often considered to be superior compared to the single dose in terms of effectiveness, efficiency and coverage. In addition, the Expert Working Group was asked to look at how to better engage with HCPs and the public to achieve higher coverage rates by promoting the benefits of the Varicella Vaccinations.

The following report summarises the invited expert's briefings, discussions, and proposed action plans that were debated during the proceedings of the **Varicella Vaccinations Working Group meeting. The Group was tasked with looking at exploring and defining the best path towards Universal Varicella Vaccination across Europe.**

# TWO-DOSE VARICELLA VACCINATIONS

## Working Group Briefing

Dr Dace Zavadska, a pediatric infectious disease specialist from Riga, Latvia, was invited to share first-hand experience of successfully implementing a Two Dose Varicella Vaccination programme, with a view to helping other country representatives present to follow the approach taken in Latvia.

Dr Zavadska, started her briefing by declaring that coverage is always the main factor in preventing the disease. Going on to show how implementing the two-dose vaccination program in Latvia resulted in a very high coverage rate above 90%. Considering that the WHO states that the impact of the vaccination cannot be easily perceived with a coverage rate below 80%[1], we can conclude that coverage is well above target in Latvia from that perspective. Dr Zavadska also suggested **that a single dose is very efficient when it comes to reducing the severity of the varicella while implementing two doses protects against any amount of severity in these cases and is more frequently used depending on whether we want to eliminate varicella or simply address severe cases[2] [3]**.

According to the WHO, in the vast majority of the 40 countries reviewed there are two-dose vaccination strategies implemented. Dr Zavadska then shared her experience from Latvia where they have the Merck vaccine and efficacy was measured at 94% for the one dose and at 98% for two dose strategy in a 10-year period. The GSK vaccine was measured at 64-65% for the one dose and at 94% for two doses. As for effectiveness, it's 55-87% against any type of varicella and 84-98% against moderate or severe varicella for the one dose[4] and 70-98% and 95-98% for the two doses, respectively.

Also breakthrough rates are decreased in Latvia with the two doses because it happens with a rate of 8-32% after the single dose and just about 4% after two doses of the vaccine[5]. **As for varicella outbreaks studies show shifting to two dose vaccination had an impact on decreasing the number, the size and the duration of the varicella outbreaks[6]**. It's important to point out that for several years, in Latvia, a single dose vaccination strategy was implemented but the outbreaks of the disease kept coming and a disbelief about the necessity of the vaccination was starting to prevail, making it difficult for the experts to explain to the parents (and even some of the GPs) why vaccination is still very important as it protects from the severe cases of varicella.

Whereas, now with the success of two doses strategy confidence has grown again amongst both parents and healthcare professionals (HCPs). As for the interval between the two doses, Dr Zavadska suggested that the second dose

[1] Varicella and herpes zoster vaccines: WHO position paper, June. Recommendations. Vaccine. 2014;2016(34):198–199.

[2] European Centre for Disease Prevention and Control. Varicella vaccination in the European Union. Stockholm: ECDC; 2015

[3] Peter Wutzler, Paolo Bonanni, Margaret Burgess, Anne Gershon, Marco Aurélio Sáfadi & Giacomo Casabona (2017) Varicella vaccination - the global experience, Expert Review of Vaccines, 16:8, 833-843, DOI: 10.1080/14760584.2017.1343669

[4] Marin M, Marti M, Kambhampati A, et al. Global varicella vaccine effectiveness: a meta-analysis. Pediatrics. 2016;137:1–10.

[5] Spackova M, Wiese-Posselt M, Dehnert M, Matysiak-Klose D, Heininger U, Siedler A. Comparative varicella vaccine effectiveness during outbreaks in day-care centres. Vaccine. 2010 Jan 8;28(3):686-91.

[6] Spoulou et al The Pediatric Infectious Disease Journal • Volume 38, Number 2, February 2019 Impact of the US Two-Dose Varicella Vaccination Program on the Epidemiology of Varicella Outbreaks: Data from 9 States, 2005–2012Pediatr Infect Dis J. 2015 October ; 34(10): 1105–1109. doi:10.1097/INF.0000000000000821

should be issued at least three months after the first dose or 3-4 years later. **The program in Latvia suggests that the first dose will be given at the age of 15 months together with the MMR and the second dose is to be given at or just before the age of seven years old again with the MMR**.

Concerns were stated at the end of this part of the working group discussion regarding whether the mild cases of varicella that are expected especially with the single dose strategy have an adverse effect on suffering from herpes zoster later in life or not but it was concluded that further data and research in this is needed in order to establish a firm understanding of a possible link.

## MODELING AND ANALYSING THE IMPACT OF UNIVERSAL VARICELLA VACCINATION ON THE DISEASE AND HOSPITALISATION RATES IN ITALY

### Working Group Briefing

Prof. Paolo Bonnani, Professor of Hygiene in the Faculty of Medicine and the Director of the Specialization School for Hygiene and Preventive Medicine at the University of Florence, Italy, was invited to provide an analysis of the impact of universal varicella vaccinations on hospitalisation rates in Italy.

Prof. Bonnani started his briefing by explaining that the first region in Italy that introduced a specific vaccination program for varicella was Sicily, but one of the best in terms of performance was Puglia, where a single dose strategy was implemented in 2006 and the second dose was added in 2009. Incidence rates dropped from 6-7 patients per 1,000 to below 1 and almost zero in some regions due to the implementation of the universal varicella vaccination program[7]. Data from 8 italian regions showed an average of 3-4 incidents per 1,000 habitants, per year, with almost no reported cases now, and all this within a very small amount of time.

The same effect is evident concerning the hospitalizations rate numbers and the decrease is not only statistically significant but rapid. Prof. Bonnani went on to share how the cost of hospitalizations were also decreasing in these regions and the hospitalization rates were decreased by a factor of 3.5 from the point when the universal program was first introduced to the community[8] [9]. A study in Tuscany from 2009 to 2012 revealed that the impact of the vaccination was not only with regard to the age groups that were vaccinated but to age groups below one year of age, as well and that a clear impact was noted regarding the 25-49 age group**.** Prof. Bonnani outlined that a model study is used in Italy, which he is really proud of, and this study helps us to determine which of the following three parameters is the most important when it comes to impact: **coverage, efficacy** and **dose interval**.

**According to the model developed, Prof. Bonnani suggested to the Working Group that the most important factors that influences the outcome of vaccination the most is coverage rate. When high coverage was reached the impact of dosing interval and first dose vaccine efficacy was relatively lower in disease prevalence in the population[10]. Effectiveness, efficacy and dose interval are also important but not as much as coverage and that, according to Prof. Bonnani, this is the key factor for a successful implementation.**

Continuing his analysis, Prof. Bonnani explained about endogenous and the exogenous boostings, citing an increase in zoster cases noted several years after the implementation of universal varicella vaccination in Tuscany. **Endogenous boosting occurs due to the reactivation of internal varicella zoster virus and exogenous boosting happens due to exposure to VZV from other people with varicella**, so if someone could reduce the circulation of VZV, varicella vaccination could reduce exogenous boosting but this statement is complete nonsense according to him because exogenous boosting is not the only way to boost immunity. Prof Bonnani suggested that **there is no point in trying to protect the elderly by letting children suffer from varicella, but it is instead much better to implement a universal vaccination program[11]**.

During the discussion that followed it was stated that cellular immunity boosting is the most important factor when we try to prevent herpes zoster in the elderly so the more a patient's

[7] 1. Tafuri S et al. Hum Vaccine Immunother 2015;11:214–19; 2. Bechini A et al. Hum Vaccin Immunother 2015;11:63–71.

[8] Bechini et al., Impact of universal vaccination against varicella in Italy, Experience from eight Italian Regions, Human Vaccines & Immunotherapeutics 11:1, 1-9; 2015 Landes Bioscience

[9] Boccalini et al., Preparing to introduce the varicella vaccine into the Italian immunization program: varicella-related hospitalizations in Tuscany, 2004-2012. Euro Surveill. 2016;21(24):pll=30527. DOI: http://dx.doi.org/10.2807/1560-7917.ES.2016.21.24.30257

[10] Holl et al., Coverage, efficacy or dosing interval: which factor predominantly influences the impact of routine childhood vaccination for the prevention of varicella? A model-based study for Italy. BMC Public Health (2016) 16:1103 DOI 10.1186/s12889-016-3738-x

[11] Adam Finn, 2018, The Hope-Simpson Hypothesis, Varicella Vaccination and Herpes Zoster Control The Journal of Infectious Diseases published online November 16, 2018

immunization system is weak, the more likely it is for him/her to suffer from herpes zoster.

## VACCINE EFFECTIVENESS AFTER THE INTRODUCTION OF REGIONAL SCHEDULES IN SPAIN

### Working Group Briefing

Prof. Francisco Gimenez-Sanchez from the Hispalense Institute of Pediatrics in Spain was asked to reflect on the effectiveness of varicella vaccinations following on from their recent introduction into regional schedules. At the beginning of the briefing Prof. Gimenez-Sanchez reminded the Working Group of the severe complications of varicella as a bacterial infection, which is exactly why Spain has insisted on the need of a universal varicella vaccination program. Prof. Gimenez-Sanchez then shared the four options to tackling Varicella in Spain: i) vaccination of susceptible adolescents only, ii) one dose of the vaccine at 12-15 months old, iii) two doses of the vaccine at 12-15 months and 3-4 years old and iv) do nothing, which is equivalent to condemning everybody to suffer from the disease.

At first, the National Council recommended varicella vaccination for adolescents 10-14 years old but most of them were already ill when they reached the vaccination age. Madrid was the first region which took one step ahead and introduced one dose of vaccination at 12 months of age and the results were very good in terms of the disease burden with a 92% effectiveness of the vaccination followed by a decline after 2-3 years[12]. **In the Navarra community all four strategies were consecutively implemented and we had even greater results with a very rapid reduction from 8 cases per 1,000 habitants to just 0,21 cases per 1,000 habitants (97% reduction) in just six years.** The effectiveness calculated during these years was 96% for any dose schedule of the vaccine (one or two). One dose of varicella vaccination effectiveness was 93% but declined to 61% after three years. But this decrease was even more significant when only susceptible adolescents were vaccinated[13].

So, finally in 2016 the National Council in Spain decided to introduce two doses of the vaccine at 15 months and at 3-4 years of age in the whole country. Up until October 2019 there were 37,000 cases in Spain (more than 50,000 in 2018) with an epidemic index of 0,47. Prof. Gimenez-Sanchez concluded that **one dose of varicella may be highly effective but this effectiveness is expected to decline over the years so the second dose is necessary in order to control the disease.**

During the subsequent Working Group discussion the optimum dose interval was debated regarding whether it can be shortened. It was agreed that it was a significant factor but not as significant as a high coverage. **The audience agreed that we need at least 60% of coverage before we actually see any impact on the infection rates and that the goal should always be the reduction of the circulation of the virus and this can only be achieved with the additional catch-up dose.**

## CENTRAL AND EASTERN EUROPE

### Working Group Briefing

Dr. Zsofia Meszner, Director of Methodology, a paediatrician and specialist in infectious diseases at the National institute of Paediatrics in Heim Pal, Hungary, was then invited to brief the Working Group on the current state and approach to Varicella vaccinations in Central and Eastern Europe.

Dr. Meszner initially stated **the two main goals which are the immunization against chickenpox and the risk of severe chickenpox**. Dr. Meszner presented data for many countries in the region, covering: Poland, Czech Republic, Estonia, Slovenia and Greece. Dr. Meszner added that It is very difficult to find supportive data because of the different policies, strategies, cultures, reporting methods in various countries and regions.

**Nevertheless, one common finding was that the majority of children fall ill from chickenpox between 1 and 9 years of age and that complications are always more severe in the older age groups[14]**. There is a group of countries called C-vac which includes Baltic countries, the Czech Republic, Slovakia, Poland, Croatia, Slovenia, Romania, Bulgaria and the European part of Turkey. None of these countries, apart from Latvia, has had a universal varicella vaccination program implemented at the time of systematic literature reviews.

However, it is worth noting that several of these countries have achieved quite low incidence rates per 100,000 habitants with

[12] Latasa et al. Effectiveness and impact of a single-dose vaccine against chickenpox in the community of Madrid between 2001 and 2015 Human vaccines & Immunotherapeutics 2018, vol. 14, No.9, 2274-2280, https:// doi.org/10.1080/21645515.2018.1475813

[13] García-Cenoz M, et al. Impact of universal two-dose vaccination on varicella epidemiology in Navarre, Spain, 2006 to 2012, Eurosurveillance 2013

[14] Varicella surveillance report, 2010; EUVAc.net http://ecdc.europa.eu/en/publications/Publications/varicella_report_2010_euvacnet.pdf accessed in November 2015

the implementation of the universal vaccination[15]. Severe cases of chickenpox usually go unnoticed by GPs in Hungary and in other countries as well. The cost of fighting varicella exceeds 1 million euros but this is rather an underestimation and we also have the societal impact to consider[16].

**Another significant finding of Dr. Meszner's review is that younger age groups have higher hospitalization rates but older age groups suffer from more severe chickenpox than others. The socio-economic impact of chickenpox left un-vaccinated was also discussed and that is one of the main reasons why we need to move towards immunization**. Dr. Meszner summarized by saying that many decision-makers follow instructions from the WHO so her strong recommendation is that WHO should be very clear on the best route because many countries depend heavily on its published position papers.

## TARGETED VARICELLA VACCINATION OF HIGH RISKS GROUPS

### Working Group Briefing

Prof Simon de Lusignan, Professor of Primary Care and Clinical Informatics, University of Oxford, Nuffield Department of Primary Care, Director, Royal College of General Practitioners Research and Surveillance Centre, United Kingdom was invited by the Working Group to analyse the benefits of targeting varicella vaccinations of high risk group, as opposed to universal vaccinations.

Prof de Lusignan is a member of the Royal College of GPs research Units which conducts and manages one of Europe's oldest surveillance systems. In the UK a two-dose vaccination is recommended for immune-compromised persons, for non-immune pregnant women and for healthcare workers. Prof de Lusignan also presented new data with regard to varicella vaccination in terms of age-groups, North-South separation, color, ethnicity and household size.

**A significantly higher vaccination rate was noted in London and in Southern England, in general, compared to the rates in North England which are quite low. Unsurprisingly, if you're in households of six or more, much more vaccination is happening than if you're in households of less people and it stacks up nicely in order of households with two in the households of six or more.**

In the Working Group discussion that followed, it was made very clear that the varicella vaccine, which is a live vaccine, should not be given to pregnant women but to non-immune women who plan to be pregnant. A regular tactic by paediatricians who tend to over-ICD-code varicella vaccination to immune-compromised people was also discussed.

## ORGANIZATIONS STATEMENTS

### European Association of Hospital Pharmacist (EAHP) - Statement

Mr. Steffen Amann, Director of Professional Development – European Association of Hospital Pharmacist, Belgium, was then invited to provide a statement on behalf of the European Association of Hospital Pharmacist (EAHP). Mr. Amann started by pointing out the usual trends nowadays in terms of public threats. So, if there is a big threat it's quite easy to convince the people that there is something that solves the problem. And if the problem is being solved we have to deal with the fact that so many people are actually feeling threatened by the solution itself. **Pharmacists along with GPs and other healthcare workers need to be better at convincing the parents that vaccination and medication are here to do good and cause no harm**. Mr. Amann then went on to underline the significance of drug shortages in pharmacies and hospitals, which also affects the vaccines available.

## DISCUSSION POINT 1

### Improved Targeting of Varicella Vaccination of High Risk Groups

Prof Simon de Lusignan opened the discussion suggesting that the people who need it most, even if it's free, in many cases seem to have the greatest difficulty accessing a doctor or a general practitioner, citing the example of statistical examples from South Wales. Prof de Lusignan continued that, as we move more and more digital we know that actually we are going to identify greater disparity between socio-economic groups.

Prof de Lusignan also mentioned low vaccine hesitancy within high risk groups, suggesting that only a tiny fraction of the people who refuse to vaccinate themselves and their children decide to do so due to philosophical or specific religious backgrounds.

[15] Burden of varicella in Central and Eastern Europe: findings from a systematic literature review Z Mészner, J Wysocki, D Richter et al. Published online: 27 Feb 2019

[16] Ersek et al., The disease burden of varicella in Hungary

**Prof. Timo Vesikari stepped in regarding the need to overcome vaccine hesitancy within the wider population, proposing that addressing vaccine hesitancy generally is the primary issue here when trying to eliminate the circulation of the virus in high risk groups**. **Prof. Vesikari argued that if we reduce the virus circulation then we won't need to discuss improved targeting of high risk populations.**

## DISCUSSION POINT 2

### Improving HCP's Communication to Parents

The Working Group then moved on to look at HCPs as agents of change and how they are pivotal in effectively communicating the benefits of the varicella vaccine to parents. It was agreed that **scaring people by showing severe cases and pictures with complicated cases is only a short term solution and won't work in the long run. Instead trying to explain and to really connect with the parents is not only the desired outcome but the best way to achieve it as well.**

It was also discussed and agreed that famous athletes and/or actors can play a hugely positive role here because what they say and what they do has clearly a great impact on, especially younger people's, decision making process. So if someone declares that people should not vaccinate against varicella because he/she had a bad experience with it then it's a catastrophe in terms of communicating the campaign in favor of implementing a universal vaccination strategy.

**Mr. Amann suggested that we should aim at both the mind and the soul by providing the parents with the information necessary on one hand and by sharing real stories on the other**.

Dr. Mihai Craiu then addressed the phenomenon under the scope of social media, underlining that three out of four patients google their symptoms before visiting a physician[17]. He proposed two solutions for the lack of communication between the doctors and the people. **One is infotainment so graphics and videos and other interactive tools should be used towards that direction** and the **second one is gamification. Information about vaccines in general should be given to the children but in a more fun and enthusiastic way in order for that to penetrate and to have as large an impact as possible.**

[17] Medic ONE in ICEE.fest site - http://www.iceefest.com/news/healthcare-in-the-digital-era-romanian-patients-point-of-view-research-by-medic-one-presented-for-the-first-time-at-icee-health-2017/ , accessed in 26.08.2019

## DISCUSSION POINT 3

### Accessing Public Funding and Policy Maker Prioritisation

The Working Group then explored how policy makers are hard to persuade because of the political and socio-economic cost involved. It's getting even harder to come up with a plan for all the countries due to huge and vast differences between them and between their people. Healthcare associations don't make it easier either because there is usually much conflict of interest combined with the embedded difficulty of having scientists who have to agree on a specific agenda. **It was agreed that a strong surveillance system has to be implemented in order to improve efficiency of money spent on public health and the advantages of vaccination need to be communicated through social platforms so that penetration and positive impact will grow along with coverage rates.**

## CONCLUSIONS

There were several important take-home messages from the Working Group. In particular the Working Group raised the following areas that need to be explored in more detail with necessary actions taken to achieve increased varicella vaccination rates across Europe, they include:

- **Vaccine hesitancy is growing and pharmacists, GPs and physicians must play a critical role in trying to convince undecided or wavering parents to vaccinate their children.**
- **Pharmacists along with GPs and other healthcare workers need to be better at convincing the parents that vaccinations are here to do good and cause no harm.** Ways to achieve this should include better social media engagement, infotainment and gamification of the vaccination's benefits.
- **HCPs should aim at both the mind and the soul by providing the parents with the information necessary on one hand and by sharing real stories on the other** to increase vaccination uptake.
- **HCPs must better utilize social media to overcome the** lack of communication between the doctors and the public - especially as three out of four patients google their symptoms before visiting a physician.

- **Infotainment (graphics and videos and other interactive tools) should be better utilized by HCPs, as well as gamification (information about vaccines in general should be given to the children but in a more fun and enthusiastic way)** in order for that to penetrate and to have as large an impact as possible.

- **Coverage is predominantly the main factor in varicella vaccination effectiveness and to achieve this we must implement two doses of the vaccine instead of a single dose**. By following this approach it will boost effectiveness and efficacy even more.

- **Agreeing on the optimum dose interval was debated by the group as to whether it should be shortened. Although a significant factor, it is not as significant as a high coverage** the two main goals which are the immunization against chickenpox and the risk for severe chickenpox.

- **There is no point in trying to protect the elderly from herpes zoster by condemning and letting children suffer from the disease.** Varicella can sometimes be seriously complicated and the vast majority of the severe cases are in older children.

## SUGGESTED ACTION PLAN FOR 2020/2021

### Target 1
### Overcome Vaccine Hesitancy Towards Varicella Vaccinations Across Europe through HCP Education

**Need:** Vaccine hesitancy is growing and pharmacists, GPs and physicians must play a critical role in trying to convince undecided or wavering parents to vaccinate their children. Pharmacists along with GPs and other healthcare workers need to be better at convincing the parents that vaccination and medication are here to do good and cause no harm.

**Proposed Actions –** A dedicated educational campaign designed to make HCPs better understand that they are the trusted and preferred agents of change. HCPs should aim to have the tools, information and communication skills, along with sharing real stories to increase vaccination uptake.

### Target 2
### Improve the Use of Social Media by Authorities and HCPs to Effectively Engage with the Public

**Need:** Anti-vaccination activity and material on social media is rife, yet public health authorities and HCPs have been slow to fight back. HCPs must better utilize social media to overcome the lack of communication between the doctors and the public - especially as three out of four patients google their symptoms before visiting a physician.

**Proposed Actions:** Development of Infotainment (graphics and videos and other interactive tools) to utilized by HCPs and the public directly. As well as gamification (information about vaccines in general) that can be given to the children but in a more fun and enthusiastic way regarding vaccines.

### Target 3
### A Unified European Approach and Policy Covering Both Coverage and Optimum Dose Interval for the Two Dose Vaccine.

**Need:** Increased coverage universally across Europe is needed to guarantee varicella vaccination effectiveness. All countries must commit to implementing two doses of the vaccine, as well as agree on the optimum dose interval.

**Proposed Actions –** A dedicated Policy Working Group formed to agree the adoption of the two doses of the vaccine, as well as agreeing optimum dose interval and was whether it should be shortened from current recommendations.