

EAP RESEARCH IN AMBULATORY SETTINGS NETWORK (EAPRASnet) & VACCINATION STRATEGIC ADVISORY GROUP

MINUTES

SPRING MEETING 2021 LARNACA, CYPRUS / VIRTUAL JULY 2, 2021 16.15 - 17.00 CY / 15.15 - 16.00 CET (List of attendees attached)

EAP RESEARCH IN AMBULATORY SETTINGS NETWORK (EAPRASnet)

- 1. Welcome and Approval of previous EAPRASnet Minutes & current Agenda.
- 2. Publication Update Zachi Grossman
 - a. SARS-CoV-2 vaccination in children and adolescents, a joint statement of EAP and ECPCP has meanwhile been published in Frontiers.

EAP VACCINATION WORKING GROUP

- 1. Welcome and Approval of previous Vaccination SAG Minutes & current Agenda.
- 2. Update EU Projects (JAV, EU Commission) HJ Dornbusch & Adamos Hadjipanayis Current projects include:
 - a. ImmuHubs (Stefano del Torso, Hans Juergen Dornbusch, Adamos Hadjipanayis) *Vienna Vaccine Safety Initiative*
 - b. EU RIVER Horizon 2020 (Stefano del Torso, Hans Juergen Dornbusch, Adamos Hadjipanayis) Academisch Ziekenhuis Groningen
 - c. EU Coalition for Vaccination (EAP/Advisory Board), SEKI, Immunion, Think Young
 - d. EU JAV (EAP Stakeholder)

Elaboration on the ImmuHubs Project

- a. Increased access to vaccination for disadvantaged, isolated and difficult to reach groups of population in 6 European countries (Cyprus, Finland, Greece, Poland, Portugal and Serbia).
- b. Israel and Ukraine were excluded due to not being EU countries.
- c. The project is structured into 6 work packages (WP).
- d. WP 4 is led by EAP, a project manager was appointed.

Elaboration on River EU

Target Populations:

- a. Migrant community (measles and HPV) in Greece
- b. Turkish females (HPV) in the Netherlands
- c. Moroccan Females (HPV) in the Netherlands
- d. Ukrainian minority (measles and HPV) in Poland
- e. Roma community (HPV) in Slovakia
- EAP is in an advisory role, the project is yet in a developmental phase.
- 3. Talk "Vaccination of children and adolescents in the Corona-Pandemic"
 - The Influenza Pandemic in 1918 caused 50 to 70 million deaths.
 - a. So far (1 July 2021), the COVID-19 pandemic had claimed close to 4 million lives with more than 180 million cases.

- b. Children are affected to a lesser degree, but can also suffer acute disease, hyperinflammation, "long COVID", death and indirect effects like quarantine, testing, mandatory masks with psychological effects.
- c. COVID-19 in children Austrian experience:
 - n = 780 (0-14 a), 41.4% asymptomatic, 3.4% hospitalised, MIS-C (~1/1000)
 - Frequently common symptoms (22% Fever, 33% Respiratory Symptoms, 14% Gastrointestinal Symptoms, only 12% Ageusia/Anosmia)

"Long COVID" - various features:

- Duration of symptoms: 14% > 1 month, 7.7% > 3 months
- Mean Age: 11 years (Long COVID +) vs. 9 years (Long COVID -)
- Limitations: History taking with parents/family. No control group (Long COVID vs. Pandemic Blues).

US paediatric COVID-19 experience:

- Infants and adolescents are most affected age groups.
- COVID-19 may also take a serious course in children. 11.4% of paediatric patients with COVID-19 were hospitalized, 3.6% required intensive care (LE Preston et al. JAMA 2021)

Children and COVID-19 (AAP 17 June 21):

- 4,024,335 total child COVID-19 cases reported (= 14.2% of all 28,402,723 cases)
- Overall rate: 5,347 cases per 100,000 children.
- 335 paediatric deaths

"Kawasaki-like Syndrome" (PIMS, MIS-C).

a. Hyperinflammation syndrome mainly affecting previously healthy children with a mean age of 10 years presenting with lethargy and irritability. Ethnic predominance (Hispanic and non-Hispanic black).

4. Vaccination Update

a. As of July 2021, there were four available COVID-19 vaccines:

Comirnaty® (BNT163b2, BionTech/Pfizer),

Spikevax® (mRNA 1273 COVID-19 vaccine, Moderna)

Vaxzevria® (ChAdOx1/AZD 1222, AstraZeneca)

Johnson & Johnson Adenovirus 26 vectored COVID-19 vaccine

- b. Overall, all registered vaccines show high efficacy close to 100% in preventing severe disease. Monitoring for long term efficacy and safety is ongoing. Main objective: change clinical course of COVID-19 from a life-threatening condition to a manageable disease.
- c. Healthcare authorities around the globe carry out pharmacological surveillance on adverse events following immunization (AEFI). This process also includes events of special interest, like thrombosis with thrombocytopenia after vectored vaccines or anaphylaxis and myocarditis after mRNA vaccines. Some countries temporarily suspended usage of specific batches of vaccines; others changed practical recommendations and target population (e. g. sparing vectored vaccines from younger age groups, particularly women, since there are other options) with continued further pharmacological surveillance, investigation of reported phenomena and re-evaluation of risk-benefit assessment.
- d. Currently, the burden of COVID-19 far outweighs any side effect from licensed vaccines. Based on Phase 3 studies in adolescents and after approval of the BNT/Pfizer vaccine by FDA and EMA in May 2021 many countries started to vaccinate teenagers from 12 years of age. At the beginning of July 2021 4 million US adolescents had already been vaccinated at least once. Aiming at immunization recommendation for younger children, clinical trials are ongoing for all licensed vaccines (starting with dose finding in defined age groups), first results being expected in fall/winter 2021.

- e. Due to natural mutations triggered by selection pressure several SARS-CoV-2 Variants of Concern (VoC) have emerged. The first (British) was followed by the South African, the Brazilian and the currently dominating indian "Delta" VoC. Large unvaccinated parts of the population give way to circulation and development of future variants with yet unknown impact on children. Currently, decreased vaccine efficacy requires completed vaccination schedules with any of the registered products for sufficient protection.
- f. Generally decreased vaccination rates are a global threat. US reports showed a decline in paediatric vaccine ordering during the COVID-19 pandemic by 3 million (non-influenza) (including 400.000 measles) doses from Jan to April 2020.

 Any disruption of immunization services, even for short periods, will result in an accumulation of susceptible individuals and a higher likelihood of VPD outbreaks. It is important to have precautions ready and counter measures, wherever it is possible.
- g. Epidemiology of other infectious diseases: There was almost no influenza or RSV circulation in Europe in winter/spring 2021, probably due to season and epidemiological measures. There are serious hints that as soon as the protection measures stop, infections rise, including vaccine preventable infectious (e. g. measles, invasive bacterial infections).
- h. Vaccination is probably the most effective preventive public health measure. A prospective European Vaccination record with a European vaccination passport would certainly be supportive in achieving higher vaccine coverage.

5. Discussion & Questions:

- Ketil Størdal (Norway representative) stressed the importance of using well-tested medicines (and vaccines) in children and post-marketing monitoring. The Working Group chair responded that all registered COVID-19 vaccines had undergone all necessary stages of clinical trials including security check and continued post-marketing surveillance for all products.
- Zachi Grossman (Israel representative) and Shimon Barak (president of ECPCP) shared their country's experience in vaccinating children. They indicate that the safety profile of vaccines used in children doesn't differ from that in adults. In addition, currently there is a discussion in Israel on further reducing the vaccination age in children.
- Aman Pulungan (IPA Executive Director) confirmed a possible danger due to a decline of paediatric vaccines around the globe and talked about IPA Vaccine Trust Project.
- Yevgenii Grechukha (Young EAP rep. from Ukraine) noted that the company Sinovac has made changes to the instructions of its inactivated COVID-19 vaccine and allowed its use in children from 3 years. This is important because this product is registered in several European countries.

List of Attendees:

Timestamp	Name	Surname	EAPRASnet-Vaccination Session on 2 July 2021 from 15.15 - 16.00 CET
7/2/2021 13:02	Hans Juergen	Dornbusch	I confirm my attendance
7/2/2021 13:02	Iuliia	Zaharova	I confirm my attendance
7/2/2021 13:03	Joana	Rios	I confirm my attendance
7/2/2021 13:10	Miqueas Augusto	Fontana	I confirm my attendance
7/2/2021 13:20	Süleyman	YILDIZ	I confirm my attendance
7/2/2021 13:23	Mohamed	Ghazi	I confirm my attendance
7/2/2021 13:40	Risto	Lapatto	I confirm my attendance
7/2/2021 14:28	Lars	Gelander	I confirm my attendance
7/2/2021 14:32	Pavelescu	Carmen	I confirm my attendance
7/2/2021 14:32	Geitmann	Karin	I confirm my attendance
7/2/2021 14:54	Daniela	Kohlfürst	I confirm my attendance
7/2/2021 15:12	Chris	Pruunsild	I confirm my attendance
7/2/2021 15:21	Marta	Petryshyn	I confirm my attendance
7/2/2021 15:21	Alexiu	Sandra Adalgiza	I confirm my attendance
7/2/2021 15:22	Maria	Gutu	I confirm my attendance
7/2/2021 15:22	Stephanie	Antoun	I confirm my attendance
7/2/2021 16:16	Lia	Syridou	I confirm my attendance
7/2/2021 16:32	Koray	Boduroglu	I confirm my attendance
7/2/2021 16:36	RUBEL	Francis	I confirm my attendance
7/2/2021 17:13	Stanislava	Hadzhieva	I confirm my attendance
7/2/2021 17:14	Martin J	White	I confirm my attendance
7/2/2021 17:16	Barbara	RATH	I confirm my attendance
7/2/2021 17:18	Sofia	Hernandez	I confirm my attendance
In person	Adamos	Hadjipanayis	Attendance confirmed
In person	Marina	Mamenko	Attendance confirmed
In person	Bert	Koletzko	Attendance confirmed
In person	Ivan	Bambir	Attendance confirmed
In person	Yevgenii	Grechukha	Attendance confirmed
In person	Ann	De Guchtenaere	Attendance confirmed
In person	Miguel	Martins	Attendance confirmed
In person	Artur	Mazur	Attendance confirmed
In person	Aida	Mujkic	Attendance confirmed
In person	Liesbeth	Siderius	Attendance confirmed
In person	Arunas	Valiulis	Attendance confirmed
In person	Karoly	Illy	Attendance confirmed
In person	Ivanna	Romankevych	Attendance confirmed