PHIRI
Population Health Information Research Infrastructure

# Rapid Exchange Forum – Special Edition

November 8th 2021 09:00-10:00

## Contents



## Attendees

*Edit Fekete (Romania), David Novillo Ortiz (WHO Europe), Mechili Enkeleint-Aggelos (Albania), Jane Idavain (Estonia), Estrella (unknown), Elena Veiga (Spain), Henrique Gouveia e Melo (Portugal), Ronan Lyons (UK/Wales), Marília Silva Paulo (Portugal), Mariana Peyroteo (Portugal), Michael Courtney (Ireland), Shona Cosgrove (Belgium), Richard Pentz (Austria), Anda Ioana Curta (Romania), Luís Lapão (Portugal), Robert Lang (Hungary), Teresa Montez (Portugal), Luigi Palmieri (Italy), Małgorzata Stróżyk-Kaczyńska (Poland), Howard Needham (ECDC), Irini Kessissoglou (Belgium), Ester Angulo-Pueyo (Spain), Sarka Dankova (Czech Republic), Merike Rätsep (Estonia), Ailish Kelly (Ireland), Mariken Tijhuis (Netherlands), Metka Zaletel (Slovenia), Irisa Zile (Latvia), Nienke Schutte (Belgium), Rosa Gonzalez-Quevedo (EMA), Petronille Bogaert (Belgium), Claudia Habl (Austria), Teresa Valero (Spain), REF Secretariat*

## Aim of the meeting

The goal of the Rapid Exchange Forum – Special Edition is to act as a matchmaker between COVID-19 related international activities of organizations or expert groups that are already in place or that have been setup during the pandemic to exchange information on measures.

## Welcome by Petronille Bogaert - PHIRI

Members of the Joint Action on Health Information (JA InfAct) started in April 2020 to meet regularly online to foster cross-country exchange. In these meetings, partners could approach each other for questions and shared views in a trusted environment on an ad-hoc basis. This initiative became an

integral part of PHIRI, the Population Health Research Infrastructure, allowing a quick exchange of data, indicators, good practices and experiences in the COVID-19 crisis response in a structured and efficient way. Today we have our 3rd Special Edition of the Rapid Exchange Forum (REF). In this Special Edition, we do not only want to exchange experiences and discuss urgent questions between PHIRI-members, we aim to look beyond our consortium and bring together key experts and international organizations who are working in the field of COVID-19 to present their main COVID-19 activities.

## David Novillo Ortiz - WHO Regional Office for Europe

*David Novillo Ortiz has many years of experience in public health, working on health information and data and innovation. Currently, he works as unit head at the World Health Organization, providing senior technical leadership to the countries in the European region on the development and improvement of national data and health information systems.*

See presentation slides below.

An update on the activities conducted by WHO/Europe during the pandemic:

1) **Technical guidance**: six technical documents were developed (and are publicly available) to provide technical guidance and include tools to support member states and European countries:
    a. Guidance for health information system governance (2021)
    b. Integrating gender data in health information systems: challenges, opportunities and good practices (2021)
    c. Tools for making good data visualizations: the art of charting (2021)
    d. Support tool to strengthen health information systems: guidance for health information system assessment and strategy development (2021)
    e. The protection of personal data in health information systems - principles and processes for public health (2021)
    f. Strengthening population health surveillance: a tool for selecting indicators to signal and monitor the wider effects of the COVID-19 pandemic (2021)
2) Scientific publications**:**
    a. **A call to strengthen data in response to COVID-19 and beyond**. Journal of the American Medical Informatics Association, 28(3), 2021, 638–639. doi: 10.1093/jamia/ocaa308. PMID: 33275146, https://doi.org/10.1093/jamia/ocaa308
    b. **Health Information Systems in the COVID-19 Pandemic: A Short Survey of Experiences and Lessons Learned From the European Region.** Front. Public Health. 2021 9:676838. https://pubmed.ncbi.nlm.nih.gov/34650946/
    c. **Data and Digital Solutions to Support Surveillance Strategies in the Context of the COVID-19 Pandemic**. Front. Digit. Health. 2021 3:707902. https://pubmed.ncbi.nlm.nih.gov/34713179/
    d. **Technological progress in electronic health record system optimization: Systematic review of systematic literature reviews**. Int J Med Inform. 2021 Aug;152:104507. https://pubmed.ncbi.nlm.nih.gov/34049051/
    e. **Digital Data Sources and Their Impact on People's Health: A Systematic Review of Systematic Reviews.** Front Public Health. 2021 May 5;9:645260. https://pubmed.ncbi.nlm.nih.gov/34026711/
    f. **Routine Health Information Systems in the European Context: A Systematic Review of Systematic Reviews**. Int J Environ Res Public Health. 2021 Apr 27;18(9):4622. https://pubmed.ncbi.nlm.nih.gov/33925384/
    g. **Impact of Big Data Analytics on People's Health: Overview of Systematic Reviews and Recommendations for Future Studies**. J Med Internet Res. 2021 Apr 13;23(4):e27275. https://pubmed.ncbi.nlm.nih.gov/33847586/

3) Capacity building:
    a. Training on COVID-19 Coding and Death Certification
    b. The Better Data for Better Health webinar series
        i. #4 Gender data – Thursday, 25 November 2021
        ii. #3 Data visualizations
        iii. #2 Data protection
        iv. #1 Monitoring the wider effects of the COVID-19 pandemic
4) EPW Measurement Framework:
   WHO has adopted a new framework that will support countries in measuring progress in implementing the European Programme of Work (EPW): this measurement framework allows to see what indicators are relevant for the European Region: 26 indicators were selected together with the Member States (MS) and 20 indicator areas (mental health, ageing, digital health etc.) were developed to see where data is lacking. WHO works together with the MS, with OECD and the European Commission (EC) to look for proper indicators to cover these areas. Many countries are complaining about data request from international organisations as working on recent data is key. WHO aims to work together closely with the OECD and the EC to improve this situation.

### Questions

**Petronille Bogaert**: It is very useful to get an overview of all these activities, not only for the REF but also for the other activities in PHIRI. Regarding the 20 indicator areas: Could you please share some information on the methodology that you use(d) to develop these indicators; are there some indicator areas that are particularly relevant with regards to the wider impact of COVID-19?

**David Novillo Ortiz**: We have established technical working groups that will be led by the technical units, after which we will continue with the data side. Any of you who have interest in these 20 indicator areas you are invited to work with us on this. There are 3 core priorities: Moving towards UHC; Protecting against health emergencies; and Promoting health and wellbeing. Within these priorities there are indicators for which data is lacking. These indicator areas have been developed together with the MS, so they are relevant for the European Region. This is part of consultation process with the MS. Our top priority is mental health, so we will start working on this topic and start developing a Mental Health Data Lab. We also want to look at social media and infodemic. Another priority is digital health; we do not have any measurements on this topic, so this will get some extra attention. We are open to work with everyone, please reach out to us so we can start working together.

## Rosa Gonzalez-Quevedo - European Medicines Agency

*Rosa Gonzalez-Quevedo works in the Stakeholders and Communication Division of the European Medicines Agency. We haven't had the opportunity to have an interaction with the EMA just yet, so we are grateful to have Rosa at the REF today.*

See presentation slides below.

EMA presents its role in the COVID-19 vaccine booster doses. The EMA is in charge of evaluating the benefits and risks of medicines and this includes pharmacovigilance activities, including COVID-19 vaccines. Its Pandemic Task Force (ETF) supports the scientific evaluation by EMA committees and supports developers. The EMA reviews data that the manufacturer is providing. When an application is submitted, the scientific committee carries out the evaluation: this also includes looking at real word evidence on vaccine safety and effectiveness to complement clinical trial data. The EMA exchanges information with national authorities and the European Centre for Disease Prevention and Control (ECDC) to evaluate available data and support campaigns to protect the public during the ongoing pandemic.

The EMA has approved of booster doses of Comirnaty (by Pfizer) and Spikevax (by Moderna) for people **with normally functioning immune systems**. The decision of when and for whom to implement this 3rd dose should be made based on available effectiveness data, taken into account that we limited safety data on the 3rd dose. For Comirnaty, the decision is based on interim safety and immunogenicity data of a 3rd booster dose of a Phase 1/2/3 study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-CoV-2 RNA vaccine candidates against COVID-19 in healthy individuals and based on published real-world effectiveness data from Israel and the US. The safety and immunogenicity of a 3rd dose of Comirnaty in individuals 65 years of age and older is based on safety and immunogenicity data in adults of 18 to 55 years of age. See the whole assessment report here. For Spikevax, current trial data show that a booster of Spikevax 6 to 8 months after the second dose leads to a rise in antibody levels in adults whose antibody levels were waning The safety and immunogenicity of a booster dose of Spikevax are evaluated in an ongoing Phase 2, randomized, observer-blind, placebo-controlled, dose-confirmation study in participants 18 years of age and older.

The EMA has also approved an extra dose for the **severely immunocompromised (aged 12+)**, which may be given at least 28 days after the second dose. The assessment report is based on published literature. Studies showed that an extra dose of these vaccines increased the ability to produce antibodies against the virus that causes COVID-19 in organ transplant patients with weakened immune systems. Although there is no direct evidence that the ability to produce antibodies in these patients protected against COVID-19, it is expected that the extra dose would increase protection at least in some patients.

The pattern of side effects is very similar to what happens after the 2nd dose for both of the vaccines, but there is limited data is available. No specific safety concern has been raised. The safety appears appear reassuring. EMA will monitor very rare side effects, such as myocarditis. EMA's Pharmacovigilance and Risk Assessment committee (PRAC) is currently evaluating a safety signal on risk of myocarditis/pericarditis for both Comirnaty and Spikevax. On the basis of existing evidence, the CHMP considers there is no reason to restrict the use of booster doses in certain age groups.

For the Janssen's vaccine, the EMA is waiting data on addition data on booster doses to be given 2 to 6 months after the first dose.

EMA gets many questions on **heterologous vaccination** for booster doses: the use of a different vaccine than the one used for the primary series for boosting the immune response, EMA calls this **'mix and match' boosting strategy**. Several studies prove that certain vaccine combinations would trigger a strong immune response. EMA is currently evaluating these data and will consider if clinical data is sufficient to update the product information for each individual vaccine.

An important part is to share data and be transparent. EMA publishes assessment reports. They will also publish the clinical data that lead to the approval of these booster doses. More data from companies marketing the vaccines are expected in the coming weeks and EMA will keep reviewing the information. EMA is engaging with vaccine developers to coordinate submission of these data. EMA closely monitors breakthrough infections and vaccine effectiveness (against infections, severe disease and deaths). Finally, member states need to prepare for possible adaptations to their vaccination programs in case of a substantial decrease in vaccine effectiveness is noted in specific population groups or in the population at large.

## Questions

**Claudia Habl**: There is a big debate in Austria on cross vaccination. Especially for people that have received the vaccine by AstraZeneca. We are promoting boosters, but it is a difficult discussion on how to deal with this.

**Rosa Gonzalez-Quevedo**: These mix and match strategies are indeed an attractive option. The EMA is currently looking at mix and match data. But it is up to each member states, based on the availability of vaccines and their epidemiological situation to make a decision. But it is important for the EMA to review the scientific evidence that is out there and inform the member states. The mRNA-vaccine booster after the vector vaccines is for many member states an attractive option, the EMA is waiting on data to become available.

**Howard Needham**: Could you give any insight/update on assessment of efficacy/safety of therapeutics against COVID? (Antivirals/MAbs etc?)

**Rosa Gonzalez-Quevedo**: There are a number of antibodies and therapeutics under review. Molnupiravir is now undergoing a rolling review.

## Admiral Henrique Gouveia e Melo

*Following an impressive and successful navy career, Admiral Gouveia e Melo, took on an high-profile role during the COVID-19 pandemic, with his appointment as Coordinator of the COVID-19 Vaccination Plan Task Force.*

In Portugal there is not a large group of 'antivaxxers', generally Portugal has a relatively high vaccination rate. When the vaccination campaign started in early 2021; about of the Portuguese 40% had some doubts. My strategic was to use **war rhetoric**: 'It is us against the virus. There is no neutral camp; when you are not getting the vaccination; you are on the side of the virus'.

We working in a triangle: **leadership, communication and organisation**. For the organisation part, the organisation of the vaccination centres, there are generally no issues. There are issues in leadership and the communication: You have to have a clear communication and clear leadership. When you leave a vacuum, someone will try to fill it up and spread misinformation. From the start, the leadership and the media campaign were very important. When you talk about the pandemic of being a war, you can communicate the importance of protecting yourself. I told everyone that I would not take of the uniform before we have reached an 85% vaccination uptake. That creates a **strong image**.

It was a **combination of these strategies that led to results**; one the one side, eroding the anti-vaccine camp, and on the other side the increasing the speed of vaccination by requesting the vaccines that were not used in other European countries. Today we have a percentage of 86.5% of fully vaccinated people in Portugal. But even with this percentage we still see an increase in cases in Portugal. The vaccination protected not very well against getting infected, but it did protect your health: we did not see a big increase in hospitalized persons.

We cannot vaccinate more people in Portugal as we already reached such a high vaccine uptake, unless we decide to vaccinate children, so there is not much room to improve. Many countries are now discussing the 3rd dose of the vaccine. The question remains if we can fight the positivity rate with more doses? The problem are not the people who are vaccinated, but the people who are not vaccinated. We see a pandemic in this last group. In Portugal, we communicated to the public using this war strategy; **very clear language**. An example: You cannot try to escape; you will be vaccinated by either the vaccine or by the virus. With these kind of very simple messages, we bring everybody to vaccination.

My **campaign was not politicized**. If you do so, other parties and groups will try to attack the campaign. Being the military nobody will attack you. We brought doctors and nurses together to talk in an orchestrated way in favour of the vaccine. My only worry is that **we won the battle in Portugal, but this is a global war**. We can vaccinate the same person 20 times, but need to vaccinate the other one who is currently unvaccinated. Vaccines need to go to poorer countries that really need it and to boost the global war against the virus.

### Questions

**Petronille Bogaert:** Using your war rhetoric, do you reach the hard-to-reach group, the vulnerable groups, that have been hit the hardest by the crisis, both directly (mortality and morbidity) and indirectly?

**Admiral Gouveia e Melo**: We have a large number of people working illegally in Portugal. We made a plan only for these people: we spread the message that if they came to the vaccination centres, they would not be arrested. We starting campaigning in different communities and asked their community leaders to their people to the vaccination centres. We also did campaign in agriculture: with a group of military personnel we vaccinated the people in the places where they were working. In 3 days we vaccinated thousands of people this way. We asked the employers to bring their people and informed them that we would not be taking any information from them, that we only want to protect them. Furthermore, I use very simplified messages. I'm not a doctor, I tried to translate the doctors' message.

**Luís Lapão**: How was the relationship with the Ministry of Health? In terms of lessons learned; what will be the future role of army forces in future pandemics?

**Admiral Gouveia e Melo**: The relation with the Ministry of Health was difficult in the beginning. But I use consent leadership; I try from the beginning to show that I was not there to be a military person, but a person that tried to help them to get organised. It is important to keep into account the government's opinion and integrate them and in the management strategy. I asked the government to retire me when 85% vaccination uptake was reached. We are trying to help the health system to cope with the pandemic, but not to impose ourselves and we are using this opportunity to make an advance from the military to the civil society.

## Concluding remarks

We thank all the speakers for their contribution to this Rapid Exchange Forum Rapid Edition.

## Disclaimer

## Presentation Slides

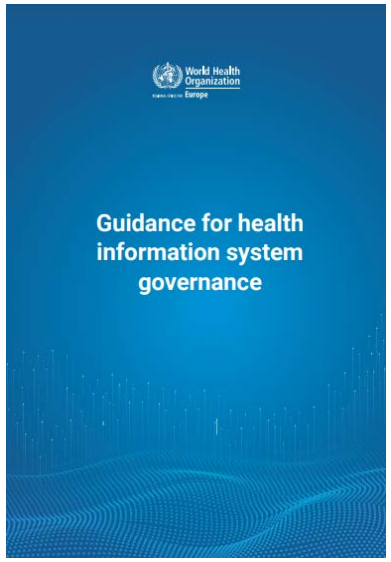
World Health Organization
REGIONAL OFFICE FOR Europe

# PHIRI – WP8
# Rapid Exchange Forum

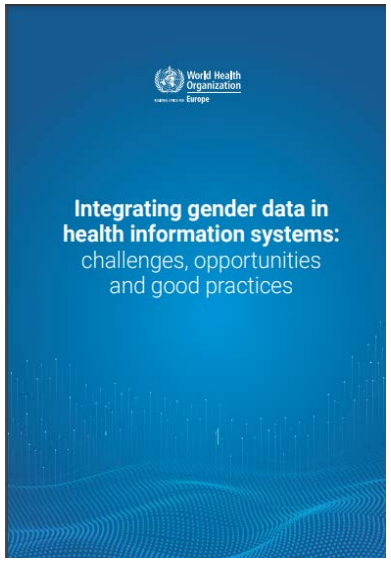
**Dr David Novillo Ortiz, WHO/EUROPE | Unit Head, Data, Metrics and Analytics**

8 November 2021

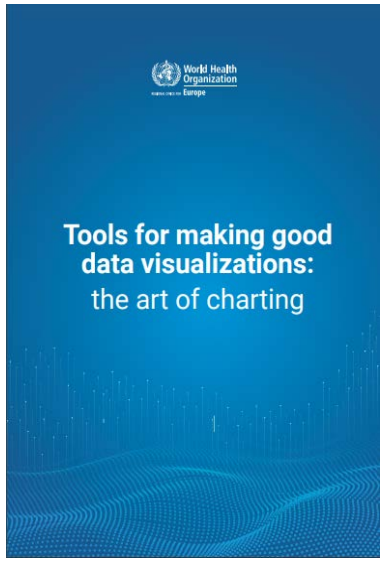
# Technical guidance



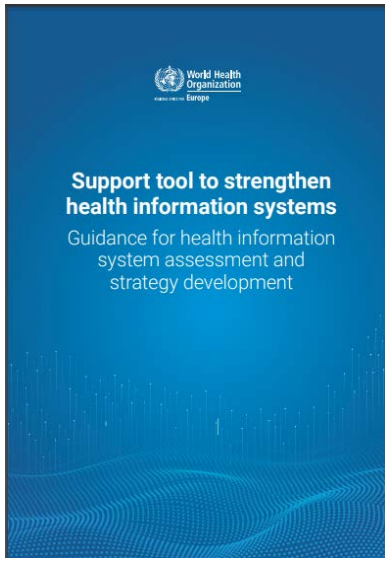

HIS governance



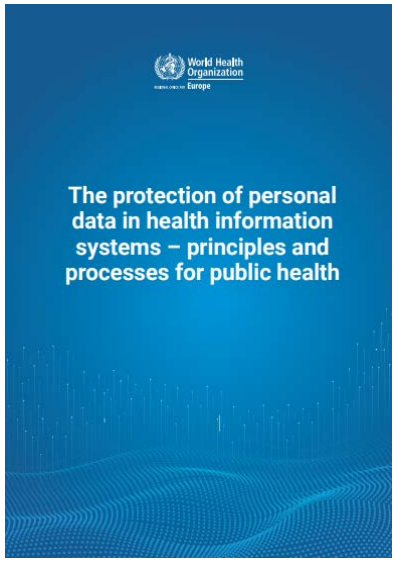

Gender data



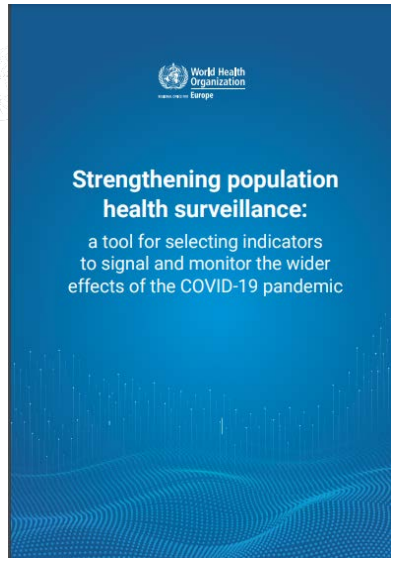

Data visualizations




HIS assessment




Data protection




Surveillance

# Scientific publications


"To develop or enhance a national data governance plan that includes a clear coordination mechanism, well-defined and documented data processes (manual or electronic), the exchange of data, and a data culture to empower users."

Azzopardi-Muscat N, Kluge HHP, Asma S, Novillo-Ortiz D. **A call to strengthen data in response to COVID-19 and beyond**. Journal of the American Medical Informatics Association, 28(3), 2021, 638–639. doi: 10.1093/jamia/ocaa308. PMID: 33275146, https://doi.org/10.1093/jamia/ocaa308

# Scientific publications

- **Health Information Systems in the COVID-19 Pandemic: A Short Survey of Experiences and Lessons Learned From the European Region**. Front. Public Health. 2021 9:676838. https://pubmed.ncbi.nlm.nih.gov/34650946/
- **Data and Digital Solutions to Support Surveillance Strategies in the Context of the COVID-19 Pandemic**. Front. Digit. Health. 2021 3:707902. https://pubmed.ncbi.nlm.nih.gov/34713179/
- **Technological progress in electronic health record system optimization: Systematic review of systematic literature reviews**. Int J Med Inform. 2021 Aug;152:104507. https://pubmed.ncbi.nlm.nih.gov/34049051/
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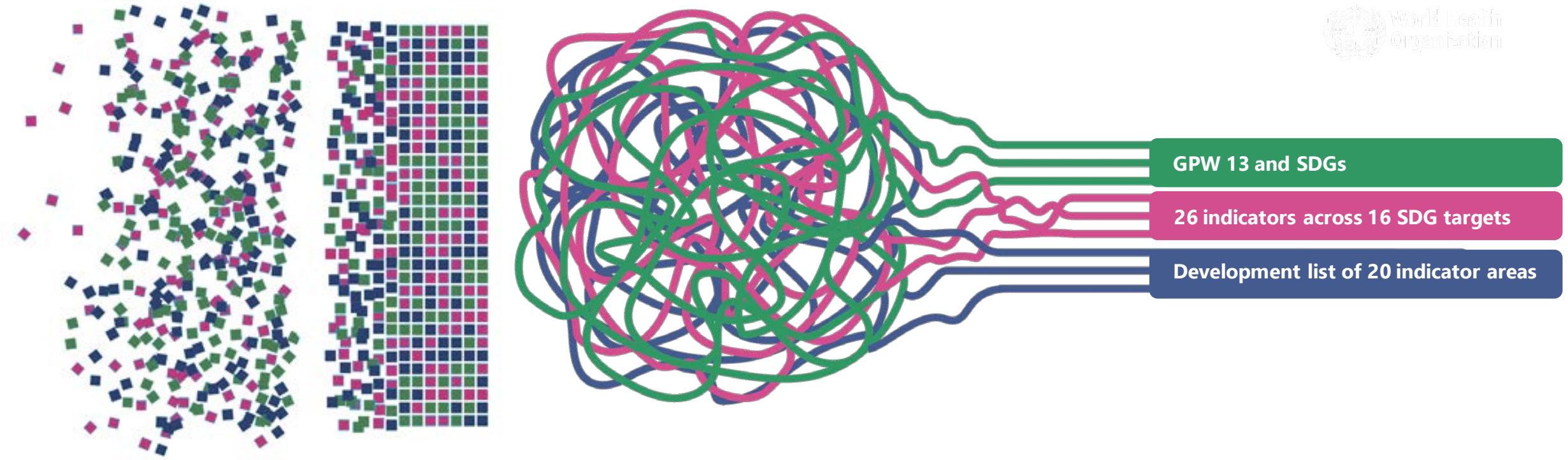
- **Impact of Big Data Analytics on People's Health: Overview of Systematic Reviews and Recommendations for Future Studies**. J Med Internet Res. 2021 Apr 13;23(4):e27275. https://pubmed.ncbi.nlm.nih.gov/33847586/

# Capacity building

- **Training on COVID-19 Coding and Death Certification**

- **The Better Data for Better Health webinar series**
  - #4 Gender data – Thursday, 25 November 2021
  - #3 Data visualizations
  - #2 Data protection
  - #1 Monitoring the wider effects of the COVID-19 pandemic

# EPW Measurement Framework



# Thank you!

World Health Organization
REGIONAL OFFICE FOR Europe

World Health Organization

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# COVID-19 vaccines' extra doses


PHIRI meeting on information exchange on COVID-19 between countries

8 November 2021

Rosa Gonzalez-Quevedo, PhD
Stakeholders and Communication Division, EMA

# Outline

- EMA's role in COVID-19 vaccine booster doses
- Comirnaty's boosters
- Spikevax's boosters
- Comirnaty and Spikevax - extra dose for immunocompromised
- Update on Janssen's vaccine and extra doses
- Update on heterologous vaccination in the context of booster doses
- Conclusions

# How EMA works to evaluate booster doses

**EMA**

- **Evaluates benefits and risks** of COVID-19 vaccines - initially and during lifecycle
- **Carries out pharmacovigilance and risk management** activities for all EU medicines
- **Its Pandemic Task Force (ETF)** supports the scientific evaluation by EMA committees & supports developers
- **Reviews the data submitted by companies** when applying to change the terms of their COVID-19 vaccine marketing authorizations (e.g. authorization of extra doses)
- **Reviews Real World Evidence** as important data source to complement clinical trial data
- If changes to marketing authorization are approvable, **updates the EU product information**
  - Summary of Product Characteristics – or SmPC - and Package Leaflet
- **Exchanges information with national authorities and the European Centre for Disease Prevention and Control** (ECDC) to evaluate available data and support campaigns to protect the public during the ongoing pandemic

# Comirnaty / Spikevax – approved use of booster doses

- Booster doses are for people with normally functioning immune systems

**Comirnaty (Pfizer COVID-19 vaccine)**

- Primary course of 2 doses given 3 weeks apart - one dose contains 30 micrograms
- A **booster dose (30 micrograms)** of Comirnaty may be administered intramuscularly **at least 6 months after the second dose in adults (18 years of age and older)**

**Spikevax (Moderna COVID-19 vaccine)**

- Primary course of 2 doses given 28 days apart - one dose contains 100 micrograms
- A **booster dose (50 micrograms**, half the dose used in primary series) may be administered intramuscularly **at least 6 months after the second dose in adults (18 years of age and older)**

*The decision **when and for whom to implement a third dose** should be made based on **available vaccine effectiveness data, taking into account limited safety data** (product information, SmPC sections 4.4 and 5.1)*

# Comirnaty – evidence base for use of booster doses

- Based on interim safety and immunogenicity data of a third booster dose of Comirnaty from **study C4591001**, a Phase 1/2/3, placebo-controlled, observer-blind, interventional, dose-finding, study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-CoV-2 RNA vaccine candidates against COVID-19 in healthy individuals
- **Further evidence - published real-world effectiveness data from Israel and the US** [1]
- The safety and immunogenicity of a booster dose (third dose) of Comirnaty in individuals 65 years of age and older is based on **safety and immunogenicity data in adults of 18 to 55 years of age**
- The summary of the scientific evaluation can be found in the **assessment report**: https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-ii-0067-epar-assessment-report-variation_en.pdf


- 1. Hause et al, MMWR Morb Mortal Wkl. 2021 Oct 1;70(39):1379-1384. doi:10.15585/mmwr.mm7039e4; Bar-on et al, N Engl J Med 2021 Oct 7;385(15):1393-1400. doi: 10.1056/NEJMoa2114255

# Spikevax – evidence base for use of booster doses

- Current **trial data** show that a booster of Spikevax 6 to 8 months after the second dose leads to a rise in antibody levels in adults whose antibody levels were waning

- The safety and immunogenicity of a booster dose of Spikevax are evaluated in an ongoing Phase 2, randomised, observer-blind, placebo-controlled, dose-confirmation study in **participants 18 years of age and older** (NCT04405076).
- The summary of the scientific evaluation will be found in the **assessment report**, once published

# Extra doses for immunocompromised

**Comirnaty and Spikevax**

- **An extra dose** (considered the third dose of the primary series) **of Comirnaty / Spikevax may be given at least 28 days after the second dose**
- Indicated for individuals who are **severely immunocompromised aged 12 years and older** (SmPC section 4.4)
- Studies showed that **an extra dose of these vaccines increased the ability to produce antibodies** against the virus that causes COVID-19 in organ transplant patients with weakened immune systems[1,2]
- Although there is no direct evidence that the ability to produce antibodies in these patients protected against COVID-19, it is **expected that the extra dose would increase protection at least in some patients**
- EMA will continue monitoring any data that emerges on its effectiveness


1. Kamar N, Abravanel F, Marion O, Couat C, Izopet J, Del Bello A. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med 2021;385:661-662

2. Hall VG, Ferreira VH, Ku T, et al. Randomized trial of a third dose of mRNA-1273 vaccine in transplant recipients. N Engl J Med 2021;385:1244-1246

# Safety of booster doses – effect on myocarditis and pericarditis

- Current data indicate that the pattern of **side effects after the booster is similar to what occurs after the second dose** for Comirnaty and Spikevax
- **Limited data on safety of third dose** for both vaccines, however **no specific safety signal** has been identified following 3rd dose of Comirnaty/Spikevax
- **Real World Evidence** from Israel / US on the safety of the 3rd dose is **reassuring**
- The risk of inflammatory heart conditions or other **very rare side effects after a booster are carefully monitored**
  - Risk of **myocarditis/pericarditis with mRNA vaccines after a third dose has not been characterised**
  - EMA's Pharmacovigilance and Risk Assessment committee (PRAC) is currently evaluating **a safety signal on risk of myocarditis/pericarditis for Comirnaty / Spikevax**
- **Younger people may suffer from severe COVID-19**, including infection-induced myocarditis/pericarditis
- On the basis of existing evidence, the CHMP considers there is **no reason to restrict the use of booster doses in certain age groups, instead it has granted approval for all adults** with a warning in the SmPC

# Janssen's – use of booster doses

- **Some Member States have started recommending a second vaccine dose with an mRNA vaccine following a first vaccination with Janssen**
- This is because, as more data on effectiveness become available, **one dose of Janssen does not seem to provide longer term protection**
- Over coming weeks, **the Agency expects to receive data on additional/booster doses of Janssen's vaccine given 2 to 6 months after the first dose**
- This will help EMA determine if data are sufficient to recommend a booster dose
- **EMA will communicate** as the situation develops

# Heterologous vaccination for booster doses

- Use of a different vaccine than the one used for the primary series for boosting the immune response
- This '**mix and match' boosting strategy is being used and considered by some EU Member States**
- Also **approved by FDA** (for heterologous boosters)
- Several studies prove that **certain vaccine combinations would trigger a strong immune response**
- **EMA is currently evaluating these data** and will consider if clinical data is sufficient to update the product information for each individual vaccine
- At present, the product information for Comirnaty/Spikevax states that *Interchangeability with other COVID-19 vaccines to complete the primary vaccination course or the booster dose (third dose) has not been established*.

# Transparency and data

## Use of booster doses

- EMA is publishing the Assessment Reports summarizing the evaluation on use of booster and extra doses

### Comirnaty

- Booster doses: https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-ii-0067-epar-assessment-report-variation_en.pdf
- Extra doses for immunocompromised: https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-ii-0062-epar-assessment-report-variation_en.pdf

### Spikevax

- Booster doses: to be published here under 'assessment history – changes since initial authorization of the medicine': https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax
- Extra doses for immunocompromised: https://www.ema.europa.eu/en/documents/variation-report/spikevax-previously-covid-19-vaccine-moderna-h-c-5791-ii-31-epar-assessment-report-variation_en.pdf

- EMA has put extra transparency measures in place for COVID-19 medicines
  - the relevant clinical data will be put in the public domain

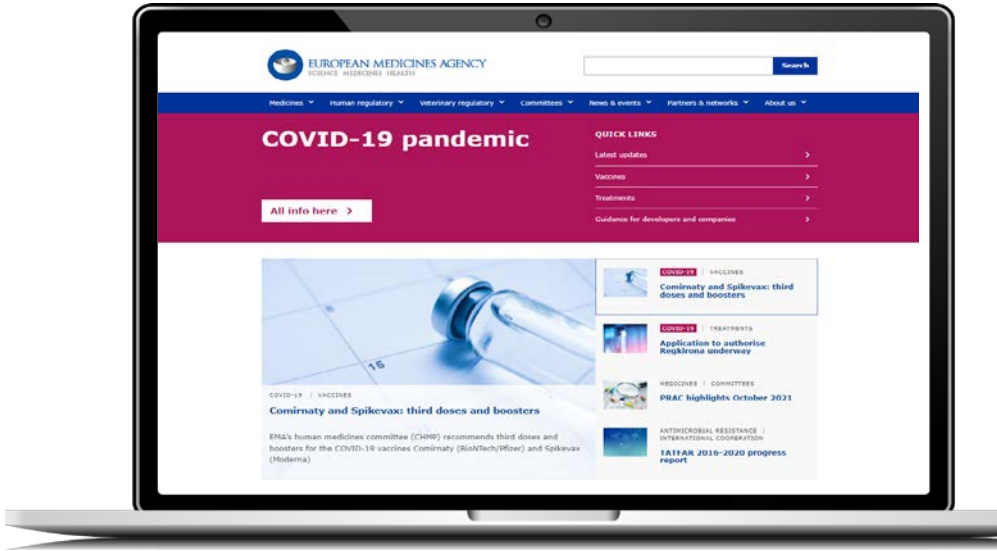
# Conclusions

## Use of booster doses

- Most Member States have started giving booster doses
- **EMA has assessed and made recommendation for third doses for mRNA vaccines**, which are the basis for national vaccination decisions. **Transparency measures ensure clinical data will be published**
- Advice on how vaccinations should be given remains the **responsibility of the national immunisation technical advisory groups** (NITAGs). EMA and ECDC are already collaborating with NITAGs
- **Real world effectiveness data** from Europe and other parts of the world are of particular interest to supplement data from clinical trials investigating booster doses
- **More data from companies marketing the vaccines are expected in the coming weeks** and EMA will keep reviewing the information. EMA is engaging with vaccine developers to coordinate submission of these data
- **Close monitoring of breakthrough infections and vaccine effectiveness** (against infections, severe disease and deaths), should be continued
- **Member States need to prepare for possible adaptations to their vaccination programs** in case of a substantial decrease in vaccine effectiveness is noted in specific population groups or in the population at large

# Latest updates on EMA's corporate website:

COVID-19 pandemic

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# Vaccination of people recovered from COVID-19

- Data suggest that **natural immunity, while effective, wanes over time**

- For individuals who have already recovered from the infection with natural immunity, evidence shows that **vaccination helps develop an increased ability to fight future infection**

- The optimal schedule for these individuals to be vaccinated has not been identified, and **more data are needed to understand how to maximise protection**

- From data on severe disease, hospitalisation and death caused by COVID-19, as well as from the incomplete understanding of so-called “long-Covid”, it is clear that **the cost of natural immunity is not tolerable**