



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA's vaccines outreach strategy

Vaccines Outreach Group (VOG)

3 July 2024

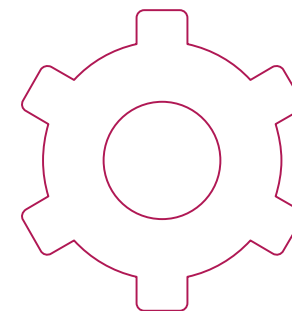
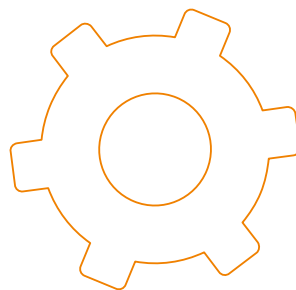
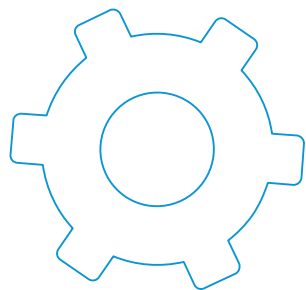
Presented by Marco Cavaleri / Melanie Carr
Head of Public Health Threats / Head of Stakeholders and Communication

An agency of the European Union





In this presentation



Why does EMA need a Vaccines Outreach Strategy?

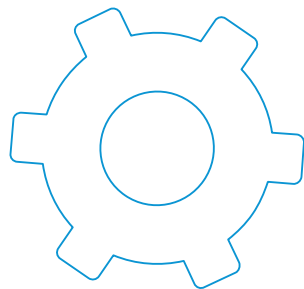
- Rationale
- Analysis driving EMA strategy

What would we like to achieve?

- Goal and areas of work
- Collaborating with ECDC/EC

How can we work?

- Opportunities for collaboration



Why does EMA need a Vaccines Outreach Strategy?

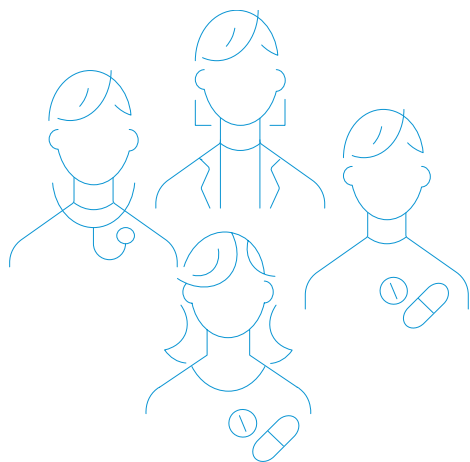
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Analysis



Identifying the **external trends and changes** that will affect the Agency and its upcoming work to increase confidence in the regulatory system for vaccines



- Environment stakeholders and publics (pre-COVID)
- Organisation challenges and opportunities (pre-COVID)
- Updated Strategy paper with COVID-19 context



Key outcomes from analysis - 2024

- **Mistrust** landscape: vaccine **hesitancy**, **misleading information** online, scepticism in public authorities
- Lack of knowledge/minimisation of **consequences of infectious diseases** (e.g. Long COVID)
- **Lack of alignment** among public health authorities + '**pandemic fatigue**'
 - *Still thousands of excess deaths/hospitalisations from COVID-19 (mainly vulnerable groups) despite available boosters*
- Increasing perception that **natural infections** with pathogens are beneficial for building **strong immunity** (perceived lack of benefit with 'spillover vaccine hesitancy')
- **Gaps in knowledge** on vaccines to address public health **concerns**
- Pushing out information not sufficient – **fundamental to listen and engage with professionals at the forefront of patient care**
- **Education on vaccine science** as a new field – leverage existing initiatives



A **proactive, long term** approach to **enhance knowledge** on **vaccine science** is needed



Focus efforts on **audience with genuine concerns** willing to take in the facts



Key trends 2024 – Analysis by FDA

Opinion

VIEWPOINT

Is Vaccination Approaching a Dangerous Tipping Point?

Peter Marks, MD, PhD
US Food and Drug
Administration,
Silver Spring, Maryland.

Robert Califf, MD
US Food and Drug
Administration,
Silver Spring, Maryland.

Vaccination is one of the most highly effective public health interventions, responsible for saving millions of lives each year. In the US, authorized or approved preventive vaccines must be manufactured with high quality, and the effectiveness and favorable safety profile of vaccines must be demonstrated. Their safety over time is also closely and continuously monitored through multiple overlapping passive and active safety surveillance systems, including the Vaccine Adverse Event Reporting System, the Vaccine Safety Datalink, and the BEST Sentinel Initiative.¹

Despite the care taken in the development and deployment of vaccines and their clear and compelling benefit of saving individual lives and improving population health outcomes, an increasing number of people in the US are now declining vaccination for a variety of reasons, ranging from safety concerns to religious beliefs. Setting aside for now the controversial issue of vaccine mandates at the federal, state, or local level in the US, which are not within the purview of the Food and Drug Administration (FDA), the situation has now deteriorated to the point that population immunity against some vaccine-preventable infectious diseases is at risk, and thousands of excess deaths are likely to occur this season due to illnesses amenable to prevention or reduction in severity of illness with vaccines.

To counter the current trend, we urge the clinical and biomedical community to redouble its efforts to provide accurate plain-language information regarding the individual and collective benefits and risks of vaccination. Such information is now needed because vaccines have been so successful in achieving their intended effects that many people no longer see the disturbing morbidity and mortality from infections amenable to vaccines. For example, smallpox has been eradicated, and polio has been eliminated from the US, through effective vaccination campaigns.

Measles was similarly eliminated, but imported cases remain a threat to those who are unvaccinated as well as to those who are immunocompromised. Regrettably, pe-

diatric vaccination campaigns to date, increasing numbers of people have become complacent and underestimate the actual risk of forgoing vaccination.

In addition to making a difference regarding childhood immunization, communication regarding the potential benefits of vaccination can hopefully also improve the number of individuals accepting vaccination to protect against COVID-19, influenza, and respiratory syncytial virus disease. Vaccination rates against these respiratory pathogens are inadequate, and this is most distressing in older individuals in whom the benefits of vaccination in reducing hospitalization and death are eminently clear. In fact, uptake of the updated COVID-19 vaccine (XBB.1.5 monovalent) in the US is only about 35% in those older than 65 years, which is about half the rate in this age group in the UK.

What can we do to start tipping the scales in the direction of evidence-informed vaccine acceptance to reduce the risk of death and illness from diseases in which vaccines are effective? Evidence indicates that the most trusted source of information about health decisions remains clinicians who provide care. Broadly interpreted this also includes retail pharmacists, who may serve as the only source of medical advice for the many individuals in the US who lack a primary care clinician or who are uninsured. All those working in health care, while being straightforward about the risks, need to better educate people regarding the benefits of vaccination, so that individuals can make well-informed choices based on accurate scientific evidence. For example, contrary to a wealth of misinformation available on social media and the internet, data from various studies indicate that since the beginning of the COVID-19 pandemic tens of millions of lives were saved by vaccination (Figure).² The benefits of these vaccines in prevention were largest in older individuals. However, studies show that people of all ages who are up to date on vaccination benefit and have a lower risk of developing long COVID.³

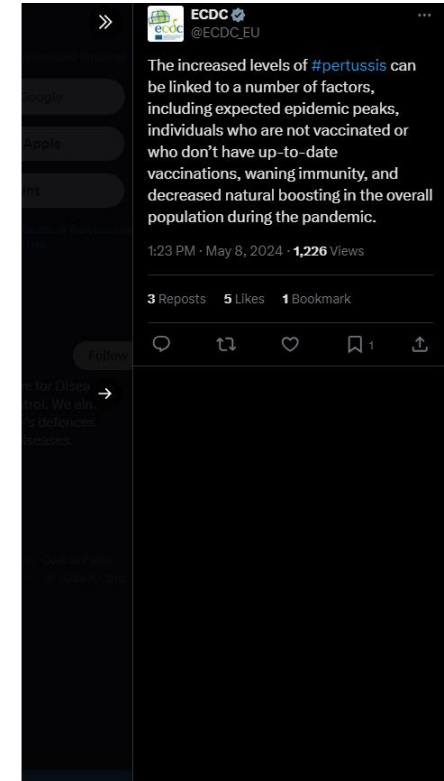
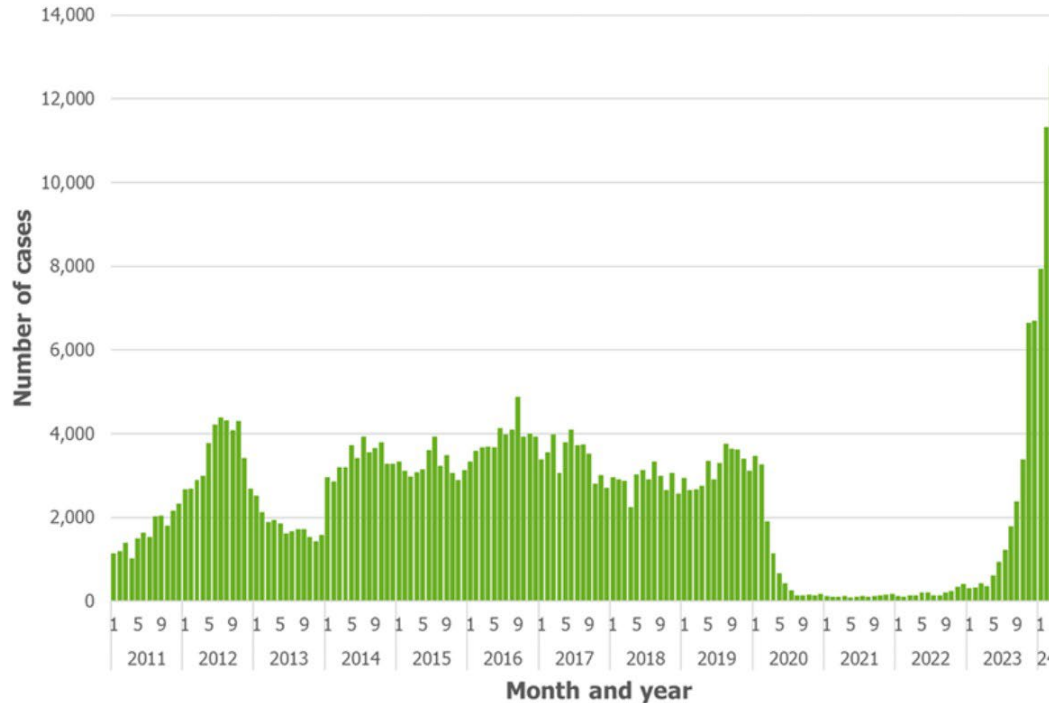
And although the argument is sometimes made that COVID-19 is not a serious illness in younger individuals,

- **“We urge the clinical and biomedical community to redouble its efforts to provide accurate plain-language information regarding the individual and collective benefits and risks of vaccination.**
- **Such information is now needed because vaccines have been so successful in achieving their intended effects that many people no longer see the disturbing morbidity and mortality from infections amenable to vaccines”**



Increased pertussis in the EU – ECDC data

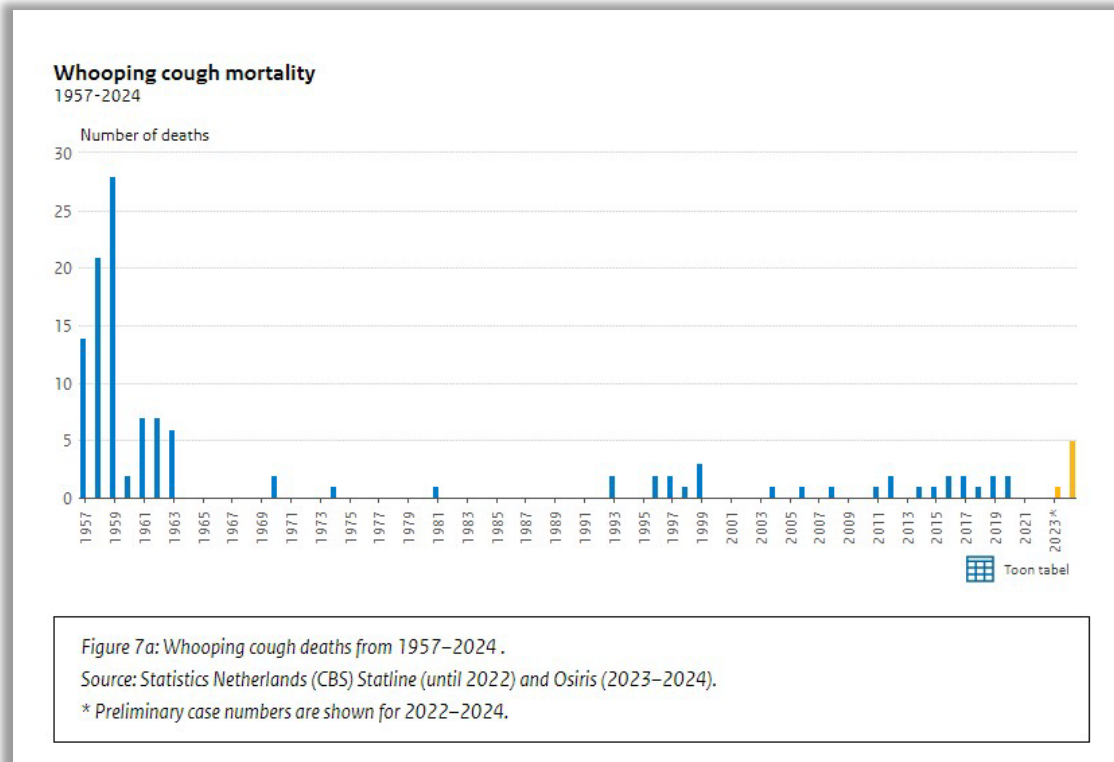
Figure 1. Number of pertussis cases reported to ECDC, by month and year, 1 January 2011 to 31 March 2024², EU/EEA³

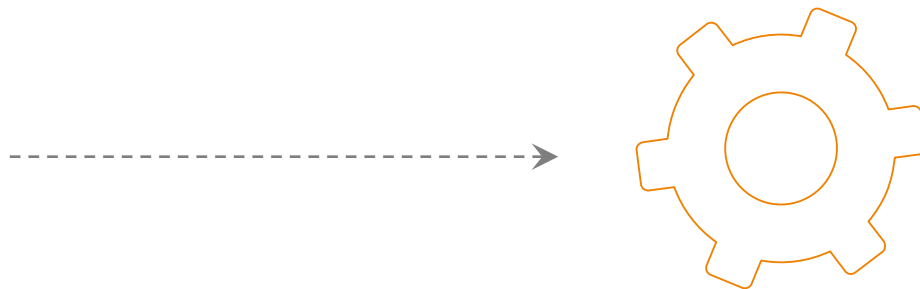




Mortality due to whooping cough – Netherlands case study

- Before vaccination against whooping cough was introduced in 1957, about 200 Dutch children died each year from the disease
- After whooping cough vaccination was introduced in the Netherlands, the number of children with whooping cough fell sharply
- From 1964 on, there were about 0–2 deaths from whooping cough annually in the Netherlands
- As of 17 April 2024, the total number of deaths from whooping cough in 2024 is currently 5



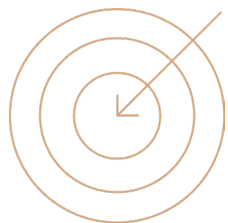


What would we like to achieve?

- Goal and areas of work
- Collaborating with ECDC/EC



What would we like to achieve?



Our goal

To increase knowledge of and trust in the quality, safety and effectiveness of vaccines, and empower the EU public and healthcare professionals to take well-informed vaccination decisions.





What would we like to achieve?

Objectives

- **Environmental monitoring and analysis of vaccine concerns**, in collaboration with **EU partners and stakeholders** and existing EU initiatives
- **Science outreach activities** to increase public knowledge and understanding of vaccines
- Collaborate in **ongoing initiatives** into and new ways to **improve access to information** on vaccines
- **Strengthen strategic collaboration with EU and international partners** to improve outreach and coordinated vaccine messages
- Promote **research on vaccines and public engagement** in vaccine-related issues

Proposed primary focus



Safety



Effectiveness – more and more an issue. Doubts about effectiveness contribute to further eroding public trust – especially considering concomitant scepticism amongst some healthcare professionals



Risk Perception/Minimisation of impact of infectious diseases

Confidence in Quality - Many safety / efficacy issues derive from quality aspects



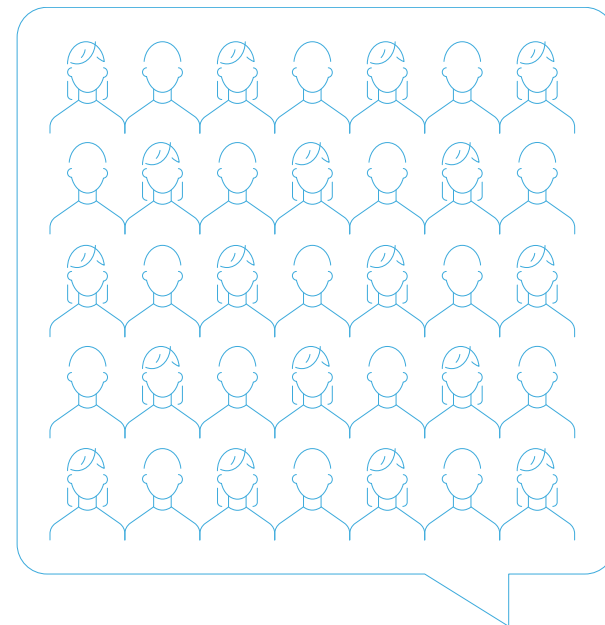
Handling of scientific uncertainty is at the core of the exercise - both an opportunity and threat – we should invest on how to best address and communicate it

– Lessons learnt from HPV referral and assessment of uncertainty



Who should we involve?

- **Patients, consumers and healthcare professionals** (including pharmacists, GPs and nurses)
- **EU experts, ECDC** and **European Commission**
- **NCA**s
- **Health authorities** at national level (in collaboration with ECDC)
- **International health authorities** (e.g. WHO, FDA)
- **Academia:**
 - Research agenda to drive research in areas where more scientific evidence is needed
 - Experts on vaccine science education
- **Other relevant players?**

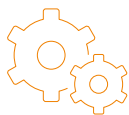


How are we planning to achieve it? Focus areas (1)



New vaccine information and educational materials

Patients, consumers, academics and healthcare professionals as **advocates on vaccine science**



Continuous monitoring of public perception, including through stakeholder listening, dialogue & engagement and identification of false rumours/misinformation



Maximise communication channels/tools

Identify **new channels** and opportunities to enhance vaccine knowledge



Coordinate public health messages on vaccines across the EU Network and with **international** partners



How are we planning to achieve it? Focus areas (2)



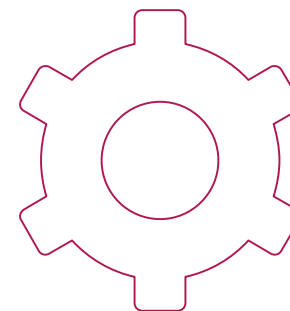
Engage with academia to drive research in areas where further scientific evidence regarding the benefit/risk of vaccination is considered important



Disseminate new data generated post-authorisation on the impact of vaccination



Support the Agency's activities to increase **preparedness for public health threats/pandemics**



How can we work?

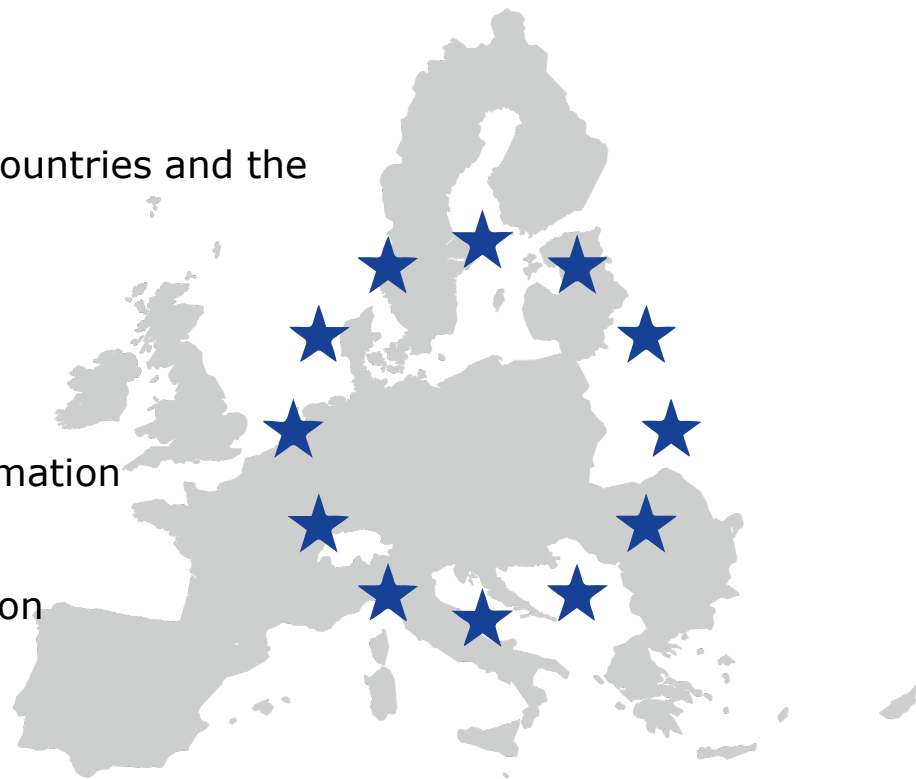
- Opportunities for collaboration



Collaborating with the European Commission and ECDC

EMA is **supporting the ongoing work** of EU countries and the European Commission

- **EC Council Recommendation**
- **ECDC's portal** (European Vaccination Information Portal, EVIP)
- **Member States' Joint Action** on Vaccination





Opportunities for collaboration



HCPWP/PCWP

- Input into EVIP and EMA materials
- User-testing

Discussion with academics working on vaccine educational initiatives

- With representative from HCPWP/PCWP
- International partners & WHO

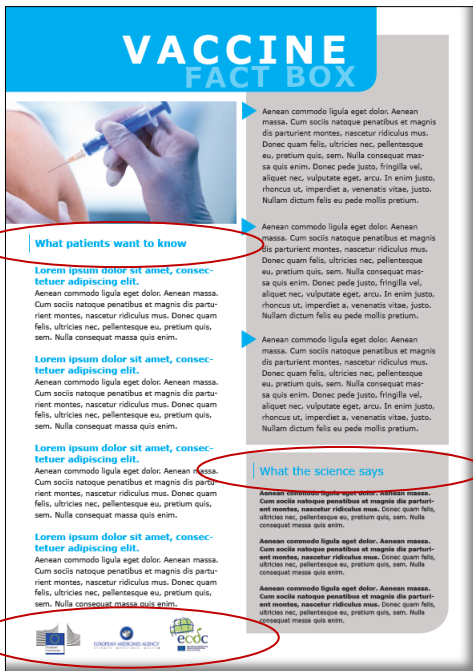
Workshop on vaccines tbc



Proposal for pilot: Vaccine fact boxes

'What patients want to know'

- Proactively addressing recurrent concerns identified through stakeholder listening
- Simple messages agreed with experts
- Ad hoc for relevant topics – vaccine science literacy/misinformation
- Repurposing EMA scientific articles
- Reviewed by patient & HCP organisations
- Include scientific references
- In collaboration with other public health authorities or learned societies
 - ECDC , WHO as needed - supporting epidemiological data
 - European Academy of Paediatrics
 - Etc.
- Joint campaigns





Thank you for your attention

Further information

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