Wat als…
ik een bijwerking van een vaccin meld?
Van Registratie tot Evaluatie

23e Valentijn Vaccinatiesymposium

UAntwerpen, 7 Februari 2025

Prof. Dr. Jean Michel Dogné (Université de Namur)

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fagg
federaal agentschap voor geneesmiddelen en gezondheidsproducten

.be

slido

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Heeft u ooit al eens een bijwerking gemeld? (meerder opties mogelijk)

ⓘ Start presenting to display the poll results on this slide.

Inhoud

- Registratie (waarom, hoe, wat?)
- Evaluatie: individueel niveau
- Evaluatie: populatieniveau
- Conclusie

Registratie: waarom?

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 January 2023
EMEA/CHMP/VWP/164653/05 Rev. 1
Committee for Medicinal Products for Human Use (CHMP)

Guideline on clinical evaluation of vaccines

7.2. Size of the safety database

The size of the pre-authorisation safety database must be decided on a case by case basis.

If a candidate vaccine contains components not previously included in licensed vaccines it would be usual to aim for a safety database that is sufficient to estimate the frequency of uncommon adverse events (occurring in between 1/100 and 1/1000 vaccinated persons). Nevertheless, this should not be regarded as a generally applicable target since there may be special concerns that need to be addressed for which a larger database would be needed.

Table 1 — Chance that a very rare side-effect (0.01%) will not be observed

Number of patients treated	Chance of missing (%)
500	95.1
1000	90.5
2500	77.9
5000	60.7
7500	47.2
10000	36.8
15000	22.3
20000	13.5
25000	8.2
30000	5.0

Why There is a Need for Pharmacovigilance

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY **8**: 61–64 (1999)

Grootte van de veiligheidsdatabase bij autorisatie (zie SKP/bijsluiter):

- *Hexyon*: 4 661 zuigelingen (13 591 dosissen)
- *Gardasil 9*: 15 776 jongeren (9-26 jaar)
- *Bexsero*: 10 565 waarvan 6 837 kinderen < 2 jaar
- *Imvanex*: 5 261 volwassenen, 2 dosissen
- *Abrysvo*: 3 682 zwangere vrouwen, 18 575 volwassenen > 60 jaar, 1 dosis

Registratie: waarom?

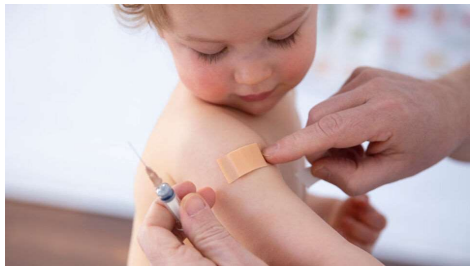
Aanpassen van de SKP/Bijsluiter
Zie Geneesmiddelendatabank/BCFI

Zeer vaak (≥ 1/10)
Vaak (≥1/100 tot <1/10)

Meestal niet ernstig

Vb. Algemeen: koorts, irritabiliteit, malaise
Locale reacties: roodheid, zwelling, pijn

- ➔ Treden meestal op binnen de 48u
- ➔ Weinig impact op de gezondheid
- ➔ Matige impact op aanvaarden van vaccinatie



Soms (≥1/1.000 tot <1/100)
Zelden (≥1/10.000 tot <1/1.000)
Zeer zelden (<1/10.000)

Matig ernstig

Vb. Febriele convulsies,
Urticaria, Hypotonische-hyporeactieve episodes, myocarditis

- ➔ Matige impact op de gezondheid
- ➔ Belangrijke impact op aanvaarden van vaccinatie

Zeer zelden (<1/10.000)
Frequentie niet bekend

Ernstig

Vb. Invaginatie na rotavirus vaccinatie, Narcolepsie na vaccinatie met H1N1-AS03 (Pandemrix), Anaphylaxie, TTS na Vaxzevria

- ➔ Belangrijke impact op de gezondheid (hospitalisatie, sequellen, overlijden)
- ➔ Belangrijke impact op aanvaarden van vaccinatie

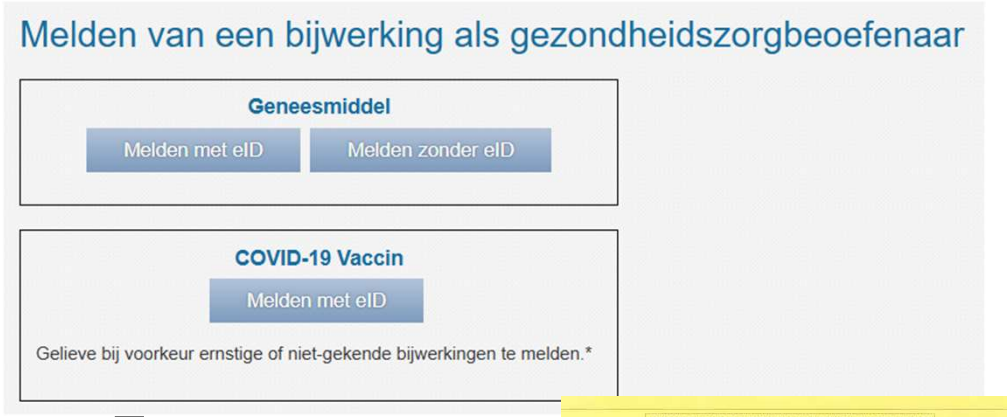
Bijkomend informeren (FAGG VigNews, DHCP, BCFI, HGR..)
Intrekking, schorsing vaccin

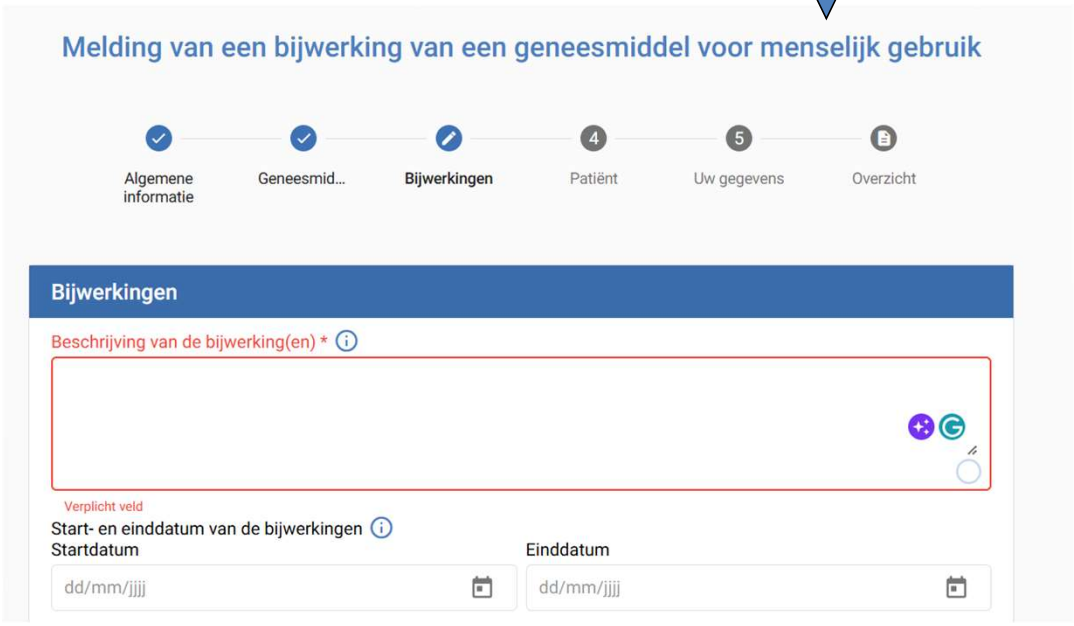
Registratie: hoe?

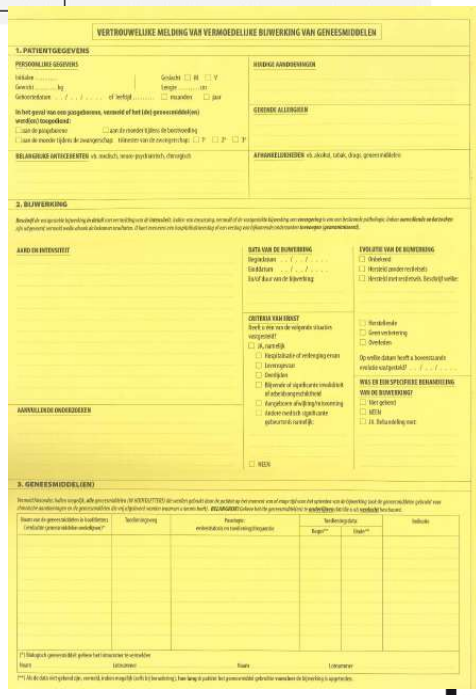
www.**eenbijwerkingmelden**.be

www.fagg-afmps.be

Mail naar: ADR@fagg-afmps.be







Registratie: wat?

Elk vermoeden van schadelijke en onbedoelde reacties na vaccinatie/bij medicatie

Aarzel niet om te melden…

Bijwerking:

- Ernstig: overlijden, levensbedreigende aandoening, ziekenhuisopname, invaliditeit of arbeidsongeschiktheid, aangeboren afwijking of misvorming of een medisch significante gebeurtenis
- Onverwacht: aard, ernst of verloop niet in overeenstemming met de SKP/bijsluiter
- Verdacht: bekend maar abnormaal in frequentie, ernst of afloop

- Speciale populaties: pathologie, immunologische status …
- Off-label
- Toedieningsfouten
- Speciale gebeurtenissen: nieuw vaccin, verandering van vaccin, kwaliteitsprobleem met het vaccin, kwaliteitsprobleem met de spuit, enz.

Het oorzakelijk verband hoeft niet te worden vastgesteld om te registreren

Overzicht Bijwerkingen voorbije 10 jaar (01/01/2014 - 31/12/2023)

N=580 (0-17 jaar)

Tabel 2 – Meest gemelde bijwerkingen na vaccinatie van een zuigeling, een kind of een adolescent

a. Volgens leeftijdscategorie

Zuigelingen/Jonge kinderen 0 - 2 jaar N=311		Kinderen 3 - 11 jaar N=115		Adolescenten 12 - 17 jaar N=154	
Bijwerking	**Percentage van de gevallen (%)**	**Bijwerking**	**Percentage van de gevallen (%)**	**Bijwerking**	**Percentage van de gevallen (%)**
Koorts	21,2 %	Koorts	17,4 %	Hoofdpijn	22,7 %
Braken	15,1 %	Roodheid op de injectieplaats	13,9 %	Duizelig gevoel	14,3 %
Diarree	11,9 %	Braken	11,3%	Braken	12,3 %
Bleekheid	6,8 %	Pijn op de injectieplaats	9,6 %	Pijn op de injectieplaats	11,7 %
Huilen	5,8 %	Verharding op de injectieplaats, roodheid, hoofdpijn	7,0 %	Koorts, pijn in de bovenbuik	8,4 %

Vb. Meldingen van ernstige bijwerkingen:

- 17 gevallen van convulsie
- 11 gevallen van darminvaginatie
- 10 gevallen van uitgebreide zwelling van het gevaccineeerde lidmaat
- 7 gevallen van anafylaxie

Inhoud

- Registratie (waarom, hoe, wat?)
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Categoriën Oorzakelijk verband (WHO-UMC)

Categorie	Criteria (vereenvoudigd)
(1) Zeker	Plausibel tijdsverband Andere oorzaak(en) uitgesloten Mechanisme plausibel, erkend fenomeen
(2) Waarschijnlijk	Redelijke tijdsrelatie Andere oorzaak onwaarschijnlijk
(3) Mogelijk	Redelijke tijdsrelatie Andere oorzaak is mogelijk
(4) Onwaarschijnlijk	Tijdsrelatie is onwaarschijnlijk Andere oorzaak is waarschijnlijker
(5) Voorwaardelijk/Ongedefinieerd	Meer gegevens zijn nodig (tijdelijke code)
(6) Niet Beoordeelbaar	Onvoldoende of tegenstrijdige informatie

https://www.who.int/medicines/areas/quality_safety/safety_efficacy/WHOcausality_assessment.pdf

Evaluatie: individueel

Melding N° 1

Meisje, 9 jaar

Datum van vaccinatie: 21/03/2019 – Bexsero

Start: 22/03/2019

Melding: intense pijn de dag na Bexsero vaccinatie in de dij. Onmogelijk om het been te plooien of te bewegen.

Behandeling: Verbetering met Nurofen Siroop

Evolutie: volledig herstel op dag 4

Einde: 24/03/2019

Oorzakelijk verband N° 1

1. **Tijdsrelate**: start dag na vaccinatie
2. **Andere oorzaken**: geen andere behandeling of oorzaak gemeld
3. **Andere gegevens**:
   - SKP en Micromedex: pijn op injectieplaats, hypotonie en artralgie vermeld
   - Vigibase: 187 meldingen van '*incapacity to walk*'

→ Code 1, zeker

Melding N° 2

Evaluatie: individueel

jongen, 11 jaar

Date of vaccination: 27/05/2024 - Infanrix IPV

Andere behandelingen: geen

Start: 29/05/2024

Bijwerking: gedeeltelijke facialisparese

Behandeling: cortisone en antibiotica start op spoed

Evolutie: herstellende, verminderd maar nog niet verdwenen (14/06/2024)

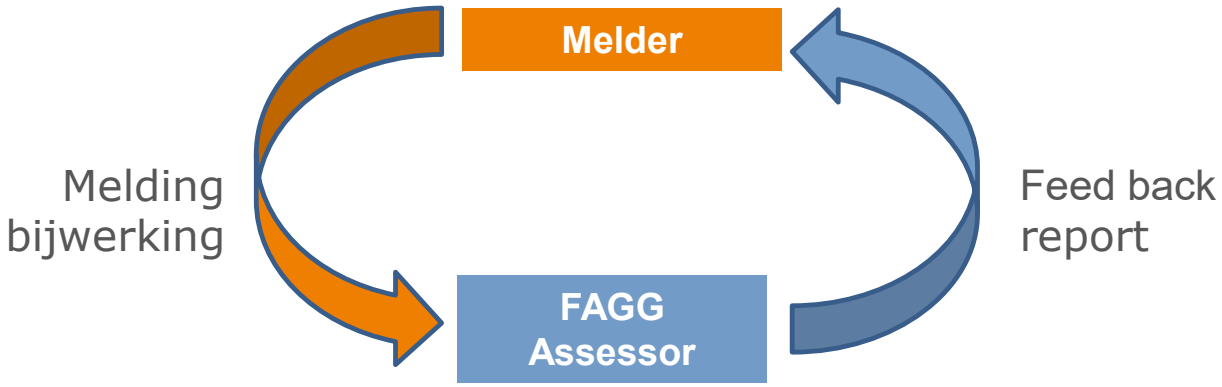
Oorzakelijk verband N° 2

1. Tijdsrelatie: 2 dagen
2. Andere oorzaken: geen
3. Andere gegevens:
   - SKP en Micromedex : not vermeld
   - Literatuur: geen artikels na Infanrix IPV (wel case-reports na influenza, hepatitis B, Comirnaty vaccinatie)
   - Vigibase: 44 meldingen van gelaatsparese (tov. 19 verwacht)

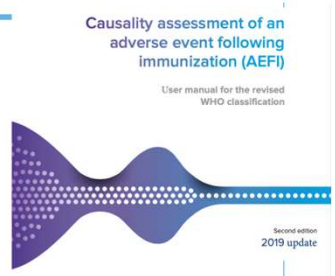
→ Code 3, Mogelijk

Evaluatie: individueel en populatieniveau

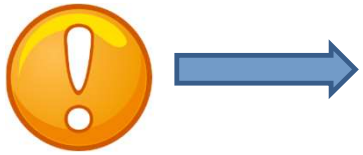
1) Evaluatie van een individuele melding report



Causality assessment usually will not prove or disprove an association between an event and the immunization. It is meant to assist in determining the level of certainty of such an association. A definite causal association or absence of association often cannot be established for an individual event.



2) Evaluatie op populatieniveau: EMA (PSUR, 'signalen'), WHO, CDC…



- **Review van meldingen**
- **Review van andere bronnen:** literatuur, epidemiologische studies, adviesgroepen,…

World Health Organization

EUROPEAN MEDICINES AGENCY

Inhoud

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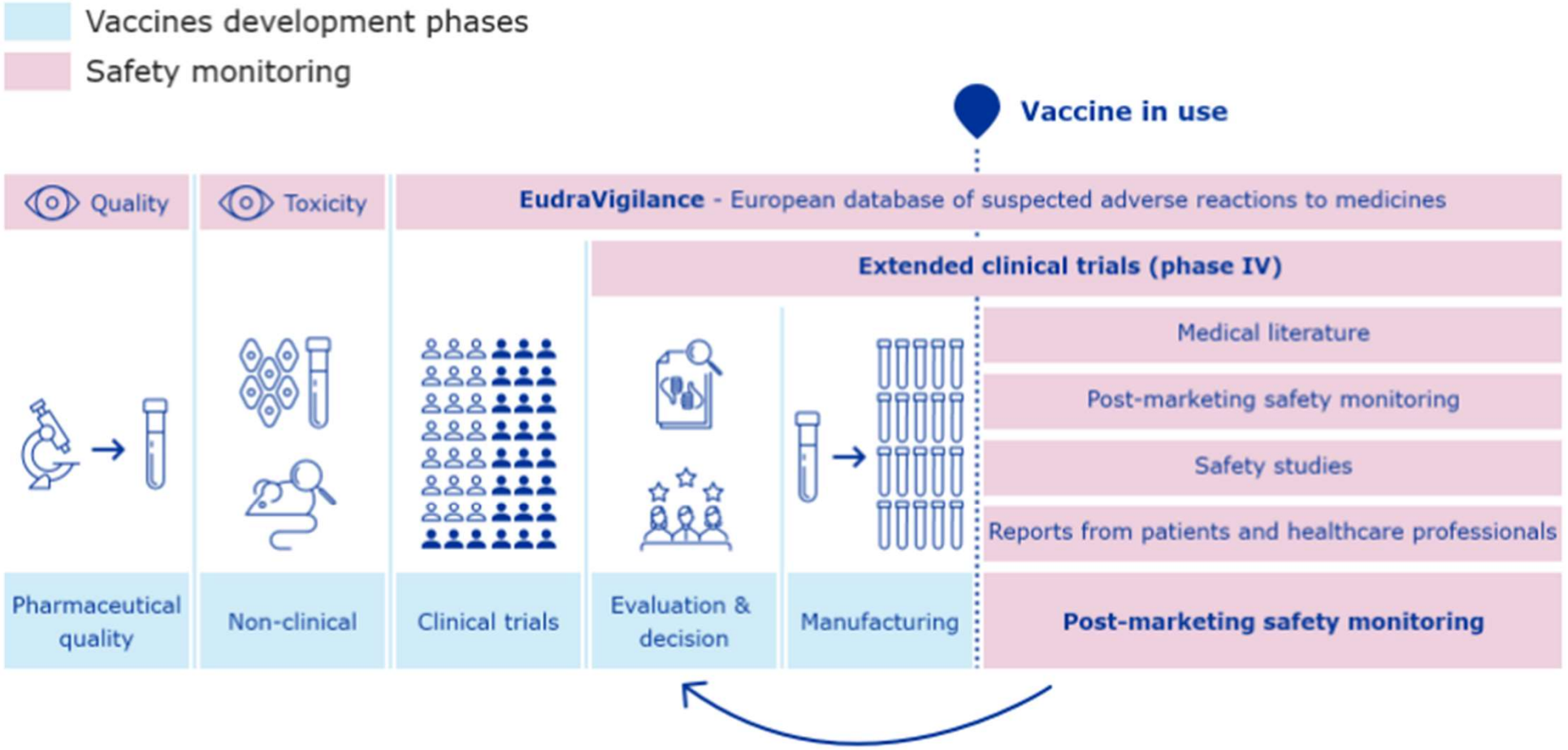
EMA –How vaccine safety is studied



Why monitor Adverse Events Following Immunization (AEFI) (in each country)?

Different immunization schedules	Different vaccines	Batch related problems
Cold chain problems	Immunization errors	Different background rates
Coincidental events	Genetic differences	Vaccine safety communication

PATIENT

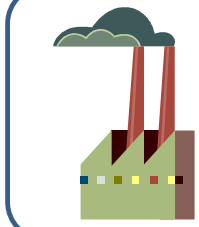
> Juli 2012

Artsen
Apothekers
Verpleegkundigen
Vroedvrouwen
Tandartsen

Spontane meldingen

fagg federaal agentschap voor geneesmiddelen en gezondheidsproducten

Pharmaco-vigilantie



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EudraVigilance Human

EUROPEAN MEDICINES AGENCY

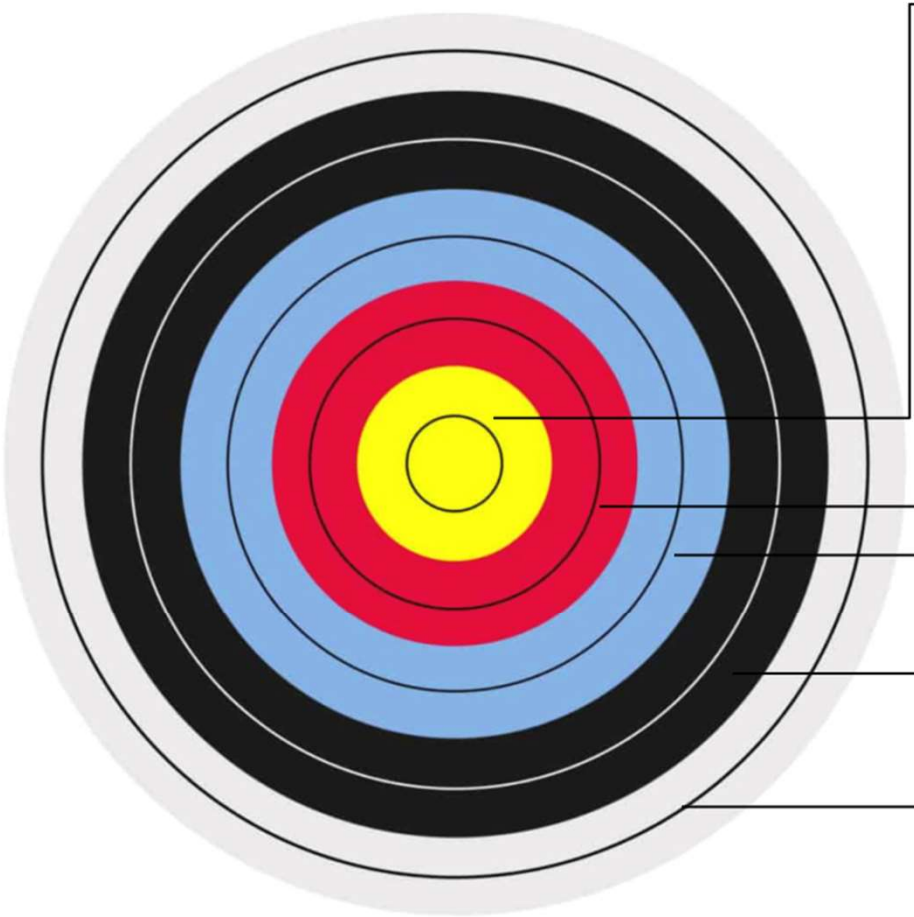
VigiBase

the UPPSALA MONITORING CENTRE

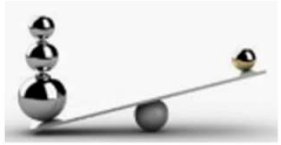
WHO

- Verplicht om alle ernstige ADR's (<15 dagen) en niet-ernstige ADR's (<90 dagen) te registreren.

Vaccines safety



AdverseEventSpeciaInterest (AESI): high priority based on experience with similar vaccines in terms of manufacturing process, composition (e.g. adjuvants), immunogenicity and novelty. Potential risks that would need immediate investigation or regulatory action and could lead to a change in the benefit-risk balance or require prompt communication to the public



Observed vs Expected (OE) analysis based on background incidence rates

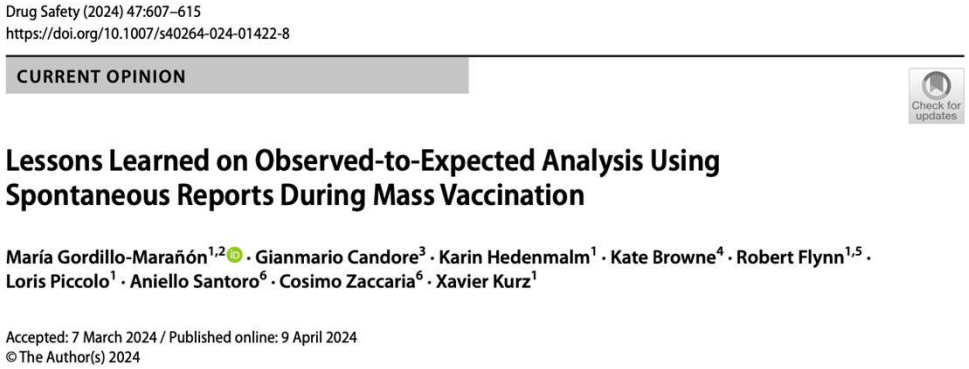
Imbalance Analysis: Adjusted Stastical Methods to compare competing vaccines

TimetoOnset: qualitative analysis based on the assumption that reporting trends may differ during vaccination

Combine all methods using specific features normally not available for routine PhV to optimise signal detection methods for a vaccination campaign against an epidemic

Observed to expected analyses

- ***Observed-to-expected analysis compares the number of cases spontaneously reported for an event of interest after vaccination ('observed') to the 'expected' number of cases anticipated to occur in the same number of individuals had they not been vaccinated.***



Drug Safety (2024) 47:607–615
https://doi.org/10.1007/s40264-024-01422-8

CURRENT OPINION

Check for updates

Lessons Learned on Observed-to-Expected Analysis Using Spontaneous Reports During Mass Vaccination

María Gordillo-Marañón[1,2] · Gianmario Candore[3] · Karin Hedenmalm[1] · Kate Browne[4] · Robert Flynn[1,5] · Loris Piccolo[1] · Aniello Santoro[6] · Cosimo Zaccaria[6] · Xavier Kurz[1]

Accepted: 7 March 2024 / Published online: 9 April 2024

« When undertaking an observed-to-expected analysis within the context of safety monitoring, several aspects need attention. In particular, we emphasise the importance of stratified and harmonised data collection both for vaccine exposure and spontaneous reporting data, the need for alignment between coding dictionaries and the crucial role of **accurate background incidence rates for adverse events of special interest** »

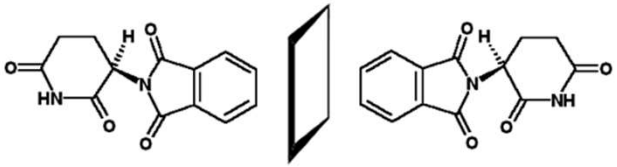
Observed to expected analyses

Australian doctor McBride WG (1962).

Thalidomide and congenital abnormalities.

Lancet 2:1358.

Letter to the editor



R-Thalidomide
(sleep-inducing)

S-Thalidomide
(teratogenic)

THALIDOMIDE AND CONGENITAL ABNORMALITIES

SIR,—Congenital abnormalities are present in approximately 1·5% of babies. In recent months I have observed that the incidence of multiple severe abnormalities in babies delivered of women who were given the drug thalidomide (' Distaval ') during pregnancy, as an antiemetic or as a sedative, to be almost 20%.

These abnormalities are present in structures developed from mesenchyme—i.e., the bones and musculature of the gut. Bony development seems to be affected in a very striking manner, resulting in polydactyly, syndactyly, and failure of development of long bones (abnormally short femora and radii).

Have any of your readers seen similar abnormalities in babies delivered of women who have taken this drug during pregnancy?

Hurstville, New South Wales. W. G. MCBRIDE.

*** In our issue of Dec. 2 we included a statement from the Distillers Company (Biochemicals) Ltd. referring to " reports from two overseas sources possibly associating thalidomide (' Distaval ') with harmful effects on the fœtus in early pregnancy ". Pending further investigation, the company decided to withdraw from the market all its preparations containing thalidomide.—ED.L.

Coincidental observation of new diabetes cases if 1 million young girls/women were injected with a placebo

Disease	Diagnosed cases after the injection of a placebo per 1 million adolescents and young women / period of observation		
	1 Day	1 Week	6 Weeks
Asthma (ER)	27	188	813
Allergy (ER)	15	106	458
Inflammatory bowel diseases (ER)	2	10	45
Diabetes (ER)	4	29	128
Thyroiditis (H)	1	9	40
Systemic lupus (H)	1	5	20
Multiple sclerosis / Optical neuritis (H)	0	2	10

Estimated risk of selected diseases in young girls/women (9-18 years) assuming vaccination with a saline placebo based on US rates for emergency room visits (ER) and hospitalizations (H) without vaccination

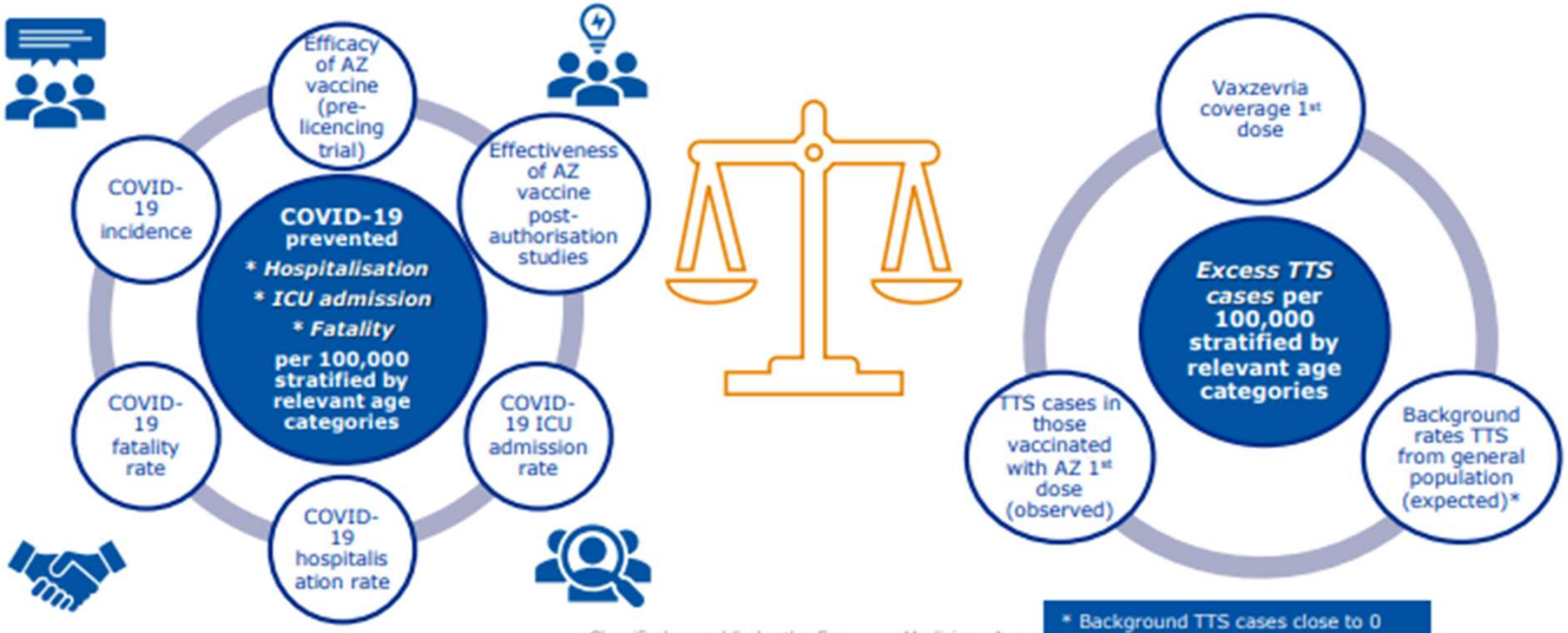
Paolo Bonanni et al Human Vaccines 7: Supplement, 128-135; 2011;

EMA - Signals

Example as PRAC Rapporteur for Vaxzevria

EUROPEAN MEDICINES AGENCY

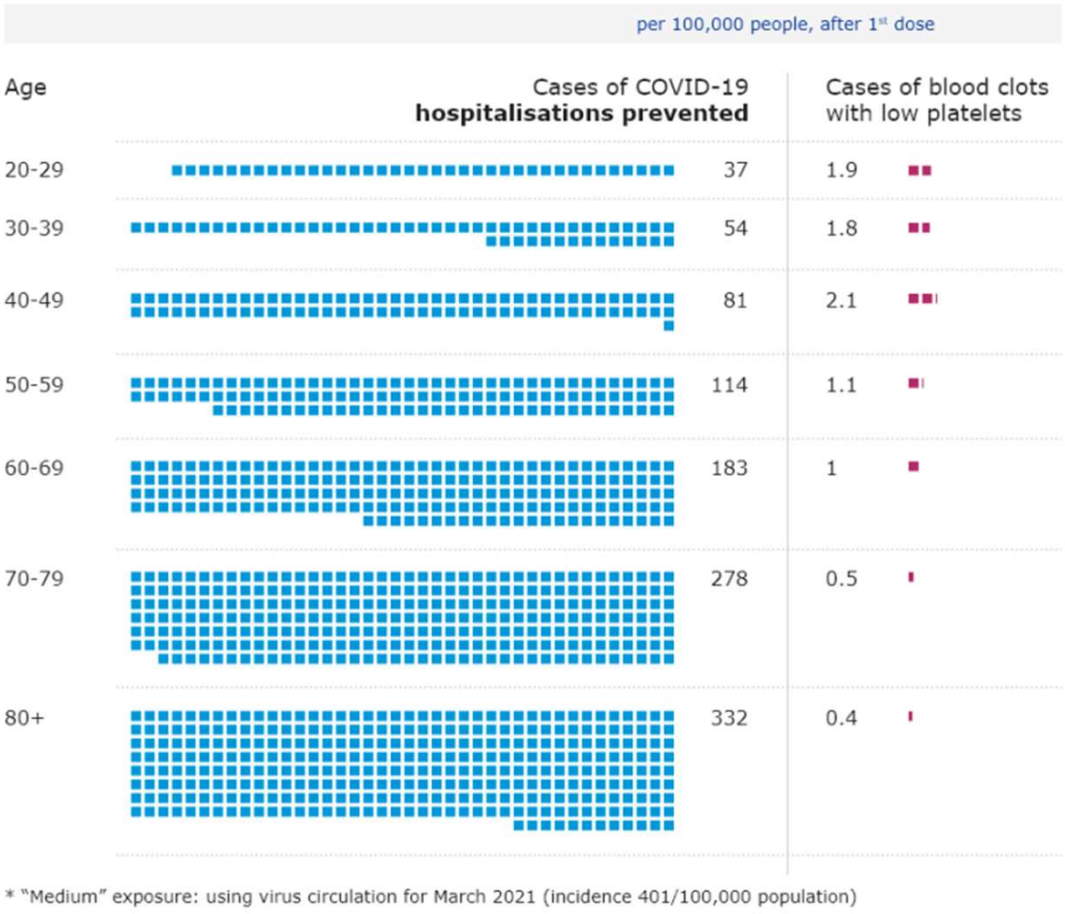
Benefits of having AZ vaccine versus potential risks associated with AZ vaccine by relevant risk factors: contextualisation exercise (EU/EEA)



* Background TTS cases close to 0

EMA Communication - Visual benefit risk contextualisation

Medium infection rate*



* "Medium" exposure: using virus circulation for March 2021 (incidence 401/100,000 population)

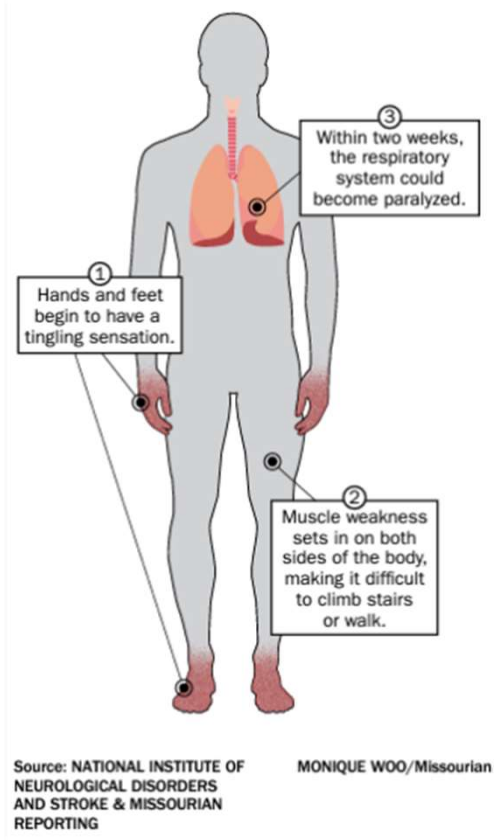
- To support national decisions on roll out of vaccine
- Analysis for different age groups, different levels of infection rate and outcomes (hospitalisations, ICU admissions, deaths due to COVID-19)
- Benefits of vaccination increase with increasing age and infection rates
- Member States can take different actions depending on pandemic situation, vaccine availability etc.

Example: RSV vaccines and Guillain-Barré Syndrome

Protein subunit (based on RSV F protein in prefusion conformation)	**Indication**
GSK **Arexvy** : monovalent RSV-A, $AS01_E$ adjuvant (06/06/2023)	• adults 60 years of age and older; • adults 50 through 59 years of age who are at increased risk for RSV disease. *GBS not listed in the SmPC– under close monitoring in the PSUR, together with transverse myelitis.*
Pfizer **Abrysvo** : bivalent RSV-A/RSV-B, no adjuvant (23/08/2023)	• Passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy (weeks 24 and 36 of gestation) • individuals 60 years of age and older *GBS is listed with frequency 'rare' for individuals 60+y in the SmPC. Important Identified risk in the RMP*
Messenger RNA (mRNA, encoding RSV F protein in prefusion conformation)	
Moderna **mResvia** : monovalent RSV-A, no adjuvant (22/08/2024)	• adults 60 years of age and older. *GBS not listed, followed in PSUR*

Guillain-Barré Syndrome

- Incidence estimated: 1 to 2/100.000 people
- Men 1.5 > women
- Increasing incidence with age - peak at 50-70 years
- About 3-7% dies
- Long term revalidation needed of 1-2 years (sometimes permanent sequalae up to 20%).
- Exact cause = unknown, but associated with:
    - Campilobacter infection (1/1000 infected develops GBS)
    - Often preceded by diarrhea or respiratory illness
    - Viral infection: influenza, cytomegalovirus, Epstein Barr virus, Zika virus, COVID-19 disease
    - Vaccines:
        - Influenza: variable data; 1-2 additional cases/million doses
        - Vaxzevria and Jcovden: 6 additional cases/million doses
        - Shingrix: 3–6 additional cases of GBS/per million doses



https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/06-RSV-Adult-Melgar-508.pdf

van den Berg. *et al.* Guillain–Barré syndrome: pathogenesis, diagnosis, treatment and prognosis. *Nat Rev Neurol* **10**, 469–482 (2014). https://doi.org/10.1038/nrneurol.2014.121

Le Vu S, et al. Risk of Guillain-Barré Syndrome Following COVID-19 Vaccines: A Nationwide Self-Controlled Case Series Study. Neurology. 2023 doi: 10.1212/WNL.0000000000207847.

Discussion

- **Observed vs. Expected Analysis**
  - An elevated risk of GBS was observed following both RSV vaccines
  - Results were not statistically significant for RSVPreF3+AS01 when adjusting for PPV
- **Early-Season SCCS**
  - Statistically significant elevation in GBS risk was observed following RSVPreF vaccine
  - Results did not remain statistically significant for RSVPreF vaccine when adjusting for PPV-based multiple imputations
- **End-of-Season SCCS**
  - A statistically significant elevated IRR was observed for GBS following vaccination with RSVPreF3+AS01; GBS risk was elevated yet not statistically significant following RSVPreF vaccination
  - Results remained the same when restricting to confirmed GBS cases through MRR
  - There was no evidence of difference in GBS risk among persons with and without same day concomitant vaccination with RSV vaccines

ACIP Presentation Slides: October 23-24, 2024 Meeting

What have we learned about GBS risk from the FDA-CMS self-controlled case series analysis since June 2024?

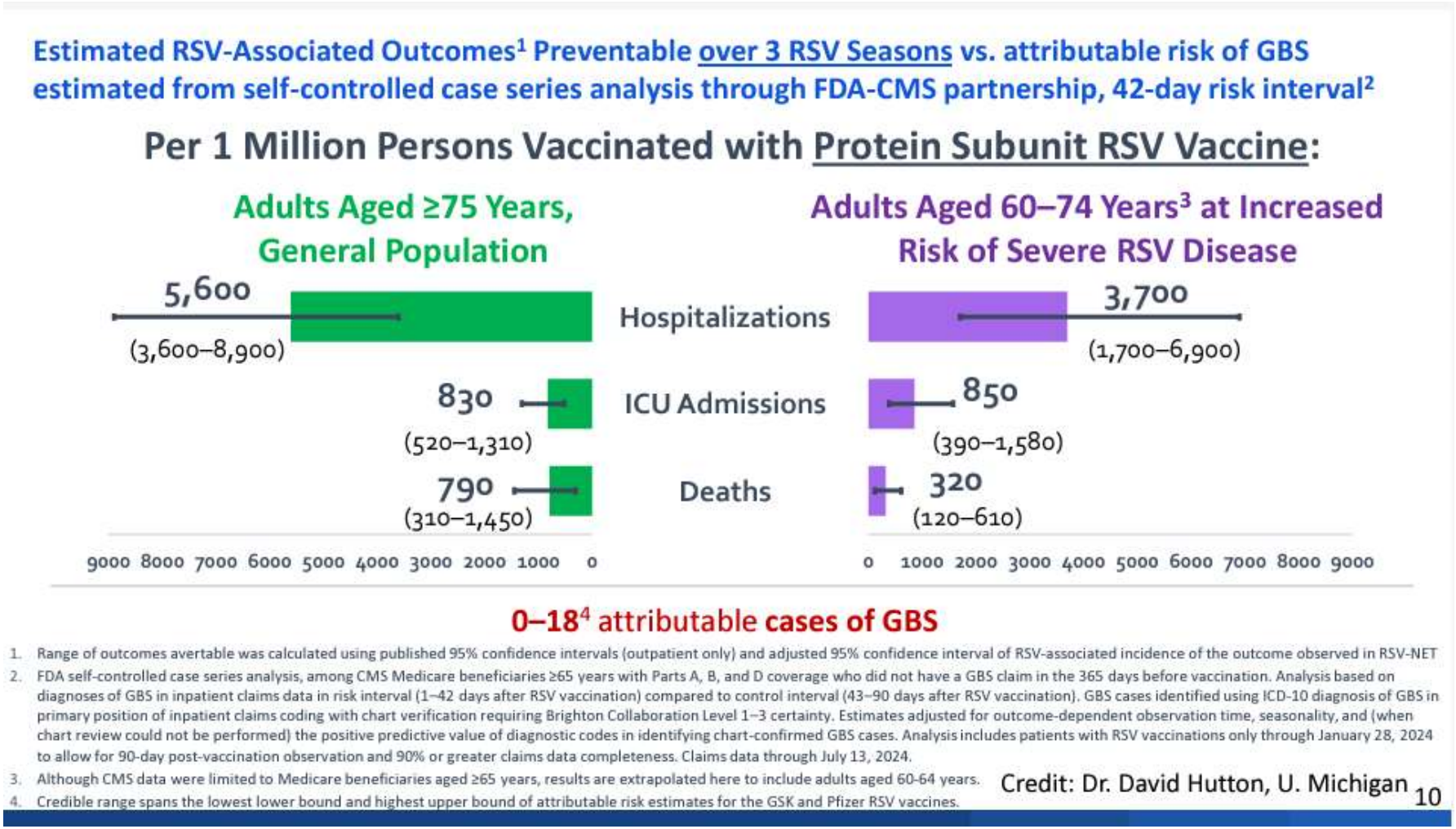
As of June 2024:

- ~1.3 million protein subunit RSV vaccine doses, 28 GBS cases identified through diagnostic codes
- Elevated incidence rate ratio of GBS following both GSK Arexvy and Pfizer Abrysvo vaccination, but estimates were not statistically significant
- Data suggested difference in attributable risk by product[2]
  - GSK Arexvy: 3 excess cases per 1 million doses (95% CI: -3, 10)
  - Pfizer Abrysvo: 16 excess cases per 1 million doses (95% CI: 3, 29)
- No data available regarding concomitant vaccinations

Update October 2024:

- ~3.2 million protein subunit RSV vaccine doses, 95 GBS cases identified through diagnostic codes (24 excluded through medical record review[1])
- Elevated incidence rate ratio of GBS following both vaccines; results reached statistical significance for GSK Arexvy, but not for Pfizer Abrysvo, which had fewer doses administered
- Attributable GBS risk similar for both products[2]
  - GSK Arexvy: 7 excess cases per 1 million doses (95% CI: 2, 11)
  - Pfizer Abrysvo: 9 excess cases per 1 million doses (95% CI: 0, 18)
- 30–50% of doses were concomitantly administered with another vaccine; no evidence that concomitant vaccination explains the increase in GBS rate after protein subunit RSV vaccination

1. Brighton Collaboration (BC) case definition for GBS was applied, requiring Level 1–3 certainty: https://brightoncollaboration.org/guillain-barre-and-miller-fisher-syndromes-2/. Of the 95 initially identified cases, 51 were confirmed through medical record review, 24 were excluded (BC Level 4–5), and 20 did not have medical record available for review.
2. Residual confounding is possible, and the analysis was not designed to compare risk between the two vaccines. Baseline risk of GBS may impact estimated attributable risk.



mResvia: so far no GBS (nor myo/pericarditis) reported

Number of preventable hospitalizations larger than possible GBS cases

EMA – Game changer: BIG DATA: DARWIN EU®

2 YEARS OF EXPERIENCE

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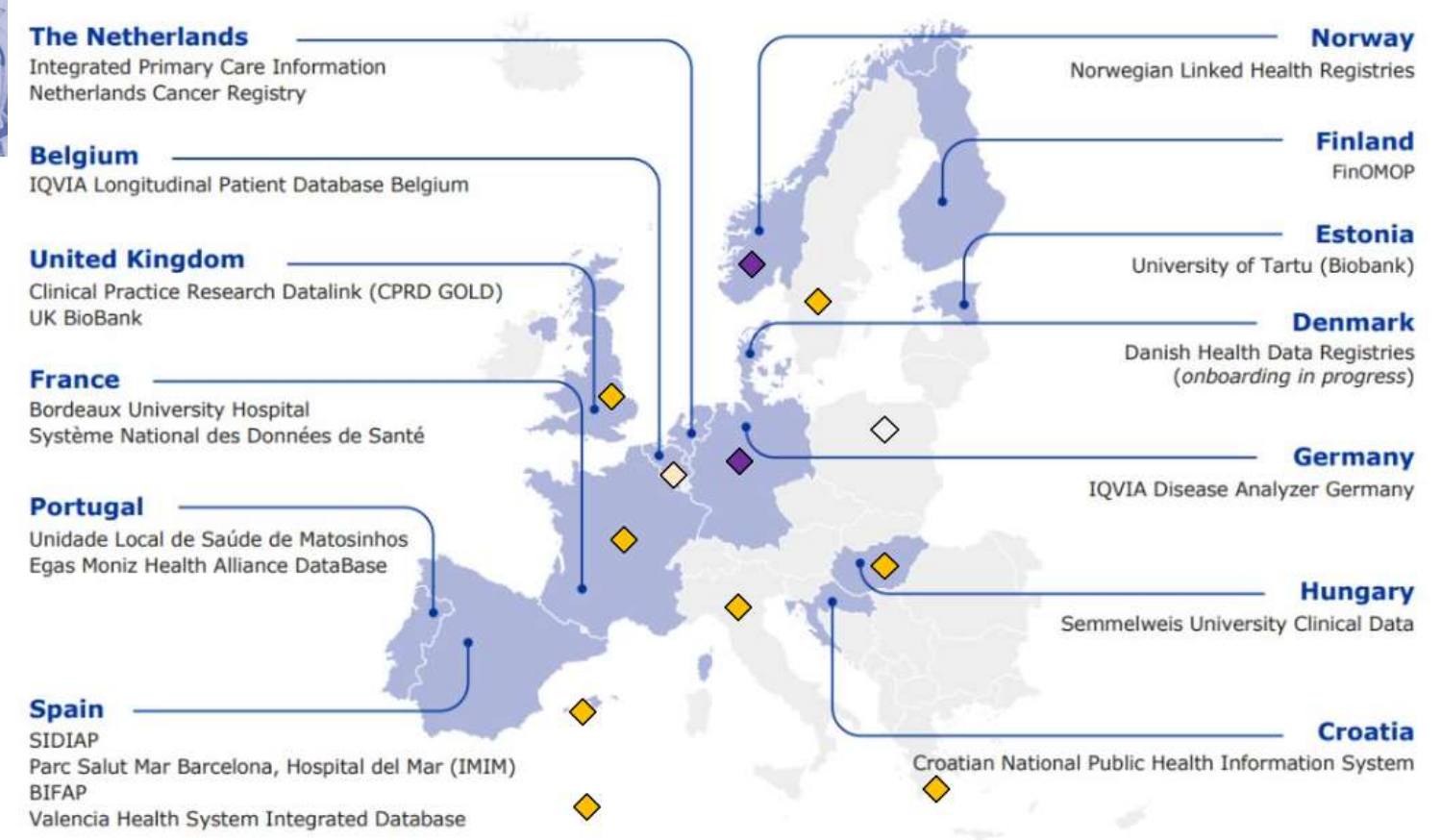
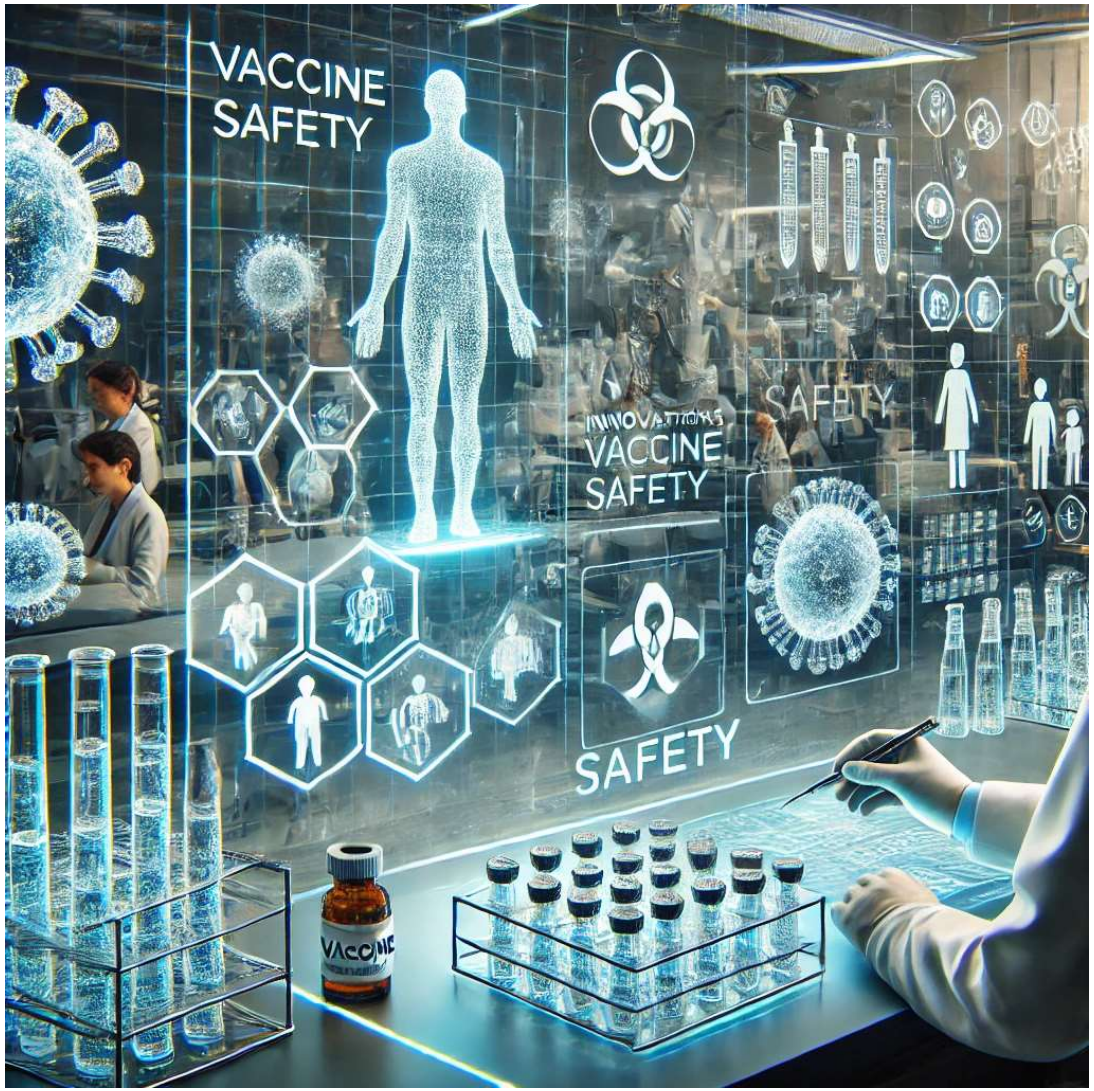


Game changer: Use of AI in vaccine development



Game changer: Use of AI in vaccine development

HMA
Heads of Medicines Agencies

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SCIENCE MEDICINES HEALTH

9 September 2024
EMA/CHMP/CVMP/83833/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Draft agreed by Committee for Medicinal Products for Human Use (CHMP) Methodology Working Party	July 2023
Draft adopted by CVMP for release for consultation	13 July 2023
Draft adopted by CHMP for release for consultation	10 July 2023
Start of public consultation	19 July 2023
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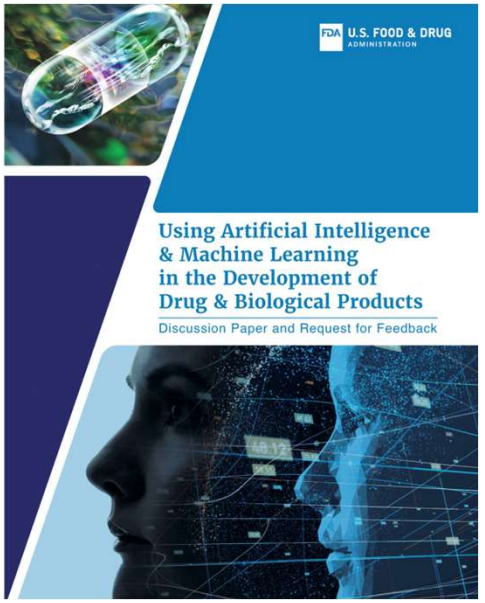
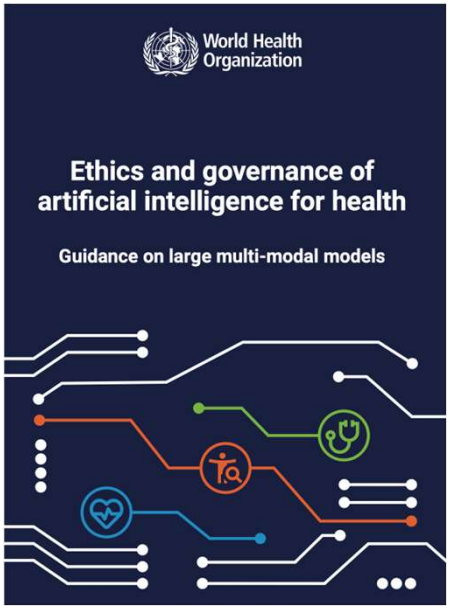
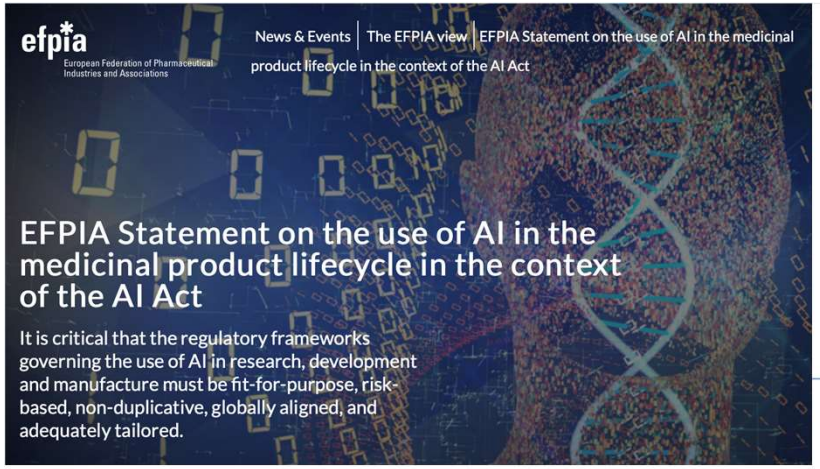
Final version agreed by MWP	6 September 2024
Final version adopted by CHMP	9 September 2024
Final version adopted by CVMP	11 September 2024

Keywords	*Artificial intelligence, AI, machine learning, ML, regulatory, medicine, human medicinal product, veterinary medicinal product*







EPF European Patients Forum

Big Data and Artificial Intelligence

EU Policy Briefing for Patient Organisations

European Patients' Forum, April 2020

Game changer: Use of AI in vaccine development

Drug Safety (2024) 47:173–182
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ORIGINAL RESEARCH ARTICLE

Optimizing Signal Management in a Vaccine Adverse Event Reporting System: A Proof-of-Concept with COVID-19 Vaccines Using Signs, Symptoms, and Natural Language Processing

Guojun Dong[1] · Andrew Bate[2,3] · François Haguinet[2] · Gabriel Westman[4] · Luise Dürlich[5,6] · Anders Hviid[1,7] · Maurizio Sessa[1]

JMIR Infodemiology. 2024 Dec 20;4:e53424. doi: 10.2196/53424

Application of a Language Model Tool for COVID-19 Vaccine Adverse Event Monitoring Using Web and Social Media Content: Algorithm Development and Validation Study

Chathuri Daluwatte [1], Alena Khromava [2,✉], Yuning Chen [1], Laurence Serradell [3], Anne-Laure Chabanon [4], Anthony Chan-Ou-Teung [5], Cliona Molony [1], Juhaeri Juhaeri [6]

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Front. Public Health 12:1360597.
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Medical knowledge of ChatGPT in public health, infectious diseases, COVID-19 pandemic, and vaccines: multiple choice questions examination based performance

Sultan Ayoub Meo[1]*, Metib Alotaibi[2], Muhammad Zain Sultan Meo[3], Muhammad Omair Sultan Meo[3] and Mashhood Hamid[4]

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Background: At the beginning of the year 2023, the Chatbot Generative Pre-Trained Transformer (ChatGPT) gained remarkable attention from the public. There is a great discussion about ChatGPT and its knowledge in medical sciences, however, literature is lacking to evaluate the ChatGPT knowledge level in public health. Therefore, this study investigates the knowledge of ChatGPT in public health, infectious diseases, the COVID-19 pandemic, and its vaccines.

Methods: Multiple Choice Questions (MCQs) bank was established. The question's contents were reviewed and confirmed that the questions were appropriate to the contents. The MCQs were based on the case scenario, with four sub-stems, with a single correct answer. From the MCQs bank, 60 MCQs we selected, 30 MCQs were from public health, and infectious diseases topics, 17 MCQs were from the COVID-19 pandemic, and 13 MCQs were on COVID-19 vaccines. Each MCQ was manually entered, and tasks were given to determine the knowledge level of ChatGPT on MCQs.

Results: Out of a total of 60 MCQs in public health, infectious diseases, the COVID-19 pandemic, and vaccines, ChatGPT attempted all the MCQs and obtained 17/30 (56.66%) marks in public health, infectious diseases, 15/17 (88.23%) in COVID-19, and 12/13 (92.30%) marks in COVID-19 vaccines MCQs, with an overall score of 44/60 (73.33%). The observed results of the correct answers in each section were significantly higher ($p = 0.001$). The ChatGPT obtained satisfactory grades in all three domains of public health, infectious diseases, and COVID-19 pandemic-allied examination.

Conclusion: ChatGPT has satisfactory knowledge of public health, infectious diseases, the COVID-19 pandemic, and its vaccines. In future, ChatGPT may assist medical educators, academicians, and healthcare professionals in providing a better understanding of public health, infectious diseases, the COVID-19 pandemic, and vaccines.

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Vaccination hesitancy: agreement between WHO and ChatGPT-4.0 or Gemini Advanced

Matteo Fiore [1], Alessandro Bianconi [1], Cecilia Acuti Martellucci [2], Annalisa Rosso [2], Enrico Zauli [3], Maria Elena Flacco [2], Lamberto Manzoli [1]

Affiliations + expand

PMID: 39373234 DOI: 10.7416/ai.2024.2657

Free article

Abstract

Background: An increasing number of individuals use online Artificial Intelligence (AI) - based chatbots to retrieve information on health-related topics. This study aims to evaluate the accuracy in answering vaccine-related answers of the currently most commonly used, advanced chatbots - ChatGPT-4.0 and Google Gemini Advanced.

Methods: We compared the answers provided by the World Health Organization (WHO) to 38 open questions on vaccination myths and misconception, with the answers created by ChatGPT-4.0 and Gemini Advanced. Responses were considered as "appropriate", if the information provided was coherent and not in contrast to current WHO recommendations or to drug regulatory indications.

Results and conclusions: The rate of agreement between WHO answers and Chat-GPT-4.0 or Gemini Advanced was very high, as both provided 36 (94.7%) appropriate responses. The few discrepancies between WHO and AI-chatbots answers could not be considered "harmful", and both chatbots often invited the user to check reliable sources, such as CDC or the WHO websites, or to contact a local healthcare professional. In their current versions, both AI-chatbots may already be powerful instrument to support the traditional communication tools in primary prevention, with the potential to improve health literacy, medication adherence, and vaccine hesitancy and concerns. Given the rapid evolution of AI-based systems, further studies are strongly needed to monitor their accuracy and reliability over time.

Keywords: ChatGPT; Gemini; AI; WHO; Vaccine; Vaccine Hesitancy.


Registratie (waarom, hoe, wat?)
Evaluatie: individueel niveau
Evaluatie: populatieniveau
Conclusie

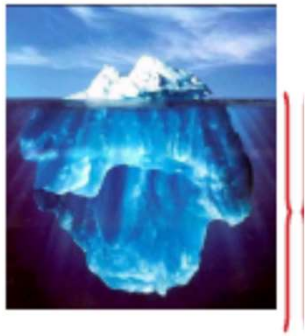
Veiligheid van vaccinatie wordt voortdurend gecontroleerd

- Absolute veiligheid bestaat echter niet: bijwerkingen zijn mogelijk.
- Het aantal meldingen van bijwerkingen blijft zeer laag in verhouding tot het aantal gevaccineerden.
- Aangezien vaccinatie gericht is op mensen in goede gezondheid, is de tolerantiedrempel voor de veiligheid van vaccins zeer laag - we volgen zeldzame gebeurtenissen op.

- Vaccinovigilantie maakt het mogelijk de juiste actie te ondernemen:
  - ❑ Wijzigingen in SKP's en bijsluiters
  - ❑ Informatie voor beroepsbeoefenaren in de gezondheidszorg: DHPC, BCFI, VigNews (www.afmps.be), Hoge Gezondheidsraad…
  - ❑ Schorsing of intrekking van het vaccin

- U hoeft geen oorzakelijk verband aan te tonen om een voorval te melden.

Take-home message



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