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Main expertise: Pharmacovigilance

# SESSION 5:
# RECORDING AND REPORTING OF VACCINATION DATA

## VACCINE SAFETY SURVEILLANCE AND COMMUNICATION IN PORTUGAL


MÁRCIA SILVA | Risk Management for Medicines Department

LISBON - PORTUGAL | INFARMED - National Authority of Medicines and Health Products, I.P.


REPÚBLICA PORTUGUESA
SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

Adult Immunization Board

# VACCINE CLINICAL TRIALS

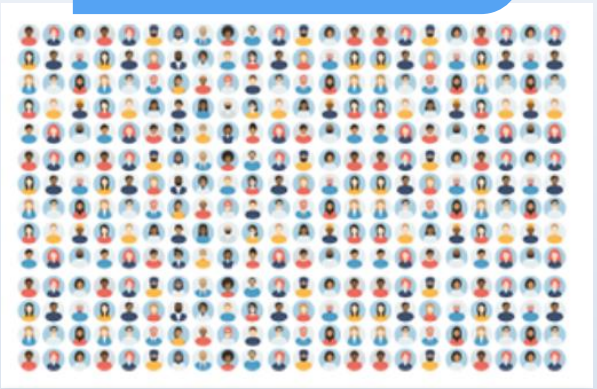
## Phase 1 trials

**20-100 healthy volunteers**

### What is checked:

- Does the vaccine seem to work?
- Are there serious side effects?
- Is the vaccine safe?

## Phase 2 trials

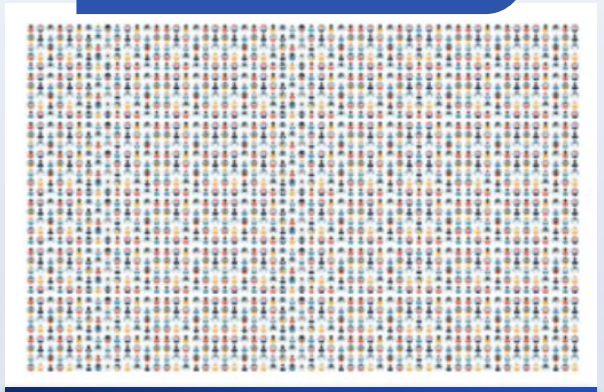


**Several hundred volunteers**

### What is checked:

- What are the most common short-term side effects?
- What is the optimal use?
- How are the immune systems of the participants responding to the vaccine?

## Phase 3 trials



**Thousands of volunteers**

### What is checked:

- Is the vaccine effective?
- What are the most common side effects?
- Is the vaccine safe?

# VACCINATION CAMPAIGNS




# SPONTANEOUS REPORTING SYSTEM


DGS
Direção-Geral da Saúde


1. Collection
2. Validation
3. Technical-scientific analysis
4. Request – aditional data
5. ADR codification (MedDRA)
6. Loading database
7. Causality assessment

# VACCINE COMPONENTS


| | | |
|---|---|---|
| 1 | **Antigens** | Live attenuant; Whole cell inactivated; Split virion; Subunit; Recombinant proteins; Toxoid; Polysaccharide (conj.) |
| 2 | **Adjuvants** | Al-salts; O/W-emulsion; LPS-derivate (MLP); VLP/Virosom Phospholipids; Other |
| 3 | **Stabilisors** | Polygeline; Albumin; Sugar /saccharose) |
| 4 | **Preservatives** | 2-Phenoxy-ethanol; Thiomerosal |
| 5 | **Residual from manufacturing process** | Egg protein; Formaldheyd; Antibiotics |

# VACCINES PHARMACOVIGILANCE

***Adverse event following immunization (AEFI):*** any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

**1**

Vaccine product - related reaction

**An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.**

**2**

Vaccine quality defect - related reaction

**An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product.**

**3**

Immunization error - related reaction

**An AEFI that is caused by Inappropriate vaccine handling, prescribing or administration.**

**4**

Immunization anxiety - related reaction

**An AEFI arising from anxiety about the immunization.**

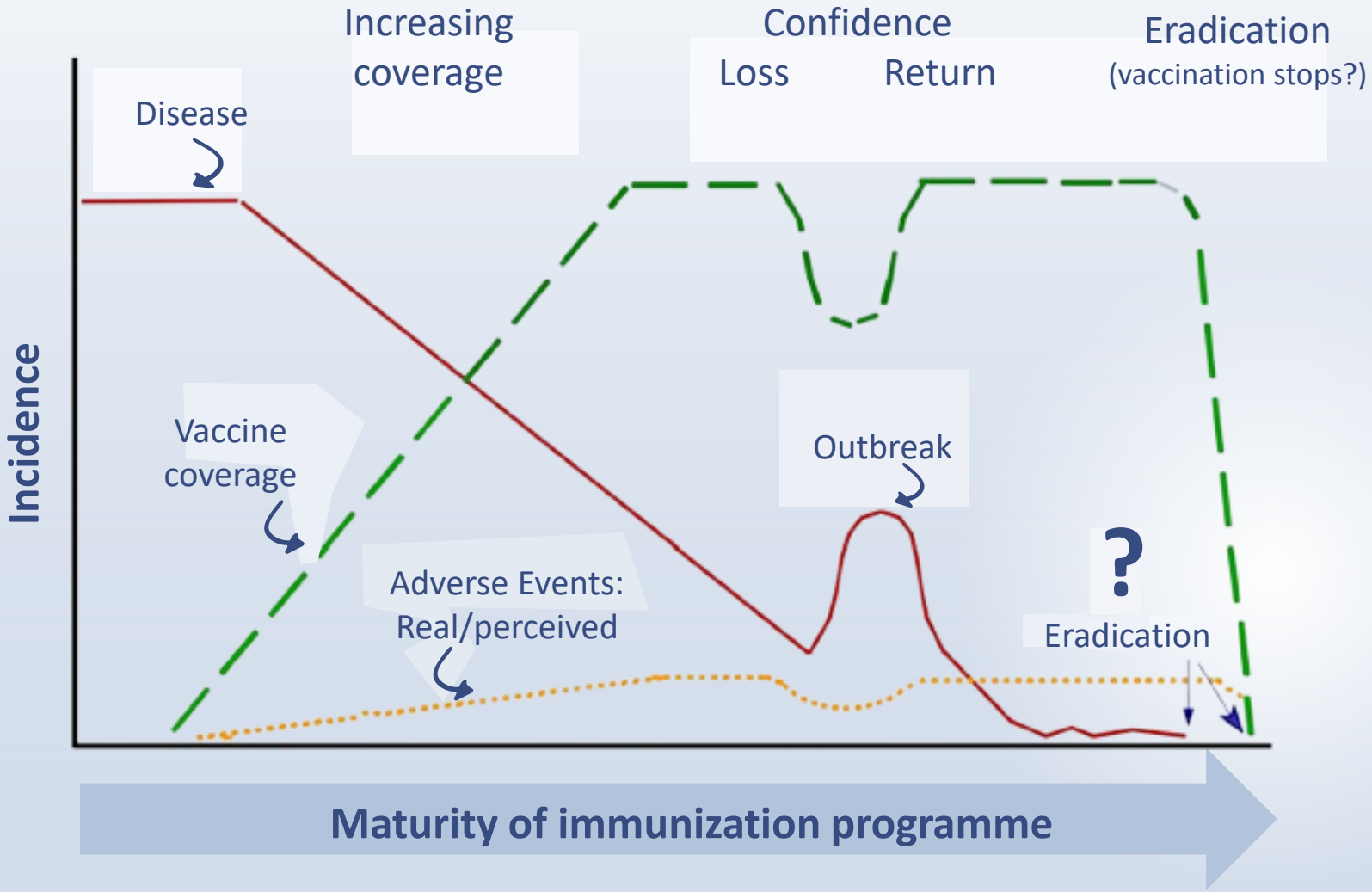
**5**

Coincidental event

**An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.**

Adapted from: Definition and Application of Terms for Vaccine Pharmacovigilance - Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance
https://cioms.ch/publications/product/definitions-and-applications-of-terms-for-vaccine-pharmacovigilance/

# IMPACT OF AEFI IN VACCINATION CAMPAIGNS




Adapted from: Chen RT et al, Vaccine 1994; 12:542-50

# SAFETY COMMUNICATION

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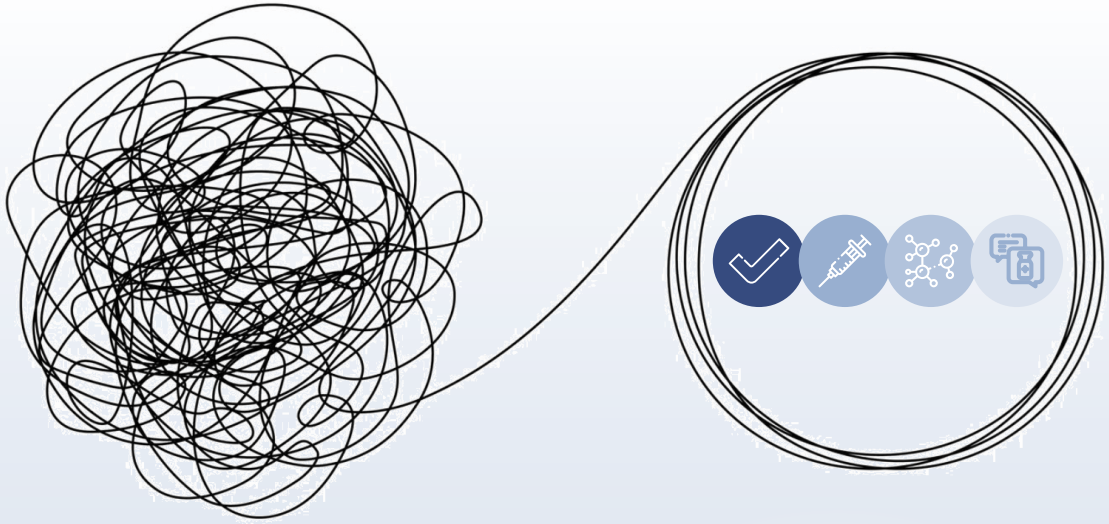
*"Safety communication is a broad term covering different types of information on medicines, including statutory information as contained in the product information (i.e. the summary of product characteristics (SmPC), package leaflet (PL) and the labelling of the packaging) and public assessment reports."*

*Guideline on good pharmacovigilance practices: Module XV – Safety communication*

Communicating safety information to patients and healthcare professionals is a **public health responsibility** and is essential for achieving the objectives of pharmacovigilance in terms of promoting the **rational**, **safe** and **effective** use of medicines, **preventing harm** from adverse reactions, **minimising risks** and contributing to the **protection of patients'** and **public health**

# SAFETY COMMUNICATION



- Communication is not just a soft skill – it's a scientific and regulatory enabler
- Every recommendation, question, or clarification has an impact
- Trust grows through:
  - Clarity
  - Respect
  - Shared understanding

- Structure scientific arguments logically
- Avoid ambiguity – clarity earns trust
- If the message can be misunderstood, it will be
- Clarity improves the quality of the communication
- Tone and empathy matter as much as accuracy
- Trust is built when communication is transparent and consistent

# SAFETY COMMUNICATION

- Communication translates data into understanding, and understanding into trust
- Every word contributes to patient confidence and public health decisions
- Communication is science made human
- Communication turns expertise into impact
- Communicate with clarity, empathy and purpose

# QUESTIONS

Infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde, I.P.

# OBRIGADO

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