Adverse Events Following Immunisation

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Definitions

Adverse Event Following Immunisation (AEFI)

Any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine

Adverse Reaction (AR)

Response to a medicinal product which is noxious and unintended

No vaccine 100% effective

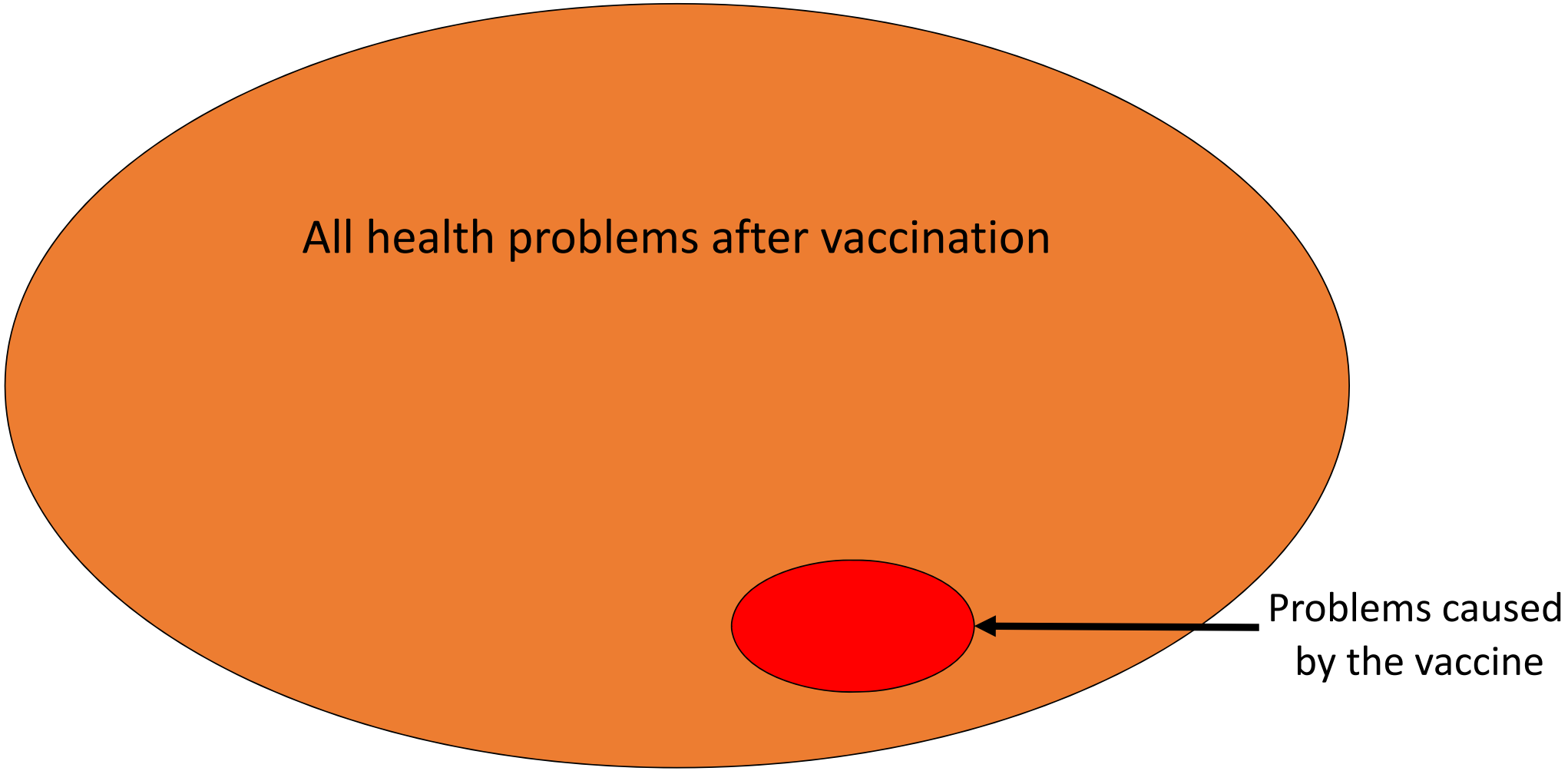
No vaccine 100% safe

But they ARE very safe and very effective

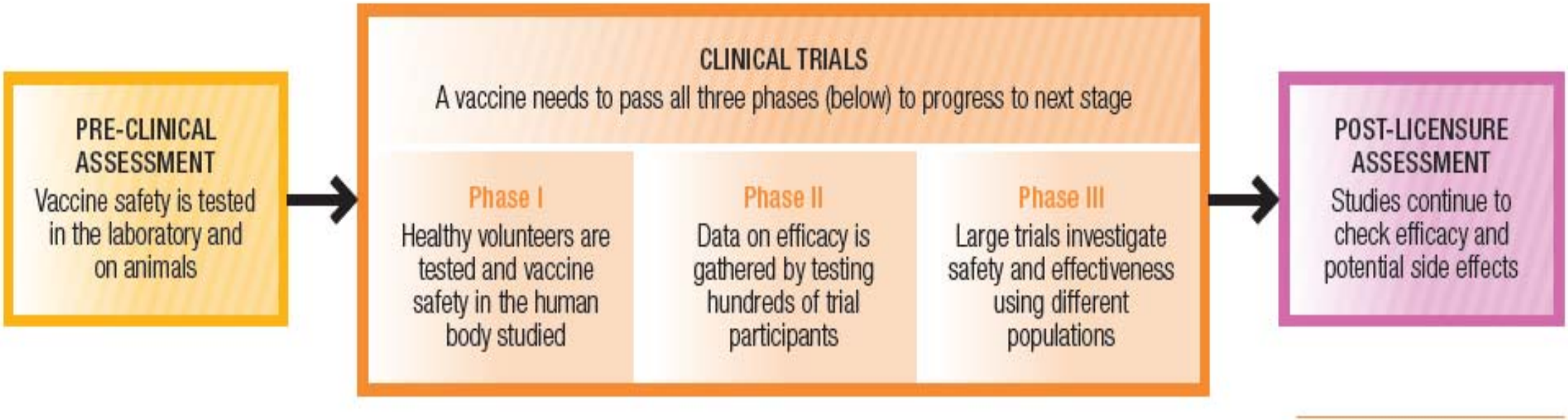
Benefit-risk Balance of Medicines

- Efficacy- tested in trials (selected, relatively few subjects)
- Effectiveness-used in patients who differ from trial subjects (age, additional diseases, other medicines)

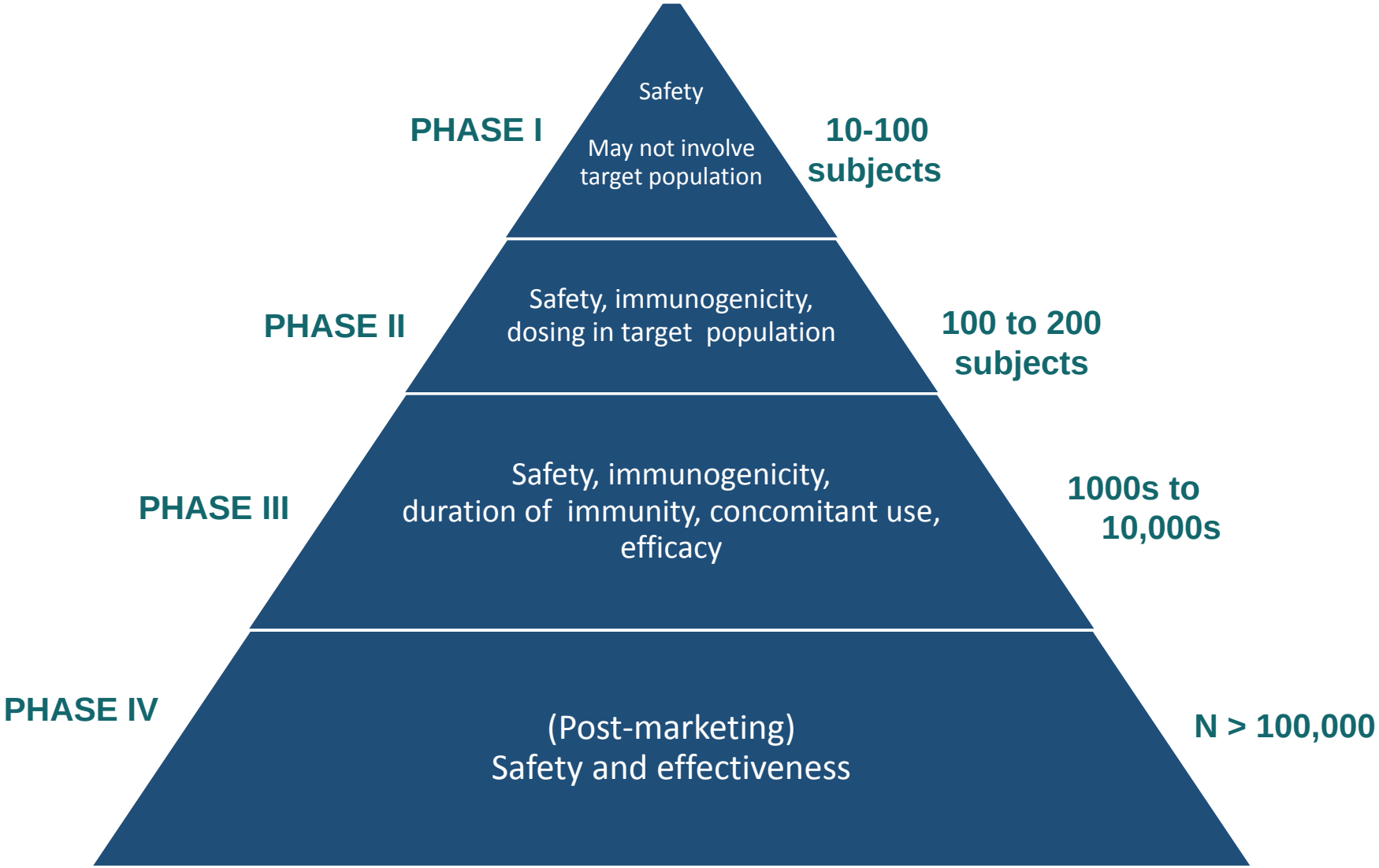
AEFI – Cause or Coincidence?



Vaccine Safety and Efficacy Studies



Vaccine Safety and Efficacy Studies



Known AEFIs

More Common (>1 in 100)	Less Common (<1/100)
• Redness • Swelling, nodule • Pain, tenderness • Fever, irritability, loss of appetite • Nausea, D+V	• Encephalitis • Paralysis • Arthritis • Allergic reaction • Thrombocytopoenia • Febrile seizure • Fainting • Narcolepsy • Death

AEFI Frequency Terminology

Very common*	≥ 1/10	≥ 10%
Common (frequent)	≥ 1/100 and < 1/10	≥ 1% and < 10%
Uncommon (infrequent)	≥ 1/1,000 and < 1/100	≥ 0.1% and < 1 %
Rare	≥ 1/10,000 and < 1/1,000	≥ 0.01% and < 0.1%
Very rare*	< 1/10,000	< 0.01%

* Optional categories

Timing of Vaccine Reactions

- **Non-live vaccines**: generally within 48hrs

- **Live vaccines**: according to time for organism to replicate

MMR: - mini-measles 6-11 days (SSPE years)

- rubella 2nd week

- mumps 3 to 6 weeks

BCG: days - 12 months +

Number needed to test for increased relative risk of an AR

	Rate In Vaccinated Population		
Background rate in general population	**2-fold higher**	**10-fold higher**	**100-fold higher**
1 in 10,000	141,000	5,500	500
1 in 100,000	1,238,000	53,500	2,500
1 in 1,000,000	12,951,500	532,500	23,500

Evans D et al. J Infect Dis. 2009;200:321-8.

Criteria of Causality

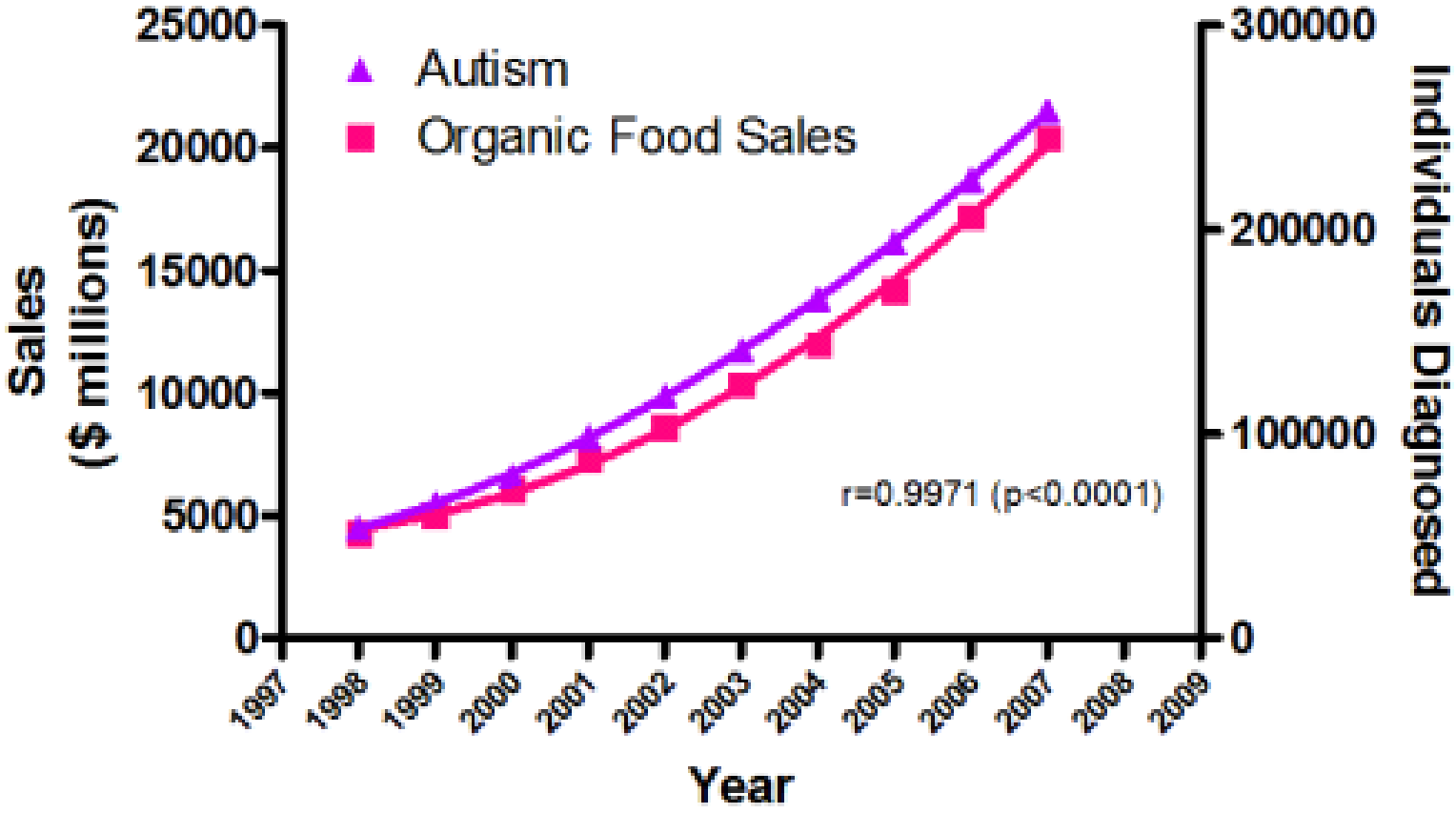
- **Data must be strong** - substantial increase in risk compared to control population
- **Data must be consistent** across studies (gender, ethnicity, income, age)
- **Data must be specific** – e.g. VAPP, congenital rubella
- **Data must be temporal** – drug before effect
- **Data must possess a dose response effect –**

  more cigarettes → more cancer; more

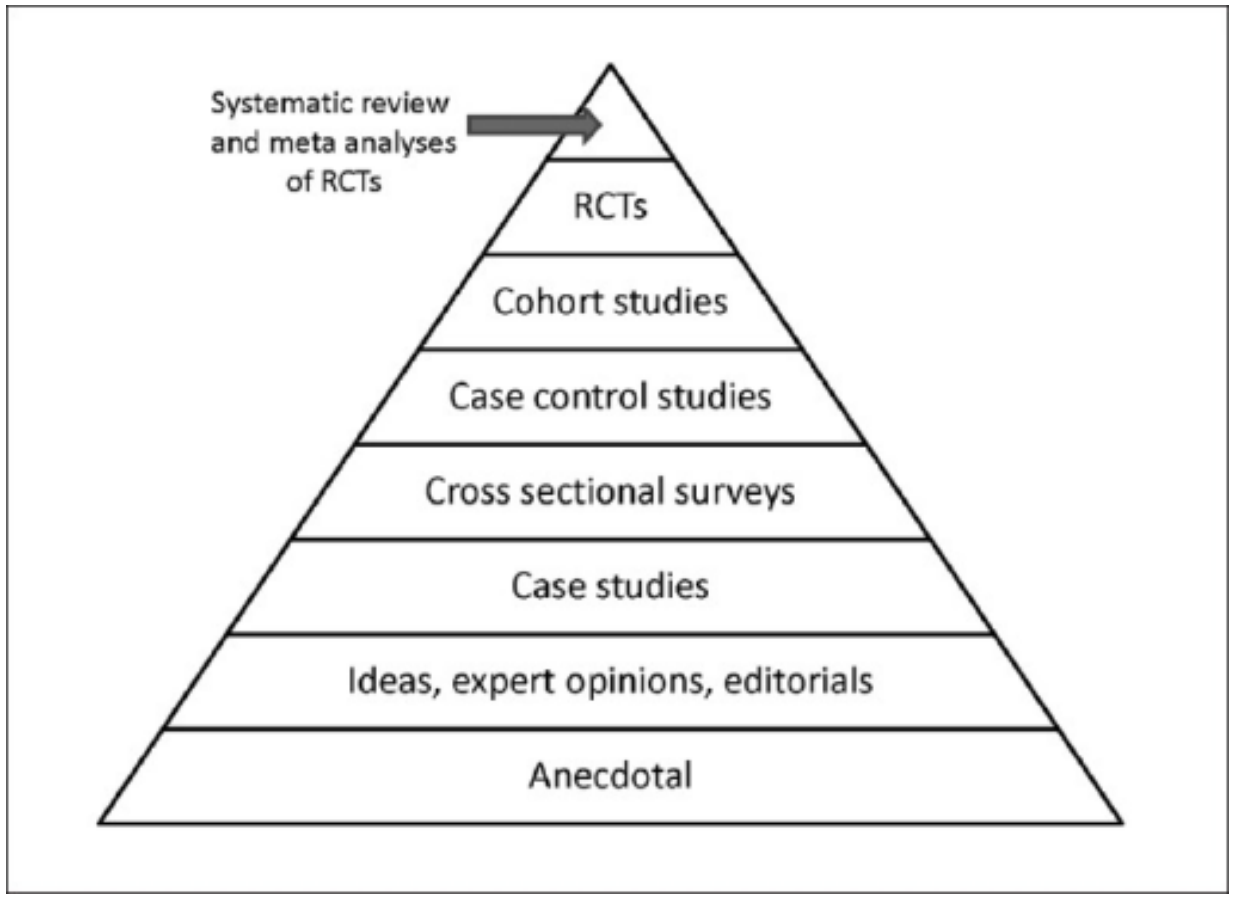
Causal effect must be plausible

necessarily

Correlation is not ^ causation

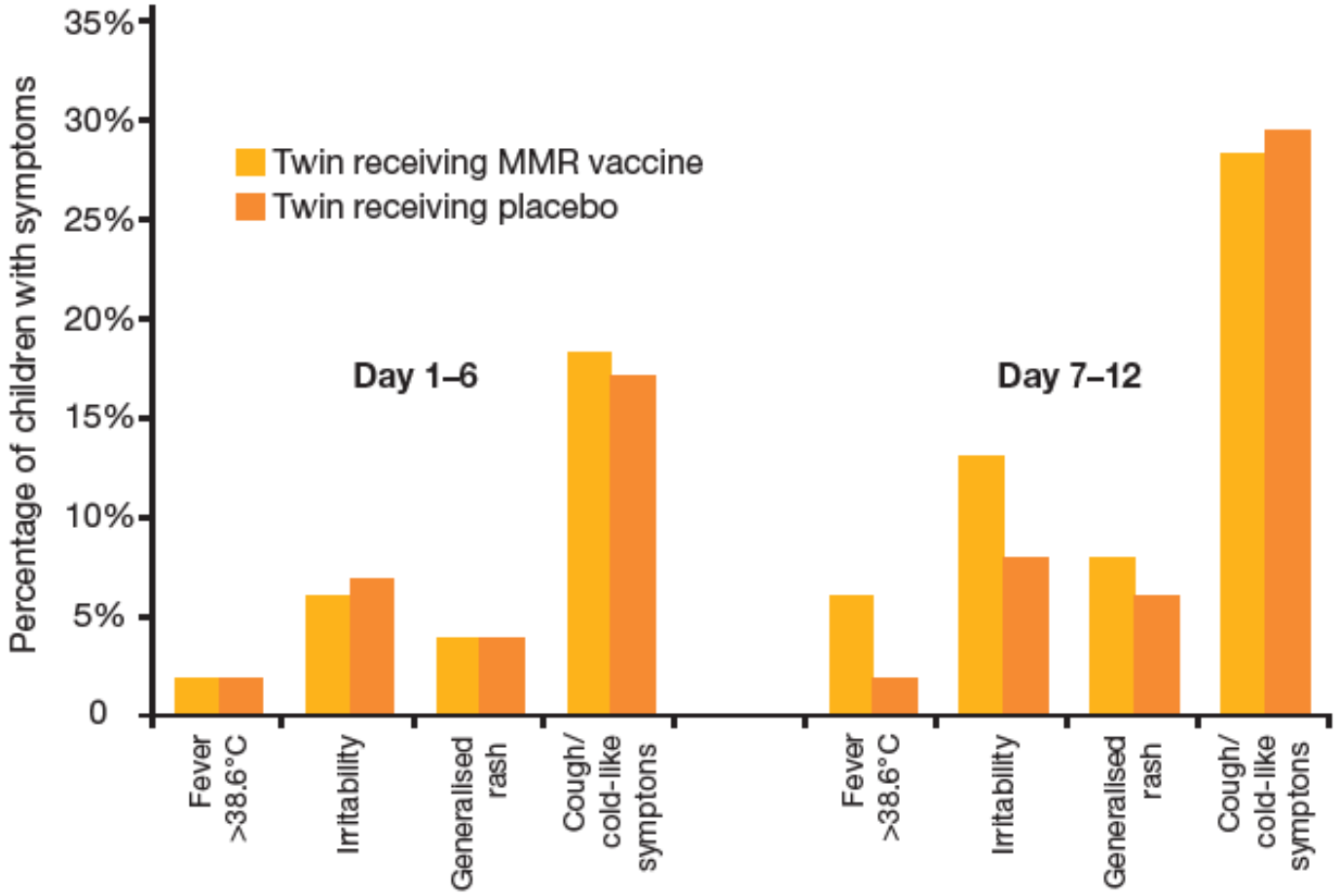


Hierarchy of scientific evidence



Not Scientific Evidence

Common symptoms - paired twin study (MMR v. Placebo)



What Causes AEFIs?

Vaccine – inherent properties, over-attenuated live vaccine, instability, mixing interferences, strain variation

Programme, administration – storage, site, mixing, wrong vaccine

Injection reaction – anxiety, pain

Coincidence

Why Monitor AEFIs?

- No vaccine is 100% safe
  - Safety profile established in pre-license trials
  - Detectable frequency depends on numbers studied
    - (rule of 3)
  - Rare events require huge numbers
- Risk / benefit balance changes over time
  - as incidence falls - e.g. VAPP
  - as society becomes more critical

Pharmacovigilance (PhV)

Detection, assessment, understanding, prevention of ARs

Objectives : - preventing harm

- promoting safe, effective use

Why Pharmacovigilance?

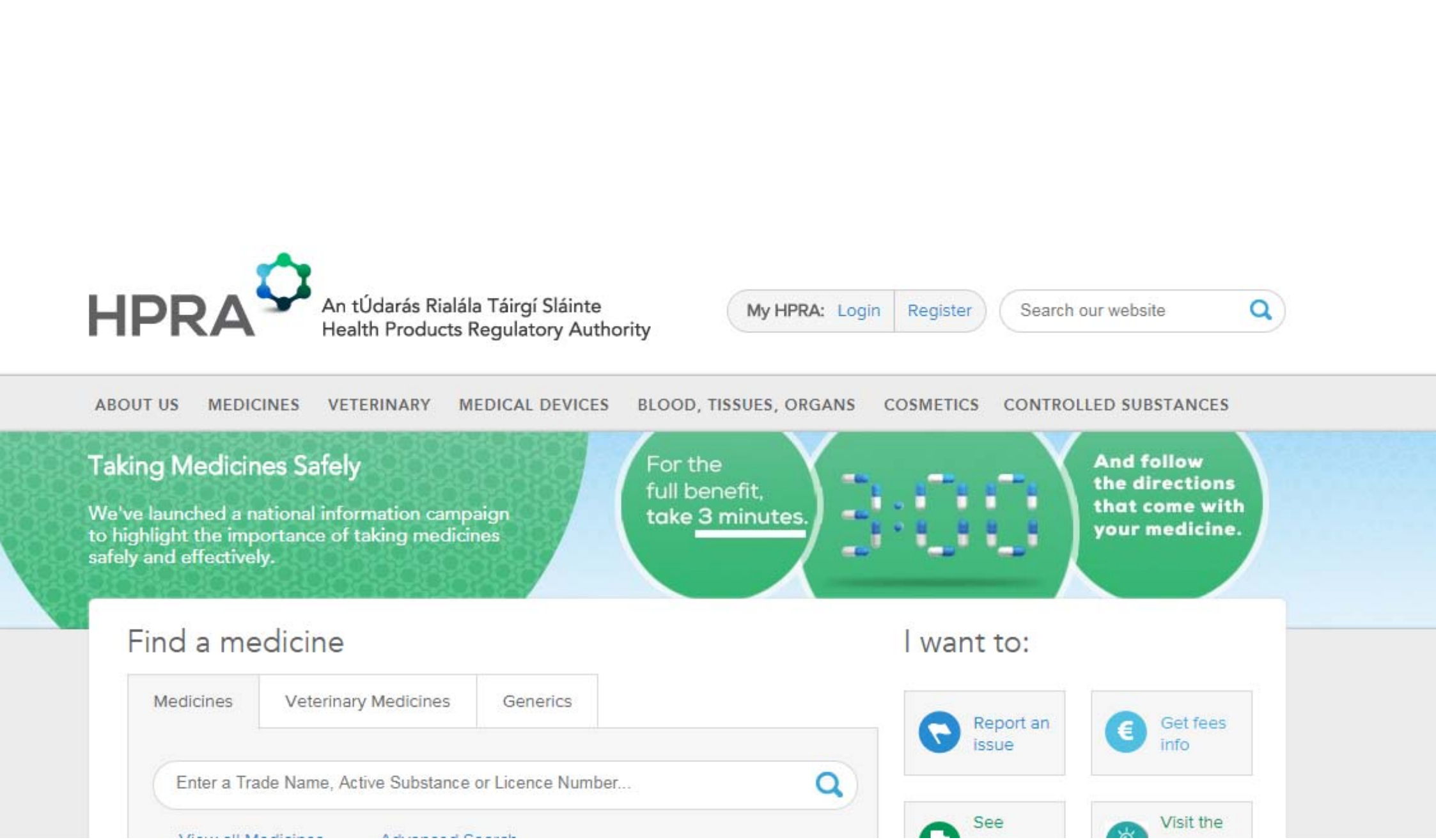
- Identify previously unrecognized/new/frequent/severe ARs
- Identify subgroups of patients at particular risk of ARs
- Continue surveillance to ensure benefits/harms balance remains acceptable

Why Pharmacovigilance?

- Detect clinically important drug–drug, drug–food interactions
- Communicate appropriate information to HCPs, recipients
- Confirm or refute of false-positive signals that arise

Reporting Suspected AEFI

Follow links on **www.hpra.ie**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Taking Medicines Safely
We've launched a national information campaign to highlight the importance of taking medicines safely and effectively.
For the full benefit, take 3 minutes.
3:00
And follow the directions that come with your medicine.
Find a medicine
Medicines
Veterinary Medicines
Generics
Enter a Trade Name, Active Substance or Licence Number...
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- Information and transparency
- Privacy and Data Protection
- Consultations
- Quality Management
- Recruitment
- Publications & Forms
- Report an Issue

Report an Issue

Reporting Safety and Quality Concerns

If you are concerned that you have had a side effect to a medicine, or experienced a problem with any other type of healthcare product regulated by the HPRA, you may need to contact your healthcare professional who can advise on any treatment that may be needed. They can also report the issue to the HPRA on your behalf.

If you wish to directly report issues relating to the use or quality of healthcare products you can use the HPRA's online reporting service. Anyone can report issues relating to the safety and quality of healthcare products to the HPRA. This includes patients, carers, other members of the public and healthcare professionals.

Please note that in completing a report form, we understand that you are consenting to the information provided, including your contact details, to be stored securely by the HPRA. Your contact details will be used solely for the purposes of interaction with you regarding the report submitted. For the purposes of complying with our statutory and legal reporting requirements, summary details of this report (excluding personal information) may be shared with other bodies also involved in monitoring activities in accordance with HPRA obligations and data protection requirements. This ensures that the information is available to all relevant parties. The right exists to request a copy of personal data held by the HPRA and to have any inaccuracies in such data corrected or deleted.

Online Report Forms

The following forms can all be completed using the HPRA online reporting system:

Human Medicine Adverse Reaction

Veterinary Medicines Adverse Reaction

› Our vision, mission and values
› How We Regulate
› Contact Us
› Our Structure
› Standards of Service
› Information and transparency
› Privacy and Data Protection
› Consultations
› Quality Management

Privacy notice for reporting human medicines adverse reactions

The HPRA operates the national system for recording and reporting details of suspected adverse reactions occurring in Ireland. Please see full details of how personal data is processed in this area.

Human Medicines Adverse Reaction Report

Fields marked with an asterisk (*) are mandatory.

To move through the steps of the form please use the Next and Previous buttons that are at the bottom of the form.

Reporter Information

Title: * Please Select

Minimising Errors

- Right patient
- Right vaccine, diluent
- Right time (age, interval, expiry)
- Right dose
- Right site
- Right route
- Right documentation

The End