Deviations to the Schedule
&
Adverse Events

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National Immunisation Office

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Catch up schedule

- **Review** documented evidence of previous vaccinations
- Observe minimal **intervals** and **age**
- Interval between doses may be reduced
- Give **age appropriate** schedule
  - The number of doses may reduce with age (e.g. PCV)
  - Recommended vaccines change or may be omitted
- **Never restart** schedule, regardless of interval (except cholera)
- May give all vaccines at one visit (minimum 2.5 cm apart)
- Use optimal intervals when child is back on course
- Children living in Ireland require **Irish schedule**

Catch-up schedule for children and adults

Vaccine	4 months to <12 months	12 months to < 4 years	4 to <10 years	10 to <18 years	18 years and older
6 in 1[1]	3 doses, 2 months apart	3 doses, 2 months apart	3 doses, 2 months apart		
Men B	2 doses, 2 months apart (1 dose if ≥ 10 months)	2 doses 2 months apart (if born on or after October 1st 2016)			
Men C	1 dose	1 dose	1 dose	1 dose (if given after 10 years of age, adolescent MenC booster not required)	1 dose (up to 23 years of age)
PCV	2 doses 2 months apart	1 dose (omit if >2 years of age[2])			
MMR[3]		1 dose	2 doses 1 month apart	2 doses 1 month apart	2 doses 1 month apart[4]
Rotavirus[5]	2 doses 4 weeks apart (up to 8 months 0 days)				
Tdap/IPV				3 doses 1 month apart	1 dose[6]
Td/IPV					2 doses 1 month apart (1 month after Tdap/IPV)
NOTE	*Continue with routine childhood immunisation schedule from 12 months.*	*Continue with routine school immunisations [4 in 1 (Tdap/IPV) at least 6 months and preferably 3 years after primary course, MMR at least 1 month after previous dose]*	*Continue with routine school immunisations [4 in 1 (Tdap/IPV) at least 6 months and preferably 3 years after primary course]*	*Booster of Tdap/IPV 5 years after primary course and Tdap 10 years later*	

1 One dose of single Hib vaccine may be given to children over 12 months of age and up to 10 years of age if this is the only vaccine they require
2 Unless at increased risk
3 The second dose of MMR is recommended routinely at 4-5 years but may be administered earlier. Children vaccinated before their first birthday in the case of an outbreak should have a repeat MMR vaccination at 12 months of age, at least one month after the first vaccine with a further dose at 4-5 years of age. If a child aged <18 months receives a second MMR vaccine within 3 months of the first MMR a third MMR should be given at 4-5 years of age.
4 For health care workers without presumptive evidence of immunity; for contacts in outbreaks born in Ireland since 1978 or born outside Ireland and for adults from low resource countries, without evidence of two doses of MMR vaccine
5 One dose if 7-<8 months
6 Only one dose of Tdap/IPV is required due to likely previous exposure to pertussis infection

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Immunisation requirements
Interval between doses

	Interval between doses (months)			
Vaccine	1/2	2/3	3/4	4/5
DTaP/IPV/Hib/HepB	2	2	6	5 years
Tdap/IPV (low dose vaccine)	1	1	6	5 years
MMR	1			
Rotavirus	4 weeks			
MenB	2			

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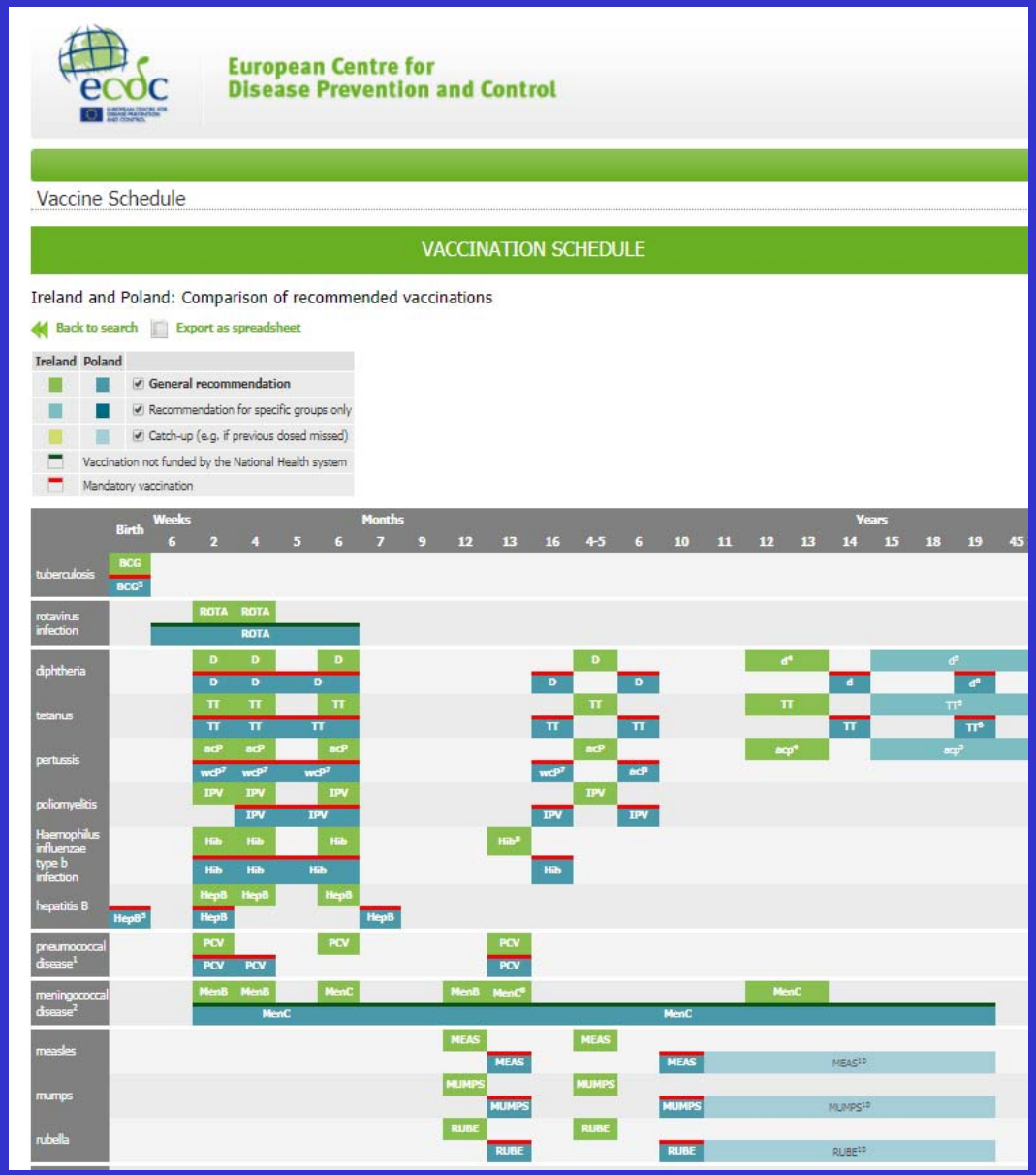
Contraindications and Precautions

Contraindications

- **Anaphylaxis** to any of the vaccine constituents
- Rotavirus
    - Severe Combined Immunodeficiency Disorder (SCID)
    - Previous history of **intussusception**
    - Malformation of the gastrointestinal tract (?lead to intussusception)
    - **Hereditary** fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption
- MMR
    - Significantly **immunocompromised** persons, and those receiving immunosuppressive therapy, high-dose x-ray therapy and current high-dose systemic corticosteroids
    - **Pregnancy** and avoid for 1 month after MMR

Precautions

- Acute severe febrile illness: defer until recovery
- MMR/ Varicella/ Zoster/ Yellow fever



http://vaccine-schedule.ecdc.europa.eu/Pages/Scheduler.aspx

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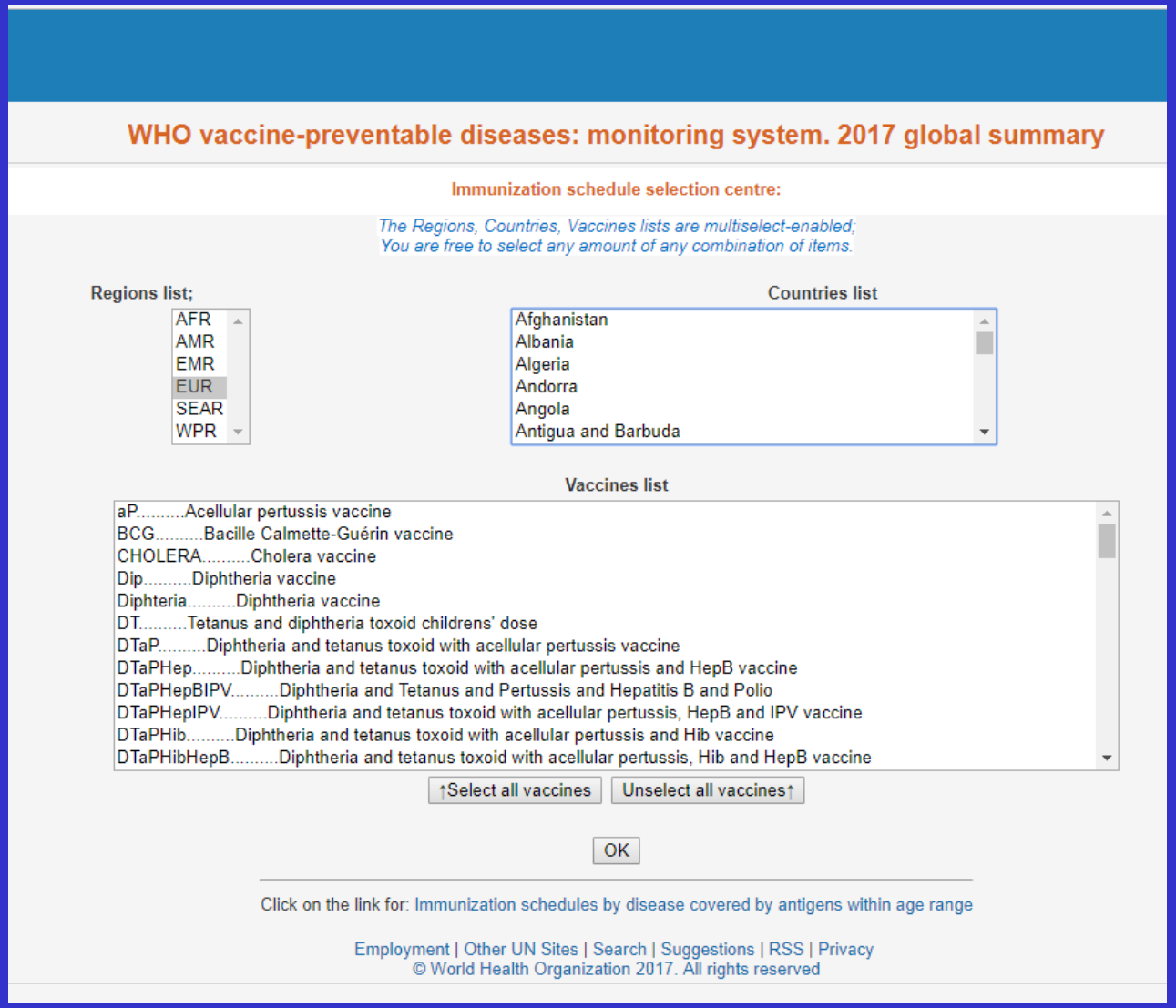

http://apps.who.int/immunization_monitoring/globalsummary/schedules

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Premature Babies

- More at risk from vaccine preventable diseases
- Should have vaccinations carried out according to chronological age
- May start vaccinations in hospital

More information

http://www.hse.ie/eng/health/immunisation/hcpinfo/frequentlyaskedquestions/catchupvacc/catchupvacc.html

- Chapter 2 of the Immunisation Guidelines

http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter2.pdf

Summary Catch-up

If in doubt, give them all

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Adverse Events Outline

- Abbreviations, Definitions
- Adverse Event (AE), Adverse Reaction (AR) or coincidence?
- How are AEs recorded?
- How are ARs identified?
- Frequency of ARs
- Reporting of AEs

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Definitions

- **Adverse Event (AE)**

  -Any untoward medical occurrence … which does **not necessarily** have a **causal** relationship with the treatment

- **Adverse Reaction (AR)**

  -A response to a drug which is noxious and unintended, …

- **Adverse Event Following Immunization (AEFI)**

  -Any untoward medical occurrence which follows immunisation 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

- **Immunisation Error**

  -An adverse event following immunisation that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable

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Known AEFIs

Common (>1 in 100)	Rare (<1/1,000)	Very rare (<1/100,000)	Extremely rare < 1/ million
• Redness • Swelling, nodule • Pain • Fever, irritability, loss of appetite • Nausea, D+V	• Fainting or collapse • Febrile seizure • Thrombo-cytopoenia	• Serious allergic reaction • Arthritis	• Encephalitis • Paralysis • Death

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What is “Less Common”?

Frequency of known injury*	What else is this common?
1/1,000 to 1/100,000 – Fainting or collapse – Febrile seizure – Thrombocytopoenia	Having quadruplets
1/100,000 to 1/1,000,000 – Serious allergic reaction – Arthritis	Getting struck by lightning
< 1 in a million – Encephalitis – Paralysis – Death	Winning the lotto

www.immunisation.ie

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Presenting Risk Information

- Understand the specific concerns
  - Not all the same
  - Don't bring up new concerns
- Frame your message

√	×
25% fat beef burgers	75% lean beef burgers
There is a 1% risk of side effects	It is 99% safe
About 1 to 3 children out of 10,000 will experience a serious reaction	This vaccine rarely causes serious reactions - about 1 to 3 children out of 10,000 who receive it

- Avoid academic jargon

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AEFIs: potential sources

- Manufacturing potency issues
  - over-attenuation of live vaccines
  - instability over time
  - reconstitution, mixing interferences
- Storage issues
- Administration issues
  - technique
  - concomitant administrations
- Patient profile
  - age, weight
  - immune deficiency e.g. AIDS
- Environmental
  - epidemiology: strain variation

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Timing of Vaccine Reactions

- **Inactivated vaccines**
  - generally within 48hrs
- **Live vaccines**
  - according to time for organism to replicate
- MMR
  - mini-measles 6-11 days
  - rubella 2nd week
  - mumps 3 to 6 weeks

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Minimising Errors

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

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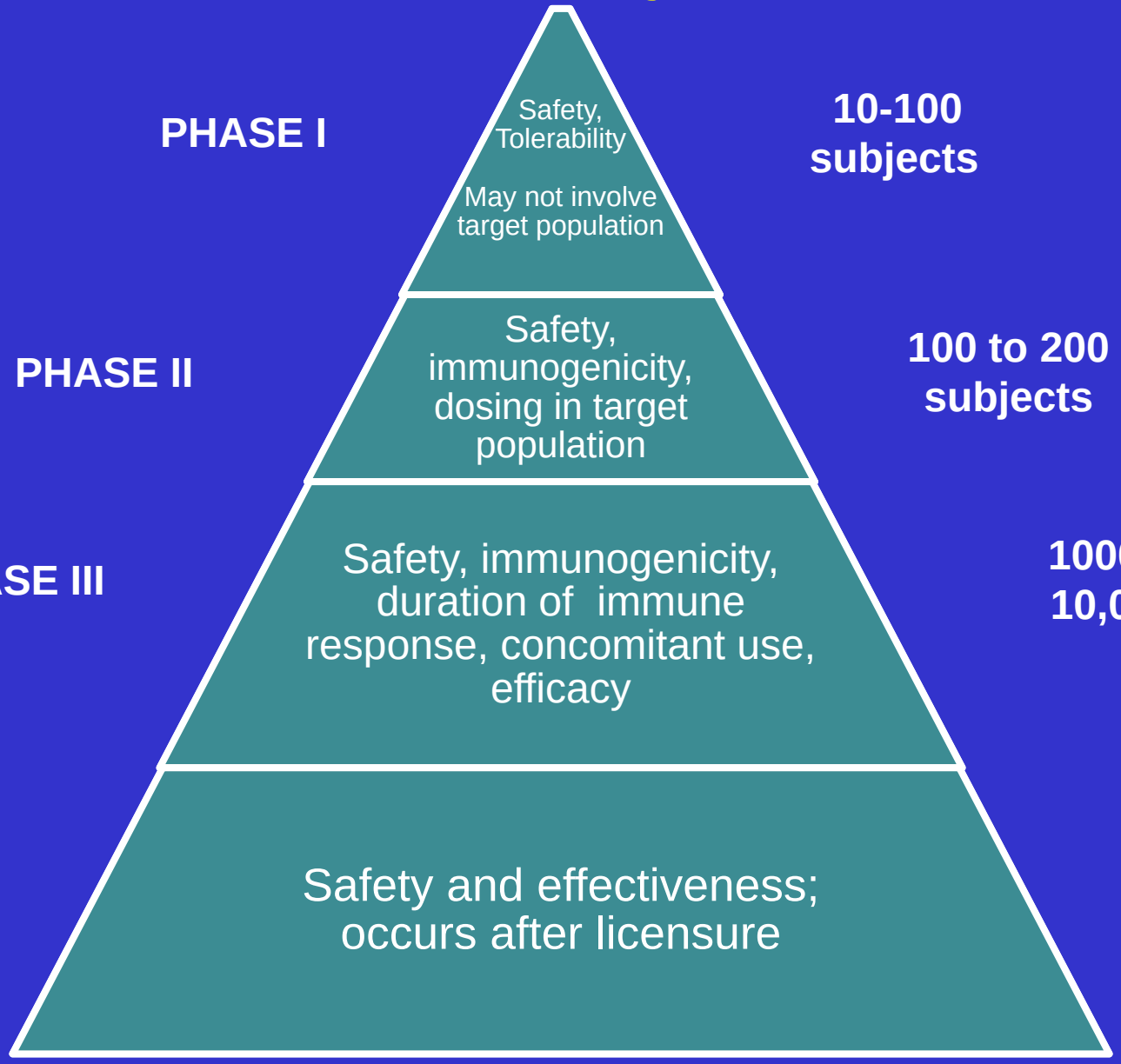
Vaccine Safety Studies



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Why Monitor AEFIs?

- **No vaccine is 100% safe**

  Safety profile established in pre-license trials

  Rare events require huge numbers to detect

- **Risk / benefit balance changes over time**

  as incidence falls-e.g. VAPP with oral polio vaccine

  as society becomes more critical

Pharmacovigilance

Science and activities relating to the detection, assessment, understanding and prevention of adverse effects

Objectives

- preventing harm from adverse reactions
- promoting safe and effective use of medicinal products

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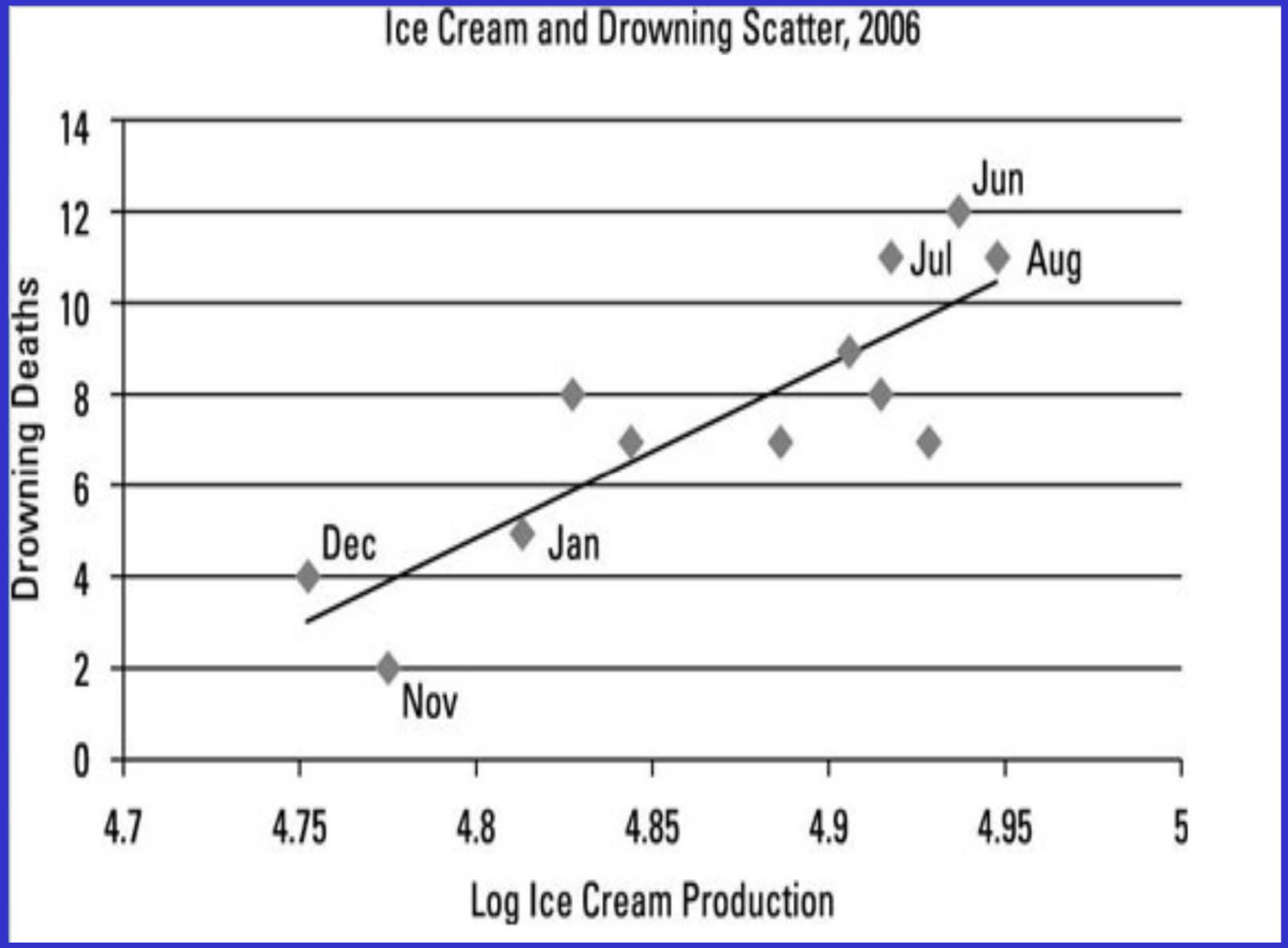
Benefit-risk balance

- Medicines may have unintended, harmful effects.
- Active substance tested in trials
- Licenced only if benefits outweigh risks
- Used in patients who may differ from the study population, e.g. age or additional diseases
- Important to identify any new risk ASAP, and to take measures to minimise risk and promote safe and effective use

Correlation is not Causation



Spurious Correlations, tylerviggen.com

Criteria of Causality (Bradford Hill)

The **B**ad **D**og **A**te the **C**at

- **Temporality** - occurs after, change in incidence over time
- **Biological Plausibility** - biological mechanism can make causality more plausible
- **Dose** - Response Relationship
- **Association** (strength of) - measured using RRs and ORs
- **Consistency** - similar results from different studies, researchers, populations, times

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Reporting AEFIs

- <10% are reported
- Up to 99% are not reported
- Safety is provisional at time of licencing - Rotashield, Pandemrix
- Every report is important
- If in doubt, write one out

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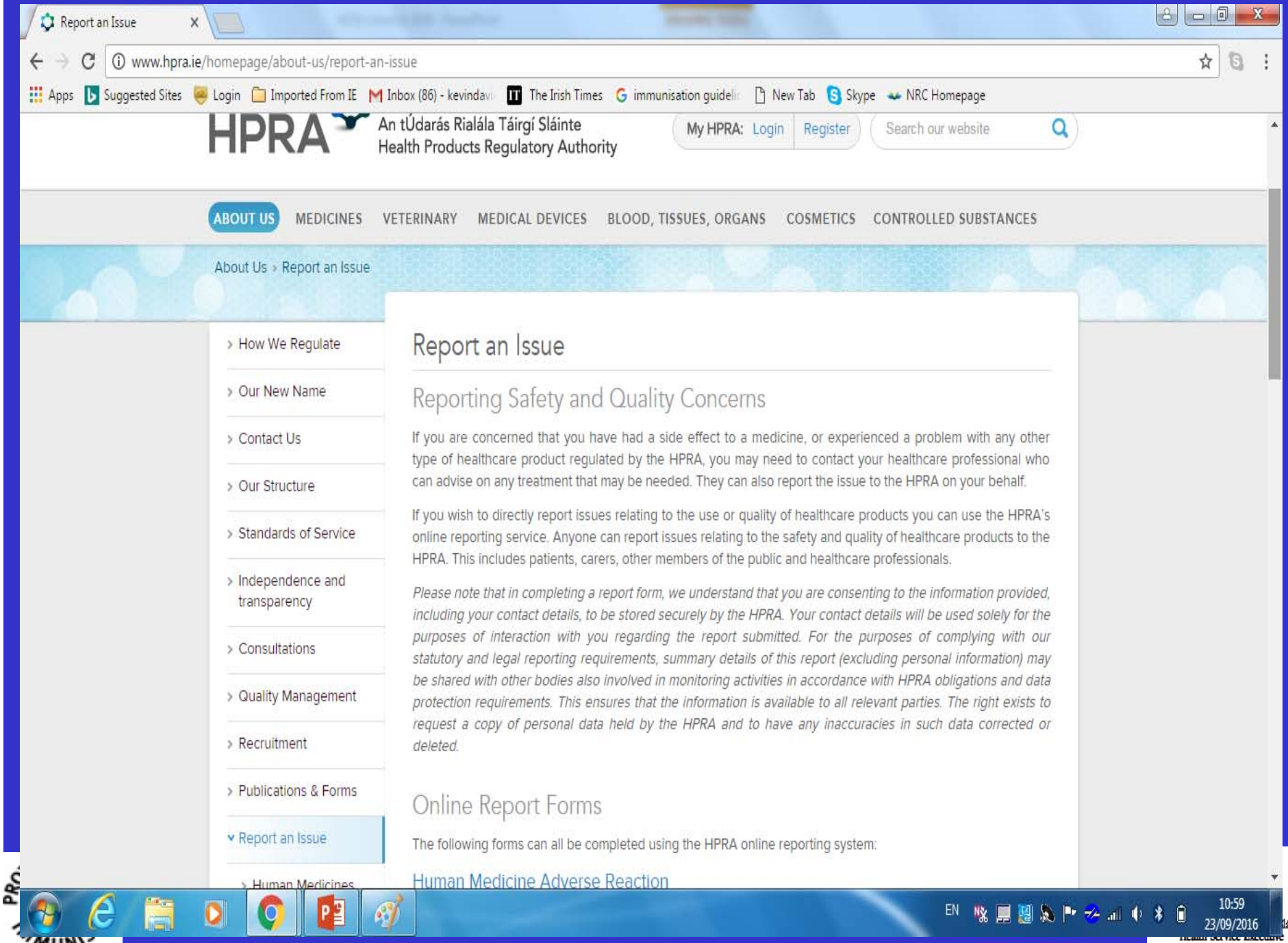
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