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Real world safety and effectiveness across the lifespan

Jim Buttery, University of Melbourne & Epidemiology Informatics, MCRI

8th May 2026

Clinical trial gaps: COVID vaccines

Not studied

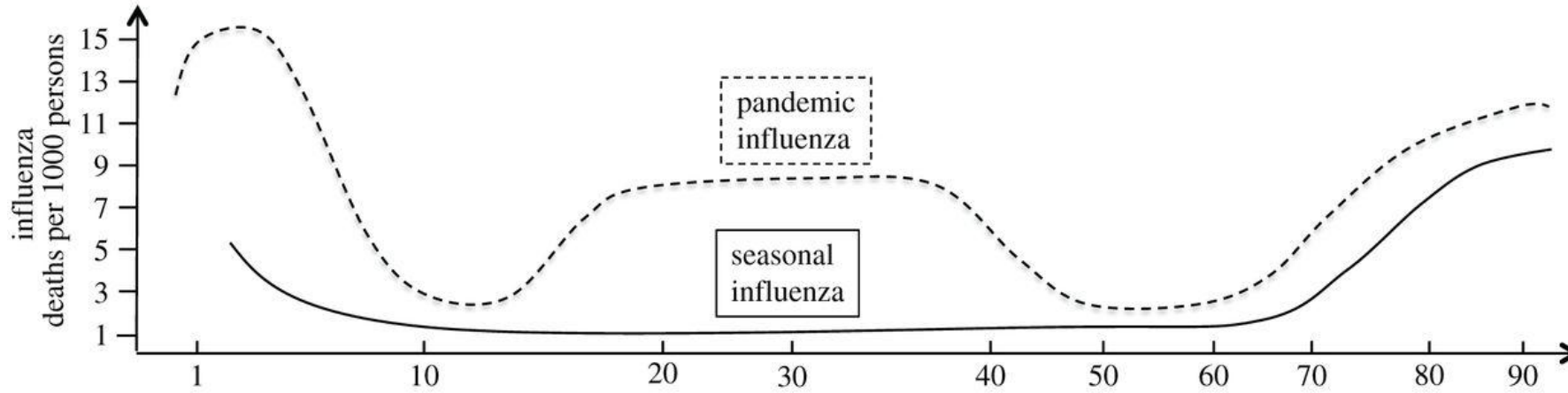


Evolution of the immune system in humans from infancy to old age.

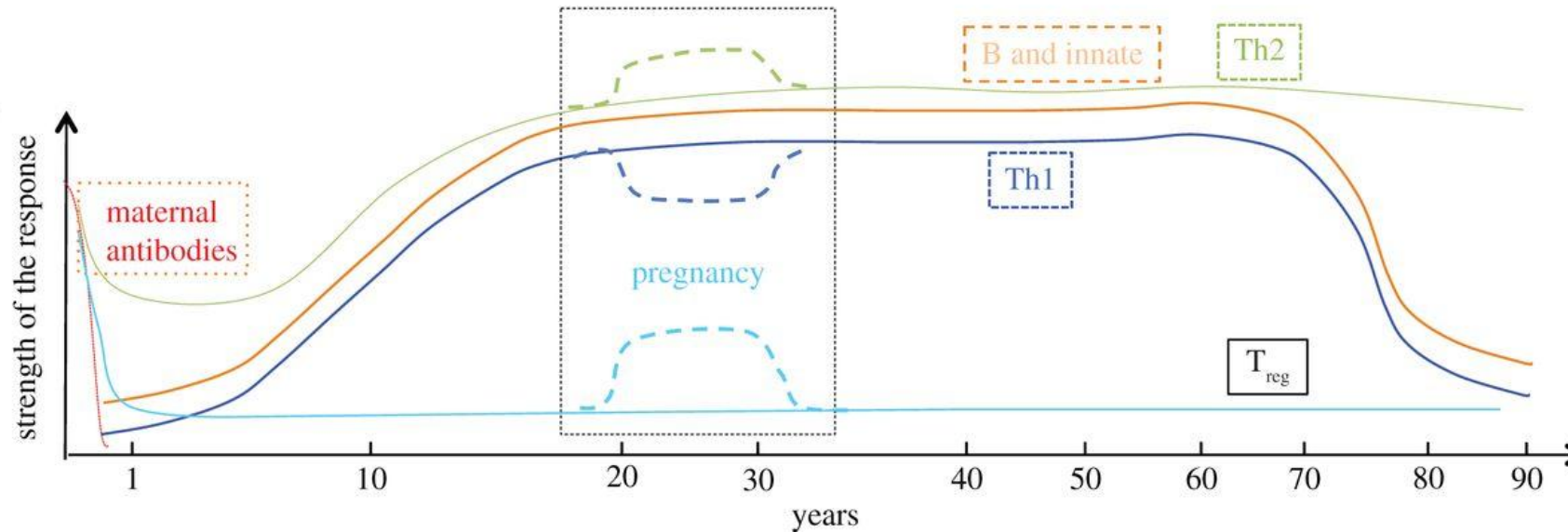
(a)



(b)



(c)



A. Katharina Simon, Georg A. Hollander, Andrew McMichael; *Proc Biol Sci* 1 December 2015; 282 (1821): 20143085.
<https://doi.org/10.1098/rspb.2014.3085>



Vaccine Safety



Infants/toddlers:

Multiple vaccines

Repeated doses

Systemic reactogenicity

- Fever, irritability

Childhood conditions

- Febrile convulsions
- apnoea

Older adults:

Less obvious reactogenicity

Non-specific reactogenicity

- Feel crap, Stop drinking....

Comorbidities....

- Eg Renal

AESI- rising background rates

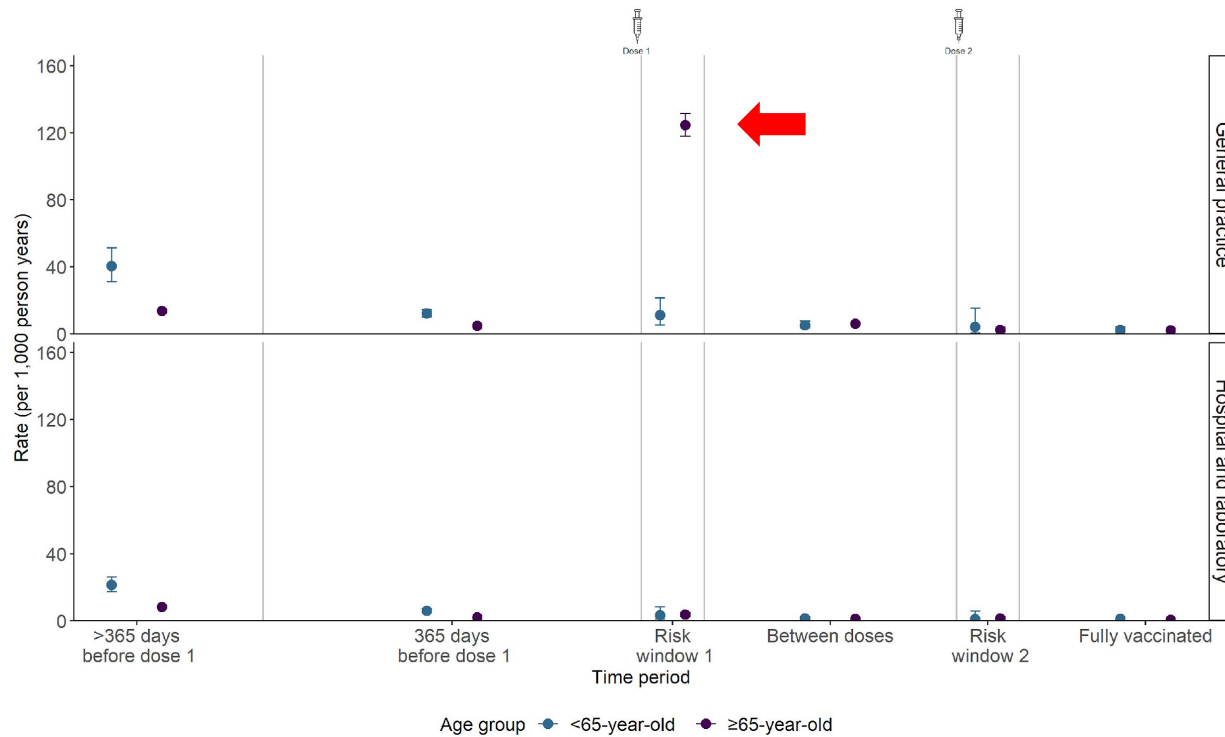
Immunosenescence

- Higher doses, adjuvants



Transient Increased Risk of Shingles Post-Shingrix Vaccination: Self-Controlled Case-Series Analysis

Aishwarya N. Shetty,^{1,2} Daneeta Hennessy,^{1,2} Gonzalo Sepulveda Kattan,^{1,2} Samar Ojaimi,^{3,4} Hazel J. Clothier,^{1,2,5} and Jim P. Buttery^{1,2,5,6}



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Immunisation

Patient counselling advised regarding Shingrix vaccine

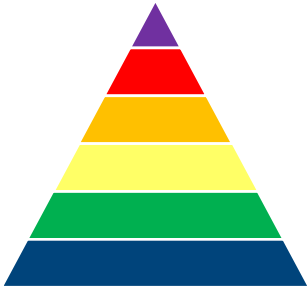
30 October 2024

Some practices in South Western Sydney provide de-identified data for research projects relevant to general practice. SAFESIG GP, in collaboration with SAEFVIC, is investigating vaccine safety using primary care data.

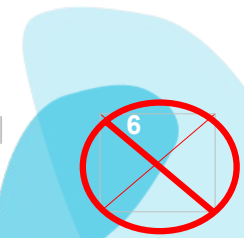
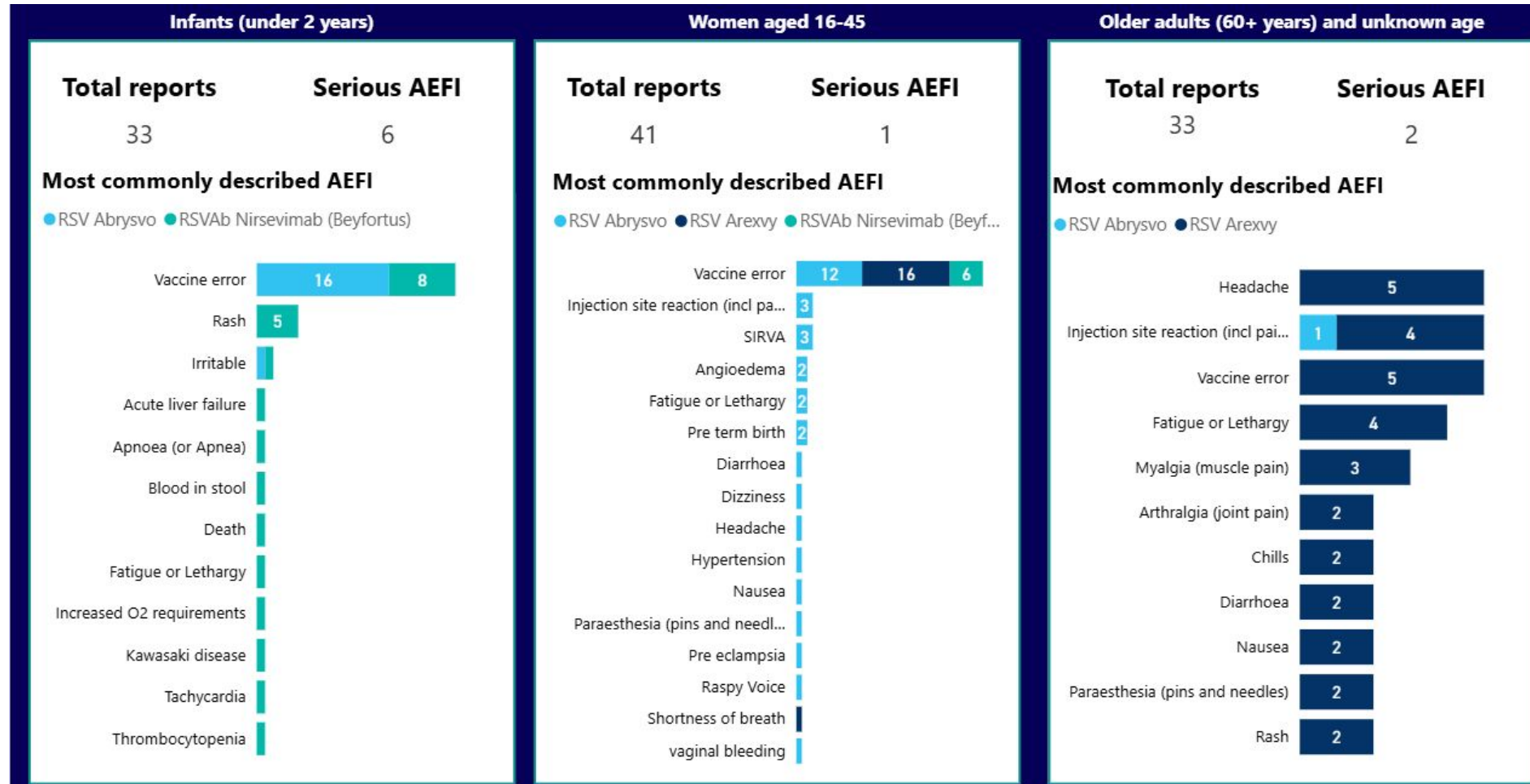
The Therapeutic Goods Administration (TGA) noticed a potential safety issue with early shingles cases after Shingrix vaccination and asked SAEFVIC to investigate. Although Shingrix is highly effective in preventing shingles¹, some cases of shingles soon after vaccination suggest it might cause varicella reactivation².

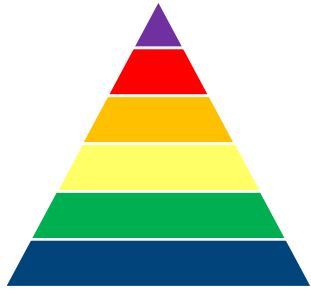
There was found to be an increase in shingles cases within 21 days after the first Shingrix dose in people over 65. The risk drops below pre-vaccination rates after this period, showing strong protection and the vaccine's benefits still outweigh the risks. Patient counselling is advised.



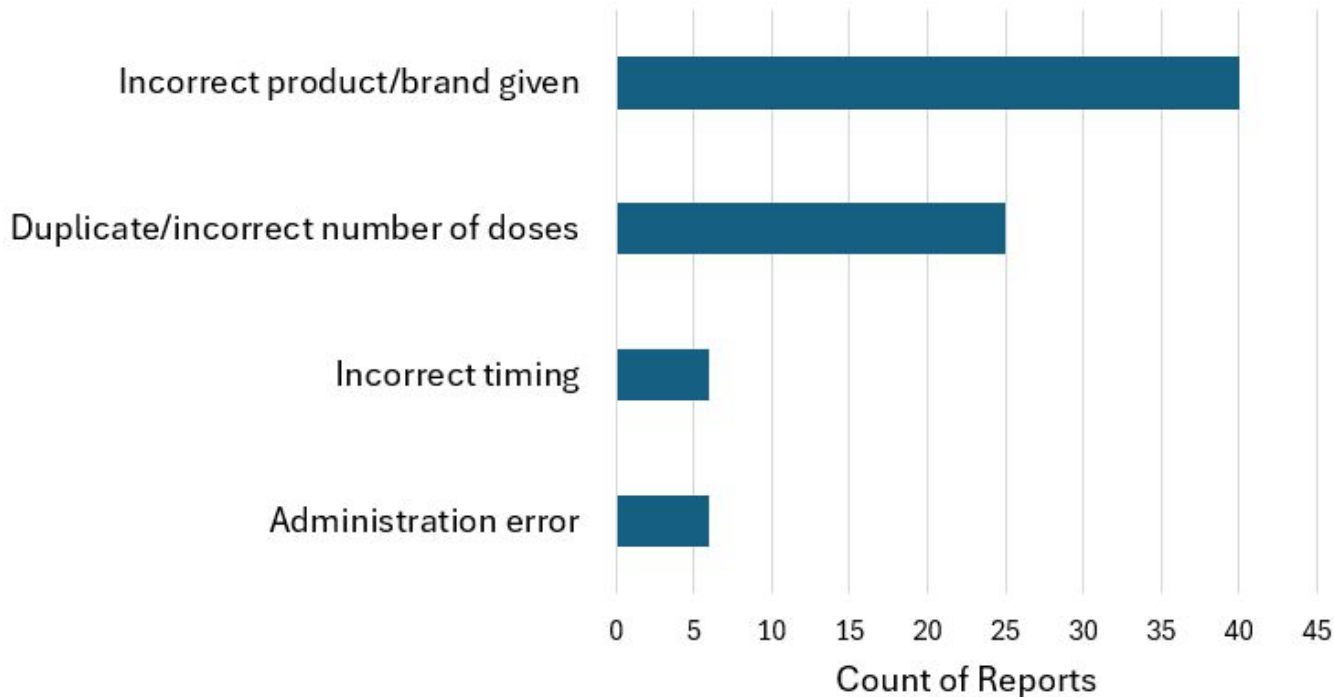


Adverse event reports





Adverse event reports Immunisation Errors



- Incorrect product
 - Abrysvo given to infants
 - Arexvy given in pregnancy
- Incorrect number of doses
 - Multiple Abrysvo doses given in pregnancy
 - Multiple Beyfortus doses given
- Incorrect timing
 - Abrysvo administered too early in pregnancy
- Administration error
 - Shoulder Injury Related to Vaccine Administration (SIRVA)
 - Insufficient dosing



Vaccine Safety



Known knowns

- reactogenicity often lower
- Non-specific egg falls, dehydration

AESI

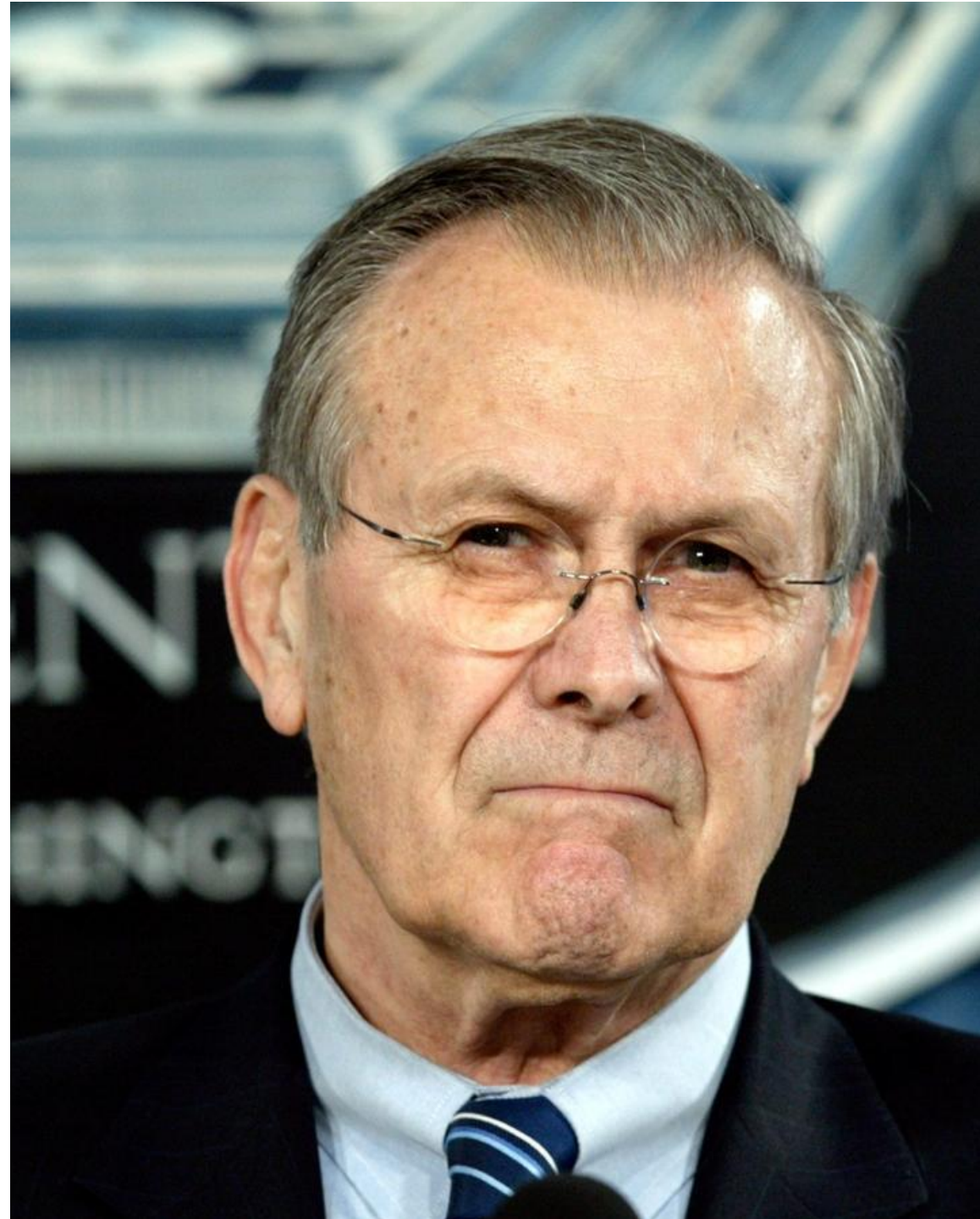


Known unknowns – AESI

- Background rates change with age
- Age can influence susceptibility and severity

Unknown unknowns

- VITT, myocarditis and COVID vaccines





Vaccine efficacy

refers to how the vaccine performs in ideal conditions - controlled clinical trials.



Vaccine effectiveness

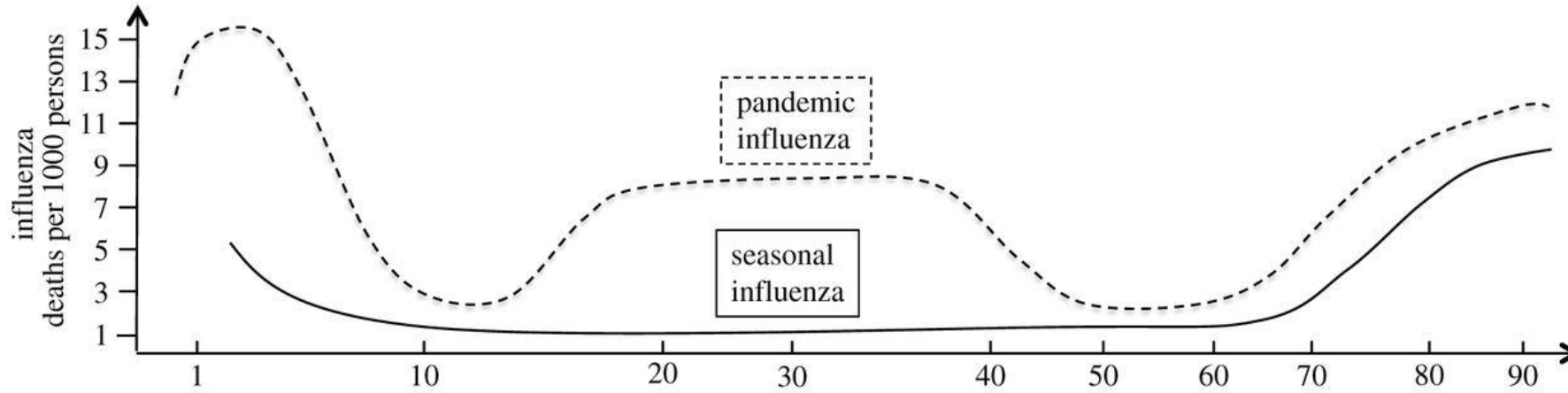
refers to how the vaccine performs in the wider populations.

Evolution of the immune system in humans from infancy to old age.

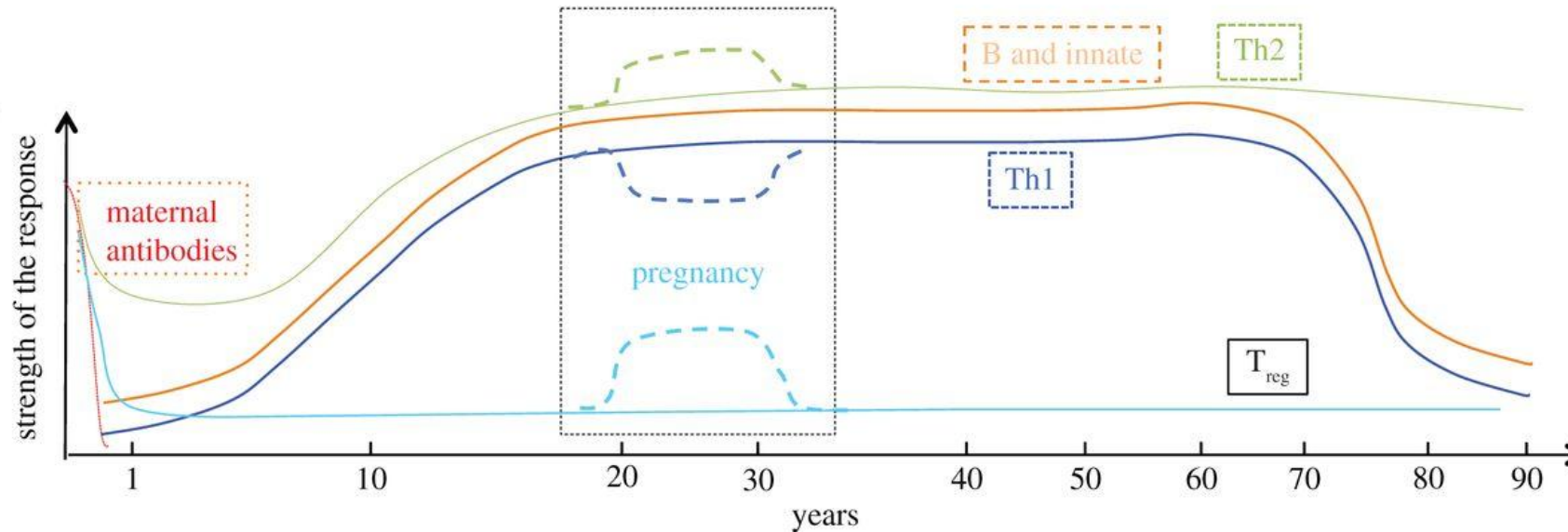
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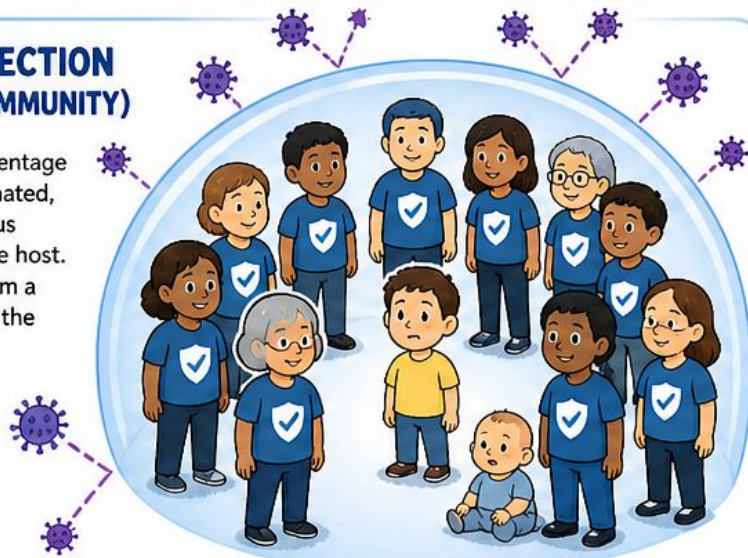
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5 INDIRECT WAYS VACCINES PROVIDE PROTECTION

1 HERD PROTECTION (COMMUNITY IMMUNITY)

When a high enough percentage of the population is vaccinated, it's harder for the infectious agent to find a susceptible host. Vaccinated individuals form a protective barrier around the unvaccinated.



2 REDUCED INFECTIONOUSNESS OF VACCINATED INDIVIDUALS

When vaccinated individuals do experience "breakthrough" infections, they are often less contagious, have a shorter duration of shedding, and lower viral loads compared to infected, unvaccinated individuals.

VACCINATED (BREAKTHROUGH INFECTION)

- ✓ Lower viral load
- ✓ Shorter shedding
- ✓ Less contagious

UNVACCINATED (INFECTED)

- ✓ Higher viral load
- ✓ Longer shedding
- ✓ More contagious

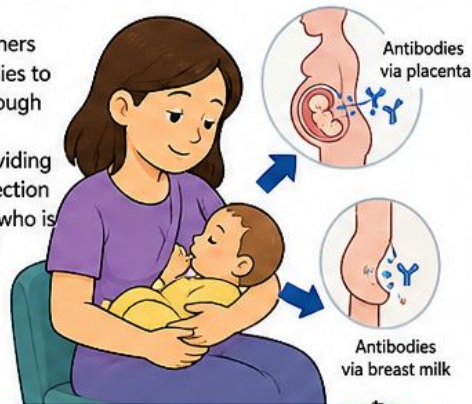
3 REDUCED TRANSMISSION RISK (HOUSEHOLD/CLOSE CONTACT)

Vaccinated individuals are less likely to bring the pathogen into their home or work environment, thus protecting unvaccinated family members or colleagues.



4 PASSIVE ANTIBODY PROTECTION (MATERNAL IMMUNITY)

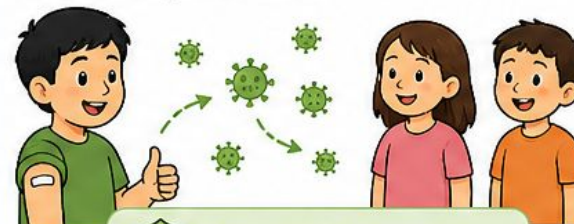
Vaccinated mothers transfer antibodies to their infants through the placenta or breast milk, providing temporary protection to the newborn who is too young to be vaccinated.



Provides temporary protection until the baby can be vaccinated.

5 INDIRECT DISPERSION OF LIVE-ATTENUATED VACCINES

In certain cases, particularly with live-attenuated vaccines, the weakened virus from a vaccinated individual can spread to unvaccinated individuals, inducing immunity in them without causing severe disease.



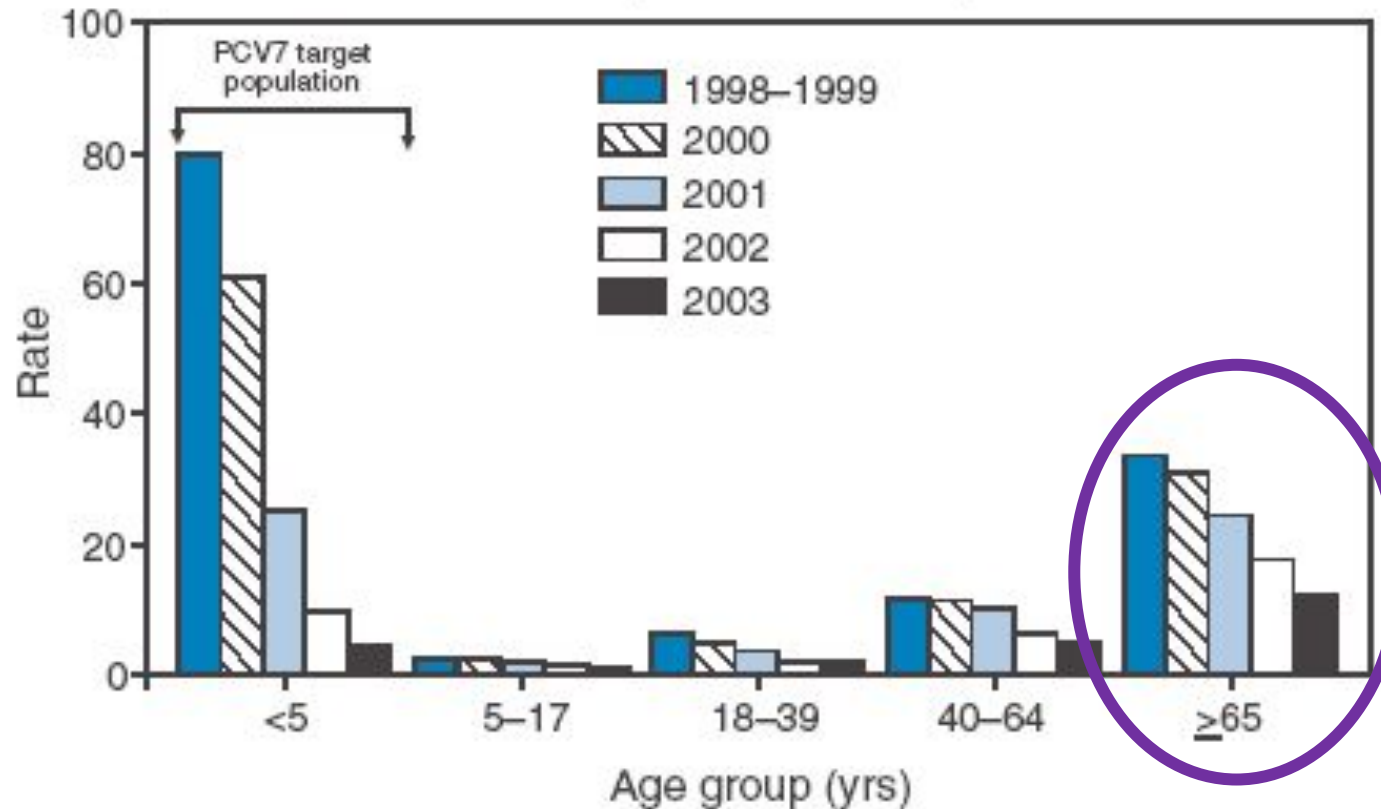
They develop immunity without getting severely ill.

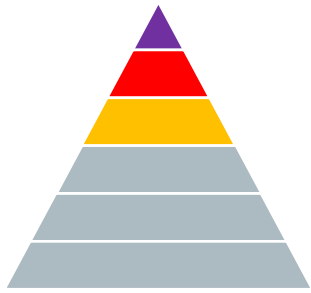
**IF WE HAD KNOWN
GRANDCHILDREN
WERE SO MUCH FUN,
WE WOULD HAVE HAD
THEM FIRST!**



2 REDUCED INFECTIONOUSNESS OF VACCINATED INDIVIDUALS

FIGURE 1. Rate* of vaccine-type (VT) invasive pneumococcal disease (IPD) before and after introduction of pneumococcal conjugate vaccine (PCV7), by age group and year — Active Bacterial Core surveillance, United States, 1998–2003



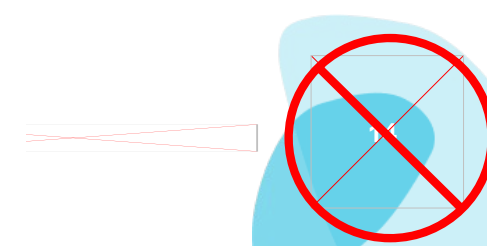
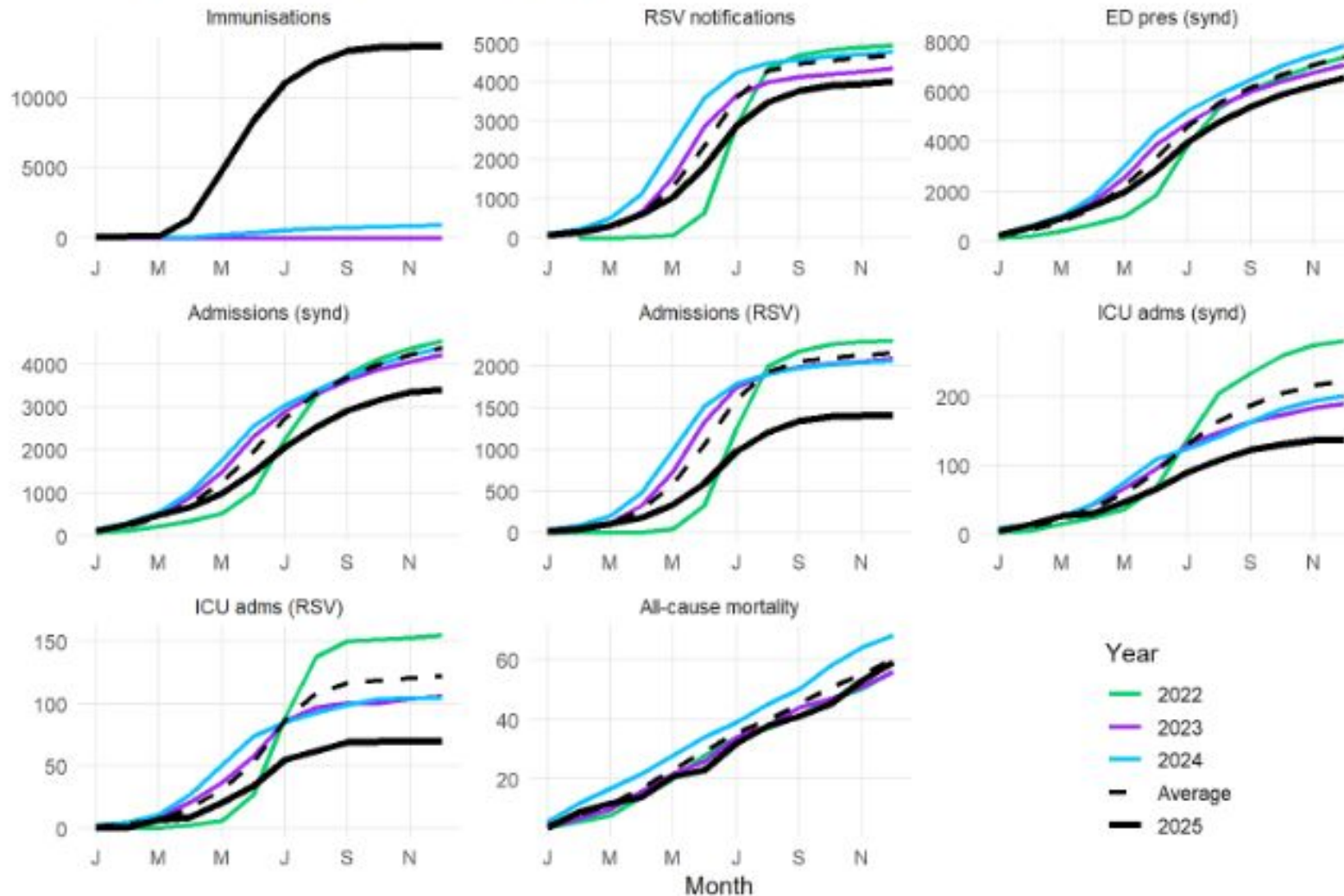


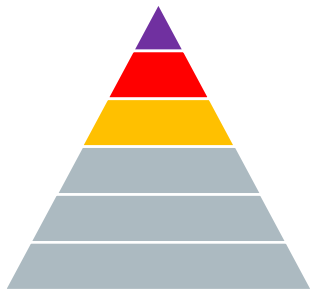
Linked administrative datasets

Population-level impact of RSV immunisation

First year of life

Cumulative measures - First year of life



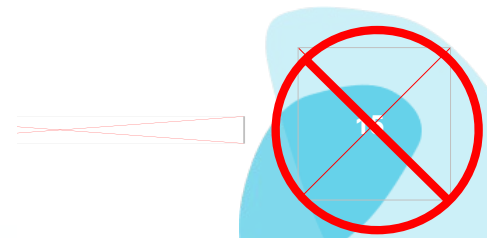
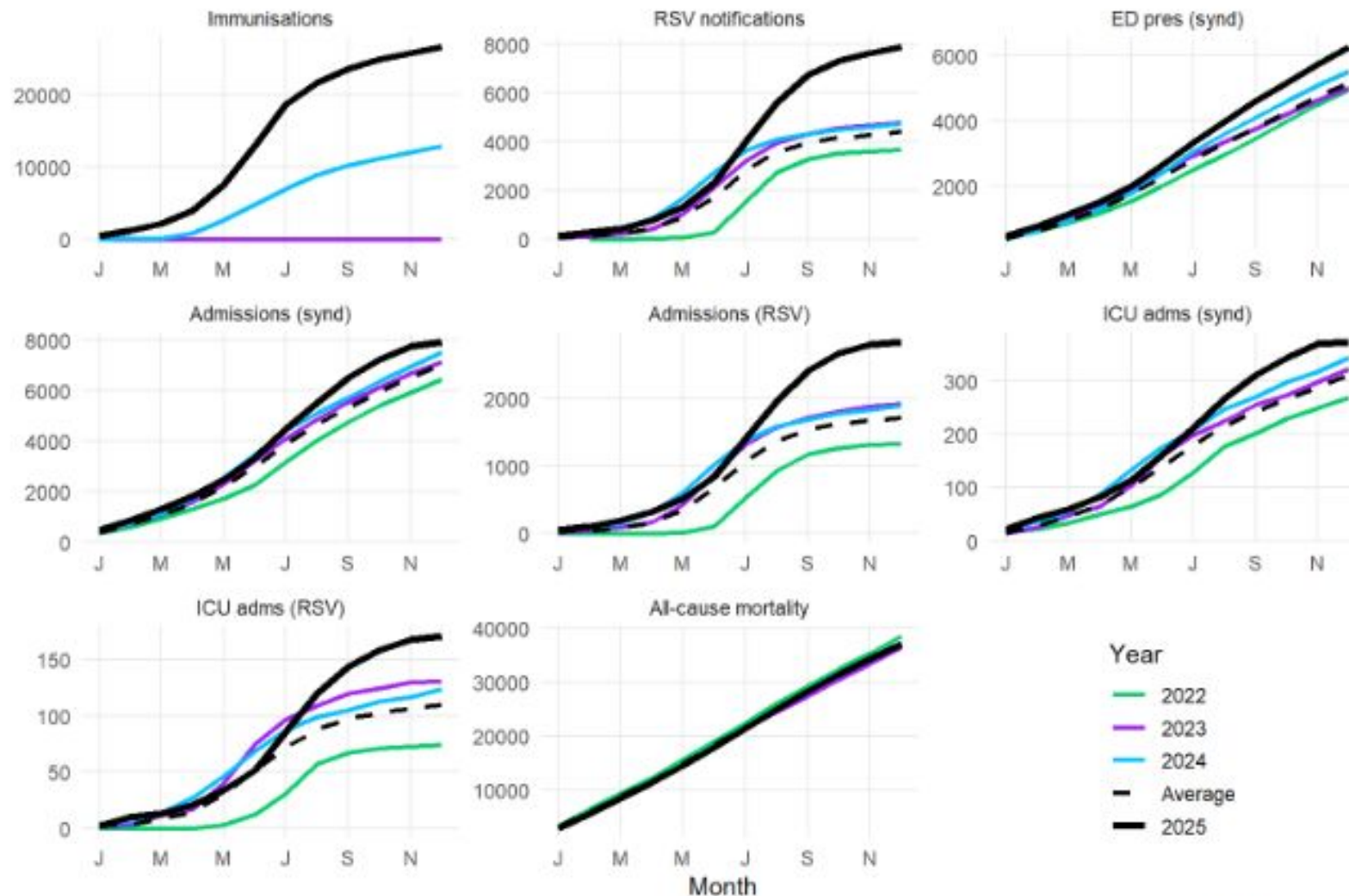


Linked administrative datasets

Population-level impact of RSV immunisation

Older Victorians

Cumulative measures - Older adults



Vaccine Effectiveness

Immunosenescence

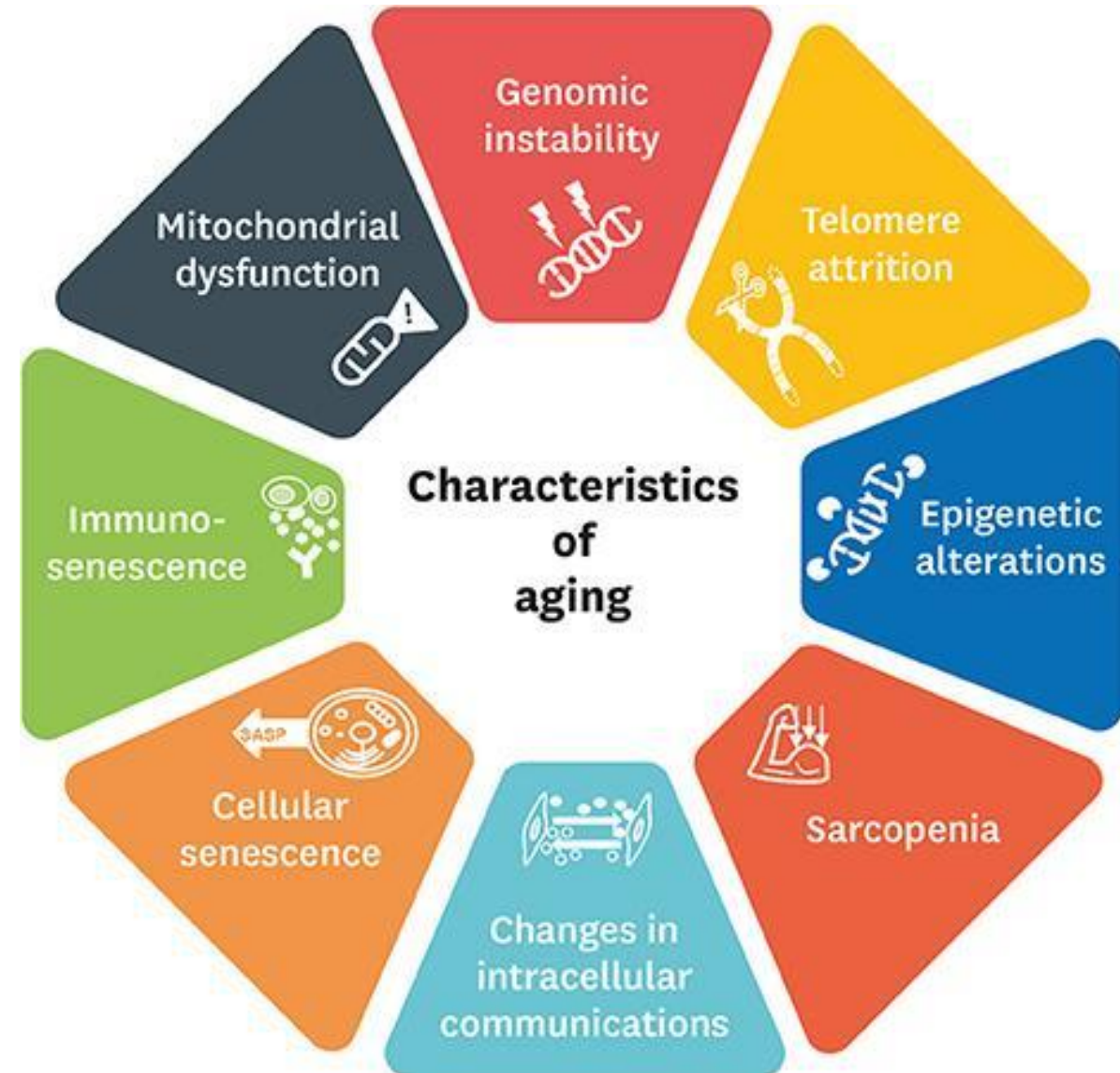
- Lower responses and effectiveness
- Reduced duration

Changed exposure risk

- Some good some bad

Less organ reserve

- More severe sequelae if vaccine failure



Conclusions

Real world often first time we understand safety and effectiveness in elderly

Immunosenescence real but vaccine strategies to overcome it

Safety: reactogenicity often milder but beware non-specific consequences

Effectiveness of a vaccine program not just direct protection to recipients



Acknowledgements



Centre for Victorian Data Linkage



SynSurv
Immunisation
Communicable Diseases

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