



## Early findings from Victoria's Vaccine Safety Health Link (VSHL)

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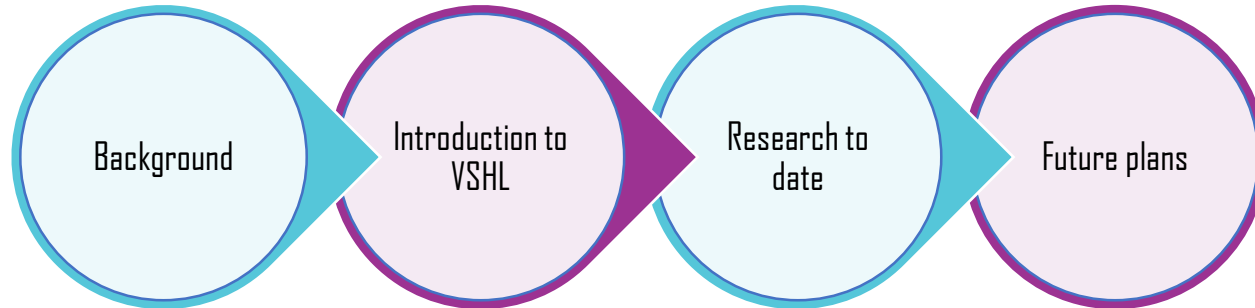


**SAEFVIC**



## Outline

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## Vaccines

25 vaccine preventable diseases<sup>1</sup>



Five million deaths prevented per year<sup>1</sup>

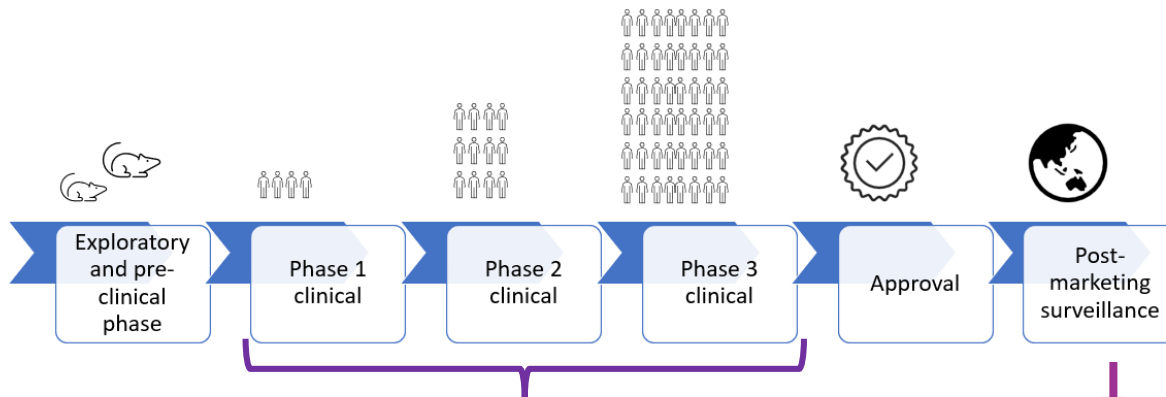


Significant economic benefit<sup>2</sup>

Scientific advances and increased coverage continue to improve benefits



## Adverse event surveillance



### Limitations:

- Underrepresentation of populations<sup>1</sup>
- Rare adverse events
- Adverse events with delayed onset



Surveillance of Adverse Events Following Vaccination In the Community<sup>2</sup>

1. Flores LE, Frontera WR, Andrasik MP, et al. Assessment of the Inclusion of Racial/Ethnic Minority, Female, and Older Individuals in Vaccine Clinical Trials. JAMA Network Open. 2021;4(2):e2037640-e.  
2. Clothier HJ, Crawford NW, Kempe A, BATTERY JP. Surveillance of adverse events following immunisation: the model of SAEFVIC, Victoria. Communicable diseases intelligence quarterly report. 2011;35(4):294-8.



## Existing post-marketing adverse event surveillance

Surveillance type	Description	Limitations
Spontaneous	Service providers and consumers report their AEFI	<ul style="list-style-type: none"> <li>• Underreporting</li> <li>• Reporting bias</li> </ul>
Active	Actively seeks vaccinees AEFI <sup>1,2</sup>	<ul style="list-style-type: none"> <li>• Labour intensive and expensive</li> <li>• Reporting bias</li> </ul>



Epidemiological analysis to investigate trends in vaccinee outcomes

1. Deng L, Glover C, Dymock M, et al. The short term safety of COVID-19 vaccines in Australia: AusVaxSafety active surveillance, February – August 2021. Medical Journal of Australia. 2022;217(4):195-202.  
 2. McRae JE, Quinn HE, Saravanos GL, et al. Paediatric Active Enhanced Disease Surveillance (PAEDS) annual report 2016: Prospective hospital-based surveillance for serious paediatric conditions. 2019;43(10.33321).



## Vaccine Safety Health Link (VSHL)



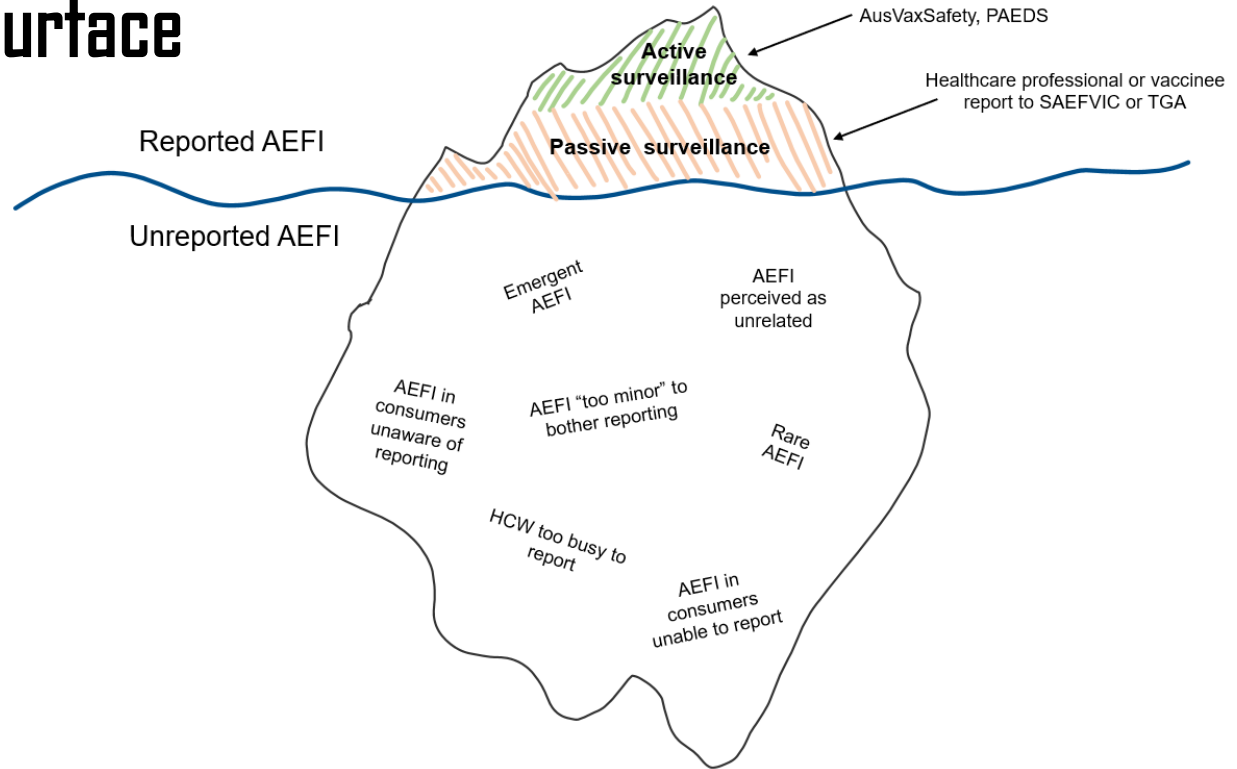
- Wide population
- Low data bias
- Relatively hands-free
- Cost effective



## Reveals below the surface

### Information guides:

- Policy
- Education

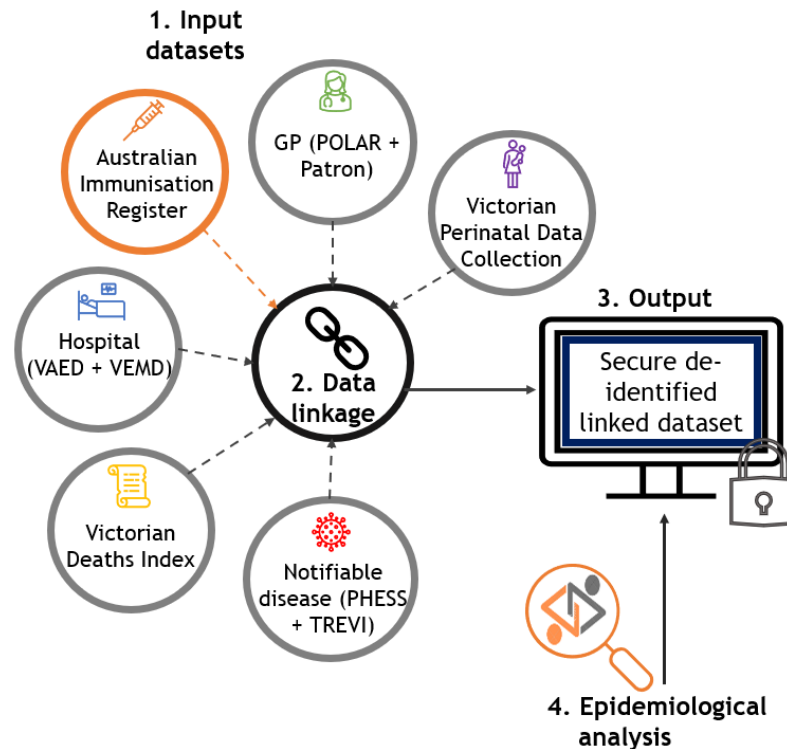




## VSHL Design

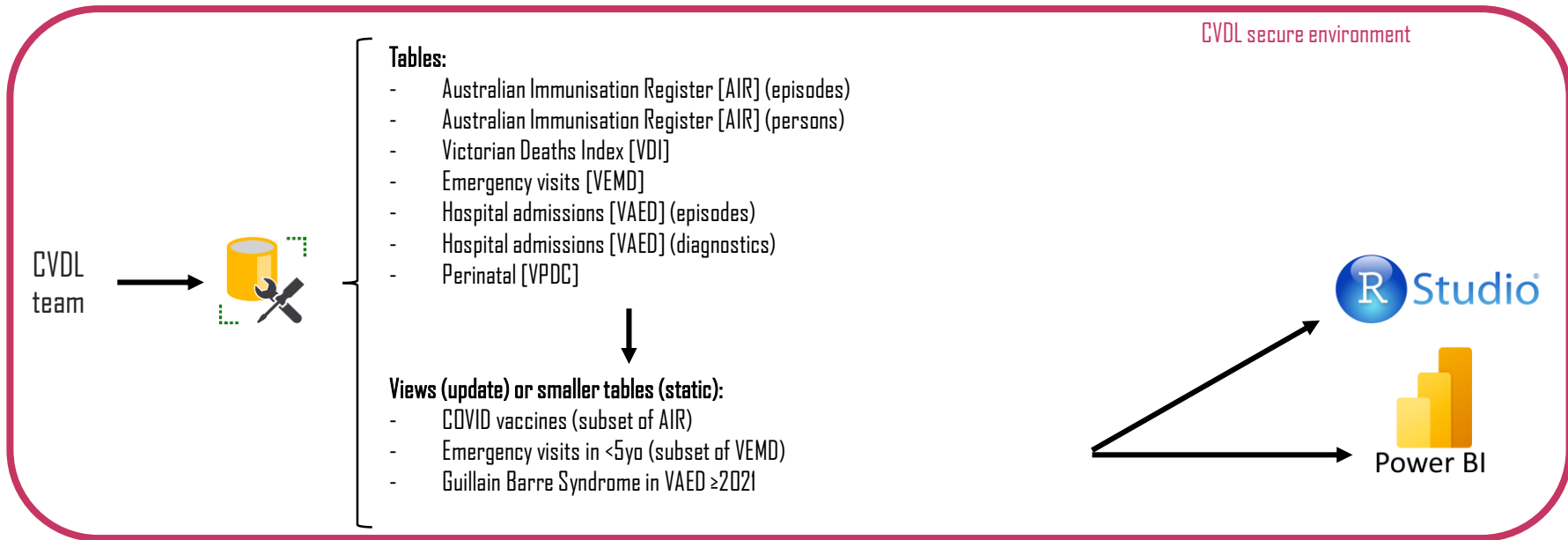
Deterministic linkage using a combination of:

- UR number
- Hospital campus visited
- Medicare suffix
- First name
- Last Name
- Birthdate





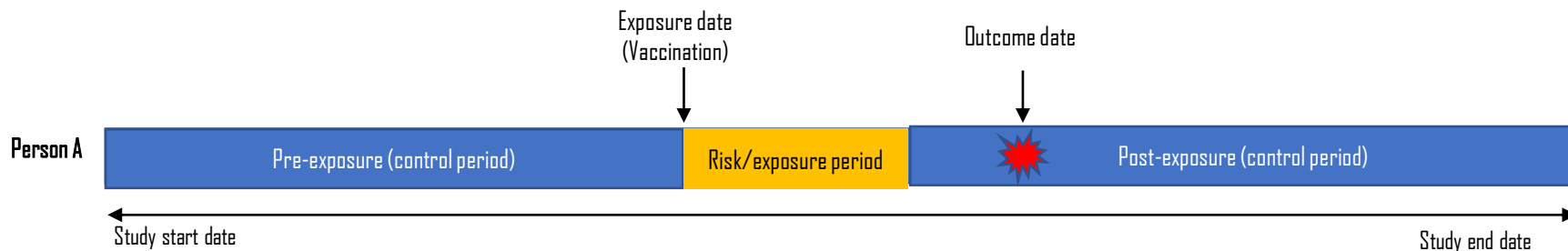
## VSHL data warehousing





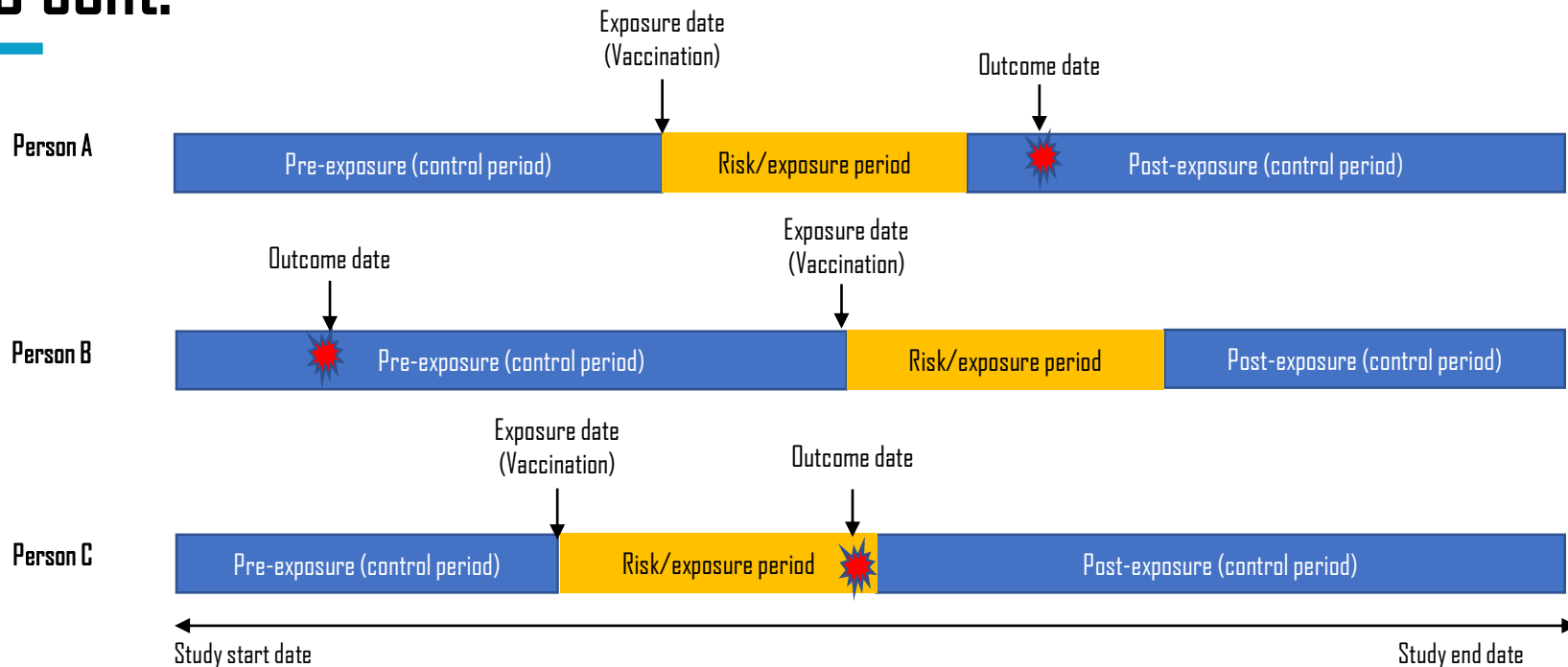
## Self-Controlled Case Series (SCCS) methodology

For every person with the outcome in study period





## SCCS cont.





## Validation of VSHL

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Can VSHL find known vaccine safety signals?





## Validation – Guillain-Barre Syndrome

Step 1: CURRENT DAY DATA (as at 15 Feb 2023) SCGS

Parameters

Exposure: Vaxzevria COVID-19 vaccination

Outcome: Guillain-Barre Syndrome diagnosis in VAED dataset

Study period: 1 Jan 2021 – 31 Dec 2022

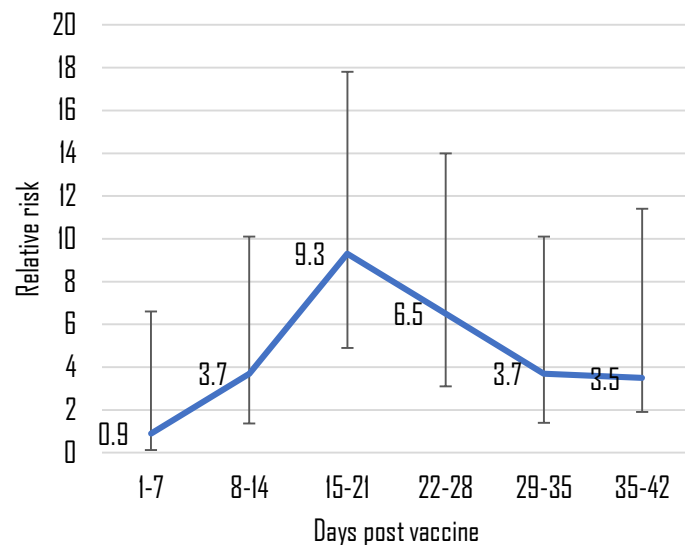
Risk period: 1-42 days after vaccination

Overall relative risk:

4.8 (95% CI: 3.2,7.2)  $p < 0.001$  in a 42-day risk window

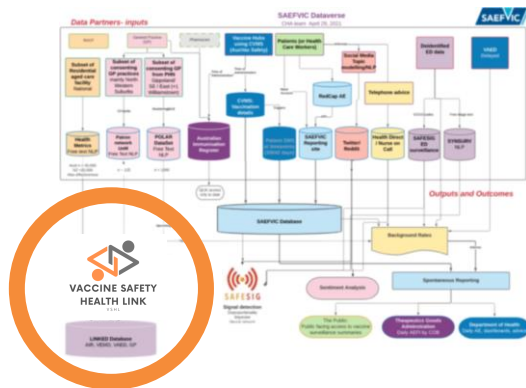
All doses, all ages, all sex

Relative risk of GBS post Vaxzevria vaccination





## Integration of VSHL to SAFEVIC





## Future direction

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- Communicate VSHL via a plain language summary
- Investigate other possible data analysis methodologies
- Expand validation work to describe potential time improvement with VSHL
- Validate VSHL on perinatal and general practitioner datasets
- Propose a distributed data model structure to collaborate with Australia's other states and territories
- Remain flexible to answer emerging vaccine safety questions



## Co-Authors and Acknowledgements

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Rebecca Gang

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## Validation – Myocarditis

Step 1: CURRENT DAY DATA (as at 21 Feb 2023) SCGS

Parameters

Exposure: mRNA COVID-19 vaccination

Outcome: Myocarditis diagnosis in VAED dataset

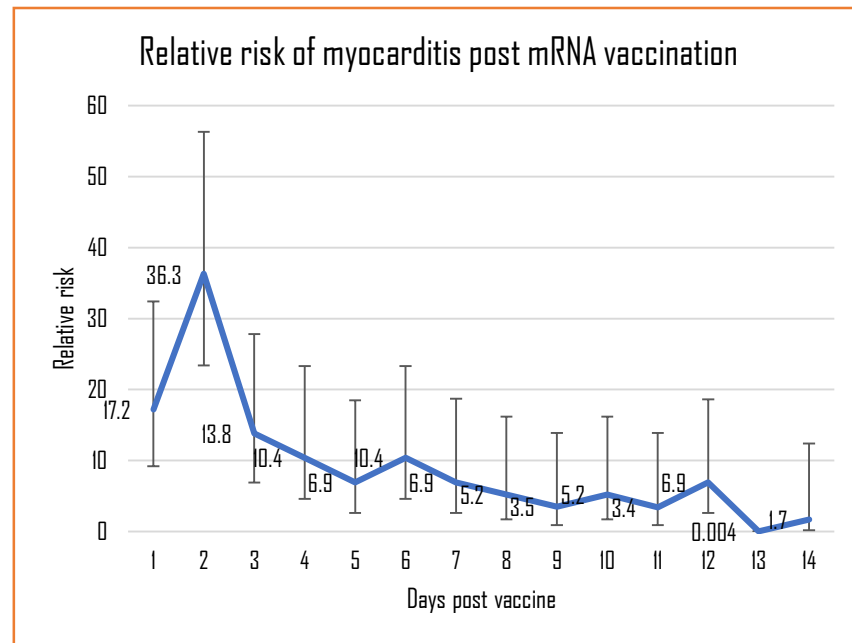
Study period: 1 Jan 2021 – 31 Dec 2022

Risk period: 1-14 days after vaccination

Overall relative risk:

10.2 (95% CI: 8.0,12.9)  $p: <0.001$  in a 14-day risk window

All doses, all ages, all sex





## Integration into SAEFVIC – Appendicitis

Step 1: CURRENT DAY DATA (as at 23 Dec 2022) SCCS

Parameters

Exposure: Any COVID-19 vaccination

Outcome: Appendicitis emergency presentation (VEMD)

Study period: 1 Jan 2021 – 23 Dec 2022

Risk period: 1-21 days after vaccination

Overall relative risk:

0.9 (95% CI: 0.8,1.1) p:0.02

All doses, all ages, all sex

