Australia needs a vaccine injury compensation scheme

Upcoming COVID-19 vaccines make its introduction urgent

Nicholas Wood, Kristine Macartney, Julie Leask, Peter McIntyre

RECIPROCAL JUSTICE is an ethical principle that acknowledges that people acting to benefit themselves, but also the community, should be compensated by the same community if harm has resulted from action as an individual. For immunisation programs, the community owes a debt of gratitude to an individual who experiences serious injury due to a vaccine offered and accepted in good faith. In Australia, we also have strong compulsion for individuals to receive routine vaccines through legislative requirements such as 'No Jab No Pay' and, in some states, 'No Jab No Play'. Countries that mandate childhood vaccination without providing no-fault injury compensation schemes for rare vaccine injury could be abrogating the social contract.[1]

Vaccine injury compensation schemes – What are they?

A vaccine injury compensation scheme (VICS) compensates individuals who have a vaccine injury following administration of properly manufactured vaccines.[2,3] Australia, in stark contrast to 25 other countries including the USA, UK and New Zealand (Table 1),[2,4,5] does not have a no-fault VICS. Individuals who experience a vaccine injury must bear the costs associated with their injury by themselves or access treatment via our publicly-funded health system, but they will not receive any compensation for their injury and suffering. Australia's National Disability Insurance Scheme (NDIS) provides funding support to access therapies for individuals with a permanent and significant disability. The NDIS does not cover temporary vaccine-related injuries. Participants in clinical vaccine trials can be compensated for injuries resulting from their participation.[6]

A VICS compensates those who have had non-permanent, as well as permanent, vaccine injuries and death. The World Health Organization has developed a systematic, standardised global causality assessment process for individual serious adverse events following immunisation (AEFIs).[7] Known serious AEFIs include acute intussusception following rotavirus vaccine (a rare bowel blockage estimated at six additional cases for every 100,000 infants vaccinated).[8] Guillain-Barré syndrome (GBS) is another example of a rare vaccine injury (at most one case per one million doses of influenza vaccine) that may be very debilitating but for which individuals may not qualify for NDIS funding. GBS cases usually require admission to hospital, intravenous medication, time off work or study and, in some cases, a long period of rehabilitation to recover. In extremely rare instances, a death may occur following a vaccine and fall under the 'no-fault' category. Recently, the Australian Therapeutic Goods Administration (TGA) released a safety advisory to remind healthcare practitioners not to administer the live zoster vaccine to people who are immunosuppressed.[9] This occurred after the death, three weeks following a zoster vaccine administered in line with current recommendations, of a man who was on a low dose of hydroxychloroquine and prednisolone to treat arthritis. There was 'no fault' but a rare and most serious result deemed related to vaccination by an expert panel. More typical types of compensation awarded under a VICS include income replacement indemnities, personal assistance expenses and reimbursement of expenses resulting from the incident, including medical expenses.

Upcoming COVID-19 vaccines make introduction of a VICS urgent

At present, >140 COVID-19 candidate vaccines are in development globally. Australian vaccine programs are safe, equitable and trustworthy, and the COVID-19 vaccine program will be required to go through the same robust process. The use of new 'first-in-human' vaccine technologies, and the limited sample size and duration of follow-up in phase III clinical trials, make it possible that rare, but serious, vaccine-related adverse effects will not be identified before widespread population use is needed in the context of the current devastating pandemic. SARS-CoV-2 appears to be uniquely able to generate immune pathologies post-infection in the lung and other organs, immune-related vascular disease and a still poorly characterised multisystem inflammatory syndrome in children.[10] Even a small increase in the risk post-vaccination of these phenomena on re-exposure to SARS-CoV-2 virus, especially antibody-mediated enhanced disease, will be important and difficult to exclude in trials.

Conclusion

There is a strong public health ethical justification to introduce a VICS in Australia, and it needs to be in place before widespread use of COVID-19 vaccines. If we are to encourage target groups to receive COVID-19 vaccines for the benefit of the entire community, much more so for young adults and the healthy who derive the least individual benefit, it follows that the Australian Government should compensate for any unforeseen rare but serious adverse event deemed to be due to a COVID-19 vaccine. Should options to increase COVID-19 vaccine uptake include mandates or penalties,[11] such as employment or travel restrictions if not vaccinated, a VICS would be even more essential.

A VICS would increase and build trust rather than undermine confidence in vaccine programs. Vaccines are designed to be very safe and effective, but this 'insurance policy', if communicated appropriately, should give confidence to underpin the success of a COVID-19 vaccine program. Legislation to introduce and allocate funds to support an Australian VICS for all vaccines in our otherwise world-leading National Immunisation Program is overdue, but it is now essential for COVID-19. Action at a national policy level is urgently required.

First published online 9 September 2020.

Authors

Nicholas Wood MBBS (Hons), PhD, FRACP, Associate Professor, Faculty of Medicine and Health, The University of Sydney Children's Hospital Westmead Clinical School, NSW; Associate Director Clinical Research, The National Centre for Immunisation Research and Surveillance (NCIRS), NSW. nicholas.wood@health.nsw.gov.au

Kristine Macartney MD, FRACP, Professor, Faculty of Medicine and Health, The University of Sydney, NSW; Director, The National Centre for Immunisation Research and Surveillance (NCIRS), NSW

Julie Leask PhD, MPH, Dip Health Sci (Nursing), Midwifery Cert, Professor, Faculty of Medicine and Health, The University of Sydney, NSW; Professorial Fellow, The National Centre for Immunisation Research and Surveillance (NCIRS), NSW

Peter McIntyre PhD, FRACP, Professorial Fellow, National Centre for Immunisation Research and Surveillance (NCIRS), NSW; Professor, Faculty of Medicine and Health, The University of Sydney Children's Hospital Westmead, NSW

Competing interests: None.

Provenance and peer review: Not commissioned, peer reviewed.

Citation: Wood N, Macartney K, Leask J, McIntyre P. Australia needs a vaccine injury compensation scheme: Upcoming COVID-19 vaccines make its introduction urgent. Aust J Gen Pract 2020;49 Suppl 36. doi: 10.31128/AJGP-COVID-36.

References

1. Attwell K, Drislane S, Leask J. Mandatory vaccination and no fault vaccine injury compensation schemes: An identification of country-level policies. Vaccine 2019;37(21):2843–48. doi: 10.1016/j.vaccine.2019.03.065.
2. Mungwira RG, Guillard C, Saldaña A, et al. Global landscape analysis of no-fault compensation programmes for vaccine injuries: A review and survey of implementing countries. PLoS One 2020;15(5):e0233334. doi: 10.1371/journal.pone.0233334.
3. Looker C, Kelly H. No-fault compensation following adverse events attributed to vaccination: A review of international programmes. Bull World Health Organ 2011;89(5):371–78. doi: 10.2471/BLT.10.081901.
4. ACC. Improving New Zealand's quality of life. Wellington, NZ: ACC, 2020. Available at www.acc.co.nz [Accessed 7 September 2020].
5. Health Resources and Services Administration. Vaccine injury compensation data. Rockville, MD: HRSA, 2020. Available at www.hrsa.gov/vaccine-compensation/data/index.html [Accessed 7 September 2020].
6. Medicines Australia. Indemnity and compensation guidelines. Deakin, ACT: Medicines Australia, 2020. Available at https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines [Accessed 7 September 2020].
7. World Health Organization. Causality assessment of an adverse event following immunization (AEFI): User manual for the revised WHO classification (Second edition). Geneva, CH: WHO, 2018.
8. Department of Health and Ageing. Rotavirus immunisation: Information for parents and guardians. Canberra, ACT: DoH, 2013.
9. Therapeutic Goods Administration. Zostavax vaccine. Woden ACT: TGA, 2020. Available at www.tga.gov.au/alert/zostavax-vaccine-0 [Accessed 7 September 2020].
10. Law B, Sturkenboom M. D2.3 Priority list of adverse events of special interest: COVID-19. Oslo, NO: CEPI, 2020.
11. Mello MM, Silverman RD, Omer SB. Ensuring uptake of vaccines against SARS CoV-2. N Engl J Med 2020. doi: 10.1056/NEJMp2020926.

Table 1. Vaccine injury compensation schemes by region and countries (n = 25) and operational characteristics

Region	Countries	Administration	Funding source(s)
Oceania	New Zealand[8]	Accident Compensation Corporation	Contribution of general taxation, and levies collected from employee earnings, businesses, vehicles licensing and fuel
Asia	China, Japan, South Korea, Vietnam, Nepal, Thailand	Central government, provincial government, insurance sector or combinations of these	Central government, pharmaceutical company contribution to insurance sector, special insurance organisations, medical institution contributions
Europe	Austria, Denmark, Finland, France, Germany, Hungary, Iceland, Italy, Luxembourg, Norway, Russia, Latvia, Slovenia, Sweden, Switzerland, UK		
Americas	Canada*		
	USA[9]		Flat-rate tax per vaccine dose

**In Canada, only the province of Quebec has a vaccine injury compensation program*