

EDITORIAL

# Injuries and deaths following Covid-19 vaccination: The ethical and legal case for compensation

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In April 2024, in a class action suit for compensation to families of persons suffering injury or death after vaccination with AstraZeneca's (AZ) Covid-19 vaccine [1], the manufacturer admitted in a UK court that the Oxford-AZ Covid-19 vaccine could cause a rare and potentially fatal blood clotting disorder ("thrombosis with thrombocytopenia syndrome" or TTS, which when triggered by a vaccine is called "vaccine-induced thrombocytopenia and thrombosis, or VITT) [2]. The AZ Covid-19 vaccine is a chimpanzee adenovirus vectored vaccine encoding the SARS-CoV-2 spike protein (ChAdOx1-S) marketed under the names Covishield and Vaxzevria.

As the vaccines started to be administered nation-wide, in most countries where vaccines were available, serious adverse events (SAEs) following administration of the Covid-19 vaccines were reported, though rare, in some sections of the population. From March 11, 2021, a number of countries in Europe paused the use of the AZ vaccine, while others delayed the start of their vaccination programmes, pending investigation [3]. It was found that the risk of TTS was greater in younger people [4]. As of May 12, 2021, 15 countries had restricted its use to certain age groups [5] and two countries discontinued its use [6]. Since then, it has been confirmed that there is a statistically significant increased risk of Guillain-Barre Syndrome and cerebral venous sinus thrombosis following the viral vector vaccines, and of myocarditis and pericarditis after being administered the mRNA vaccines from Pfizer and Moderna. Acute disseminated encephalomyelitis and transverse myelitis have also been identified as possible safety signals for the viral vector vaccines [7]. However, the World Health Organization (WHO), European Medicines Agency, and others stated that the benefit of the vaccine (to the individual) outweighed the risk of rare serious side-effects [8, 9].

In this editorial, we discuss compensation for serious injuries and death following the Covid-19 vaccine. We argue that according to the principle of justice, governments and vaccine manufacturers have an ethical responsibility to provide no-fault compensation to people who suffered serious injury or who died following administration of the vaccine. The requirement for no-fault compensation is particularly important, given the difficulties of ascertaining a causal relation between the vaccine and the injury in the conditions in which the Covid-19 vaccine programme was rolled out. The Indian government's actions in the programme — approving the fast-tracked vaccines without collecting the safety data necessary even for emergency approval, administering the vaccines without informed consent, issuing directives that coerced people into taking the vaccine, and not conducting a systematic investigation into injuries following vaccination — place a further burden on it to compensate those who were injured by these ethical and legal violations in the programme. We point to existing options for those seeking compensation for Covid-19 vaccine injury.

## India's Covid-19 vaccination programme

The vaccination programme that was rolled out in India during the SARS-CoV-2 pandemic was primarily using Covishield (manufactured by Serum Institute of India by way of a licence from AZ), that was administered to almost 79.2% of the vaccinated population [10]. Other vaccines administered in India were Covaxin (16.5%), Sputnik V (0.06%), Corbevax (3.35%), and Covovax (0.001%) [10]. Violations in the set protocols for granting approval — albeit emergency approval — were noted regarding Covishield and Covaxin [11,12].

In India, the vaccines were first rolled out to healthcare workers and frontline workers. From January 16 to 30, 2021, at least 11 deaths were reported following administration of the vaccines. News articles on these deaths reported that they were ascribed to cardiovascular problems or "brain stroke" [13]. These 11 deaths were in a relatively young population, primarily aged 42-56 years; one frontline worker who died after receiving the vaccine was 23 years of age. Civil society representations called on the

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government to urgently investigate reported deaths following vaccination, arguing that they met the WHO's definition of a "cluster" of serious adverse events following immunisation (AEFIs), for which the WHO has guidelines for immediate investigation. They also asked the government to amend the vaccination programme based on investigation of the deaths, and issue warnings, take informed consent, and provide no-fault compensation to the families of those who had died <sup>a</sup> [13]

However, the government did not make public the results of any such urgent assessment. Even after the rare but serious adverse events following the Covid-19 vaccine became known, and several countries restricted the use of the AZ vaccine to certain age groups, while some discontinued its use altogether, the Indian government did not restrict the use of the AZ vaccine. Moreover, the government and the manufacturers of the vaccines failed to disseminate information on the rare but serious risk of the Covid-19 vaccines, in an accessible form to the general public. The government acknowledged these rare but serious side-effects only in May 2021 but stated that the vaccine "continues to have a definite positive benefit risk profile with tremendous potential to prevent infections and reduce deaths due to COVID-19 across the world and in India." [14] The government's statements were incorrect and misleading to a public seeking protection from Covid-19 disease. The Covid-19 vaccine was shown to prevent symptomatic disease, not infection, and to reduce the risk of severe disease and death [8,15]. Furthermore, the benefit may apply at the population level but not necessarily for any particular individual. Later on, when charged with administering the vaccines without the vaccinee's informed consent, the government went so far as to suggest that it was up to the vaccinees to collect the information, and their entry into the vaccination centre constituted informed consent [16].

The government also issued discriminatory directives that mandated vaccinations, like restricting access to certain services and places to the vaccinated [17,18]. While the government's stand has been that taking the vaccines was voluntary [17], its directives required people to take the vaccine in order to move around, earn a livelihood, and so on, such that people did not have a choice other than to take the vaccines [17,18]. Between January 2021 and October 2022, the Government of India reported 1,148 deaths following Covid-19 vaccination, possibly a gross undercount of the actual number of deaths following Covid-19 vaccination in India [18]. A report of the government's AEFI committee concluded that of the 700 serious AEFIs reported as of April 2021, about 26 were potential cases of thromboembolic events [14], but do not mention what happened to these 26 people or the others confirmed to have suffered serious injury after being given the Covid-19 vaccine as of April 2021 — whether they received prompt treatment at the cost of the State, and how many died. An analysis of AEFI investigations of Covid-19 vaccines in India found that they do not mention the documents and reports provided to them, or the process by which they arrive at a causality assessment [17]. As a result, there is no way of evaluating the quality of the assessment process. A detailed investigation published in the media found that AEFIs were under-reported and poorly investigated, and the affected people or their families were not even informed of the findings of the investigations [19].

### **Ethical and legal obligation to pay compensation in a vaccination programme**

The public health benefits of vaccination are known. However, vaccines come with risks, albeit rare, that may be manageable and treatable adverse events, or severe adverse events causing irreversible disability or death [20].

A basic principle of vaccination is that the benefits to the population outweigh the risk of rare but serious injuries to individuals [20,21]. As individuals who are injured or harmed by the vaccines or vaccination bear the burden for the benefit of the population and vaccine manufacturers, it is the duty of the government and manufacturers to provide them adequate compensation [22].

In a vaccine programme, government and vaccine manufacturers have a duty to:

1. *Minimise the risk of harm to those administered the vaccines:* This includes ensuring that healthcare facilities are available and accessible to those being vaccinated; gathering information relating to SAEs; conducting transparent and thorough investigations of these SAEs and making the results public; and not offering the vaccines to populations most at risk of harm.
2. *Care for those who experience injuries, especially serious injuries, following vaccination:* Even if very few people are injured, it is the duty of the government and/or manufacturer to give them appropriate medical care free of charge, or reimburse treatment taken at private hospitals, to ensure that these individuals are given everything necessary to save their lives. This is an ethical obligation to care for those who have been harmed by the public health programme [22].
3. *Disclose the risks and benefits of the vaccine:* In large-scale immunisation programmes, as the decision to be vaccinated is not an individualised medical judgement, there is an added legal duty to disclose the risks of vaccines and vaccination. Vaccines are given to healthy people for prevention of a disease or — as in the case of Covid-19 vaccines — to reduce the severity of the disease. These healthy people have a right to know that they may be at risk of getting severe symptoms if they are *not* vaccinated, and also that there is a risk of harm from the vaccine itself — through an adverse event or a

serious adverse event post-vaccination. Informing people of the vaccine's known risks, however remote those risks may be, is a duty of both the manufacturer and the government (where the vaccine rollout is run or aided by the government). This is imperative for the vaccination to be truly voluntary and informed. Further, not providing full disclosure may lead to vaccine hesitancy and public distrust, and may also lead to misinformation [23].

4. *Take informed consent prior to vaccination:* This duty arises from the fact that administration of a vaccine is necessarily a medical intervention. There is not only the code of medical ethics, but also enough case law that states that informed consent is required prior to any medical intervention, with a few exceptions, to acknowledge the individual's right to be informed and to take decisions about their own health [24]. Individuals have a right to evaluate the benefits they will get from a vaccine — and the risks they will face if not vaccinated — against the risks of taking the vaccine [21]. In the case of the Covid-19 vaccines, the vaccine did not necessarily prevent infection with the virus, or its transmission. This is all the more reason that the decision to take the risk of the disease, or reduce the severity of the disease through vaccination — even though there could be a risk, however remote, of serious side-effects from the vaccine — must be a choice of the individual vaccinee. Thus, informed consent for vaccination is imperative. Not taking informed consent is a violation of the right to autonomy [21].
5. *Adhere to the law and rules relating to procedures and approvals of vaccines, follow-up, monitoring and surveillance, etc:* Vaccines receive regulatory approval on the basis of ethical and scientific research on their efficacy and safety. Vaccines may receive emergency use authorisation, as in the case of the Covid-19 pandemic, on the basis of evidence from trials conducted for shorter periods of time and on smaller populations, thereby with limited data. However, the law has requirements, under the Drugs and Cosmetics Act, 1945, read with the New Drugs and Clinical Trial Rules, 2019, for post-approval safety monitoring to ensure that adverse events, especially severe adverse events, are identified, based on which instructions for the vaccine's use are modified, or approval withdrawn [25].
6. *Establish a no-fault vaccine injury compensation programme to reduce the burden on individuals who are harmed or injured in the vaccination programme:* Providing compensation to those who suffered SAEs following vaccination, or, in the case of their death, to their families, irrespective of a causal association between the SAE and the vaccine, on the basis of a no-fault compensation system, is an “obligation based on human rights and ethical principles of justice and fairness” [22]. The right to life and right to health are violated when healthy individuals become unhealthy or die post vaccination. When these healthy individuals are harmed following vaccination, it is incumbent upon the government to compensate them adequately for the burden of harm or injury that they face. No-fault compensation is to create an alternative legal recourse to a quick, fair compensation for injuries or harm post-vaccination. The adversarial legal recourse is tedious, time consuming, and expensive, wherein those harmed need to file cases in courts for compensation or damages against the manufacturers of the vaccines, and others involved (under the law of Tort, or the Consumer Protection Act). Where the government is involved, legal action may be taken through writ petitions or class action (public interest litigations) where a group of people are adversely affected for a violation of their right to life and good health [22,26].

Being open, transparent and honest about the SAEs or AEs that could harm individuals in a vaccination programme undertaken on a mass scale, and providing treatment and compensation to those few vaccinees who faced SAEs or died post vaccination, reduce vaccine hesitancy and instil confidence in the vaccine programme, and are also virtues in themselves.

### **The no-fault vaccine injury compensation system**

Prior to the Covid-19 pandemic, some developed countries had a no-fault compensation system for injuries following vaccination. The UK government has a vaccine damage payment scheme of compensation, with a one-off payment of 120,000 GBP [2]. During the Covid-19 pandemic, many developing countries too implemented a no-fault compensation scheme. In 2022, about 43 countries implemented no-fault vaccine injury compensation schemes. These included Australia, Brazil, Canada, Colombia, the Czech Republic, Estonia, Guatemala, Honduras, Hong Kong, Lebanon, Malaysia, Peru, the Philippines, Poland, Singapore, South Africa, Tunisia and Ukraine [20]. Some countries, such as South Africa, included no-fault compensation systems not only due to the nature of the risks and burdens on the people, but also due to the bilateral contracts between governments and pharmaceutical companies manufacturing the vaccines, wherein the companies wanted indemnity or protection against any legal claims relating to the risks from the use of the vaccine [20]. Thailand, too, provided no-fault compensation to about 14,000 vaccinees injured post-Covid-19 vaccination [27, 28].

There are many compensation models for Covid-19 vaccine-related adverse events [26]. Various administrative methods of establishing a no-fault vaccine injury compensation system, and funding systems, can be used to provide compensation to those injured in a vaccination programme. During the Covid-19 pandemic, developing countries used existing bureaucratic infrastructures such as national health or social security systems, established evaluation or expert committees, and worked with social insurance corporations to evaluate the claims and pay no-fault compensation [20]. Such steps are an indication of how

much the government respects its citizens, and how much it is willing to do to reduce the burden on people facing harm or injuries. Being proactive in establishing a no-fault compensation system increases the chances of a more effective immunisation system and reduces the costs to society [26].

## Conclusion

Following AZ's deposition in the UK class action suit, the Indian Supreme Court received a plea [29] seeking the formation of a panel of experts from the All India Institute of Medical Sciences (AIIMS), headed by the director of AIIMS and supervised by a retired Supreme Court judge, into Covishield's side-effects and risk factors. It also called for the Court to direct the government to establish a vaccine damage payment system for those severely disabled as a result of the Covid-19 vaccination drive, and to compensate those "who are severely disabled or died because of the side effects of corona vaccine administered to them during Covid-19." [29]

However, compensation cannot be limited to cases in which a clear link can be shown between the vaccine and the injury. Not only was AEFI reporting incomplete in India, the data gathered for causality assessment was of poor quality, and the subject expert committee's conclusions have, at best, been vague in many cases. Moreover, the government's vaccine policy has been coercive, with non-disclosure of the risks, and administration of the vaccine without informed consent.

*As causality is linked to liability and given the social benefits arising from individual vaccination, AEFIs categorized as indeterminate, or inconclusive, which is due to lack of evidence, should be presumed to have a causal connection to give the benefit of the doubt to persons facing the AEFI or to the relatives of the person who has died. [17]*

For all these reasons, compensation is due to all vaccinees who suffered a serious injury following administration of a Covid-19 vaccine. The government and vaccine manufacturers who collaborated in the development, manufacture and rollout of the vaccines do have a legal and ethical duty to pay compensation for injuries or harms post-vaccination.

**Note:** The authors were signatories to the letter calling for investigation of injuries and deaths in the Covid-19 vaccine rollout.

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