

# Covid-19 vaccines: Legal Issues that communities should be concerned about

Covid-19 Vaccine Information and  
Access in Asia Workshop

Day 2: 17<sup>th</sup> August 2021

Session 3: Key issues – Consent,  
Confidentiality, Indemnity, Adverse  
Events

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# Individual rights v. Public health

- The COVID-19 pandemic has brought to the forefront many legal and ethical issues
- Abrogation of individual rights and freedoms for the greater public good/ health
- Was it justified? Was it least intrusive? Or was it authoritarian governments/ attitudes of persons in power to impose long restrictions and excesses on people?
- Can breach of confidentiality, inequity / discrimination, and lack of informed consent be justified in the name of the greater good or public health?

**The threat is the virus,  
not the people**

Human rights at the heart of the response #COVID19



# Some of the Legal Issues that have come to the forefront with COVID-19 vaccines

Confidentiality

Informed  
consent

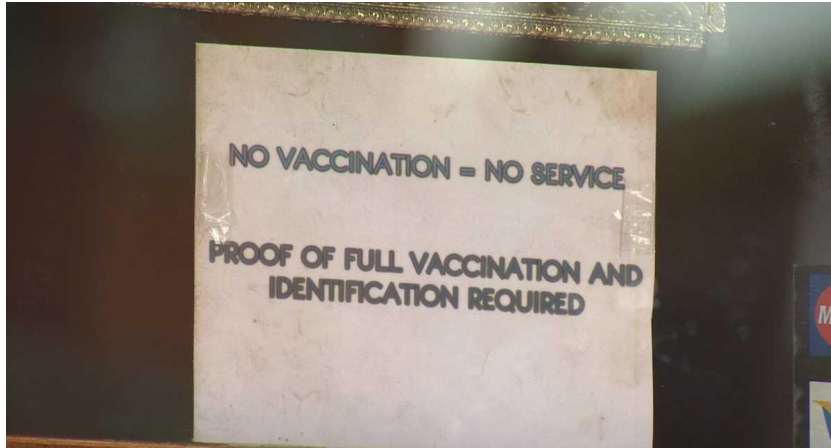
Serious/  
Adverse Events -  
Compensation

Voluntary v.  
Mandatory –  
loss & no access

Transparency  
-Information,  
Knowledge,  
Data



- Testing for COVID – no pre-test counselling (could have learnt from HIV)
- Information of positive result – goes first to the authorities - not to the person awaiting the test result
- Big poster outside the house - with names displayed at the entrance. Was it required?
- Isolation, quarantine – also done for people living in crowded places.
- Contact tracing – in some places only – not whole heartedly. Was this the only way?
- Police used excesses – beat people – while implementing a public health law!!
- **Breach of confidentiality, and forceful quarantine – without counselling – people fearful of getting tested, even if unwell!!!**



- Inequities in vaccine distribution, vaccine access, vaccine affordability . Small percentage of population vaccinated. Services can be availed by only those who are fully vaccinated!! (though they can also be at risk and be carriers)
- Vaccine available for few days, and out of stock for many days! **Why are there shortages?** Only few producers!!!
- Vaccine certificates, vaccine passports, etc. – is it just, and is it fair? Who gets access – who is left out? Who is prioritised? Were daily wage earners prioritised, who cannot work from home?
- What about those who have recovered from COVID and have antibodies?
- What about those who are allergic to vaccines, or cannot take it due to religious or medical reasons or any reason whatsoever?



# Voluntary v. Mandatory vaccination

- If not vaccinated – cannot access services – cannot go for work, cannot go back to college – it becomes Mandatory. Now social stigma – if not vaccinated do not visit friends and family!!!
- Breach of confidentiality – unable to get vaccines, or unable to take it for any reason – need to provide reasons – other conditions also exposed.
- If not kept confidential, drive things underground, lead to false certificate rackets
- Voluntary – may work better - provide information, knowledge, and data is shared with the people honestly – does away with rumours and myths
- Helps people take decisions for themselves to protect themselves and others from the disease
- Information – knowledge - empowering
- If it is made mandatory – then will it be fair and just? Can be done while protecting confidentiality and taking informed consent.

## From offices to restaurants, companies are requiring proof of vaccination



By Alexis Benveniste, CNN Business

Updated 1857 GMT (0257 HKT) August 4, 2021



8.com...

## MOH to take stern action against those who forge vaccination certificate



NATION

Tuesday, 10 Aug 2021

3:48 PM MYT



# Informed Consent for vaccination

Consent – implied/ expressed – but also needs to be informed – as intervention with bodily integrity.

Generally, IC not taken for vaccination, but is required legally

Risks- Benefits should be informed. All Serious/ adverse events – long term and short term not known. Known S/AEs people can watch out for – early medical intervention is possible

Time to stop being patriarch or think the risks will drive away people from vaccines

Alternative public health measures also need to be informed, importance of wearing masks in spite of vaccination, sanitization, social distancing, etc. Vaccines a small part of public health measures.

Voluntary

# Compensation - Serious/Adverse Events (S/AE)

- During clinical trial, compensation is paid for any serious/ adverse event that a participant may face.
- After approval of vaccines, there is no provision for compensation.
- Emergency use approval, and now some may get full approval – should pay compensation for the rare events that occur.
- Pharma cos. asking for indemnity – they want the government to take care of the risk of S/AEs
- However, there is no follow up post vaccination to record S/AEs – scanty data is being collected

## How Pfizer tried to bully Argentina and Brazil in exchange for vaccines

Edited By: Gravitas desk • WION

New Delhi, India • Published: Feb 24, 2021, 11:01 PM (IST)





# Lack of Transparency

- Total lack of transparency in names & qualifications of Committee members looking into AEFIs (adverse events following immunizations)
- No information on what data is collected of persons facing S/AEs, how the data is analysed, how it is concluded that it is 'not related' to the vaccine?
- Clinical Trial data is not made public yet! What basis was emergency use given?
- Post approval – Phase IV trials and post licensure data – how many taking place in the country?
- Response to RTIs (right to information) by the govt. has been standard – confidential, or relates to third party so cannot reveal, though some things can be accessed on their website.

## Malaysia sets up compensation fund for COVID-19 vaccinations

By Joseph Sipalan

2 MIN READ



KUALA LUMPUR (Reuters) - Malaysia on Monday announced it had established a \$2.4 million compensation fund to provide cash assistance for any COVID-19 vaccine recipients who suffer severe reactions due to inoculations.



# Govt. & Pharma cos. need to act ethically

- No information on the contracts signed by the government with the private pharma cos. on vaccine trials, vaccine procurement & prices, roll out. Public money used to conduct trials – but no information provided to the public
- Pharma cos. have been knowledge hoarding, secret pricing, unreasonably high profits, unfair bilateral deals, extortionist demands for indemnity against liability.
- No accountability. No transparency.
- Need evidence based public health leadership – where there is transparency, accountability, data is shared, and policies are based on scientific data, not political whims

## News

### Vietnam discusses purchase deal as Pfizer says no to price negotiation

By Viet Tuan May 18, 2021 | 11:40 am GMT+7



A healthcare worker prepares a Pfizer coronavirus disease vaccination shot in Los Angeles, California, U.S., January 7, 2021. Photo by Reuters/Lucy Nicholson.

# Demand for:

- Public health measures – based on evidence, from experiences of other public health programs, respect rights of people, take informed consent, protect confidentiality – breach only in rare cases
- Equity in distribution of vaccines, medicines. Do not leave out non-citizens, those without identity documents, do not base it only on digital platforms, remove gender barriers in accessing health services
- Govt. should allow other manufacturers to make the approved vaccines by providing them licenses, know-how, and must control costs and prices of vaccines. (revoke patents/issue CLs)

## UNHCR urges stronger support for refugee vaccinations in Asia

*This is a summary of what was said by UNHCR spokesperson Andrej Mahecic – to whom quoted text may be attributed – at today's press briefing at the Palais des Nations in Geneva.*

01 June 2021 | [Español](#) | [Français](#) | [عربي](#)

With COVID-19 raging in many parts of the world, UNHCR, the UN Refugee Agency, is warning about shortages of vaccines in the Asia-Pacific region, including for refugees and asylum-seekers.

We urge immediate and stronger support for the COVAX initiative, a worldwide effort aimed at achieving equitable access to COVID-19 vaccines. This is critical to save lives and curb the impact of the virus, particularly in developing nations. These countries host the vast majority of more than 80 million forcibly displaced people in the world. Yet so far, they have benefited from only a fraction of the world's COVID-19 vaccines.

# Demand for:

- Community outreach required – provide correct, honest and complete information.
- Informed consent for vaccination, explain adverse events, and pay compensation, maintain confidentiality, stop discrimination by classifying people who are vaccinated or not
- Provide information on how to mitigate the risks, and use all public health measures to stop the spread of the virus
- Balance individual rights and public health measures – use least intrusive measures
- We need to come out of COVID-19 stronger by respecting human rights and upholding social justice!!





# Demand for:

- Rights based approach works in public health measures.
- Human rights and freedoms need to be respected and protected
- Use local laws/ guidelines to bring about transparency in use of public funds, data sharing and accessibility. In India – RTI Act, Biotech PRIDE (Promotion of Research & Innovation through Data Exchange), & National data Sharing and Accessibility Policy, 2012
- International Covenants on human rights, health, etc.

Thank You

