

## VACCINOLOGY II

### LEGAL AND ETHICAL ISSUES IN IMMUNIZATION

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**Abstract:** *Epidemiology, economics and ethics demand that the health professionals and the policy makers should alleviate the misery caused by various infectious diseases and related complications. Adequate immunization is an important and time-tested health intervention in preventing infectious diseases. The need is to prepare a standardized national recommendations or guidelines regarding vaccination. Many pediatricians are facing ethical dilemma regarding the need of costly vaccines for the general population at the cost of basic necessities of life like nutrition, safe drinking water, pollution free environment, etc. Medical graduates should keep themselves updated with the recent advances in the field of immunization. There is a need for strengthening the surveillance of adverse events following immunizations in the country. All the necessary safe guards should be in place and the regulations should be followed in letter and spirit in vaccine trial in vulnerable child population. Right things should be done so that the future generation can live a healthy life.*

**Keywords:** *Informed Consent, Vicarious liability, Medical Negligence, Child Rights, Conflict of interest, Crosspathy.*

### Points to Remember

- *There is a need to have quality control in the manufacture, transport and storage of vaccines.*
- *Issue of clear guidelines is an increasing responsibility on the government and the academic organizations in this era of biased and confusing promotions.*
- *Millions of children suffer from morbidity and mortality for either want of vaccine or optimal, ethical and rational use of vaccines.*
- *We should understand the various legal issues related to vaccinations, otherwise there may be allegations of negligence in future.*
- *The profession and commerce need to be separated and conflict of interest of various stake-holders shall be kept in mind.*

### References

1. Tiwari SK. Legal issues related to Vaccinology today. In: Vashishta VM, Kalra Ajay editors; IAP Text Book of Vaccines: 2<sup>nd</sup> edn, Jaypee brothers Medical Publishers, New Delhi 2020; pp810-818.
2. Baldwa M, Tiwari S. Punishment for refusing OPV. Indian Pediatr 2009; 46:540-541.
3. Mathew JL. Inequity in childhood immunization in India: A Systematic review. Indian Pediatr 2012; 49:203-223.
4. Tiwari S. Consumer Problems & the Pediatrician. In: Gupte Suraj (ed). Recent Advances in Pediatrics - 19: Hot Topics, Volume 19. Jaypee Brothers Medical Publishers (P) Ltd, New Delhi, 2010; pp72-84.
5. Mittal SK, Mathew JL. Expanded program of immunization in India: time to rethink and revamp. J Pediatr 2010; 5:e43.
6. Lavin J, Broutin H, Harvill ET, Bjornstad ON. Imperfect vaccine-induced immunity and whooping cough transmission to infants. Vaccine 2010; 29:11-16.
7. Vashishtha V. The business of vaccines. Editorial, Pediascene 2016; 17(1-2). Available from: <http://pediascene.com/journal/page.php?id=319#> Accessed on 5<sup>th</sup> October 2020.

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8. Indian academy of Pediatrics Committee on Immunization (IAPCOI) Consensus recommendations on immunization and IAP immunization Timetable 2012. *Indian Pediatr* 2012; 49:549-564.
9. Phatnani P. Medical Negligence. In: *The medical profession & the law*. 1<sup>st</sup> edn, Editor Lele RD, Mumbai Sajjan & sons 1992; pp11-22.
10. Klein NP, Bartlett J, Rahbar AR, Fireman B, Baxter R. Waning protection after fifth dose of Acellular Pertussis vaccine in children. *N Engl J Med* 2012; 367:1012-1019.
11. Centers for Disease Control and Prevention (CDC). (2020). Vaccine Information Statements (VISs). [online] Available from: [https://www.cdc.gov/vaccines/hcp/vis/index.html?CDC\\_AA\\_r efVal=https%3A% 2F%2F www.cdc.gov% 2Fvaccines% 2Fpubs% 2Fvis% 2Fdefault.htm](https://www.cdc.gov/vaccines/hcp/vis/index.html?CDC_AA_r efVal=https%3A% 2F%2F www.cdc.gov% 2Fvaccines% 2Fpubs% 2Fvis% 2Fdefault.htm). Last accessed on 5<sup>th</sup> August, 2020.
12. Paul Y, Tiwari SK. Ethical issues in Immunization; In: Vashishta VM, Kalra Ajay editors; *IAP Text Book of Vaccines*: 2<sup>nd</sup> edn, Jaypee Brothers Medical Publishers, New Delhi 2020; pp3819-823.