TWENTY PROBLEMS WITH VACCINE SCIENCE

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1. No placebo-controlled studies with saline injection as the placebo[1,2,3,4]
2. Short duration of follow-up (as little as days to weeks)[5,6,7]
3. Sixty percent of vaccines contain aluminum, but there are no human or animal studies involving SC or IM injections of aluminum to establish the safety of injecting infants and children with aluminum hydroxide, aluminum phosphate or amorphous aluminum hydroxyphosphate sulfate.[8,9]
4. One-size-fits-all. Newborns have 20% of the kidney function of a 2 year old[10] (excretion of aluminum through the kidneys is the main route to remove systemic aluminum) yet both receive the same dose of aluminum-containing vaccines; the one-size-fits-all approach is in stark contrast to precision medicine, an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.[11]
5. No safety studies on the entire vaccine schedule;[12,13] Institute of Medicine (IOM) recommended studies which have not been done. IOM noted, "…studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted."[12]
6. Monitoring largely for pre-specified and solicited adverse events in clinical trials leading to vaccine approval[14]
7. No active post-marketing surveillance (Vaccine Adverse Events Reporting System is passive and voluntary)[15]
8. No vaccinated versus unvaccinated studies by CDC to learn true adverse events of vaccines[12]
9. No research to identify those with preexisting susceptibilities to vaccine injury[16]
10. Small sample sizes in clinical trials that do not allow detection of less frequent severe adverse events compounded by underreporting in voluntary, passive post-market surveillance.[14,17]
11. No incentive to improve vaccine safety because vaccine makers cannot be sued (and consequently no changes to improve safety in a particular vaccine during the 17-year life of the patent)[18]
12. Underreporting of vaccine injuries—less than 1% (Harvard 2010 study)—so no good way to assess balance of benefits versus harms[17,19]
13. No studies for carcinogenicity, mutagenicity and impairment of fertility[20]
14. No adequate research base to evaluate vaccine safety—Institute of Medicine concluded there was insufficient science to accept or reject a causal relationship for 135 adverse events reported with vaccines—"The absence of evidence is not the same as evidence of absence." IOM 2012 report, *Adverse Effects of Vaccines: Evidence and Causality.*[15]
15. Excessive reliance on observational retrospective studies in which confounding variables cannot be examined (weak science).[21,22]
16. No accounting for healthy user bias in observational retrospective and prospective studies.[22,23]
17. Scientific misconduct in which there is selective or misleading reporting of data or omission of conflicting data to arrive at a desired conclusion[24,25,26,27]
18. Scientific misconduct in which there is deceptive reporting of results to omit important limitations to generalizability of results (e.g., vaccination status of groups are not comparable) or in which groups are deceptively misrepresented as "unvaccinated" when they had received a number of vaccines[28,29]
19. Conflicts of interest of those conducting the studies ("investigator determined that deaths associated with vaccine were not vaccine-related"; no Data Safety Monitoring Boards) and those approving the vaccines (Advisory Committee on Immunization Practices)[30,31]
20. No safety testing of vaccines and vaccine ingredients in pregnant women even though CDC recommends vaccines to pregnant women[32]

**Dr. Moss has more than 40 years of medical practice, research, and teaching experience. His interest in vaccine safety and vaccine injury was first prompted by ethical concerns regarding conflicts of interest in vaccine research and in public policy. The opinions expressed here are his own and do not represent those of his employer.*

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[1] https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Boostrix/pdf/BOOSTRIX.PDF
[2] https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/published/Package-Insert---Adacel.pdf
[3] https://www.fda.gov/media/75195/download
[4] See the package inserts for the remaining childhood vaccines under 6.1 Clinical Trials experience
[5] https://www.fda.gov/media/79341/download
[6] https://www.fda.gov/media/79341/download
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[11] https://ghr.nlm.nih.gov/primer/precisionmedicine/definition
[12] https://www.nap.edu/read/13563/chapter/2#5
[13] https://www.ncbi.nlm.nih.gov/pubmed/26830300
[14] See Section 6.1 Clinical Trials in vaccine package inserts
[15] https://www.ncbi.nlm.nih.gov/pubmed/23063829
[16] http://nationalacademies.org/hmd/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx
[17] https://www.ncbi.nlm.nih.gov/pubmed/23597717
[18] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3393829
[19] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[20] See Section 13.1 in vaccine package inserts
[21] https://www.sciencedirect.com/science/article/pii/S0040595718302464
[22] https://journals.sagepub.com/doi/full/10.1177/0141076815596690
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[30] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf
[31] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf
[32] See Section 8.1 Pregnancy in vaccine package inserts