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Challenges in pharmacovigilance of vaccines in clinical trials and risk management strategies

The global vaccine market size will touch 48 billion USD by 2025. With 15 new introductions this century millions of children and adults are being immunised globally. Research on new vaccines for *HIV, Ebola, Zika, Dengue,* Universal Influenza vaccines and yellow fever are in the pipeline. New manufacturing technologies, new routes of administration, advances in genomics, emerging disease pandemics & outbreaks, innovation and demand from emerging economies makes the vaccine segment profitable. Support from WHO, UNICEF, GAVI and Gates foundation has stirred new vaccine introductions in Asia, Africa e.g. Meningococcal, Pneumococcal vaccines. Vaccines have a high generic barrier and potential to generate blockbuster sales e.g. Shingrix. Vaccines differ from drugs as they are preventive while drugs are curative. Increased demand has necessitated increasingly stringent safety requirements during preclinical, clinical and post licensure thereby making vaccine vigilance and risk mitigation more precise to be able to pre-empt detection, assessment, analysis and prevention of new SAEs or SUSARs, to make vaccine recipients safe. The author discusses case reports to reinforce effective methods and outcomes. The immunization and pharmacovigilance gap needs to be addressed globally as 50% of 20.8 million unvaccinated children are from South Asia & Africa with poor PV facilities. Though 20.4 million deaths have been prevented by Measles vaccine from 2000-2016, yet 254 children die each day! It costs only 2 USD to protect a child against Measles, rubella in developing countries. There is need for enlarging the pharmacovigilance perspective with better understanding of vaccine components, linkage to clinical trials, increased awareness, PV concepts, pitfalls- as a child receives 37 shots from birth through 6 years of age & vaccine safety has a very narrow margin for error.

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