

Vaccine safety and the widespread use of newer vaccines in the developing world – how to mitigate the risk of vaccine safety scares

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Immunization is dually recognized as one of the most significant medical advances of the 20th century and among the most effective public health interventions to prevent disease and promote health. On the other hand, over the last 40 years public immunization programmes have been repeatedly challenged by media fuelled controversies, vaccine safety scares, loss of public confidence and scepticism even among healthcare providers. This seeming paradox can be explained in part by the outstanding success of immunization in reducing vaccine preventable diseases and their attendant morbidity and mortality such that public attention has shifted from the diseases prevented by vaccines to the adverse events that follow immunization. Negative perceptions about vaccines are as old as immunization itself, however, the impact of anti-vaccine sentiment, pseudoscience, rumours, misinformation, disinformation and media sensationalism have been amplified in a world shrunken by the internet and social networking. Adding volatility to the mix are consumer activism and general distrust of governments and industry. While no vaccine is 100% safe, there are too many concrete examples to doubt the very real harm that results when immunization programmes are disrupted by loss of public confidence in vaccine safety. When the first major challenges to immunization arose in the 1970s, due to the allegation that whole cell pertussis vaccine caused encephalopathy, the public health community was ill prepared to deal with the growing crisis in public confidence. Having observed the near disappearance of one childhood killer after another, it was difficult to take the anti-vaccination movement seriously until it became apparent that ignoring them or engaging them in public debate were not effective mitigation strategies. A more pro-active approach was taken that included: understanding how people perceive risk; developing more effective risk-communication strategies; standardizing and strengthening the regulatory oversight of vaccine safety; ensuring that pre-licensure studies were powered appropriately for safety as well as efficacy; introducing standard case definitions for adverse events; improving national and international systems for monitoring post-market vaccine safety; developing better methodologies for assessing vaccine safety at the individual and population levels; referring specific vaccine safety issues to independent expert bodies for unbiased review and recommendation; and perhaps most importantly, understanding the critical importance of global cooperation and communication to identify, validate and address emerging vaccine safety issues as effectively as possible. When it comes to vaccine safety we truly live in a global village. High, middle and low income countries have all been impacted by vaccine safety scares. While there is still much to do, very real progress has been made to expand immunization programmes in low/middle income countries and to develop vaccines specifically targeting diseases not seen in high income countries such as epidemic invasive serogroup A meningococcal disease. To maximize and safeguard the benefit of these efforts it is essential that the lessons learned regarding mitigation of vaccine safety scares are applied along with adequate training and resources for effective vaccine pharmacovigilance programmes