Optimal safety assessment system for future vaccines against poverty-related diseases (e.g., HIV, malaria, TB) in developing countries

Robert Chen, Centers for Disease Control and Prevention, Atlanta, USA

The combination of the biotechnology revolution, genomics, and philanthropy and reinvigorated the search for vaccines against target poverty-related diseases such as HIV, malaria, and TB. Many of these vaccine candidates will use “high tech” approaches with limited past human experience such as live viral vectors, DNA. Therefore we need to increase our ability to capture safety data in pre- and post- licensure settings, especially in countries with highest incidence. In developed world, linkage of large health care administrative datasets for vaccination and medical care for individuals using unique personal identifiers has permitted rigorous vaccine safety studies. Our ease to replicate this in developing countries is governed somewhat by the “digital divide”: the gap between those people with effective access to digital and information technology and those without access to it. This gap is more manageable in middle income countries (e.g., China, Brazil, India), where a growing middle class is beginning to bridge such gaps as seen by the popularity of internet cafes. More challenging are the least developed countries (who often have the highest disease incidences). Even here however, the impressive growth of cell phone access in even the most remote locations may make it possible for limited digitization of health care information. The Achille’s heel in such settings may be less technology by human, however. Poor specificity of medical diagnosis (due to any cause, from lack of appropriate laboratory to understaffing) will result in a false negative vaccine safety study. Correcting these underlying causes will likely take some time. In the interim, linking good Adverse Event Following Immunization (AEFI) surveillance with mass vaccination campaigns in developing countries may provide an effective alternative. Other relevant lessons from vaccine safety monitoring in the developed world and developing world will also be discussed.