Proactive Management of Drug Recalls in Resource-Limited Settings: Implementation of Statistical Sampling Methods in a Pharmacovigilance Study

by

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ABSTRACT

The development of new drug formulations and the increase in funding for HIV/AIDS, Malaria and Tuberculosis is allowing an increase in the degree of coverage for the new generation medicines for these diseases in developing countries. Pre-approval studies of these new drugs typically involve only several hundred to several thousand patients and all possible side effects of a drug can not be anticipated based on these studies. A system of pharmaco-vigilance and post-marketing surveillance thus becomes critical in ensuring the continued safety of these drugs and setting control limits on adverse reactions to ensure early detection of grave risks and proactively managing recalls.

There is however a lack of functional and reliable infrastructure in low and middle income countries to carry out rigorous pharmacovigilance activities. This makes it imperative to include it as a priority agenda for responsible management of public health supply chains.

This study aims to develop a framework for the design of an active pharmacovigilance program in a resource limited setting. It develops a model to determine the optimal cohort size of patients and devises strategies for the optimal selection of sentinel sites for collection data on adverse events. The problem of sentinel site selection is modeled as a mathematical program and includes sampling frameworks to ensure future causality assessments of adverse drug reactions for a given treatment with the minimal number of sites subject to various constraints.