THE SRI LANKA ASSOCIATION OF CLINICAL PHARMACOLOGY AND THERAPEUTICS

ACADEMIC SESSIONS 2020

"Medicine optimization through safe, effective and economic prescribing"

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2) Recent signals in pharmacovigilance

Dr. Chamila Mettananda

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem of already marketed drugs. The main goal of this is to promote safe and effective use of health products by providing timely information about the safety of health products to patients, health-care professionals, and the public. There are several bodies involved in this process. The World Health Organisation (WHO) established its Programme for International Drug Monitoring, in response to the thalidomide disaster detected in 1961. World Health Organization (WHO) Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (UMC), promotes pharmacovigilance of the WHO member countries. At the end of 2010, 134 countries were part of the WHO Pharmacovigilance Programme.

The WHO defines a safety signal as a "Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously". Information received from patients and healthcare providers via pharmacovigilance agreements as well as other sources such as medical literature is considered in signal detection. Once it is decided that there is a plausible association between an adverse effect and a drug, UMC signals those to national pharmacovigilance centres via "VigiLyze" and the signals will be published in the publicly-available WHO Pharmaceuticals Newsletter (online) and the individual signals are sent to the appropriate pharmaceutical company when they can be identified as uniquely responsible for the drug concerned. Regulators in individual countries may investigate these further and will decide on continued use of the medicine. Confirmed associations will lead to changing the information for patients, providing a public warning or in the most serious situations, withdrawing a drug from the market. For example, pharmacovigilance finding of "Roficoxib" causing increased risk of heart attack and stroke on long term use in high doses led to voluntary withdrawal of the drug by manufacturer from the US market in 2004.

3) Vaccine Vigilance – Role of Cohort Event Monitoring

Dr. Kumuthini Sanchayan

Pharmacovigilance activities were broadened to cover vaccines in the year 2000 and the term vaccine vigilance or vaccine pharmacovigilance emerged. Even though vaccines are approved for use with high level of safety records, when the vaccine is given to larger populations rare and unexpected adverse events (AEs) can occur. These rare AEs or some co-incidental events may create a major public concern.

Vaccine pharmacovigilance activities should be continuously available to detect, analyse and give clear information regarding these AEs to health care professionals and the public. This will ensure the public trust in immunisation programme. In many countries vaccine pharmacovigilance activities depend on the spontaneous reporting. It may vary from country to country and may not be fully functioning in many countries. Data generated from spontaneous reporting cannot be compared and pooled because of differences in reporters, case definitions and availability of details.

Cohort event monitoring (CEM) is a newly developed method where a cohort of participants are actively followed up after immunisation to detect AEs by direct interview or screening participant's clinical records. This method is known to give qualitative and quantitative data regarding AEs following immunisation. The advantages of cohort event monitoring over spontaneous reporting include the following. It can provide rates and near-complete profiles of different AEs. It is known