



PHARMACOVIGILANCE

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Parmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster detected in 1961. The aims of PV are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programs by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines. Though it was set in motion several decades ago, some countries still look upon PV as a ritual or a copycat strategy to comply with the International bodies. PV is not yet felt as an intrinsic need.

It would be worth exploring the reasons behind this lassitude. The importance of relying on collective experience generated from the reports of health care professionals is indisputable.

The arguments against PV is primarily that of a heavy patient load that makes it difficult for health care professionals to pay attention to adverse drug reactions (ADRs).

Reporting an ADR may be interpreted as an admission of weakness and incompetence. This is plain wrong. The need of the hour is to change this mindset. How is this possible? Some are of the opinion that Pharmacists should be empowered with the responsibility of ADR reporting. This should be coupled with better cooperation and collaboration with all health care professionals in general.

Together with the WHO Collaborating Centre for International Drug Monitoring, Uppsala, WHO promotes PV at the country levels. As many as 134 countries were part of the WHO PV Programme by the end of 2010.

All the reports received by the Uppsala Monitoring centre (UMC) from the participating countries are archived in the WHO Global ICSR Database called Vigibase. Uppsala Reports, the publication by the UMC reported in its issue July 2014 that the total number of reports have touched nine million.

Although it took almost 25 years for Vigibase to reach the mile stone of the first million, the growth has been rapid during the past 5 years,

with the collaborative efforts by the UMC and multiple national centers.

Previously, only reports from health care professionals of the National centers were sent to the UMC. Now the UMC started receiving consumer reports as well, which are flagged as being from patients or non- health professionals, the number has reached 1,300,000.

It is the responsibility of the National centers to create awareness among health care professionals about the need for ADR monitoring and reporting. When we attend awareness workshops among practitioners, a common question they pose is "Do we need to report already known reactions to the center?" Our answer would be "yes", because what they report are only suspected adverse reactions, a suspicion a reporter relates to a drug which would have caused the reaction. Obviously, nobody can wait until a very serious ADR is authenticated before a report is filed. It is important to develop a culture of reporting. This can happen only by constantly interacting with patients and discussing their problems during the course of therapy.

Once a suspected adverse reaction reaches a National center, it is their responsibility to assign causality to the suspected adverse reaction. It is important to address the question whether the reaction is actually caused by the drug.

Causality assessment helps classify relationship likelihood but cannot give an accurate quantitative measurement of relationship (likelihood). WHO-UMC causality categories are classified as Certain, Probable/likely, Possible, Unlikely, and Conditional / Unclassified, Unassessable / Unclassifiable.

To attribute a harmful effect falsely to a medicine could cause a lot of damage, which could be difficult to reverse. Although the principles behind causality assessment are supplied as a standard, application of it to individual cases is a scientific challenge. It would remain a question mark with the assessors whether the "drug really does it, or was the drug the cause of it or are there non drug related causes?" Because the human body is complex and each individual is different from the other, one drug may respond differently in different persons. The assessment has to take into consideration, temporal relationship, plausibility, and the absence of other explanations.

Again, the question is why do we need PV? The answer is: to protect patients from possible harm, to learn from our past experiences and to make these past experiences known to the world. All these are possible only through effective reporting.

So let's join hands with other health professionals globally and be a partner in this prodigious and righteous endeavor.

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