Keep Maternal, Newborn, and Child Health Medicines Safe

Introducing MNCH commodities into a pharmacovigilance system

This case study highlights steps taken to ensure the safe use of medicines for mothers, newborns, and children through regular adverse drug event (ADE)[1] reporting as part of the national pharmacovigilance (PV)[2] program in Bangladesh.

Introduction

As countries aim to achieve the Sustainable Development Goals, there is an emphasis on increasing the availability of medicines. However, poor quality products or dispensing methods may decrease treatment effectiveness or even result in patient death. ADEs negatively affect patient care and increase costs to the system. A functioning PV system monitors these events and triggers actions to minimize their impact. While some disease-specific areas, such as tuberculosis, have made PV a regular tenant of their treatment programs, medicines used for maternal, newborn, and child health (MNCH) are often ignored in reporting. Some priority MNCH medicines are long established and their adverse effects are well documented; however, quality issues, especially with locally produced medicines, need to be monitored. In addition, newly recommended formulations of lifesaving products, such as chlorhexidine 7.1% for umbilical cord care, require surveillance to ensure their safety and appropriate use.

Situation in Bangladesh

The US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program supported Bangladesh's national regulatory authority, the Directorate General of Drug Administration (DGDA), to strengthen regulatory processes and establish a national PV system. SIAPS helped institute an adverse drug reaction monitoring (ADRM) cell, which serves as the national PV center, to promote ADE reporting and assessment. By mid-2017, the PV system had been established in 30 public and private hospitals in Dhaka district. Under the PV system, all medicines used in Bangladesh can be monitored; however, MNCH medicines were not reported on. Bangabandhu Sheikh Mujib Medical University has been involved in the DGDA's PV program since 2013, and the Pharmacology Department regularly sends adverse drug reaction event reports to the DGDA's ADRM cell.

Discussion on including MNCH in the pharmacovigilance system. Photo credit: Dr. Afsana Alamgir Khan, Technical Advisor, SIAPS/MSH

Intervention

SIAPS took a phased approach to integrate MNCH service providers at Bangabandhu Sheikh Mujib Medical University into the PV system.

- SIAPS held initial discussions with Ministry of Health and Family Welfare stakeholders, including its directorates—

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

[1] An ADE can result from a medicine not being taken as directed; a medication error; therapeutic ineffectiveness; abuse; or a poor quality product, including a falsified medicine.

[2] Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem (The Importance of pharmacovigilance, WHO 2002).

Directorate General of Health Services, Directorate General of Family Planning, and DGDA—to promote the importance of including MNCH medicines in the PV system. We emphasized that this would not be a parallel system, but rather an expansion of the network of services implementing PV.

- Because Bangladesh already had clear guidelines on defining and reporting ADEs, adaptation for MNCH products was unnecessary. We adapted and shortened materials from the full PV training to orient providers in short sessions.
- A total of 170 MNCH service providers from gynecology, maternity, pediatric, and newborn services were oriented on how to recognize and report ADEs during half-day workshops in August and December 2017.
- A focal person was designated for each health service to liaise with the ADRM cell, including collecting, collating, and submitting all notification forms from their departments.

Poster to promote awareness of pharmacovigilance reporting

Outcomes

The providers expressed strong interest in joining the PV system and reporting ADEs related to the products they prescribe. They saw the need for this type of monitoring and had not been aware of the DGDA's PV system, despite it being functional in their hospitals. The overwhelming reaction from staff was disappointment, saying that if they had known about the PV system previously, they could have already been reporting on MNCH commodities.

The president of the Bangladesh Medical and Dental Council proposed including ADE reporting in the preservice undergraduate and postgraduate curricula so that educators, students, and physicians would all know the importance of and how and when to report on ADEs. Pharmacy students would be required to include two ADE case reports as part of their thesis.

Challenges

The chairs of the pediatric, neonatology, pharmacology, and gynecology departments committed to making PV functional, and all staff from the departments have been oriented and know how to report any ADEs they observe; however, delays in appointing focal persons delayed the start of reporting. Providers need encouragement to report, especially when product quality is suspect, because they do not want to publicly expose a manufacturer. Reassurance that the process is anonymous and that patient safety and well-being are the top priority is critical.

Next Steps

The ADRM cell will determine the appropriate steps to take depending on the ADEs reported and communicate that information to the service providers and the Directorate General of Health Services and Directorate General of Family Planning for action. The DGDA will share lists of deregistered or withdrawn medicines with all health care institutes to ensure that those medicines are taken out of circulation. The ADRM cell will look for ways to expand this intervention to other hospitals so that MNCH service providers become full contributors to the PV system.