SIAPS
TECHNICAL HIGHLIGHT

Strengthening Bangladesh's National Pharmacovigilance System: Lessons Learned and Opportunities

What is Pharmacovigilance?

The World Health Organization (WHO) defines pharmacovigilance (PV) as the science and activities concerned with the detection, assessment, understanding, and prevention of adverse reactions to medicines. The ultimate goal of PV is to improve the safe and rational use of medicines, thereby improving patient care and public health.

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CONTEXT

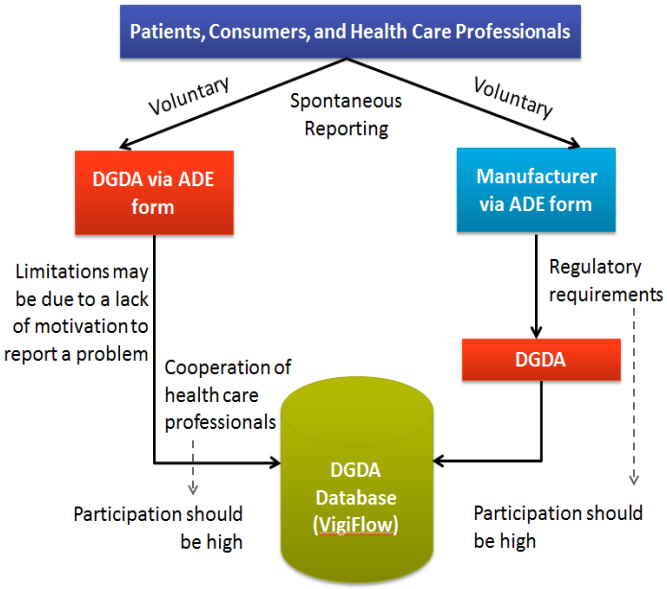
The pharmaceutical sector of Bangladesh has positioned itself well in the international and domestic markets over the last few decades. More than 97% of the local demand for medicines is met by Bangladeshi pharmaceutical companies, and roughly 30 companies export a significant quantity of medicines to 113 countries[i]. For pharmaceutical companies, it is relatively easy to obtain marketing authorization for the sale of medicines in Bangladesh, but it is becoming increasingly crucial for the Directorate General of Drug Administration (DGDA) to strengthen regulations and surveillance systems to ensure that medicines and commodities provided to patients and the public are safe and effective and that they meet approved quality standards. Although PV started in Bangladesh in 1999, several factors contributed to it going dormant, including a lack of legislation and strategic leadership, limited motivation, no common understanding among DGDA staff about PV, and coordination and communication gaps among stakeholders. As a result, many adverse drug reactions were not reported correctly.

APPROACH

In 2012, the US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health, started working with the DGDA and conducted a comprehensive assessment of the DGDA's regulatory systems and capacity. As part of the recommendations made in the assessment, SIAPS provided technical support to the DGDA to revive the national PV program and establish an Adverse Drug Reaction Monitoring (ADRM) cell. This cell, which is responsible for collecting adverse event reports from health care facilities, hospitals, and pharmaceutical companies, maintains and analyzes adverse event databases, including data entry and quality assurance, and shares adverse event information with WHO's International Drug Monitoring Center (WHO-UMC) at Uppsala.

In September 2013, the Ministry of Health and Family Welfare named the ADRM cell the National Drug Monitoring Centre (NDMC) of Bangladesh and officially launched the National

PV framework: How adverse drug event reports reach the DGDA



Pharmacovigilance Program. The PV program was initially introduced at 20 private and public hospitals and 13 pharmaceutical companies. With technical assistance from SIAPS, the DGDA formed an Adverse Drug Reaction Advisory Committee (ADRAC) and trained its members to evaluate, analyze, and make recommendations on adverse drug events (ADEs). SIAPS also helped the DGDA develop PV guidelines; tools; and information, education, and communication training materials to support an ADE reporting system. To promote ADE reporting, a team comprising DGDA officials and SIAPS technical advisors made regular monitoring visits to selected hospitals, while staff from the ADRM cell sent biweekly e-mails and made follow-up phone calls to key personnel at the hospitals and pharmaceutical companies where the PV program was being introduced. SIAPS also facilitated a series of workshops and capacity building trainings for DGDA officials and pharmaceutical industry representatives to increase PV awareness and knowledge.

RESULTS

The system-oriented approaches used by SIAPS to keep the national PV program functional and effective yielded some significant results:

- In December 2014, Bangladesh became a full member of WHO-UMC.
- A total of 30 hospitals and pharmaceutical companies with designated PV focal points are currently working as "sentinel surveillance sites" to implement PV interventions. The DGDA also extended the PV program to two divisional teaching hospitals (Chittagong and Rajshahi Medical Colleges). As of March 2016, 48% and 56% of these hospitals and pharmaceutical manufacturers, respectively, are regularly reporting adverse events.
- The DGDA received 600 ADE reports between October 2013 and October 2015, and of these, 189 had complete data and were reviewed by the committee and uploaded into the VigiFlow database. Figure 1 shows a four-fold increase in the number of reports received and a two-fold increase in the number of reports reviewed by the ADRAC during this time period. An additional 171 ADE reports that were received by the DGDA between November 2015 and March 2016 are currently being reviewed.
- Related training on PV was provided to 460 health care providers and pharmaceutical industry representatives.
- A DGDA executive order has been sent to all public medical college hospitals and local pharmaceutical manufacturing companies, including pharmaceutical importers, that asks these sites to monitor the ADEs of their products through their own channels and to report the findings to the NDMC[ii].

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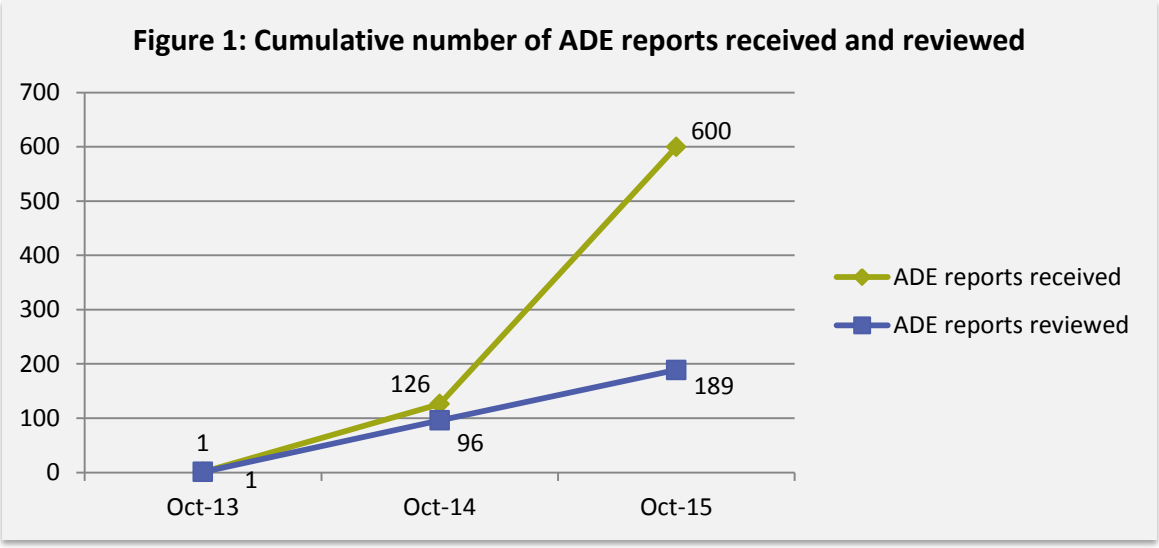

CHALLENGES AND LESSONS LEARNED

The DGDA faces several significant challenges, including a lack of public awareness on ADE reporting and inadequate experience of DGDA and other officials working in health facilities as well as policy makers on PV. Concerted efforts are needed from all stakeholders to increase public awareness and build the capacity of both DGDA officials and health care providers to increase the number and quality of ADE reports. Frequent staff changes have slowed down PV implementation in the public and private hospitals selected for this program.

CONCLUSION

PV activities currently operate on a limited scale in Bangladesh, but to ensure an optimal public health impact and safety in relation to medicine use, it is essential to expand these activities nationwide. In addition, engaging a broader range of stakeholders (e.g., patients, health care providers, academics, and researcher institutes and universities) and promoting country ownership are imperative if the effectiveness of the PV program in Bangladesh is to be sustained.

References

[i] 2015 Annual Report of the Directorate General of Drug Administration (http://www.dgda.gov.bd/index.php/downloads/annual-information/143-annual-report-2015); http://www.dhakatribune.com/long-form/2015/feb/13/prescription-growth
[ii] WHO UPPSALA Report, April 2015 (http://www.who-umc.org/graphics/28537.pdf)

ABOUT SIAPS | The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program works to assure access to quality pharmaceutical products and effective pharmaceutical services through systems-strengthening approaches to achieve positive and lasting health outcomes. SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health.

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