Monitoring and Reporting Adverse Drug Reactions in India: Initiatives and Contributions from Pharmacists

The reporting of adverse drug reactions (ADRs) is recognized throughout the health care system as an important means of ensuring the safety of medicines. Pharmacists have a major role in these activities and should promote the development, maintenance, and evaluation of such programs. Pharmacists are now being encouraged to participate and contribute to such programs in different parts of the world.

In India, the concept of pharmaceutical care and pharmacists' involvement in direct patient care is still at a preliminary stage, and the expertise of most pharmacy professionals is underutilized. The concept of "clinical pharmacy" itself is new, and health care professionals are not aware of the many patient care services that could be provided by pharmacists, including ADR monitoring and reporting. Only a few hospitals in India have a clinical pharmacist to provide patient care services.

Reporting of ADRs is another aspect of medical care that is still in its infancy in India, and only a handful of hospitals have a system for ADR reporting. Pharmacists have been instrumental in initiating and coordinating such systems in many of these hospitals as part of their clinical pharmacy activities. Of late, there has been a fresh initiative from the government of India with the launch of a national pharmacovigilance program that is being operated in association with the World Health Organization pharmacovigilance program. Pharmacists have significant involvement in the national program as well, primarily by coordinating peripheral centres under the program.

The Department of Clinical Pharmacy of Kasturba hospital, Manipal (a 1400-bed tertiary care teaching hospital), one of the peripheral centres participating in the national program, was successful in initiating an ADR reporting program in the year 2001. The unit has received more than 1400 ADR reports since its inception. Health care professionals in the hospital are encouraged to report all suspected ADRs by one of several methods, including a printed or online (intranet) notification form, telephone reporting, and reporting to a clinical pharmacist. Clinical pharmacists attending ward rounds contribute to the promotion of safe drug use by assisting physicians in the identification, assessment, and management of ADRs. All of the ADRs identified are documented and evaluated for various parameters such as causality, severity, and preventability. ADR alert cards are given to selected patients.

The ADR unit is now bringing out a drug safety bulletin for the hospital with the aim of disseminating information on the ADRs that have been reported and educating health care professionals about drug safety. A database of reported ADRs is in preparation, which will be made available through the hospital's intranet. The ADR reporting unit has taken a special interest in promoting the reporting of ADRs related to complementary and alternative medicines, and we have so far received 15 ADR reports related to these medicines, including some severe reactions.

Underreporting is a potentially major problem that we have attempted to address through awareness programs and enhanced involvement of nurses and hospital pharmacists.

Indian pharmacists have started contributing to direct patient care activities through various programs, of which the drug safety monitoring and reporting program is just one. The initiative and contributions of pharmacists are gradually being recognized, as they are in other countries.

References

Jimmy Jose, MPharm
Lecturer
Padma GM Rao, MPharm, PhD
Professor and Head of Department
Department of Pharmacy Practice
Manipal College of Pharmaceutical Sciences
Manipal, Karnataka, India

A Canadian-Trained Pharmacist in the United States

I read with great interest the recent CSHP position statement on Canadian entry-level doctor of pharmacy (ELPD) degrees. I wholeheartedly agree that adoption of this degree appears inevitable, given that a very similar system is already in place in the United States.

The position statement asked many questions that can be answered by the experiences of the American ELPD, but before describing the US-based pharmacy education system any further, it would be prudent to explain my background. I am a graduate from a Canadian bachelor of pharmacy program and a Canadian-licensed pharmacist. While practising pharmacy in Canada, I obtained a PharmD from a US institution, primarily by distance learning. This endeavour created a best-of-both-worlds option: the pursuit of a post-baccalaureate education after obtaining pharmacy practice experience while working to finance this phase of my education. This option has been and continues to be pursued by a minority of pharmacists with Canadian undergraduate degrees. However, with the post-baccalaureate doctoral programs being phased out at many US colleges of pharmacy, the availability of this option for Canadian pharmacists is increasingly limited. I completed the experiential requirements of my program within the United
States and stayed to practice pharmacy after applying to US residency programs. Subsequently, I completed a 2-year Pharmacotherapy Specialty Residency and subsequently pursue a post-baccalaureate PharmD if desired. The US pharmacy education system employs similar residencies but these follow the PharmD degree. This scenario did not change considerably with the advent of the ELPD in the United States, where residencies represent advanced practice experience.

With the large number of PharmD graduates in the United States, the number of residencies available has expanded considerably. As such, the physician education model of an MD degree followed by additional, more specialized training is being emulated by the US pharmacy education system.

Within the American system, some of the questions raised by the CSHP position statement remain to be resolved, whereas others have been overcome. ELPD graduates enter the profession, as did their predecessors, in entry-level staff positions. An ELPD graduate should have the knowledge and skills to perform dispensary functions, as do other newly licensed pharmacists. Importantly, ELPD graduates should be better prepared for undertaking more advanced patient-focused clinical functions, a direction in which the profession seeks to move.

The largest impediment to ELPD in Canada remains the availability of the infrastructure required to support students’ experiential training, as stipulated by a program that requires more extensive clinical pharmacy experiences. In the United States, the PharmD was initiated in California during the 1960s and grew across the country for over 3 decades before the ELPD was implemented. Canada is without this temporal luxury, and it may be difficult to rapidly expand the infrastructure. The suggestion by Hindmarsh (in an editorial accompanying the CSHP position statement) to develop a few ELPD programs, rather than converting all pharmacy programs to the ELPD, seems prudent. Offering an opportunity for more Canadian pharmacists to obtain advanced pharmacy training is creating an environment in which more pharmacists will receive a stronger base of clinically focused training. The patient-focused growth of the profession can only benefit.

References

Michael J Peeters, PharmD, BCPS
Clinical Assistant Professor
University of Toledo College of Pharmacy
Toledo, Ohio

Advertisers’ Index

<table>
<thead>
<tr>
<th>Advertiser / Type</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canadian AIDS Treatment Information Exchange</td>
<td>147</td>
</tr>
<tr>
<td>Medi-Dose Inc / Corporate</td>
<td>115</td>
</tr>
<tr>
<td>Mayne Pharma (Canada) Inc / Irinotecan</td>
<td>110</td>
</tr>
<tr>
<td>Novopharm / Corporate</td>
<td>112</td>
</tr>
<tr>
<td>Omega / Corporate</td>
<td>IFC</td>
</tr>
<tr>
<td>Pfizer / Lipitor</td>
<td>116</td>
</tr>
<tr>
<td>Pharmaceutical Partners of Canada / Heparin</td>
<td>OBC</td>
</tr>
<tr>
<td>Sandoz / Corporate</td>
<td>IBC</td>
</tr>
</tbody>
</table>

---

21.3 %   100.0 %