# Establishment of a Drug Information Unit and Pharmacovigilance Cell in a Provincial Hospital of Nepal: Implementation of the 2015 Hospital Pharmacy Service Guidelines

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Nabin Pathak<sup>1,2</sup>, Amod Rasaili<sup>3</sup>, Sachita Barma<sup>2</sup>, Dibyata Khatiwada<sup>3</sup>, Anusha Raila<sup>3</sup>, Devendra Raj Gautam<sup>3</sup>, Prerana Shrestha<sup>1</sup>, Shreya Dhungana<sup>4</sup>, and Sunil Shrestha<sup>5</sup>

#### Introduction

The Hospital Pharmacy Service Guideline 2015 of Nepal aims to promote accessible and quality pharmaceutical services from the hospital.<sup>1</sup> The Constitution of Nepal effectively grants all the right to information and health services by providing accessible and quality services.<sup>2</sup> Right to health (Part 3, Section 35) further explains that everyone has the right to get information about their medical treatments, including treatment therapy, choice, possible side effects, and unprecedented effects.<sup>2</sup>

Pharmacists employed in drug information centers have a prominent role in enhancing the quality of health services by providing evidence-based information to patients, preventing possible medication errors (MEs), adverse drug reactions (ADRs) and drug-drug interactions (DDIs) which improves patient safety through rational use of medicine.<sup>3-5</sup>

Similarly, the Public Health Services Act 2075 (2018), Rule 10 explains that every health institution and health worker providing treatment shall provide the service recipient with information on health conditions, treatment, alternative treatment strategy, and risks/benefits of drug therapy.<sup>6</sup>

Lack of accurate drug information in the service process poses problems in pharmacotherapy, failure of therapy, economic burden to patients, developing secondary illness as well as adverse drug effects.<sup>7</sup> In the context of multiple healthcare systems, there is a lack of reliable and appropriate information about the benefits and risks of drug therapy; hence, a system for authentic, accurate, unbiased and evidence-based drug information could contribute to the appropriate patient information.<sup>7</sup>

The quality standards and regulation division of the Ministry of Health and Population, Nepal, has prepared a checklist or minimum service standards (MSS) to determine any gaps in the quality improvement of secondary hospitals with higher services.<sup>8</sup> As per the checklist, the pharmacy department needs a separate information and counseling unit

with reference books or Information, education, and communication (IEC) materials (MSS Code 2.5.14) related to medicine and their appropriate use. Similarly, the MSS also mentions the need to initiate and operate a pharmacovigilance (PV) center for reporting ADRs (MSS Code 2.5.19.1).<sup>8</sup>

PV in a hospital is essential for ensuring the safety of medications by monitoring, detecting, assessing, and preventing ADRs and other medication-related problems.<sup>9</sup> Lack of knowledge and awareness about PV and reporting ADRs among healthcare professionals may contribute to undetected ADRs, MEs, poor patient safety, and underreporting.<sup>9,10</sup> PV aims to enhance patient care and patient safety concerning the use of medicinal products and to support public health programs by providing reliable, accurate, and evidence-based information to assess the risk-benefit profile of medicines. The existing limitation regarding information delivery and PV services within Nepal genuinely underscores the need for a coordinated department that provides evidence-based information and promotes drug safety along with the fulfillment of the MSS checklist.7,9

<sup>5</sup>Department of Research and Academics, Kathmandu Cancer Center, Tathali, Nala Road, Bhaktapur, Nepal

#### **Corresponding Author:**

<sup>&</sup>lt;sup>1</sup>Drug Information Unit and Pharmacovigilance Cell, Department of Pharmacy, Hetauda Hospital, Madan Bhandari Academy of Health Sciences, Hetauda, Nepal

<sup>&</sup>lt;sup>2</sup>Department of Pharmacy and Clinical Pharmacology, Madan Bhandari Academy of Health Sciences, Hetauda, Nepal

<sup>&</sup>lt;sup>3</sup>Dispensing Section, Department of Pharmacy, Hetauda Hospital, Madan Bhandari Academy of Health Sciences, Hetauda, Nepal

<sup>&</sup>lt;sup>4</sup>Department of Pharmacy, National Model College for Advance Learning, Tribhuvan University, Kirtipur, Nepal

Nabin Pathak, Drug Information Unit and Pharmacovigilance Cell, Department of Pharmacy, Hetauda Hospital, Madan Bhandari Academy of Health Sciences, Hetauda 44100, Nepal.

Emails: pathaknabin89@gmail.com; nabin.pathak@mbahs.edu.np

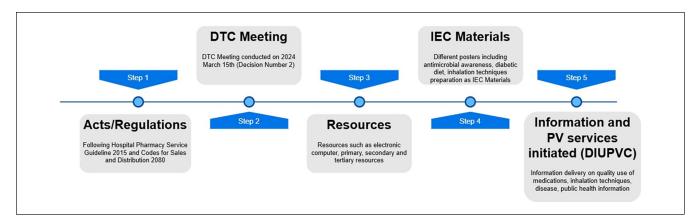


Figure 1. Steps involved in the initiation of drug information unit and pharmacovigilance cell (DIUPVC).

Note. Cell, in this context, means the room designated for providing drug information and pharmacovigilance activities. DTC=drug and therapeutic committee; IEC=information, education, and communication; PV=pharmacovigilance.

# Implementation of Hospital Pharmacy Service Guideline 2015

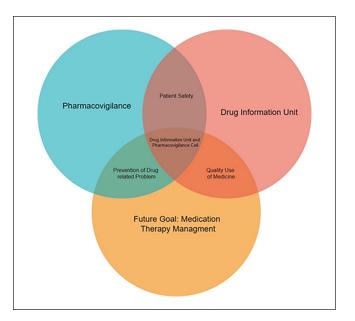
# Initiation of Drug Information Unit and Pharmacovigilance Cell

Hospital Pharmacy Service Guideline 2015 is essential for promoting hospital pharmacy practice in the country.<sup>11</sup> In response to the published literature<sup>11</sup> and to fulfill the objectives set by Hospital Pharmacy Service guideline 2015,<sup>1</sup> Codes for sales and distribution of drugs 2080,<sup>12</sup> and to promote pharmacy practice, various steps were followed. This ultimately led to the formation of the Drug Information Unit and Pharmacovigilance Cell (DIUPVC; Figure 1). Hence, in this editorial, we document how we initiated the first phase of hospital pharmacy practice along with the experience, work done, challenges, and future goals. This is a novel task in Nepal, and we believe this work will help promote hospital pharmacy practice in several hospitals in the coming days.

## Site and Aims of DIUPVC

The cell is established at Hetauda Hospital, Madan Bhandari Academy of Health Sciences. Hetauda Hospital is in the capital of Bagmati Province of Nepal, Makwanpur. It is a growing governmental hospital that provides service to an average of 800 to 1000 patients daily with more than 100 beds. Hence, to provide pharmaceutical services to patients, the cell which comes under the branch of Hospital Pharmacy aims:

• To promote the rational use of medication and provide the maximum quality of health services to patients by providing accurate, unbiased, validated, and evidence-based information to healthcare professionals and patients.



**Figure 2.** Current and future aims of the drug information unit and pharmacovigilance cell.

• To improve medication safety and treatment outcomes via prescription monitoring, detection, and reporting of ADR, as well as patient-based ADR reporting and active surveillance systems. This section aims to promote patient safety, quality medication use, and identification and resolution of drug-related problems (Figure 2).

# Experience and Works Done To Date

After the initiation, the cell employed itself to deliver drug information to patients and health care professionals by conducting various activities (Table 1). Posters have been prepared as IEC materials in the Nepalese language to convey critical

#### References/link/section used while Materials present Activities Sub domain Contents dealt with preparing the materials Counseling Medication Inhalation medication counseling GOLD guidelines and quality use N/A counseling, for patients diagnosed with of medicines for inhalers<sup>13</sup> COPD and asthma for drugs information with fixed-dose combinations delivery and Rotacaps (R/Cs) such as (R/ Cs formoterol + Budesonide, R/Cs formoterol $6 \,\mu g$ + budesonide 400 $\mu g$ , MDI salbutamol 100 µg Query on drug allergies, smoking history Query on substance history General information on OTC drugs and diseases Presentations Insurance benefit Insurance, history of health https://hib.gov.np/en/pages/health-N/A package insurance in Nepal care-packages Information on risk pooling Health insurance act and directive What medicines are included in the insurance benefits package? Pharmacovigilance Introduction of pharmacovigilance, Hospital pharmacy service ADR reporting the importance of detection, guideline 2015 rule 4 (subform rule 5),<sup>1</sup> Codes for sales and assessment, understanding, and distribution 2080 section 5 reporting of ADR subsection 15,12 minimum Concept of drug safety service standards clause 2.5.198 Pharmacovigilance is a part of MSS ADR reporting form Pharmacovigilance network in Nepal Medication errors Introduction to medication errors, National coordinating council for causes, incidence, common types medication error reporting and of medication errors, ways to prevention,<sup>14</sup> Key facts about tackle errors medication errors (MEs) in the World Health Organization (WHO) European Region,15 American Society of Health-System Pharmacy standard definition of a medication error<sup>16</sup> Preparation of Diabetic diet Concept of diabetic diet with Healthy living with diabetes, Counseling leaflet IFC materials counseling diagrammatic figures and what National Institute of Diabetes and poster kind of foods are included within and Digestive and Kidney the 9-inch plate (0 calorie drink, Disease<sup>17</sup> 1/4th carbohydrates, 1/4th protein, and 1/2 non-starchy vegetables) Inhalation device Steps to consider while using it for Inhalation technique using several Inhaler, inhalation brands of leaflets (inhaler counseling) the first time use leaflet. Step-by-step method for using the placebo inhaler Inhalation device for Prepared from literature<sup>13</sup> Inhalation device, A step-by-step method for using dry powers (eg, the inhalation device inhalation use Rotahaler handling) leaflet, placebo Antibiotic awareness Antimicrobial resistance and WHO resource materials<sup>18</sup> Posters awareness Hospital Development of Presentation on formulary, its Hospital Pharmacy Service Hospital formulary Guideline 2015 rule 19,1 Formulary hospital formulary draft contents, and importance, and process for its development via minimum service standards $2.5.3^{8}$ formulary committee

#### Table I. Activities Conducted by the Drug Information Unit and Pharmacovigilance Cell.

Note. This table summarizes the activities conducted within the drug information unit and pharmacovigilance cell since its initiation. COPD=chronic obstructive pulmonary disease; MDI=meter dose inhaler; GOLD=global initiative for chronic obstructive lung disease; OTC=over the counter; ADR=adverse drug reaction; MSS=minimum service standards; IEC=information, education and communication; N/A=not available.

Future goals	Term	Comments
Drug utilization studies	Short-term objective	To promote and assess the rationality of therapy <sup>20</sup> and adherence to MSS Clause 2.5.19.2
Continuous professional development programs	Short-term objective	To enhance the skills of pharmacy and health care professionals on regular updates
Medication therapy management	Medium-term objective	To promote the idea of clinical pharmacy services
Newsletter/drug bulletin	Medium-term objective	To share ADR and pertinent information on recent drugs and hazard
Liaison with non-governmental organizations	Long-term objective	To promote the idea of rational use of drug
Academia-hospital sessions	Long-term objective	To promote and enhance the skills and learning of students through a practical approach

Table 2. Future	Goals and Direction	of Drug Information	Unit and Pharmacovigila	ance Cell.
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Note. Short-term: goals we aim to achieve within 1-month; medium-term: goals to achieve within 1.5 to 2.5 months; long-term: goals to achieve within 3-6 months. MSS=minimum service standards; ADR=adverse drug reaction.

information. The posters were created using literature, converted to Nepalese language, and published/printed within the hospital pharmacy section on every pharmacist consensus.

## Challenges for Initiation and Implementation of DIUPVC

The major challenge resides with the continuation of the cell and the underreporting of ADR and patient engagement. It is challenging to inform patients about the importance of the cell and help them handle their medication. The majority of patients tend to be unaware and ignore their medication-taking behavior. Hence, this opens room for the initiation of social media to bring out the purpose of drug information even more widely. However, the major challenge with ADR reporting is its underreporting by nurses and healthcare professionals.<sup>9,10</sup> Thus, specific actions, such as planned awareness campaigns or additional training for healthcare staff, would help overcome these challenges.

# Future Goals and Directions of DIUPVC

In the coming days, DIUPVC aims to form a liaison with a non-governmental organization in the hospital's permission to provide information about rational drug use as outlined by the National Drug Policy 1995.<sup>19</sup> Providing information about complementary and alternative medicines in the coming days is also a priority because of its vast consumption and use. The cell aims to conduct research activities and provide evidence-based information for healthcare professionals (Table 2).

### Conclusion

Intending to promote pharmacy practice in hospital settings and implement hospital pharmacy service guidelines in 2015, DIUPVC helped provide pharmaceutical services with a major focus on the quality use of medicines, rational use of drugs, and evidence-based information delivery. With this implementation, the cell aims to promote the practice further, thus improving the quality of the hospital itself.

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#### **Author Contribution**

NP conceptualized the idea and wrote the initial version of the manuscript. AR, SB, DK, AR, DRG, and PS added contents to the manuscript later and helped in the management of the drug information unit and pharmacovigilance cell. SD and SS are experts in pharmacovigilance, pharmacy practice and research, provided valuable feedback in starting the drug information unit and pharmacovigilance cell, and critically reviewed the manuscript. All authors agreed on the final version of the manuscript.

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### **ORCID** iDs

Nabin Pathak D https://orcid.org/0000-0002-1952-642X Amod Rasaili D https://orcid.org/0009-0000-6980-7222 Sachita Barma D https://orcid.org/0009-0009-2014-4339 Dibyata Khatiwada D https://orcid.org/0009-0002-7050-0652 Anusha Raila D https://orcid.org/0009-0007-4034-8959 Devendra Raj Gautam D https://orcid.org/0009-0005-1266-4861 Prerana Shrestha D https://orcid.org/0009-0008-7016-2028 Shreya Dhungana D https://orcid.org/0000-0001-6176-0255 Sunil Shrestha D https://orcid.org/0000-0002-9174-7120

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