



**ISLAMIC REPUBLIC OF AFGHANISTAN  
MINISTRY OF PUBLIC HEALTH  
GD OF PHARMACEUTICAL AFFAIRS  
AVECINA PHARMACEUTICAL INSTITUTE**

**ADVERSE DRUG REACTION REPORTING &  
MANAGEMENT ASSESSMENT  
IN SIX HOSPITAL OF KABUL,  
AFGHANISTAN**

**March – August 2013**



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## ACRONYMS

|       |   |
|-------|---|
| ADR   | Adverse drug reaction                         |
| DTC   | Drug and therapeutics committee               |
| ENT   | Ear, nose, throat                             |
| GDCM  | General Directorate of Curative Medicine      |
| GDPA  | General Directorate of Pharmaceutical Affairs |
| IGICH | Indira Gandhi Institute of Child Health       |
| KMU   | Kabul Medical University                      |
| MoHE  | Ministry of Higher Education                  |
| MoPH  | Ministry of Public Health                     |
| NSAID | Nonsteroidal anti-inflammatory drug           |
| PPHD  | Provincial Public Health Directorate          |
| SPS   | Strengthening Pharmaceutical Systems          |
| TB    | Tuberculosis                                  |
| USAID | US Agency for International Development       |
| WHO   | World Health Organization                     |



#### ACKNOWLEDGEMENTS

Pharmacovigilance is a system to monitor the safety and effectiveness of medicines and other pharmaceutical products. A pharmacovigilance system aims at protecting patients through the efficient and timely identification, reporting, and assessment of adverse drug reactions (ADRs). Poor quality medicines, medication errors, and adverse drug reactions have an enormous impact on health. Not only do these problems increase morbidity and mortality, but also they contribute to higher health care costs and patients' mistrust in the health system.

For improvement of medicine safety management within the country the Ministry of Public Health (MoPH) of Islamic Republic of Afghanistan originated interventions in its policies and strategies. The Health and Nutrition Strategy 2009-2013 (HNS) clearly indicates that medicines safety initiatives at the hospital level are an important part of improving patient safety. The HNS 2012-2020, indicates the MoPH's intention to enhance its capacity on pre- and post-market surveillance of medicines. Subsequently, the National Strategy for Improving Quality in Health Care (2011-2015), states establishment of an adverse events and near-miss reporting system.

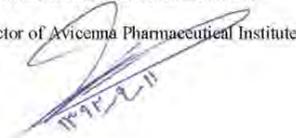
The Avicenna Pharmaceutical Institute (API), with technical and financial assistance of the Strengthening Pharmaceutical Systems (SPS) carried out the Adverse Drug Reaction Reporting & Management Assessment in six hospitals of Kabul, from March to August 2013. This report is the findings of the conducted assessment which will be used as baseline for medicine safety interventions and improvement of patient safety.

The General Directorate of Pharmaceutical Affairs (GDPA) of MoPH would like to acknowledge the technical and financial support of Strengthening Pharmaceutical Systems (SPS) project funded by the US Agency for International Development (USAID) and implemented by Management Science for Health (MSH) on proper completion of this assessment.

The General Directorate of Pharmaceutical Affairs (GDPA) also is grateful for contribution of General Directorate of Curative Medicine (GDCM), Director and professionals of Ibn-Sina Hospital for paving the way to conduct the pilot phase of the assessment and Malalai, Istiqlal, Indira Gandhi Institute of Child Health (IGICH), Khairkhana 102 beds, Ali Abad and Dasht-e-Barchi hospitals directors and professionals for their support on successful implementation of the assessment.

Pharmacist Abdul Khalil Khakzad

Director of Avicenna Pharmaceutical Institute





## **EXECUTIVE SUMMARY**

The Ministry of Public Health (MoPH), with technical and financial assistance of the Strengthening Pharmaceutical Systems (SPS) project funded by the US Agency for International Development (USAID), carried out the medicines safety assessment from March to August 2013 in six Kabul hospitals. The aim of this assessment was to determine the familiarity and knowledge of physicians about adverse drug reactions (ADRs), and to determine their opinion on some key aspects of setting up hospital-based detection, reporting, and management systems for ADRs.

### **Methodology:**

Thirty physicians in six Kabul-based hospitals were interviewed with a structured questionnaire. Obtained answers were coded and entered into pre-formatted spreadsheets. Frequency tabulations and cross-tabulation of variables were performed in Excel.

### **Key Findings:**

Physicians are familiar with ADRs in general terms: the majority described incidents that could be ADRs, and that were adequately managed. All interviewed physicians could name at least one medicine that is likely to provoke ADRs. However, they lack detailed knowledge and have limited access to reliable information about ADRs. They report limited awareness and knowledge by other hospital staff about ADRs, and note this as an obstacle to establishing ADR reporting systems.

Physicians see detecting, reporting, and managing ADRs as part of their professional duty, and are in favor of setting up hospital-based and national systems for ADR detection, reporting, and management. Physicians recognize that a multidisciplinary

approach is needed, and confirm the important role nurses and pharmacists would play in an ADR detecting, reporting, and management system.

### **Conclusions**

Three lines of action are recommended, based on the study findings:

1. The MoPH should set up a Medicines Safety Advisory Committee, made up of different stakeholders, to explore medicines safety activities appropriate to Afghanistan. These activities would be implemented at the national level, and based on the World Health Organization (WHO) minimal requirements.
2. Through the hospital drug and therapeutics committees (DTCs), define and implement medicines safety activities tailored to the need and capacity of each hospital. Stepwise early implementation and documentation of successes and failures should help define a national strategy for medicines safety at the hospital level.
3. SPS to assist the MoPH to set up linkages with international and regional institutions that can serve as resources to promote capacity building in medicines safety and pharmacovigilance for the Advisory Committee, hospital DTCs, and other stakeholders.

## **1. BACKGROUND**

A pharmacovigilance system aims at protecting patients through the efficient and timely identification, reporting, and assessment of ADRs. The WHO defines an ADR as “any response to a drug which is noxious and unintended, and which occurs at doses normally used in human for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.” In other words, an ADR is harm directly caused by the medicine at normal doses, during normal use.

Poor quality medicines, medication errors, and adverse drug reactions are part of the concept of medicines safety and have an enormous impact on health. Not only do these problems increase morbidity and mortality, but also they contribute to higher health care costs and patients’ mistrust in the health system.

A comprehensive pharmacovigilance system should include all entities and resources that protect the public from medicines-related harm, whether in personal health care or public health services. Pharmacovigilance programs should ideally monitor events that may be related to product quality, medication errors, and ADRs. A key component to the system is to monitor events and to use this information to prevent further adverse events at the health facility level.

As part of its long-term vision to develop and maintain a “comprehensive pharmacovigilance system,” the MoPH, with support from SPS, aims to implement patient safety monitoring programs at the hospital level to gain local experience while informing the development of national policy. Article 35 of the Medicines Law specifies that the GDPA’s Avicenna

Pharmaceutical Institute shall collect ADR reports, investigate reported occurrences, and publish the results of its investigation.

The Health and Nutrition Strategy 2009-2013 (HNS) of the MoPH clearly indicates that medicines safety initiatives at the hospital level are an important part of improving patient safety, and ensuring the accessibility, availability, safety, efficiency, effectiveness, and affordability of medicines. The HNS also indicates the MoPH's intention to enhance its capacity to regulate the pharmaceutical sector through different mechanisms of quality assurance including, but not limited to, strengthening the capacity of quality control labs and broadening pre- and post-market surveillance of medicines.

This assessment of ADR reporting in six hospitals was carried out with the collaboration of General Directorate of Curative Medicine (GDCM), GDPA, and senior staff in the six hospitals. SPS provided technical and financial support. The results of the assessment were intended to inform the development of recommendations and prioritization of key actions.

## **2. GENERAL OBJECTIVE**

The general objective of this assessment was to determine the availability of ADR reporting systems at the hospital level.

## **3. SPECIFIC OBJECTIVES**

Specifically, this exercise sought to:

- Assess the physician's familiarity with and knowledge of ADRs
- Gather the physician's opinion on how to establish an ADR reporting/management system

## **4. METHODOLOGY**

### **4.1 Survey Planning & Implementation**

The ADR reporting and management assessment was planned and carried out by the GDPA with technical and financial assistance from SPS between March and August 2013.

### **4.2 Selection of Interviewees**

In each hospital, 5 physicians were selected according to the inclusion and exclusion criteria listed below. Physicians qualifying according to the criteria were asked to participate in the study and were free to refuse participation.

#### **Inclusion Criteria**

- Physician (preferably chief) of the related ward
- Physicians consulting patients on a daily basis
- Physicians authorized to decide patient treatment/ follow-up

### Exclusion Criteria

- Trainee physicians
- Physicians who are volunteering in the hospital (not included in official organogram of the institution)
- Pharmacists
- Nurses
- Midwives

## 5. DATA COLLECTION TOOLS & TECHNIQUES

The two data collection tools included in the assessment were:

- **A basic information sheet (annex 1)** to gathering general information about the capacity of the hospital (number of wards), authorized key decision-makers (director or leader), and the existence of a recording system for ADRs (annex 1).
- **A structured questionnaire (annex 2)** for interviews with the individual physicians asking about:
  - Previous ADRs encountered, and management of those ADRs
  - General physician knowledge on ADRs and ADRs reporting in the hospital
  - Each physician's opinion on how to promote ADR reporting in their hospital

Data were collected mainly by a physician and pharmacist, who were each trained in the correct application of the two data collection tools. Both tools were pre-tested in a national hospital that

had not been selected for the assessment. Based on the pre-test findings, the data collection tools were revised, translated into the local languages, and back-translated into English for quality assurance by a third party.

The interviews were conducted in Dari or Pashtu as appropriate for the interviewee. The completed data collection tools were then translated into English for entry and analysis. The data were reviewed for consistency and accuracy by the local team of surveyors.

## **6. DATA ANALYSIS PLAN**

Two preformatted Excel sheets were used to enter the data. Data analysis consisted of calculating straightforward frequencies, and cross tabulating answers to similar questions.

## **7. ASSESSMENT DESIGN & SITE SELECTION**

Six hospitals in Kabul city were selected based on several criteria: the implementing stakeholder (MoPH and Ministry of Higher Education, or MoHE), and hospital capacity (including number of beds, number of wards, and number of medical staff).

Table 1. List of hospitals included in assessment

| <b>Hospital name</b>                                   | <b>Implementing agency</b>                         | <b># of beds</b> | <b># of wards</b> | <b># of medical staff</b> |
|--|--|------------------|-------------------|---------------------------|
| <b>Khairkhana 102 bed Hospital</b>                     | <b>GDCM</b>  | <b>100</b>       | <b>8</b>          | <b>97</b>                 |
| <b>Istiqlal</b>  | <b>GDCM</b>  | <b>400</b>       | <b>9</b>          | <b>310</b>                |
| <b>Indira Gandhi Institute of Child Health (IGICH)</b> | <b>GDCM</b>  | <b>250</b>       | <b>7</b>          | <b>342</b>                |
| <b>Malalai</b>   | <b>GDCM</b>  | <b>200</b>       | <b>6</b>          | <b>284</b>                |
| <b>Dasht Barchi 50 bed hospital</b>                    | <b>Provincial Public Health Directorate (PPHD)</b> | <b>50</b>        | <b>6</b>          | <b>21</b>                 |
| <b>Ali Abad</b>  | <b>MoHE/Kabul Medical University (KMU)</b>         | <b>200</b>       | <b>9</b>          | <b>198</b>                |

At least five physicians from each selected were interviewed, amounting to a total of 30 physicians interviewed for the assessment. Physicians were selected based on their work experience, level of decision-making with regard to patient treatment and follow-up, and their interest in participation (section 4.2).

## **8. RESULTS**

### **8.1 Description of Study Group Characteristics**

The interviewed physicians were experts in the following specialties: gynecology (7); pediatrics (7); general surgery (4); internal medicine (4); ear, nose, and throat (ENT) (2); anesthesiology (2); plastic surgery (2); urology (1); and neurosurgery (1). The average work experience of physicians was 16.5 years (the least was five years, and the most was 30 years).

Table 2 details the numbers of medical and paramedical staff in each hospital. The average of number of beds per nurse was three to one (ranging from 1.5 beds per nurse in IGICH and Khairkhana hospitals, to five beds per nurse in Dasht-Barchi and Malalai hospitals).

**Table 2. Sample characteristics of participating hospitals**

|                           | <b>Ali<br/>Abad</b> | <b>Dasht-<br/>Barchi</b> | <b>IGICH</b> | <b>Istiqlal</b> | <b>Khair<br/>khana</b> | <b>Malalai</b> | <b>Total</b> |
|---------------------------|---------------------|--------------------------|--------------|-----------------|------------------------|----------------|--------------|
| <b>Beds</b>               | <b>250</b>          | <b>50</b>                | <b>250</b>   | <b>400</b>      | <b>100</b>             | <b>200</b>     | <b>1,250</b> |
| <b>Physicians</b>         | <b>120</b>          | <b>10</b>                | <b>165</b>   | <b>142</b>      | <b>50</b>              | <b>134</b>     | <b>621</b>   |
| <b>Pharmacists</b>        | <b>8</b>            | <b>1</b>                 | <b>12</b>    | <b>8</b>        | <b>4</b>               | <b>7</b>       | <b>40</b>    |
| <b>Midwives</b>           | <b>0</b>            | <b>0</b>                 | <b>0</b>     | <b>40</b>       | <b>0</b>               | <b>100</b>     | <b>140</b>   |
| <b>Nurses</b>             | <b>70</b>           | <b>10</b>                | <b>165</b>   | <b>120</b>      | <b>43</b>              | <b>43</b>      | <b>451</b>   |
| <b>Beds per<br/>Nurse</b> | <b>4:1</b>          | <b>5:1</b>               | <b>1.5:1</b> | <b>3:1</b>      | <b>1.5:1</b>           | <b>5:1</b>     | <b>3:1</b>   |

The number of patients seen by the physicians during eight working hours per day varied from seven to 250. On average, a physician consults 72 patients daily and prescribes medicine to 61 of them.

## 8.2 Adverse Drug Reactions Reported

Seven physicians reported the availability of an adverse drug reaction recording system in the hospital. However, direct observation of all documents used for patient registration and recordkeeping in the six studied hospitals showed that there was no format or column in registration forms to record ADR cases among the admitted patients.

Of 30 physicians interviewed, 20 (67 percent) reported having encountered ADR, and 10 physicians (23 percent) reported that they had not faced such an event. Whether a physician had (or had not) encountered an ADR did not correlate to the physician's years of experience.

Table 3. Type and number of ADRs, by participating hospital

|                                    | Ali Abad | Dasht-Barchi | IGICH | Istiqlal | Khair khana | Malali | T  |
|------------------------------------|----------|--------------|-------|----------|-------------|--------|----|
| Respondents who faced cases of ADR | 2        | 3            | 3     | 3        | 5           | 4      | 20 |
| Respiratory problems (ADR)         | 0        | 1            | 0     | 1        | 1           | 1      | 4  |
| Psychosis (ADR)                    | 0        | 0            | 0     | 0        | 0           | 1      | 1  |
| Shock (ADR)                        | 2        | 0            | 1     | 0        | 1           | 0      | 4  |
| Hemiplegia (ADR)                   | 0        | 1            | 0     | 0        | 0           | 0      | 1  |
| Skin Rashes (ADR)                  | 0        | 1            | 2     | 2        | 2           | 2      | 9  |
| Hypotension (ADR)                  | 0        | 0            | 0     | 0        | 1           | 0      | 1  |

Of the 20 physicians who reported facing ADRs, nine (45 percent) reported skin rashes as a drug reaction, four (20 percent) reported shock, another four (20 percent) reported respiratory

problems, and one (5 percent) reported each hypotension, psychosis, and hemiplegia (figure 1).

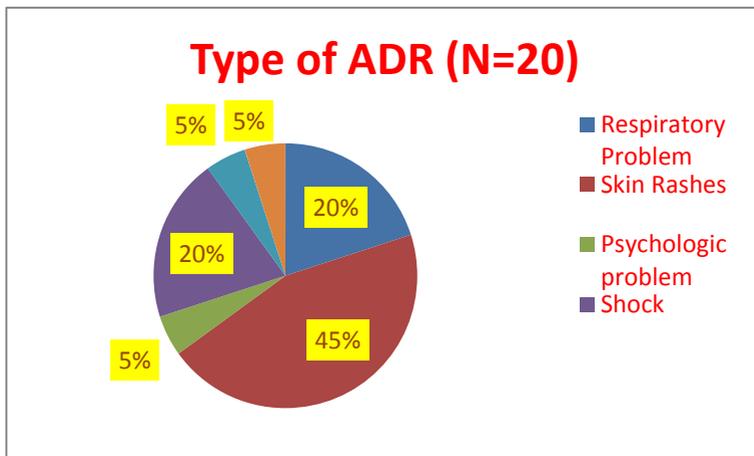


Figure 1. ADR types experienced by physicians

Only five physicians confirmed they had experienced a serious, life-threatening ADR. As shown in table 4, there are differences between claims to have encountered a life-threatening ADR and the individual instances of reported ADRs that would qualify as a serious, life-threatening ADR. This may reflect a lack of understanding (or an unclear understanding) of what qualifies as a serious, life-threatening ADR.

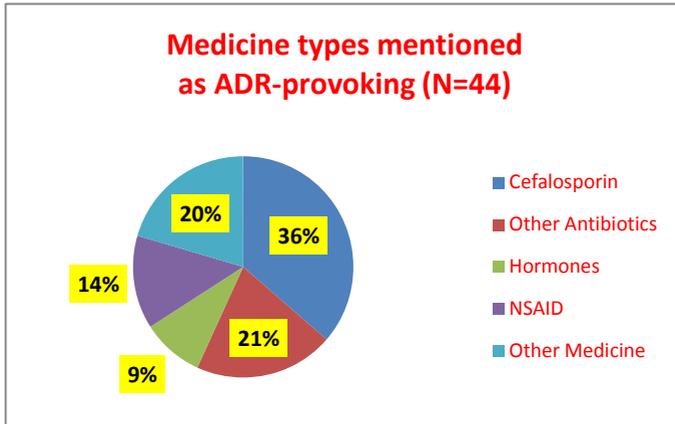
Table 4. Cross tabulation reported symptoms and life-threatening ADR

| Symptoms mentioned      | Reported serious, life-threatening |    |
|-------------------------|------------------------------------|----|
|                         | Yes                                | No |
| Anaphylactic shock      | 5                                  | 0  |
| Hypovolemic shock       | 0                                  | 2  |
| Apnea                   | 0                                  | 1  |
| Dyspnea and tachycardia | 0                                  | 1  |
| Hemiplegia              | 0                                  | 1  |
| Coma                    | 1                                  | 0  |

### 8.3 Clinical Staff Knowledge about Adverse Drug Reactions

When asked what medicine or therapeutic regime was most likely to provoke ADRs, all respondents mentioned at least one medicine, and ten mentioned more than one. In total 40 medicines were mentioned as likely to provoke ADRs. Fifteen physicians mentioned cephalosporin, six mentioned other antibiotics, five mentioned nonsteroidal anti-inflammatory drugs (NSAIDs), three mentioned hormones, and six mentioned some other medicine. Figure 2 shows the relative frequency with which several types of drugs were mentioned.

Figure 2. Types of medicines likely to have induced ADRs



Twelve respondents reported that they did not have access to information regarding ADRs and their management. Of the 18 who reported having access to an information source, seven mentioned a medical textbook, six mentioned a pharmaceutical textbook, and five mentioned the internet.

All 30 interviewed physicians agreed that ADRs cause patient admissions to hospitals, and 23 (77 percent) also believe that an ADR can happen while the patient is admitted in the hospital. Seven (23 percent) denied that an ADR can happen after admission to the hospital.

Table 5 reflects the reported opinion of physicians about their co-worker's knowledge on ADRs. Less than half of interviewed physicians report thinking that their coworkers understand what an ADR is. Only half gave an opinion whether their co-workers can distinguish between side-effects and ADRs, and ten

(37 percent) thought their co-workers would be able to make that distinction.

Table 5. Physicians co-worker's knowledge on ADR

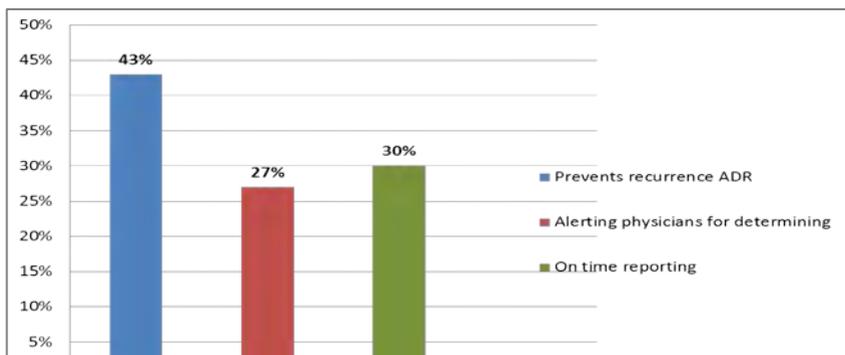
|   | Yes      | No       | Don't Know |
|---|----------|----------|------------|
| Understands what ADR is (N=30)          | 14 (47%) | 13 (43%) | 3 (10%)    |
| Distinguish ADR from side effect (N=30) | 11 (37%) | 5 (17%)  | 14 (46%)   |

#### 8.4 Clinical Staff Opinions about ADR Reporting Systems

Only seven (23 percent) of the interviewed physicians could provide the name of a country that has a reporting system. Four countries in the region, Pakistan, India, United Arab Emirates and Turkey, were each mentioned once. The USA was mentioned once and South Africa twice.

All 30 interviewed physicians agreed that ADR reporting has benefits for the patient. Thirteen (43 percent) mentioned reporting would prevent ADR recurrences, nine (30 percent) think it would promote on-time ADR reporting to related bodies for on-the-spot follow-up of patients, and eight mention that it alerts the physician to provide better care for patients suffering from ADRs.

Figure 3. Advantages of ADR reporting as mentioned by Physicians



All physicians thought that ADR detection, reporting, and management were a professional obligation for the physician.

Table 6 reflects what respondents thought to be critical factors that needed to be present in the hospital before establishing ADR detection and reporting systems.

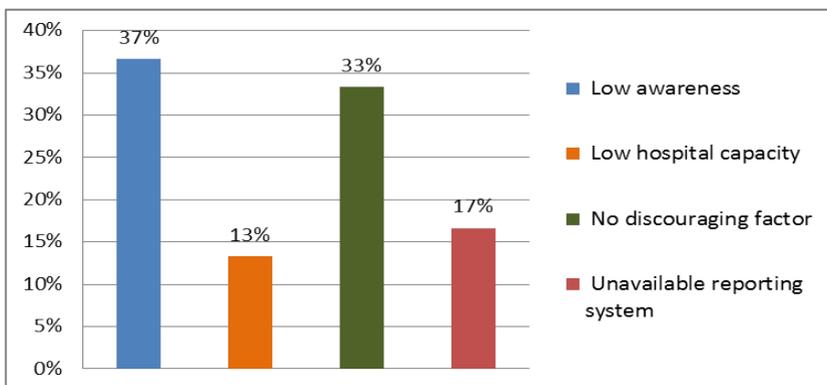
Table 6. Critical factors before establishing a ADR system

| Critical factors before establishing center for ADR      | Percent |
|--|---------|
| On-time and regular reporting                            | 22%     |
| Hospital-based focal points or controlling body          | 22%     |
| Training and awareness of staff for rational prescribing | 18%     |
| Quality control of medicines                             | 11%     |
| Reporting to MoPH  | 10%     |
| Feedback   | 10%     |
| Other factors  | 8%      |

When asked about the preferred nature of a hospital ADR reporting system, 21 of the interviewees reported preferring a compulsory system because it would increase the sense of responsibility of the staff, and promote better reporting. But nine physicians would prefer voluntary reporting, for the same reasons.

When asked about challenges and obstacles on reporting ADRs in their hospital, not one physician mentioned any. When asked what factors would discourage them from detecting and reporting ADRs, 9 (30 percent) physicians answered that there were no discouraging factors, 8 (27 percent) reported one factor, and 13 (43 percent) mentioned more than one factor. Eleven (37 percent) physicians cited the low awareness and capacity of health staff regarding ADR recording and reporting; five (17 percent) mentioned unavailability of a reporting system and formats; and four (13 percent) mentioned low hospital capacity in terms of the number of health staff, office space, and extra time to be found for report development and reporting.

**Figure 4. Challenges in ADR reporting at hospital level**

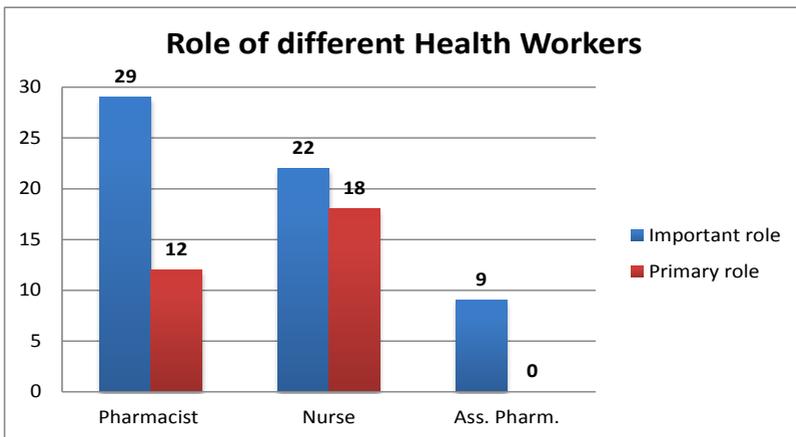


Twenty-six of the physicians reported that they were not aware of any MoPH policy regarding ADR reporting on monitoring.

When asked what health personnel would be useful in the detection, reporting, and management of ADRs, 29 physicians confirmed that pharmacists are useful, 22 mentioned nurses, and nine mentioned pharmacy assistants. It should be noted that no other type of health worker was prompted in the question.

When asked whose role was most important, 18 mentioned nurses, and 12 mentioned pharmacists, none mentioned the pharmacy assistance. It should be noted that the questionnaire left no room for other staff to be mentioned.

Figure 5. Perception of physicians on the role of health personnel in ADR detection, reporting and management



Twenty-six of the interviewed physicians reported that they provide information to their patients on ADRs.

## 9. CONCLUSION & DISCUSSION

The study has some important limitations that need to be kept in mind when interpreting the results. Firstly, that which is called “ADR” by physicians, in fact should be considered as “suspected ADR.” The study showed a lack of adequate recording and reporting tools for ADR, and hence data collectors were unable to verify whether the reported ADRs were confirmed as ADRs after an investigation. Secondly, the information in the study is only as reliable as the data sources, and data collection method and tools. Most interviewee statements could not be verified through record review and none could be verified through direct observation. Unfortunately, the one statement that was verified (availability of a ADR reporting system in the hospital) seemed incorrect: where physicians claimed that reporting system was in place, none of the inspected record or reports contained a dedicated space for ADR reporting. Nevertheless, the informants were all seasoned clinicians with ample experience in the hospital where they were interviewed.

One set of questions aimed at assessing the respondent’s familiarity with and knowledge about ADRs. Two-thirds of the interviewed physicians reported a previous encounter with an ADR. All the symptoms described by the respondents could indeed match an ADR. This was also true for the symptoms described for five reported serious, life-threatening ADRs. However, five physicians that described possible life-threatening symptoms of the encountered ADR failed to confirm that they had encountered a serious, life-threatening ADR. This may indicate uncertainty on how to classify ADRs.

The reported treatment of the suspected ADRs was adequate for the symptoms described.

All physicians were able to name at least one medicine that is known to provoke ADRs, and all mentioned ADRs are a cause of hospitalization of patients. One-fourth of those interviewed think ADRs cannot take place once a patient is hospitalized, while hospitalization in itself will not prevent ADRs from happening. More than one-third of interviewees reported having no access to information on ADRs and their management, and only five mentioned using the internet as source of information on ADRs.

Almost half of the respondents think their colleagues know what ADRs are, but only one-third think their colleagues would be able to recognize the difference between an ADR and a side-effect. Half of the respondents claimed not to know whether their colleagues would be able to make that distinction.

Less than one-fourth of the respondents mentioned the name of a country having an ADR reporting system, and 80 percent reported that they were not aware of any Afghanistan MoPH policy related to ADR reporting and monitoring.

The above findings indicate that although interviewed clinicians are generally familiar with ADRs and their treatment, the actual knowledge about what ADRs are, and where to get accurate information about ADRs and ADR management could be improved.

All interviewed physicians agreed that ADR reporting and monitoring at the hospital level can benefit patients, and all agreed that ADR detection, reporting, and management is a professional obligation for a physician.

None reported challenges or obstacles for reporting ADR in their hospital, and when asked for factors that would discourage them from detecting and reporting ADR, one-third maintained that

there were none. The most frequently mentioned discouraging factor was the low awareness and knowledge about ADR by other hospital staff, the unavailability of an established system, and several factors related to the management of the hospital that would interfere negatively with a ADR reporting system.

The majority of the physicians are of the opinion that a compulsory ADR reporting system is preferable, nine of those interviewed think a voluntary system is preferable. Both think their preferred system would increase the sense of responsibility of the individual staff and promote better reporting.

The study explicitly asked whether pharmacists, assistance pharmacists, and nurses were useful for the detection, reporting, and management of ADRs. All but one respondent thought pharmacists were useful, two-thirds thought nurses were useful, and one-third thought assistant pharmacists were useful. When further asked which of the three has the most-important role, 18 listed nurses as most important, 12 listed pharmacists, and none listed assistant pharmacists. It should be noted that there was no room in the questionnaire for reporting any other health worker types. Given that all respondents saw ADR reporting and management as a professional obligation, they would most likely have put “MD” as most important, had there been an option to do so.

In conclusion, the study indicates that—

- Physicians in the hospitals are knowledgeable about the existence of ADRs and ADR management in general terms, but could profit from access to more accurate information.

- Physicians indicate that the lack of ADR awareness and knowledge on the part of their co-workers is an important factor interfering with adequate detection and reporting.
- Physicians see the lack of well-designed systems at local hospital and national levels as negatively interfering with adequate detection and reporting of ADRs.
- Physicians see that setting up an ADR detection, reporting, and management system in their hospital can benefit patients; they also indicate that it is an obligation for physicians to participate.
- Physicians recognize that ADR detection, reporting, and management needs a multidisciplinary approach, and (excluding physicians from the list) indicate nurses as having the most important role, closely followed by pharmacists.

## 10. RECOMMENDATIONS

The previously mentioned conclusions leave room for three recommended areas of intervention that would enable the MoPH to better ensure improved detection, reporting, and management of ADRs in Afghanistan.

1. The MoPH should set up a Medicines Safety Advisory Committee, made up of different stakeholders, to explore medicines safety activities appropriate to Afghanistan. These activities would be implemented at the national level, and based on the WHO minimal requirements.
2. Through the hospital DTCs, define and implement medicines safety activities tailored to the need and capacity of each hospital. Stepwise early implementation and documentation of successes and failures should help define a national strategy for medicines safety at the hospital level.
3. SPS to assist the MoPH to set up linkages with international and regional institutions that can serve as resources to promote capacity building in medicines safety and pharmacovigilance for the Advisory Committee, hospital DTCs, and other stakeholders.

**ANNEX I. SITUATIONAL ASSESSMENT TOOLS FOR DATA  
COLLECTION AT HOSPITAL LEVEL FOR MEDICINES SAFETY**

**1. Question :** Basic information of hospital

|  |  |
|--|--|
| <b>Name of Hospital</b>                        |  |
| <b>Address/location</b>                        |  |
| <b>Size of hospital (total number of beds)</b> |  |
| <b>Number of full-time physicians</b>          |  |
| <b>Number of full-time nurses</b>              |  |
| <b>Number of full-time pharmacists</b>         |  |

**2. Question :** How many in-patient and out-patient wards exist in the hospital? List all the names of the wards in the table provided below

**In-patient wards**

| <b>Male</b> | <b>Female</b> | <b>Children</b> |
|-------------|---------------|-----------------|
|             |               |                 |
|             |               |                 |
|             |               |                 |
|             |               |                 |
|             |               |                 |
|             |               |                 |

**Out-patient wards**

- 1. General surgery -----
- 2. Plastic surgery -----
- 3. Orthopaedic -----
- 4. Internal Medicine -----
- 5. Gynaecology -----
- 6. Obstetrician -----
- 7. Paediatric -----
- 8. ENT -----
- 9. Dental -----
- 10. Psychology -----
- 11. Eye care -----
- 12. Nursery -----
- 13. Communicable disease -----
- 14. TB -----
- 15. Nutrition -----
- 16. Others ( specify) -----

**3. Question :** List the names and positions of the senior directors and leaders (e.g. CEO, Director, Medical Director) of the hospital in the table below. These are individuals who make key decisions regarding health services in the hospital. These also include senior administrators who make decisions on budget, policies, staffing, etc.

**Senior directors/Leaders:**

| Name | Position | Phone number | Email address (if available) |
|------|----------|--------------|------------------------------|
|      |          |              |                              |
|      |          |              |                              |
|      |          |              |                              |
|      |          |              |                              |
|      |          |              |                              |

**4. Question :** List names and position of at least 5 senior/junior physicians of this hospital, involved in the daily provision of health services. (E.g. chief of wards, experienced physicians, hospital opinion leaders; these are physicians who see patients on a daily basis). The top five priority individuals will be the ones with whom individual interviews should be conducted.

| No. | Name | Position | Years of Experience | Phone Number |
|-----|------|----------|---------------------|--------------|
| 1   |      |          |                     |              |
| 2   |      |          |                     |              |
| 3   |      |          |                     |              |
| 4   |      |          |                     |              |
| 5   |      |          |                     |              |

Review the Patient Treatment Charts/Medication History Charts

- a) Visit at least 3 hospital wards to review patient charts to check for consistency of format in all hospital wards.

Wards Visited (if more than 3, list them here)

1)

2)

3)

- b) Do all three (or more) wards use the same format?

Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, then document your findings to the below question after reviewing just 1 patient treatment chart.

If No, then compare both the treatment charts and note your findings in the space below

- c) Is there a dedicated section or line item entitled “ADRs” to record any observed ADRs?

Yes \_\_\_\_\_ No \_\_\_\_\_

- d) If yes, did the sample treatment chart show any ADR notes observed in the patient? Write down the ADR notes in the space below

---

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- e) If No, do you see space for information to be recorded by the physician regarding clinical notes, patient response to therapy, etc.? (E.g. sometimes, physicians may note ADRs in a separate space in the patient treatment chart). Use the space below to record your analysis of the patient treatment chart-

\_\_\_\_\_

- f) Request a blank copy of the patient chart from the hospital for internal SPS and MoPH review. Please assure the hospital in-charge that this blank patient chart will be kept confidential. If you are unable to get a blank patient chart, and are given an existing patient chart with information, please assure the hospital in-charge that the information will be confidential.

Copy received – Yes \_\_\_\_\_ No \_\_\_\_\_

- If no, explain why you could not obtain a copy of the treatment chart

\_\_\_\_\_  
\_\_\_\_\_

- What follow up-action will you take to get a copy of the patient treatment chart?

\_\_\_\_\_

- In this hospital, what is this patient treatment chart called? (e.g. patient register)

\_\_\_\_\_

**ANNEX II. QUESTIONS FOR INDIVIDUAL PHYSICIANS AT  
HOSPITAL LEVEL**

Dear Doctor,

Thank you for giving us your time to share your knowledge and experience regarding Adverse Drug Reactions encountered during your clinical practice. Both the Ministry of Public Health and the Hospital Medical Director has given us permission to meet with selected Kabul city hospital doctors. You were recommended by your Medical Director to be interviewed because of your daily clinical practice with various patients in the hospitals. We are in the process of interviewing several physicians to capture their knowledge and experience regarding ADRs.

All responses that you will share, will be used only for technical activity design and planning purposes. No doctor names will be used during analysis of responses.

If you have any questions regarding this interview, please let me know. Otherwise, may I continue?

START INTERVIEW:

Name of the physician: \_\_\_\_\_

Hospital: \_\_\_\_\_

Hospital Work Timings:

- i. Day shift (8 AM- 4 PM) \_\_\_\_\_
- ii. Night shift ( 4 PM- 8 AM) \_\_\_\_\_
- iii. Other ( specify the duration) \_\_\_\_\_

Phone number: \_\_\_\_\_

Email address: \_\_\_\_\_

**Section I - Basic Questions**

**1. Question** : What is your medical specialization? \_\_\_\_\_

**2. Question** On average, how many patients do you see

- i. Per day: \_\_\_\_\_
- ii. Per week: \_\_\_\_\_

**3. Question** : On average, how many prescriptions do you write

- i. Per day? \_\_\_\_\_
- ii. Per week? \_\_\_\_\_

Note – if the physician provides additional information, record them in your interview notes.

## **Section II - Individual Physician knowledge & experience with ADR**

Thank you. Before I proceed to ask you more questions, please allow me to read out the WHO definition of Adverse Drug Reaction (ADR) and Side Effect.

Adverse drug reaction (ADR)—The World Health Organization defines an ADR as “any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.” In other words, an ADR is harm directly caused by the medicine at normal doses, during normal use. An unexpected ADR refers to a reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or is unexpected from characteristics of the medicine.

Side Effect—any unintended effect of a pharmaceutical product occurring at doses normally used in humans which is related to the pharmacological properties of the medicine. Such effect may be either positive or negative. Such effects may be well-known and even expected and may require little or no change in patient management.

**4. Question** : In your clinical practice, did you ever detect an adverse drug reaction (ADR) in your patients? (note – if physician misunderstands this question, repeat/explain definition of ADR and clarify that you are not asking about side effects)

Yes \_\_\_\_\_ No \_\_\_\_\_

**5. Question** : If yes, then what was the ADR and how did you manage the ADR?

i. ADR type:

\_\_\_\_\_

ii. Management of ADR:

\_\_\_\_\_

**6. Question** Did you record the ADR in the patient treatment history/medication chart?

Yes \_\_\_\_\_ No \_\_\_\_\_

**7. Question** Did you ever come across a serious, life-threatening ADR in a patient?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes,

i. Please describe the serious, life-threatening ADR

\_\_\_\_\_

ii. How did you manage this severe ADR?

\_\_\_\_\_

**8. Question :** In your experience, what are the most common medicines or therapeutic regimens that induce or cause ADRs?

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**9. Question :** Do you have access to medical information sources to update your knowledge on ADRs and their management? (note – if the answer is “text-books” – ask to name them; if the answer is “internet” ask them to specify name of internet websites)

Yes \_\_\_\_\_ No \_\_\_\_\_

Name at least one source of information.

---

**10. Question:** In your opinion, are ADRs the cause of patient’s hospital admission?

Yes \_\_\_\_\_ No \_\_\_\_\_

**11. Question:** Do ADRs occur after the patient has been admitted to the hospital?

Yes \_\_\_\_\_ No \_\_\_\_\_

**12. Question:** Do you know of any examples from other countries regarding how ADRs are detected, reported, managed and communicated?

If know, name of the country \_\_\_\_\_

Don’t know: \_\_\_\_\_

**Section III - Perception of wanting an ADR system/awareness of policies**

**13. Question:** Is there any understanding of the ADR concept among the health professionals in your hospital?

- i. Yes -----
- ii. No -----
- iii. Don't know -----

**14. Question:** Can the health professional distinguish ADR from side effects of the drugs?

Yes \_\_\_\_\_ No \_\_\_\_\_ Don't know \_\_\_\_\_

**15. Question:** Do you think an ADR reporting and monitoring system in your hospital would benefit the patient?

Yes \_\_\_\_\_ No \_\_\_\_\_ Don't know \_\_\_\_\_

a. If yes, how might it be working?

\_\_\_\_\_

b. If no, what are the challenges and obstacles on reporting of ADRs in your hospital?

\_\_\_\_\_

**16. Question:** Is ADR detection, reporting and management a professional obligation of the physician? Why or why not?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, why:

\_\_\_\_\_

If no, why:

---

**17. Question:** What are the top 3 critical success factors that must be in the hospital before we establish the ADR detection and reporting system? (Note – explain question to physician. What is the enabling environment that is needed? If the physician lists many factors, prioritize/rank them for top 3 factors)

- i. –
- ii. –
- iii. –

**18. Question:** If an ADR monitoring and reporting system were established in your hospital, should the system be voluntary or compulsory?

- i. Reason for voluntary

---

---

- ii. Reason for compulsory

---

---

**19. Question:** Are you aware of any national policy by the Afghanistan Ministry of Public Health (MOPH) regarding ADR reporting and monitoring system? (Note – if the answer is “no” –

then briefly explain the MOPH's Hospital Policy on patient safety, ADR reporting/analysis, etc.)

Yes \_\_\_\_\_ No \_\_\_\_\_

**20. Question:** Is the below mentioned health personal are useful in detection, reporting and management of ADR?

- Pharmacist

Yes \_\_\_\_\_ No \_\_\_\_\_

- Pharmacist assistance

Yes \_\_\_\_\_ No \_\_\_\_\_

- Nurses

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, whose role is more important?

i. Pharmacist -----

ii. Pharmacist assistant -----

iii. Nurse -----

iv. Other (specify) -----

**21. Question:** What are the factors that would discourage you from detecting and reporting an ADR?

\_\_\_\_\_

**22. Question:** Do you educate your patients on ADR occurring during their treatment?

Yes \_\_\_\_\_ No \_\_\_\_\_

**23. Question** Does your patient report the drug effects to you when they are exposed?

Yes \_\_\_\_\_ No \_\_\_\_\_

**24. Question** Do you explain the reporting of drug effects to your patients

Yes \_\_\_\_\_ No \_\_\_\_\_

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### **About SPS**

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

