

Awareness and Attitudes of Healthcare Professionals in Baguio-Benguet towards Adverse Drug Reaction Reporting: A Cross-sectional Study

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Abstract

Background: The issue of drug related harm is currently one of the most important public health problem all over the world. Healthcare professionals play a major role in the reporting of suspected adverse drug reactions (ADRs).**Objective**: To determine the awareness and attitudes of healthcare professionals towards ADRs reporting in Baguio and Benguet. The study also sought to determine the barriers experienced and factors encouraging ADRs reporting. **Method:** Cross sectional study design was used and a self-administered questionnaire was designed and randomly circulated to 242 physicians, nurses and pharmacists.**Results**: Healthcare Professionals in Baguio and Benguet had only an "average" awareness (54%) regarding ADRs reporting. Female healthcare professionals, those with more years of experience, physicians and those who had information about pharmacovigilance had significantly higher level of awareness (p-value $\leq$0.001). The healthcare professionals had an overall favorable attitude towards ADRs reporting (mean = 1.56). The strongest barriers to ADRs reporting were lack of knowledge on where to address the ADRs reports (mean=3.35) and the reporting forms being too complicated to fill in (mean = 3.26). The most important factors encouraging ADRs reporting were the feeling that it was an obligation to do so (mean=1.53) and that the reaction is of a serious nature (mean = 1.67). **Conclusion**: Healthcare professionals in Baguio and Benguet are generally familiar with the basic concepts of ADRs reporting and view ADRs reporting as beneficial. However, there are certain constraints leading to under-reporting. ADRs reporting may be further enhanced through appropriate educational campaign. Further studies are warranted using a larger sample size and including patients as respondents.

Keywords: Adverse drug reactions (ADRs) reporting, Nurses, Pharmacovigilance, Physicians, and Pharmacists.

Introduction

The issue of drug-related harm is currently one of the most important public health problems all over the world (Ahmet A. & Sule O, 2007). Pharmacovigilance studies the long term and short term adverse drug reaction or simply stated the side effects of medicines (Joban Modha, 2010). When a pharmaceutical drug is introduced in the market there are still a lot of things that are unknown about the safety of the new drugs. These medicines are used by various patients for different diseases. These people might be using several other drugs and must be following different traditions and diets which may adversely affect the impact of medicine in them. Also the different brands of same medicine might differ in the manner of their production and ingredients. Additionally, adverse drug reactions might also occur when drugs are taken along with traditional and herbal medicines that have also to be monitored through adverse drug reaction reporting (WHO 2002)

In some cases, adverse drug reactions (ADRs) of certain medicines might occur only in one country's or region's citizens. To prevent all undue physical, mental and financial suffering by patients, pharmacovigilance proves to be an important monitoring system for the safety of medicines in a country with the support of doctors, pharmacists, nurses and other health professionals of the country. ADRs are global problems of major concern. They affect both children and adults with varying magnitudes, causing both morbidity and mortality (Beijer 2002). In addition to the human costs, ADRs have a major impact on public health by imposing a considerable economic burden on the society and the already-stretched health-care systems (Classen DC, 1997). There is no such thing as a safe drug, but there are ways to make the drug safer whether it is the medicinal product itself or the manner by which such drug is used.

Reports of suspected ADRs are the basis of post marketing surveillance of drugs and like most other

developing countries, the Philippines also suffers from lack of adequate drug information due to limited availability of current literature as well as poor documentation and dissemination of the little available information (Hartigan-Go K. 2002). It has also been observed that the culture of safety is often overlooked and disasters are recurrent. Irrational use of drugs is also very much in evidence, some examples including: polypharmacy, use of expired drugs, irrational combination drugs, and common overuse of antibiotics, vitamins / herbal remedies, brand prescribing, retail shops prescribing and unethical dispensing. Such irrational practices, combined with lack of patient information on proper handling and use of drugs can lead to pharmaceutical wastage as well as other serious consequences like ADRs and drug interactions. In addition, there are other factors further complicating appropriate use of drugs in Philippines like remote rural population, few hospitals, poverty , illiteracy, high demand for drugs not consistent with rational use in rural areas and no sense of risk in taking drugs (Hartigan-Go K. 1998).

Healthcare professionals are nowadays striving towards patient centeredness; therefore, this study aims to determine the awareness and attitudes of healthcare professionals in Baguio-Benguet towards ADRs reporting. It also assessed the barriers experienced and factors encouraging ADRs reporting.

Materials and Methods

A cross sectional study design was used to assess the awareness and attitudes of healthcare professionals in Baguio and Benguet towards ADRs reporting. The study design was used to gather information of the population at a single point in time. Meaning to say, the research took a 'slice' of its target group and based its' overall finding on the views or behaviors of those targeted, assuming them to be typical of the whole group.

The population of the study consisted of registered/licensed physicians, pharmacists and Nurses practicing in Baguio and Benguet. The respondents of the study were chosen from the population through convenience sampling method.

A questionnaire was prepared to investigate their awareness and attitude regarding ADR reporting. The questionnaire was adopted from other researches then revised and constructed based on a careful review of available literature, interviews, and discussions to suit the Philippine setup and main outcomes being measured; the items regarding awareness towards ADRs reporting was answered as "Yes", "No" or "I don't know". Attitudes towards ADR reporting, barriers to ADR reporting, and factors encouraging healthcare professions to report an ADRs were assessed with respondents indicating their responses on a 4-point likert scale as to: strongly agree, agree, disagree and strongly disagree. (Table 1)

The questionnaire items were subjected to content validity by the judgments of three competent experts and the tool scored 4.26 which was regarded as "highly valid". The researcher then floated the structured questionnaire for reliability to volunteer nurses from Benguet General Hospital and results showed that the instrument was very reliable with a Cronbach's Coefficient Alpha (α) of 0.89. Collected data was analyzed using Microsoft excel. Significance of the obtained value was set at the probability level of 0.05. Other statistics used were frequency counts, percentage, weighted mean, t-test and analysis of variance (ANOVA). The researcher utilized percentage to determine level of awareness and weighted mean to determine the attitudes, barriers and factors encouraging ADRs reporting. To determine whether there were significant difference in the level of awareness and attitudes according to gender and information about pharmacovigilance, t-test was used. For years of experience and profession, ANOVA was used.

Analysis of Results

Demographics

Table 2 presents the demographic data; a total of 242 healthcare professionals completed the questionnaire. Most of them (69%) were female. When grouped according to years of experience, most of the healthcare professionals have worked for more than five years (33%) and the majority of the respondents in the study were nurses (42%). On the information about Pharmacovigilance, around 57% of the healthcare professionals accepted to have information about pharmacovigilance and their sources being dominated by seminar/conferences, magazines and books.

Awareness

Table 3 presents the level of awareness of healthcare professionals regarding ADRs reporting. They had an overall awareness towards ADRs reporting of 54% and interpreted as "average awareness". They were most aware (97%) that the implemented ADR reporting and monitoring system benefits the patient. The survey results also revealed that, the responders were least aware of the existence of ADR reporting and monitoring system in Baguio (28%) and admit no feedback to reported ADR (23%).

Attitudes towards ADRs reporting

Table 4 presents the attitudes of healthcare professional towards ADRs reporting. The respondents had a favorable attitude towards ADRs reporting with an overall mean of 1.56. Most agreed that; An ADR should be

reported when it results in a death of the patient or life threatening situation, ADRs reporting brings more knowledge and information, and that ADRs reporting was an indication of taking patients' complaints seriously. However, for a lesser extent they agreed that ADR reporting should be made compulsory and agreed to have it voluntary.

Barriers to ADRs reporting

Table 5 shows the barriers affecting healthcare professionals' willingness to report ADR. Most of them agreed that underreporting could be due to lack of knowledge on where to address the ADR reports, the reporting forms being too complicated to fill in and that it is time consuming. Having insufficient clinical knowledge makes it difficult for them to decide whether or not an ADR has occurred was also seen to affect ADRs reporting and that they were not motivated to reporting ADR.

Factors encouraging Reporting

Table 6 presents the factors influencing healthcare professionals to ADRs reporting. Items strongly agreed to encouraging ADRs reporting included; serious, with a majority needed to be convinced of the causality between the drug and ADRs. Others factors agreed were unusual reactions and reactions related to new products. Attention drawn from publication was disagreed as a factor encouraging them to report ADRs

Significant Difference

Gender. Table 7 showed that there existed a significant difference between males and females in their awareness about ADRs reporting, the results showed that female healthcare professionals were more familiar to ADRs reporting than the males.

Years of Experience. There was a significant difference in the awareness of ADRs reporting among the healthcare professional with the awareness increasing as the years of work experience increases. Post-Hoc results showed that those who had practiced for more than five years were more familiar ADRs reporting than those who had been in practice for less than a year.

Profession. It was also noted that there existed a significant difference between Physicians and Nurses in their awareness; the results showed that physicians were more familiar to ADRs reporting than Nurses.

Information about Pharmacovigilance. There existed a significance difference in their awareness of ADRs reporting with those having information about pharmacovigilance were more familiar than those who never had information on pharmacovigilance.

However, the results showed that there was no significant difference in the attitudes with regards to ADRs reporting, as well with the barriers and factors encouraging ADRs reporting. Thus, their attitudes were not affected by gender, years of experience, Profession or whether one had information about pharmacovigilance

Discussion

This study showed that healthcare professionals in Baguio and Benguet had an average awareness and favorable attitudes towards ADRs reporting. The reason why they only had an average awareness was probably due to lack of emphasis, commitment and interest in the matter. It can be viewed that healthcare professionals are taught how to identify ADRs but not how to report them. Hence, there is a need to improve the curriculum that permits in-depth and hands-on training in addition to concepts presented. This could be seen since a significant number of the respondents were not aware of the existence of a national pharmacovigilance center in Baguio. Lack of awareness of where ADRs should be reported would automatically affect reporting, therefore, awareness programs; through publicity, would appear necessary to improve ADR reporting among practitioners in Baguio-Benguet.

This proportion of awareness is rather very low when compared to a similar reporting scheme among Healthcare professionals in the United Kingdom, America, Netherland, Spain, China and India (P. Subish, M Izham & P. Mishra 2008). The differences in awareness as compared to the reporting rates may be attributed to the priority, attention and commitment given to adverse drug reaction reporting by the government of these countries (Jacob and Kazeem 2009). According to WHO, all healthcare providers should report ADRs as part of their professional responsibility, even if they are doubtful about the precise relationship with the given medication. Through this, Healthcare professionals can reduce suffering and save thousands of patients' lives by doing just reporting suspected adverse drug reactions including lack of effect of the medication.

Responses to the attitudinal statements presented in the survey were highly favorable. The health professionals involved in the study strongly felt that it was their professional obligation to report ADRs. This is particularly true as physicians, nurses and pharmacists increasingly collaborate in providing management of medication therapy through the use of primary health care as a part of their professional practices. Since their duty is to prioritize the patient, they go above and beyond the call of duty, sacrificing their personal lives, dealing with the anxiety of families and friends, to care for their patients. This is in response to the central theme of pharmacovigilance, which is the demonstration of safety rather than the identification of risks. The benchmark should then be the medicine's proven safety rather than its proven risks (Lazarou J, 1999).

According to Lee A (2003), Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market. However, under reporting of ADRs is one of the major problems associated with pharmacovigilance programs. The health professionals involved in the study strongly felt that reporting of ADRs takes too much time, complicated to fill, and hence bring the sense that it is too bureaucratic. This might explain why even serious reactions are underreported. This is worrying as the reporting procedure has been simplified as much as possible and the reporting of ADRs is widely regarded as a matter of good medical practice (Eland and Belton, 1999). Problems of motivating reporters, commitment, and fear of recrimination for errors may be some of the factors responsible. The scheme operates on the basis of reporting all ADRs despite uncertainty about a causal relationship. Even in countries like the United Kingdom where adverse drug reaction reporting programs are well established, a high level of under reporting is documented (Rehan HS 2002). Hence, the BMA Board of Science (2006), views that clear information on how and what to report is essential. Improving ADR reporting rates is primarily about improving awareness of the need to report and the reporting methods.

When we compared the factors that may influence reporting by the respondents with those reported by Lopez Gonzalez (2009), the results were similar. This study has shown that, like most countries around the world, a large majority considered that reporting was a professional obligation and were willing to report reactions to newly marketed drugs and serious reactions to established products because they perceived post-marketing surveillance as an important part of pharmacovigilance. The WHO experience with existing adverse drug reaction reporting systems shows the great importance of acknowledging promptly the receipt of every report, and does follow up in due course with a full reply and, where possible, an explanation and reassurance.

However, this study had some limitations; the study findings could not be applied to the wider medical community as the study was restricted to physicians, pharmacist and nurses practicing in hospital setup where already a reporting system exists and not to community set-up like the community pharmacy. The study assessed only awareness and attitudes of healthcare professionals towards ADR reporting and not their knowledge. Therefore this cannot be the only basis for measuring ADRs reporting practices to develop strategies for the system in Philippines,

Conclusion

In conclusion, healthcare professionals in Baguio and Benguet are generally familiar with the basic concepts of ADRs reporting. The perspective of healthcare professionals is that they view ADRs reporting as beneficial. This ADR reporting rate in Baguio-Benguet may be further enhanced through appropriate educational campaigning and overcoming the existing barriers like lack of knowledge on where to address the ADRs reports and lack of information. However, it is possible that there may be unnoticed adverse drug reactions, unless the clinicians are trained to have a high index of suspicion. Seminars/conferences appear to be a significant influence on ADR reporting and should be continued and reinforced in order to improve ADR reporting in the long term. It is believed that education on adverse drug reaction reporting issues and the importance of reporting should be more extensively incorporated in training.

Further studies are encouraged especially to a larger population size and patients can be included to be part of the respondents. In addition, regular communication and proper feedback to reported ADRs to health care workers explaining reporting procedures and criteria may increase reporting rates of serious ADRs, unlabeled ADRs, and ADRs to new drug

Competing interests: The authors declare no conflicting of interest.

Authors' contributions

Suge conceived and developed the idea, spearheaded proposal development, data collection supervision, data management and analysis. He also took lead role in writing up the manuscript. SJK participated in proposal development, data collection supervision and manuscript preparation. JM participated in data analysis, literature review and manuscript writing. WO and ONE participated in developing the project protocol, interpretation of results, overall supervision and manuscript preparation. All authors read and approved the final manuscript.

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Tables and figures

Table 1: Qualitative Interpretation

Legend on Awareness: (Part 1)		**Legend on Attitudes:**		
0 -19%	Very Low Awareness	**Part 2 and 4. Positive (+ve)**	**Interval**	**Part 3. Negative (-ve)**
20% -39%	Low Awareness	Strongly Agree	1.00-1.74	Strongly Disagree
40% - 59%	Average Awareness	Agree	1.75-2.49	Disagree
60% - 79%	High Awareness	Disagree	2.50-3.24	Agree
80% - 100%	Very High Awareness	Strongly Disagree	3.25-4.00	Strongly Agree

Table 2: Profile of Respondents. (n = 242)

Variable	Number	%
Gender		
Female	168	69%
Male	74	31%
Years of Experience		
Less than 1 year	53	22%
1-2 years	59	24%
3-4 years	51	21%
5+ years	79	33%
Profession		
Physicians	62	26%
Nurses	101	42%
Pharmacist	79	33%
Information about Pharmacovigilance		
Yes	137	57%
No	105	43%

Table 3: Awareness of Healthcare Professionals towards ADRs reporting

Awareness of adverse Drug Reactions (ADRs)	% of Aware	Qualitative Interpretation
The existence of ADR reporting and monitoring system benefits the patient or improves the patient care.	97%	Very High Awareness
An ADR is a response to a drug which occurs at doses normally used or tested in human.	71%	High Awareness
The ADRs reporting and monitoring system at work place is functional.	68%	High Awareness
There is a difference between ADRs and side effects	55%	Average Awareness
An adverse drug reaction is considered serious when it may cause death.	52%	Average Awareness
Existence of a monitoring system creates an awareness of ADRs reporting.	46%	Average Awareness
The reporting and monitoring system that exists encourage healthcare professionals to further report ADR.	42%	Average Awareness
Adverse drug reactions (ADRs) reporting and monitoring system (National Pharmacovigilance Centre) exists in Baguio.	28%	Low Awareness
Proper feedback to reported ADRs is received.	23%	Low Awareness
Average	54%	Average Awareness

Table 4: Attitudes of Healthcare Professionals towards ADRs reporting

Attitudes towards ADRs reporting	W.M	Qualitative Interpretation
An ADR should be reported when it results in a death of the patient.	1.34	Strongly Agree
An ADR should be reported in a life threatening situation.	1.41	Strongly Agree
Reporting ADRs is part of the healthcare professionals' obligations.	1.44	Strongly Agree
An ADR should be reported when it results in a persistent disability or incapacity.	1.44	Strongly Agree
Healthcare professionals should be sure on how to report an ADR.	1.49	Strongly Agree
An ADR should be reported when it results in a congenital anomaly.	1.51	Strongly Agree
Through ADR reporting, the Healthcare Professionals gain more knowledge and information.	1.52	Strongly Agree
An ADR should be reported in case of hospitalization.	1.52	Strongly Agree
Consulting other Healthcare Professionals is important before reporting an ADR.	1.55	Strongly Agree
The process of ADR reporting gives patients the assurance that their concerns are taken seriously.	1.59	Strongly Agree
ADRs reporting should be compulsory.	1.77	Agree
ADRs reporting should be voluntary.	2.21	Agree
Average	**1.56**	**Strongly Agree**

Table 5: Barriers experienced by Healthcare Professionals to ADRs reporting

Barriers to ADRs reporting	**W. M**	**Qualitative Interpretation**
Lack of knowledge on where to address the ADR reports.	3.35	Strongly Agree
Reporting form is too complicated to fill in.	3.26	Strongly Agree
Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred.	3.07	Agree
Lack of time to fill in a report or Reporting ADRs is time consuming.	3.02	Agree
No motivation to report.	3.02	Agree
Lack of reporting forms	2.95	Agree
Don't feel the need to report well recognized reactions.	2.64	Agree
Concern that a report will generate extra work.	2.59	Agree
Lack of confidence in handling of the reports.	2.59	Agree
Insufficient knowledge on how to report ADR.	2.50	Agree

Table 6: Factors encouraging Healthcare Professionals to ADRs reporting

Factors affecting healthcare professionals to report an ADR	W.M	Qualitative Interpretation
It is an obligation to do so.	1.53	Strongly Agree
The reaction is of a serious nature.	1.67	Strongly Agree
Certainty that the reaction is a true ADR.	1.73	Strongly Agree
The reaction is to a new product in the market.	1.76	Agree
The reaction is unusual.	1.95	Agree
The reaction is well recognized for a particular agent.	2.10	Agree
Saw colleagues doing so.	2.51	Disagree
Reporting through the Internet made available.	2.55	Disagree
Attention drawn by a publication.	2.57	Disagree

Table 7: Significant Difference in the Awareness of healthcare professionals towards ADRs reporting

Variable	Mean Score	P-Value
Gender		
Female	5.10	< 0.001
Male	4.18	
Years of Experience		
Less than 1 year	4.04	< 0.001
1-2 years	4.93	
3-4 years	4.39	
5+ years	5.54	
Profession		
Medical Doctors	5.56	< 0.001
Nurses	3.97	
Pharmacist	5.25	
Information about Pharmacovigilance		
Yes	5.77	< 0.001
No	3.57