Case Study

Adverse drug reaction reporting among healthcare workers at a Nigerian Tertiary Hospital: a comparative cross-sectional survey of health care professionals

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Background

Adverse drug reactions (ADRs) remain relevant till date, particularly to everyone whose life is touched in any way by medical interventions. The problem associated with everyday use of drugs is considerable and only a small number of these are detected during clinical trials. This study assessed the current practice of healthcare workers regarding ADRs reporting and also identified some of the factors that might be militating against routine practice of this important act in a tertiary health care centre of a developing country.

Methods and materials

A cross sectional survey was conducted among all doctors and nurses in the department of medicine and all the hospital pharmacists of the Lagos State University Teaching Hospital. A total of 129 participants took part in the study between January and April 2010. Participants were asked to complete a self administered questionnaire to assess their current practice and knowledge of ADR reporting.

Results

A total of 150 questionnaires were sent out to the participants, 129 were completed and returned representing 86% response rate. There was a significant difference in the ADR reporting rates among the three categories of health care professionals in the study (p<0.05), with pharmacists being more likely than the other two category of health professionals to report ADR. Forty-eight percent of health care workers in the survey had reported ADR at least once during the period of their practice.

Conclusion

Reporting of ADR to drugs is yet to become a routine practice among the population of health care workers studied. This is largely due to lack of awareness of reporting system within the hospital studied.

Keywords: Adverse Drug Reaction, Healthcare Worker

INTRODUCTION

Adverse drug reactions (ADRs) remain a major cause morbidity and mortality among patients (Pirmohamed et al., 1998). The Institute of Medicine (IOM) reported that more than 1 million preventable adverse events occur each year in the United States and out of this figure 44,000 to 98,000 are fatal (Kohn et al., 2000). The first systematic international efforts to address drug safety issues were initiated in 1961 following the disaster caused by thalidomide use in pregnant women (World health Organisation 1973, 2002). The Sixteenth World Health Assembly (1963) following this tragedy adopted a resolution that reaffirmed the need for early action in regard to rapid dissemination of information on adverse drug reactions. From these beginnings emerged the practice and science of pharmaco-vigilance (World Health Organisation, 2002).
Worldwide physicians are daily faced with problems of adverse drug reactions to the various medications they prescribe for their patients (Pirmohamed et al., 2003; Rieder, 2002) and about 95% of such cases go unreported (Kohn et al., 2000; Fletcher, 1991). Nigeria had also experienced deaths from outbreak of ADRs for which prompt reporting could have prevented the escalation of the reported loss of life. In 1990, following an outbreak of paracetamol poisoning from the contamination of the elixir of the drug in a city in the northern region of the country, 47 deaths were recorded in children who were given the drug (Okuonghae et al., 1992). A similar outbreak happened again in Lagos and some other cities in the southern part of the country in 2008 (Safermedicine).

Reporting of adverse drug reaction is now firmly based on sound scientific principles and it is integral to effective clinical practice (World Health Organisation, 2002). There are several methods of surveillance to detect ADRs in the clinical setting. Voluntary spontaneous reporting systems are commonly used in many countries, but reporting rates have been observed to be low (Suh et al., 2000). Other methods of detecting ADRs include the computer assisted surveillance techniques (Classen et al., 1991; Levy et al., 1999) and the manual chart review (Murf et al., 2003). Manual chart review results in higher rates of detection compared to the other methods, and are considered the gold standard in ADRs detection. The system of reporting ADR in Nigeria is the spontaneous voluntary reporting method. This has been in operation since the early sixties in many Western countries. The surveillance system enables physicians and pharmacists to report suspected ADRs and thus act as a tool to identifying new ADRs and risk factors predisposing to recognized ADRs (Eland et al., 1999).

It is on this premise that this study was carried out to assess the level of adverse drug reaction reporting among health care workers and also to identify what factors might be hindering routine practice of this important act. The study aimed to assess the knowledge of health care worker about the reporting system for adverse drug reactions in our centre, how common they routinely see cases of ADRs, to know how often they report these cases and for those who do not make any report, to know their reasons for not reporting.

**MATERIALS AND METHODS**

A cross sectional survey was conducted among all doctors and nurses working at the department of medicine as well as all pharmacists at the department of pharmacy of the Lagos State University Teaching Hospital (LASUTH). The hospital is a 740 bedded tertiary health centre located in Ikeja, Lagos State, Nigeria. The hospital serves as one of the major referral centre for a population of about 17 million people in the state (Lagos state Government). The study was conducted between January and April 2010. All doctors and nurses at the medicine department of the hospital as well as all the hospital pharmacists who have spent one year or more at the hospital were included in the study. Health workers in the same department who were unwilling or have spent less than a year at the hospital were excluded from the study. A structured, self administered questionnaire was given to all the study participants, the questionnaire was designed to assess their current practices regarding reporting of adverse drug reaction, knowledge of ADR reporting, awareness of the pharmacovigilance unit and its activities within the hospital. The definition of ADR in this study is as defined by the WHO. ADR is defined as a response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function (World health organisation, 1970). The questionnaire also seek information on reasons for not reporting adverse drug reaction among participants who have not made any report in the preceding one year of the survey were also assessed in the questionnaire. Total sampling of all the eligible health workers was employed, giving a sample size of 150.

**Statistics**

Data were entered into a computer data base and analysed using the Statistical Package for Social Sciences (SPSS version 17). Qualitative variables were presented as count and percentages. Associations between qualitative variables data sets are tested using the chi-squared tests, accepting value of P<0.05 as significant.

**RESULTS**

A total of 129 health care workers participated in the survey; this represented 86% of the total one hundred and fifty questionnaires sent out. The 14% (21) that did not respond gave the following reasons for their non-response; seven claimed to have lost the questionnaires, 3 were unwilling to participate in the study while the remaining 11 were unavailable due to vacation leave. Physicians constituted 28% (37) of the respondents, 50% (64) were nurses and 22% (28) were hospital pharmacists.

Forty-eight per cent (62) of the health care practitioners who participated in this survey admitted to have reported adverse drug reactions (ADRs) at least once since qualification to practice their various professions. The detail of the number of health care workers in each professional group who had previously reported ADRs is as shown in table 1. The response rate among pharmacist was 75% for previous reporting of ADRs in the course of their professional life prior to the study, compared to 30% reporting rate among doctors and 47% among the nurses ($\chi^2 = 13.157, p < 0.01$).

Only 2% of the responding doctors claimed that ADR reporting is a routine part of their daily practise while 54% and 41% of nurses and pharmacists respectively
admitted to the same claim of routine reporting of ADRs.

The response rate among doctors as to how commonly they see ADRs in their practice was 43%, it was 39% among pharmacists and 32% among nurses. Detail of the perception of the health care workers on how commonly they see cases of ADRs in their practices is presented in Table 2.

The pattern of reporting ADRs among the different health care professionals showed that 67% of the nurses who had at least once reported ADRs did so by writing in their nurses’ note or by mere verbal reporting to a doctor in the patients’ managing team. They did not use the recommended form for reporting ADRs. Ninety per-cent pharmacists who had at least once reported ADRs did so using the recommended form for reporting. Among the doctors, only 45% of those who had ever made any report used the prescribed form. Details of pattern of reporting ADR among health care workers is presented in Table 3.

Thirty-three per cent of the participants in the study knew about the existence of a unit in the hospital that is responsible for collation and processing of ADRs reports. A quarter of the respondents admitted to ever seeing the recommended national pharmaco-vigilance form in the past.

Among the health care professionals in this study 87% (112) have not reported any ADRs in the last one year of their practice, preceding this study. Reasons for not reporting ADR included not been aware of any reporting system within the hospital (47%), the adverse effect complaint of by patient been already well known (22%) and the process of reporting been too cumbersome (17%). The detail of the reasons for not making any report in the preceding year by the health workers is presented in Table 4.

Table 1: Response to enquiry on previous reporting of ADRs among the different health care professional groups at LASUTH, Ikeja.

<table>
<thead>
<tr>
<th>Profession</th>
<th>Yes (%)</th>
<th>No (%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>11(30%)</td>
<td>26(70%)</td>
<td>37</td>
</tr>
<tr>
<td>Nurses</td>
<td>30(47%)</td>
<td>34(53%)</td>
<td>64</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>21(75%)</td>
<td>7(25%)</td>
<td>28</td>
</tr>
</tbody>
</table>

Total 62 (48%) 67(52%) 129 (100%)

Pearson Chi-Square =13.157, df=2, p<0.01
(There is a significant statistical difference in the rate of previous reporting ADRs among the different health care professional groups)

Table 2: Details of how common adverse drug reaction is seen in the practice of the health care professionals at LASUTH

<table>
<thead>
<tr>
<th>Profession</th>
<th>Common</th>
<th>Not common</th>
<th>Total (n/%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors</td>
<td>16 (43%)</td>
<td>21 (57%)</td>
<td>37 (100%)</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>11 (39%)</td>
<td>17 (51%)</td>
<td>28 (100%)</td>
</tr>
<tr>
<td>Nurses</td>
<td>20 (31%)</td>
<td>44 (69%)</td>
<td>64 (100%)</td>
</tr>
</tbody>
</table>

Total 40 (31%) 68 (69%) 129 (100%)

Pearson Chi-Square=1.582, df=2, p=0.453
(There is no significant statistical difference between the different groups of health care workers in their perception of how common ADRs are seen in their practices)
Table 3: Pattern of reporting of ADR by health care workers at LASUTH, Ikeja

<table>
<thead>
<tr>
<th>Profession</th>
<th>Use of form</th>
<th>Case report</th>
<th>Verbal/Hand over notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors</td>
<td>5</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Nurses</td>
<td>9</td>
<td>0</td>
<td>21</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>19</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
<td>3</td>
<td>26</td>
</tr>
</tbody>
</table>

Table 4: Reasons for not reporting ADR in the last one year among health workers at LASUTH, Ikeja

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number of responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too busy to report</td>
<td>1</td>
</tr>
<tr>
<td>Not responsible for reporting</td>
<td>9</td>
</tr>
<tr>
<td>Don't know what to report</td>
<td>11</td>
</tr>
<tr>
<td>Not sure of what to report</td>
<td>13</td>
</tr>
<tr>
<td>Not seen a reportable case</td>
<td>21</td>
</tr>
<tr>
<td>Process is too cumbersome</td>
<td>22</td>
</tr>
<tr>
<td>Reaction well known</td>
<td>29</td>
</tr>
<tr>
<td>Not aware of reporting system</td>
<td>60</td>
</tr>
<tr>
<td>Total number of responses</td>
<td>166</td>
</tr>
</tbody>
</table>

(Multiple responses)

DISCUSSION

The study showed that the rate of reporting ADRs is still very poor in our centre and this is in keeping with reports from previous studies (Oshikoya and Awobusuyi, 2009; Enwere and Fawole, 2008; Bello and Umar, 2011).

The results from this study have shown that pharmacists are more likely compared to other health professionals to report adverse drug reaction. In the Nigerian national pharmacovigilance policy all healthcare professionals, including doctors, nurses, pharmacist and others who are directly involved in the care of the patients are expected to report adverse drug reaction to the appropriate unit of the National Agency for Food and Drug Administration and Control of Nigeria (NAFDAC). A review of studies to assess reporting of ADR by health workers showed that pharmacists play an important role in ADR surveillance activities (Nebeker et al., 2005). The fact that the pharmacovigilance unit of the hospital is located in the pharmacy department partly explained the reason why higher proportion of the pharmacist compared to other health workers report ADR.

There is clearly a lack of awareness of what constitute a proper reporting of ADR from this study, particularly among the doctors and nurses. There is a pharmacovigilance collation centre within the hospital and it is located in the pharmacy department of the hospital. In the Nigerian national pharmacovigilance policy, health care professional reporting ADR are expected to fill and submit a prescribed form to the appropriate unit in their centre or send same by post to NAFDAC if no such unit exist in their centre. However seventy percent of nurses who claimed in the survey to have reported ADRs did not do so properly. All the nurses who reported ADRs did so in the setting of in-patient admissions and 70% of them merely make verbal report of patients’ complaints concerning their medications to a doctor in the managing team or by writing about these complaints in their nurses’ note without necessarily filling out the appropriate form. If this number of inappropriate reporting is taken into account then only 14% of nurses could be said to have properly reported ADRs as against the 47% which the result of this study would suggest if the result was based on the proportion of nurses who claimed to have reported ADRs irrespective of how the report was made. Also the proportion of doctors that reported ADRs appropriately
by filling and submitting the prescribed form is low, 45% of the doctors who reported did what was required. If the number of doctors that actually did proper reporting was taken into consideration rather than the just using the total proportion that reported irrespective of whether their method of reporting was appropriate or not, then only 14% of doctors can actually be said to have made proper report. The lack of making appropriate report among the health workers who made effort to report ADRs could be explained by the lack of awareness of the reporting system for ADRs which existed with the hospital.

Ninety-eight per cent of doctors in this study do not routinely report ADRs and yet 40% of them admitted that ADR is common in their practise. This discordant is quite alarming, doctors as prescribers of most of the medications are expected to routinely get voluntary feedbacks from their patients or ask them directly about any complaints due to the medications they are taking and then make report accordingly. This study has showed that this is not the case.

In the last one year preceding this survey, only 13% of the healthcare workers who participated in this survey had reported adverse drug reaction in any of the patients they have been in contact with. When one considers the fact that 36% of the health care workers in this study said that ADRs are commonly seen in their practise then one can conclude from the results that enough is not been done to make any report since about two-third of them do nothing despite their belief that adverse drug reaction is common. A previous study by Oshikoya and Awobusuyi (2009) at the same centre showed that knowledge of ADRs reporting and rate of reporting among health care workers was poor. This study was done among doctors and it cuts across the various clinical departments within the hospital, however in our study we have included other health care workers; pharmacists and nurses who are also expected to report ADRs according to the Nigeria’s guidelines. Reports from previous studies indicate that the inclusion of nurses and pharmacists in the reporting of ADRs has had a positive impact on the system of reporting (Davis and Coulson, 1999; Van Grootheest et al., 2004; Morrison-Griffiths et al. 2003). Enwere and Fawole (2008) in their study at another tertiary health facility in Ibadan, Nigeria, reported a 32% ADRs reporting rate among doctors. This was a better rate than what we got among doctors in our in study but less than our overall rate when other health care workers are included. This corroborated the report of the study which says that the inclusion of nurses and pharmacist in the process of reporting. The spontaneous method of reporting which is what is been practised in Nigeria has however been shown to produce a low rate of reporting globally (Suh et al.,2000).

A cursory look at the reasons for not reporting ADR by health care workers showed that many of those who did not report did so because they are not aware of any reporting system within the hospital. This underscores the importance of creating awareness about pharmacovigilance and also organising training for healthcare workers about what is reportable and the process of reporting. Some health care workers also believe that the process of reporting is cumbersome. One may find this difficult to explain as all that is required of them is to fill the form and submit to the appropriate unit. The fact that the health workers have to go to some places outside their units to collect the form and return same to such places, may perhaps be bothersome to some people. Since the process of reporting is voluntary, those health workers who are not motivated to report ADR can easily decide not to go the extra mile in order to do so. It would therefore be advisable to provide forms at points where they are needed and pharmacovigilance team then go about collecting them from such places. Some health care workers do not report because they felt that the adverse events observed are well known or they are not sure if they are reportable, the teaching is that if one is not sure if an event is reportable or not then it should be reported. It is therefore the duty of the pharmacovigilance agencies to decide upon which of the many reports they received to act on. Many of the ADRs been reported are already known and are written in the drug information sheets.

CONCLUSION

The rates of reporting of adverse drug reaction in our centre are still low and there is the need for continuous medical education for all health care workers about adverse drug reaction reporting. The thrust of this education should be about what pharmacovigilance is about, what is reportable, the process involved in reporting and where such report can be made.

REFERENCES


