Adverse drug reactions (ADRs) till date are still considered as one of the main problems of drug therapy. Pharmacovigilance is the monitoring of drug safety by means of spontaneous adverse-effect reporting systems, case control and cohort studies.

This study evaluated the levels of awareness and knowledge of pharmacovigilance (i.e., ADR reporting) amongst final year students of Rivers State College of Health Science and Technology, Port Harcourt, Nigeria. It was a cross-sectional awareness and knowledge survey amongst 200 students from the eight Schools of the institution. Specially adapted and structured questionnaires were administered to the students to obtain information on their levels of awareness and knowledge on reporting of ADRs. Simple descriptive statistics was used to analyze the data that were obtained. The result showed that over 72% of the students from each of the Schools had good knowledge of ADR, about 62% were aware of ADR reporting system, while less than 50% had knowledge of the process of reporting ADRs.

Final year students of College of Health Science and Technology, Port Harcourt have good knowledge of ADR. However, their awareness of the reporting system and particularly the process of reporting (pharmacovigilance) is poor and needs improvement.

**Keywords:** Awareness, adverse drug reaction, pharmacovigilance

## INTRODUCTION

Adverse drug reactions (ADRs) till date are still considered one of the main problems of drug therapy and are associated with considerable morbidity, mortality, decreased compliance and therapeutic success as well as high direct and indirect medical costs.

All medications, including excipients of a product are capable of producing adverse effects. Some of these are idiosyncratic and are unpredictable, but many are predictable and based on their pharmacology hence can be anticipated and prevented. 30 – 60% of ADRs can be prevented. About 20% of the ambulatory population receiving medication experiences adverse drug reactions. The Thalidomide saga since 1961 was a key event in the development of modern drug safety with the spontaneous reporting of adverse drug reactions being one of the main elements. Adverse drug reactions have historically been placed into two broad classes: A (augmented) and B (Bizarre). However, types C (Chronic), D (Delayed), E (End of use) & F (Failure of therapy) have also been suggested. Adverse events also occur with certain non-drug items that are used in patient care including blood products and medical devices.

Many countries including the United States have developed systems that encourage the reporting of adverse events. Pharmacovigilance (PV) which is a branch of pharmacoepidemiology is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

The issue of Pharmacovigilance was brought to light with the sole aim of,

- Enhancing patient care and patient safety in relation to the use of medicines and
- Supporting public health programmes by providing reliable and balanced information for the effective assessment of the risk-benefit profile of medicines.

Spontaneous adverse drug reaction (ADR) reporting is the cornerstone of pharmacovigilance. However, underreporting is a huge problem due to lack of good reporting culture amongst healthcare professionals. Spontaneous reporting of ADR is an important method for detecting new safety issues related to drugs. Studies by Zoriah et al., 2006 and Gupta et al., 2011 have revealed a high level of under reporting of ADR. This has also been noted amongst doctors according to the study by Pimpalkhute et al., 2012 and Gupta et al., 2011. The work of Hazell & Shakir (2006) also provided evidence of significant and widespread under-reporting of ADRs. Another study by...
Blenkinsopp & colleagues, (2007) noted that patients report identified new ADRs not yet reported by health professionals. Also, they report an ADR when they consider their health professionals has not paid attention to their concerns.

Nigeria was admitted into the WHO International Drug Monitoring Programme in 2004. This marked a new era of pharmacovigilance in Nigeria. The National Pharmacovigilance Centre (NPC) serves as a repository for reported adverse drug reactions from health workers all over the country. A major thrust of the NPC is to increase the participation of the public in drug safety and the contributions of public-health programmes to pharmacovigilance cannot be overemphasized.

AIM: The Aim of the study is to evaluate the Awareness and Knowledge of Pharmacovigilance amongst final year students of Rivers State College of Health Science and Management Technology, Port Harcourt, Nigeria.

Specific Objectives

- To evaluate the knowledge of ADRs among final year students of the 'College'.
- To evaluate the level of awareness about Pharmacovigilance among final year students of the College.
- To assess the knowledge of the reporting process of ADRs.

METHODS

Study design: A cross sectional awareness and knowledge survey design was used.

Study location: Rivers State College of Health Science and Management Technology, Port Harcourt, Nigeria.

Sample size determination: Using the Taro Yamane formula for sample size calculation \( n = \frac{N}{1+N(e)^2} \), where \( n \) is the sample size, \( N \) is the population size (328 students) and \( e \) is the allowable error which is 5% (0.05). This translate to a sample size of 180

Data collection instrument: Specially adapted and constructed questionnaire on knowledge, awareness and reporting of ADRs was used.

Data collection Technique: Questionnaires were distributed amongst the final year students of each School of the College during their Lecture periods. A total of 180 were distributed to students prior to a lecture period.

Data analysis: Simple frequencies and percentages of SPSS version 20 was used for the analysis.

RESULTS

Total number of students administered questionnaire - 180
Total number of students that responded = 155 (86.1%)

Total number of students administered questionnaire - 180
Total number of students that responded = 155 (86.1%)

<table>
<thead>
<tr>
<th>To whom report was made</th>
<th>BET (n=12)</th>
<th>CHEW (n=26)</th>
<th>DST (n=27)</th>
<th>ENV (n=24)</th>
<th>HIM (n=18)</th>
<th>MIT (n=14)</th>
<th>SPT (n=22)</th>
<th>SPHN (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>1(8.3)</td>
<td>3(11.5)</td>
<td>5(18.5)</td>
<td>3(12.5)</td>
<td>2(14.2)</td>
<td>4(18.1)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>1(8.3)</td>
<td>4(15.3)</td>
<td>10(37)</td>
<td>1(4.1)</td>
<td>3(16.6)</td>
<td>4(28.5)</td>
<td>1(4.5)</td>
<td>-</td>
</tr>
<tr>
<td>Nurse/Health care provider</td>
<td>2(16.6)</td>
<td>2(7.6)</td>
<td>6(22.2)</td>
<td>-</td>
<td>-</td>
<td>1(7.1)</td>
<td>1(4.5)</td>
<td>-</td>
</tr>
<tr>
<td>Medicine store</td>
<td>1(8.3)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1(7.1)</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Parent /Relative</td>
<td>1(8.3)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>2(11.1)</td>
<td>-</td>
<td>1(4.5)</td>
<td>-</td>
</tr>
<tr>
<td>Aware of ADR reporting &amp; monitoring system in Nigeria</td>
<td>4(33.3)</td>
<td>6(23)</td>
<td>15(55.5)</td>
<td>15(62.5)</td>
<td>9(50)</td>
<td>7(50)</td>
<td>12(54.5)</td>
<td>6(50)</td>
</tr>
<tr>
<td>Had knowledge of the process of reporting ADR</td>
<td>-</td>
<td>2(7.6)</td>
<td>13(48.1)</td>
<td>3(12.5)</td>
<td>6(33.3)</td>
<td>2(14.2)</td>
<td>6(27.2)</td>
<td>3(25)</td>
</tr>
</tbody>
</table>
DISCUSSION

Adverse drug reaction reporting is still an important issue in many health facilities especially in developing economies and for prospective paramedical and health care professionals to be fully grounded in this important component of their future practice, emphasis must be placed on teaching every aspect of it during the course of their training.

The fact that substantial efforts and resources have been put into the discovery, monitoring and management of ADRs does not rule out the possibility of emergence of new or previously encountered ADR. This is true as almost all the drugs implicated in this study have at one time or the other been mentioned in similar studies.

The study showed that majority of the students from the Schools had good knowledge of what ADR is, though awareness of the proper reporting system was poor. This is in agreement with the work of Robertson and Newby (2013) 12. However, the level of awareness of ADR reporting & monitoring in the College still need to be stepped up to meet the present day realities of a safe, efficient and effective medication management.

About 41% of the respondents indicated that Pharmacists can appropriately report ADRs while only about 10% reported that doctors rather could appropriately report ADRs and this is somewhat in agreement with the work of Shamim et al., 201613 that reported that Pharmacists are the chief personnel in the ADR reporting system.

It was only in the Schools of Public Health Nursing (SPHN) and Pharmacy Technician (SPT) that majority, (83.3% and 72.7% respectively) of the students reported on all the products in the study as potential adverse event candidates meaning that some students from other Schools had poor knowledge of the potential of certain non-drug items in the study to cause adverse events which should not have been expected for those in their final year in such an institution.

CONCLUSION

There is a fair knowledge about adverse drug reactions (ADRs) amongst the final year students of the College. The students also showed some level of awareness about spontaneous reporting of ADRs and adverse events from some non-drug products.

However, there is still a knowledge gap about the reporting system which can be breached through a little more emphasis on this topic in the various Schools as well as through sensitization workshops.

RECOMMENDATION

• Adverse drug reactions, its management and proper reporting should be given more attention as a training of all students in the College

Table 2: Students’ response on who can report ADR

<table>
<thead>
<tr>
<th>Descriptions</th>
<th>BET (n=12)</th>
<th>CHEW (n=26)</th>
<th>DST (n=27)</th>
<th>ENV (n=24)</th>
<th>HIM (n=14)</th>
<th>MIT (n=18)</th>
<th>SPT (n=22n)</th>
<th>SPHN (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>1(8.3)</td>
<td>1(3.8)</td>
<td>1(3.7)</td>
<td>2(8.3)</td>
<td>4(22.2)</td>
<td>3(13.6)</td>
<td>1(8.3)</td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>6(50)</td>
<td>15(58)</td>
<td>1(3.7)</td>
<td>17(70.8)</td>
<td>7(38.8)</td>
<td>9(46.2)</td>
<td>8(36.3)</td>
<td>-</td>
</tr>
<tr>
<td>Nurse</td>
<td>3(0.25)</td>
<td>-</td>
<td>-</td>
<td>1(5.5)</td>
<td>-</td>
<td>-</td>
<td>2(16.6)</td>
<td></td>
</tr>
<tr>
<td>All of the above</td>
<td>1(8.3)</td>
<td>7(27)</td>
<td>23(85)</td>
<td>5(20.8)</td>
<td>3(16.6)</td>
<td>2(14.2)</td>
<td>9(41)</td>
<td>7(58.3)</td>
</tr>
<tr>
<td>Anybody that is affected</td>
<td>1(8.3)</td>
<td>3(11.5)</td>
<td>2(7.4)</td>
<td>3(16.6)</td>
<td>-</td>
<td>2(9.0)</td>
<td>2(16.6)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Students’ response on type of products for which ADR should be reported

<table>
<thead>
<tr>
<th>Descriptions</th>
<th>BET (n=12)</th>
<th>CHEW (n=26)</th>
<th>DST (n=27)</th>
<th>ENV (n=24)</th>
<th>HIM (n=14)</th>
<th>MIT (n=18)</th>
<th>SPT (n=22n)</th>
<th>SPHN (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional medicines</td>
<td>4(33.3)</td>
<td>9(30.7)</td>
<td>6(22.2)</td>
<td>12(50)</td>
<td>7(38.8)</td>
<td>3(21.4)</td>
<td>2(9.0)</td>
<td>1(8.3)</td>
</tr>
<tr>
<td>Herbal/ Traditional medicine</td>
<td>1(8.3)</td>
<td>2(7.6)</td>
<td>1(3.7)</td>
<td>1(4.1)</td>
<td>2(11.1)</td>
<td>3(21.4)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Blood products</td>
<td>1(8.3)</td>
<td>-</td>
<td>4(14.8)</td>
<td>-</td>
<td>3(16.6)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Biologics/Medical devices</td>
<td>-</td>
<td>1(3.8)</td>
<td>2(7.4)</td>
<td>2(8.3)</td>
<td>-</td>
<td>3(21.4)</td>
<td>3(13.6)</td>
<td>1(8.3)</td>
</tr>
<tr>
<td>All of the above</td>
<td>2(16.6)</td>
<td>13(50)</td>
<td>6(22.2)</td>
<td>6(25)</td>
<td>2(11.1)</td>
<td>3(21.4)</td>
<td>16(72.7)</td>
<td>10(83.3)</td>
</tr>
<tr>
<td>None of the above</td>
<td>4(33.3)</td>
<td>2(7.6)</td>
<td>2(7.4)</td>
<td>2(8.3)</td>
<td>3(16.6)</td>
<td>2(14.2)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Don’t know</td>
<td>-</td>
<td>-</td>
<td>6(22.2)</td>
<td>1(4.1)</td>
<td>2(11.1)</td>
<td>-</td>
<td>1(4.5)</td>
<td>-</td>
</tr>
</tbody>
</table>
The College can also liaise with NAFDAC in the State to organize workshop/training on this key area of health care delivery.

There should be budgetary provision for research in the College

Conflict of interest:
The authors declare that there was no conflict of interest

REFERENCES