Research Article

TO ASSESS AWARENESS OF HEALTHCARE PROFESSIONALS AND STUDENTS TOWARDS PHARMACOVIGILANCE, MATERIOVIGILANCE, VACCINE SAFETY SURVEILLANCE AND NATIONAL POISON INFORMATION CENTRE IN GANGTOK, SIKKIM.

***Shailee Dewan**

ABSTRACT

Background:
Surveillance plays a pivotal role in providing insight into a lacuna and help the system to address it. Pharmacovigilance, Materiovigilance, Vaccine safety surveillance and Toxicovigilance programmes were started with the aim to address the need for surveillance and intervention.

Aim: To assess questionnaire-based survey on awareness of healthcare professionals and students of Gangtok, Sikkim towards Pharmacovigilance programme of India, Materiovigilance programme of India, Vaccine Safety Surveillance and National Poisons Information Centre.

Objective:

1. To assess the level of awareness among different individuals from questionnaires.
2. To investigate the role of ADR for mitigating the country's economic burden and improving quality of life.
3. To generate meaningful insight from the integration of data for improving spontaneous reporting among healthcare professionals.

Methodology:
A cross sectional questionnaire-based awareness study was conducted among healthcare professionals and students. The survey was designed using the information from the literature to assess the awareness among the healthcare professionals and students indulged in patient care andvarious literature were reviewed to investigate the role of ADR for mitigating the country's economic burden and improving quality of life.

Result:
The survey was completed with 172 participants. Out of the 172 participants, 132 (76.7%) were aware of the term PvPI, 82 (47.7%) were aware of the term MvPI, 135(78.5%) were aware of the term Vaccine Safety Surveillance and only 67 (39.0%) were aware of the term NPIC.

Key words: Pharmacovigilance, Materiovigilance, Vaccine Safety Surveillance, National Poisons Information Centre.

INTRODUCTION

Many unfortunate events in the past have led to the emergence of pharmacovigilance and the need as such arises for the same to reduce the morbidity and the mortality due to the adverse drug reactions and any drug related issues.

The origins can be traced back to more than 170 years ago on 28 January 1848, with the death of a 15-year-old Hannah Greener of Winlaton after receiving a chloroform anaesthetic for the removal of a toenail [1]. After this incident there has been many unfortunate tragedies that has led to pharmacovigilance [2] [3]. The incidence of ADRs may be even greater because some ADRs mimic natural disease states and may thus go undetected or unreported but are known to cause death in as many as 0.1%–0.3% of hospitalized patients [4].
Under the auspices of the Ministry of Health and Family Welfare, the Central Drugs Standard Control

Organisation (CDSCO), New Delhi, launched a nation-wide pharmacovigilance programme in July 2010, with the All-India Institute of Medical Sciences (AIIMS), New Delhi serving as the National Coordinating Centre (NCC) for monitoring Adverse Drug Reactions (ADR) in the country to protect public health. This Programme established 22 ADR monitoring centres (AMCs), including AIIMS in New Delhi, in 2010. In April 2011, the National Coordinating Centre was moved from the All-India Institute of Medical Sciences (AIIMS) in New Delhi to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad, Uttar Pradesh to ensure more effective programme implementation which now functions as the National Coordination Centre (NCC)for the Pharmacovigilance Programme of India (PvPI) that focuses on promoting safer drug therapy to protect public health. India contributes about 3% to the global database in the form of PvPI[5][6]. These AMCs report ADRs to the National Coordination Centre (NCC) using VigiFlow, a software developed by WHO-UMC (Sweden)[5].

The expanded patient safety scope of pharmacovigilance covers the detection of low-quality drugs as well as prescribing, dispensing, and administration errors. Other pharmacovigilance concernsinclude counterfeiting, antibiotic resistance, and the requirement for real-time surveillance in bulk vaccinations [6].

The poison information centre has grown globally with the need to reduce the morbidity and mortality due to poisoning especially in a developing country with high-rate industrialization and urbanization rate [7][14]

AIM AND OBJECTIVES

2.1. ***Aim:*** To assess questionnaire-based survey on awareness of healthcare professionals and students towards Pharmacovigilance programme of India, Materiovigilance programme of India, Vaccine Safety Surveillance and National Poisons Information Centre.

2.2. ***Objective:***

2.2.1. To assess the level of awareness among different individuals from questionnaires.

2.2.2. To investigate the role of ADR for mitigating the country's economic burden and improving quality of life.

2.2.3. To generate meaningful insight from the integration of data for improving spontaneous reporting among professionals.

METHODOLOGY

Survey Design and Data Collection: A cross-sectional study was conducted among healthcare professionals and students to assess their awareness towards Pharmacovigilance programme of India, Materiovigilance programme of India, Vaccine Safety Surveillance and National poison Information Centre.

Survey Sample: The study included healthcare professionals and students from different institutions mainly focused in Gangtok, Sikkim.

Survey Questionnaire: The survey was distributed in English and involves 5 sections which includes sociodemographic data,awareness towards Pharmacovigilance Programme of India (PvPI), awareness towards Materiovigilance Programme of India (MvPI),awareness towards vaccine safety surveillance and awareness towards National Poison Information Centre.

Sample Analysis: The data were collected initially using Microsoft excel, furthered cleaned and coded using IBM SPSS Statistics version 29.0.1.0. Multi response was tabulated for dichotomy group valued at 1.

RESULT

Sociodemographic results

The sociodemographic data of the participants (Table 1.) indicated, out of 172 participants, (n=47 male,27.3%), (n= 124, 72.1%) and (n=1 others,0.6%) with age ranging 20or below(n=19,11.0%), 21-30(n=130,75.6%), 31-40(n=16,9.3%), 41-50(n=4,2.3%), 51-60(n=3,1.7%) were involved. From the total participants 61 were from GPC, 48 from SMIMS, 6 from SGCN, 7 from SPU, 16 from STNM, 10 from CRH, 15 from HPI and 9 from other institutions all over in Sikkim. Furthermore, about (n=82, 47.67%) of the participants were from Bachelor in Pharmacy background (n=57, 33.14%) were from BSc. Nursing background, (n=15, 8.72%) were from MBBS background and (n=18, 10.47) were from other degrees that indulge in healthcare, the detailed response is mentioned in figure 1. Out of 172 participants students were (n=133, 77.3%) and professionals were (n=39, 22.9%).

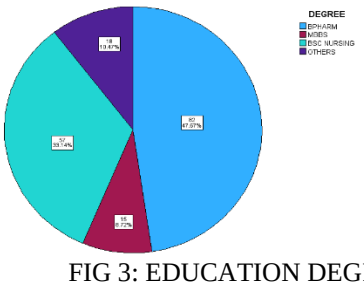

FIG 3: EDUCATION DEGREE

Table no.1 Sociodemographic data Variable		Count	Table N %
INSTITUTION NAME	GPC	61	35.5%
	SMIMS	48	27.9%
	SGCN	6	3.5%
	SPU	7	4.1%
	STNM	16	9.3%
	CRH	10	5.8%
	HPI	15	8.7%
	OTHERS	9	5.2%
AGE	20 OR BELOW	19	11.0%
	21-30	130	75.6%
	31-40	16	9.3%
	41-50	4	2.3%
	51-60	3	1.7%
	61-70	0	0.0%
GENDER	FEMALE	124	72.1%
	MALE	47	27.3%
	OTHERS	1	0.6%
CATEGORY	STUDENT	133	77.3%
	PROFESSIONAL	39	22.7%

Table 2. Dichotomy group tabulated at value 1.			
Questionnaire		Correct Response N	Percent of response
Variables	1.WOULD YOU HAPPEN TO BE AWARE OF THE CONCEPT OF PHARMACOVIGILANCE PROGRAMME OF INDIA?	132	76.7%
	2.WOULD YOU HAPPEN TO BE AWARE OF THE HEALTH AND FAMILY WELFARE, GOVERNMENT OF SIKKIM INITIATIVE IN PHARMACOVIGILANCE PROGRAMME OF INDIA?	112	65.1%
	3.PHARMACOVIGILANCE IS RELATED TO	140	81.4%
	4.PHARMACOVIGILANCE DETECTS	102	59.3%
	5.PHARMACOVIGILANCE CENTRE IN SIKKIM IS PRESENT AT	86	50.0%
	6.IN YOUR EXPERIENCE, WHICH HEALTHCARE PROFESSIONAL IS TYPICALLY RESPONSIBLE FOR REPORTING AN ADVERSE DRUG REACTION(ADR)?	101	58.7%
	7.PHARMACOVIGILANCE PROGRAMME OF INDIA IS OVERSEEN BY	69	40.1%

	8.IN YOUR OPINION WHAT WOULD YOU SUGGEST: 'REPORTING OF ADVERSE DRUG REACTION IS'	161	93.6%
	9.WOULD YOU RECEIVE ANY ELECTRONIC UPDATE RELATED TO PHARMACOVIGILANCE PROGRAMME?	91	52.9%
	10.WOULD YOU HAPPEN TO BE AWARE OF THE MATERIOVIGILANCE PROGRAMME OF INDIA?	82	47.7%
	11.WOULD YOU HAPPEN TO BE AWARE OF THE HEALTH AND FAMILY WELFARE, GOVERNMENT OF SIKKIM INITIATIVE IN MATERIOVIGILANCE PROGRAMME?	75	43.6%
	12.ARE YOU AWARE OF THE PROCESS FOR REPORTING ADVERSE EVENTS ASSOCIATED WITH MEDICAL DEVICES TO THE MATERIOVIGILANCE PROGRAMME OF INDIA?	80	46.5%
	13.MATERIOVIGILANCE IS RELATED TO	102	59.3%
	14.MATERIOVIGILANCE PROGRAMME OF INDIA IS OVERSEEN BY	68	39.5%
	15.WERE YOU AWARE THAT GOVERNMENT PHARMACY COLLEGE, SAJONG IS A MEDICAL DEVICES ADVERSE EVENT MONITORING CENTRE?	78	45.3%
	16.WOULD YOU RECEIVE ANY ELECTRONIC UPDATE RELATED TO MATERIOVIGILANCE PROGRAMME?	74	43.0%
	17.WOULD YOU HAPPEN TO BE AWARE OF THE VACCINE SAFETY SURVEILLANCE?	135	78.5%
	18.VACCINE SAFETY SURVEILLANCE IS RELATED TO	84	48.8%
	19.ARE YOU AWARE OF THE REPORTING PROCESS FOR ADVERSE EVENT FOLLOWING IMMUNIZATION?	93	54.1%
	20.WOULD YOU HAPPEN TO BE AWARE WHICH BODY IS RESPONSIBLE FOR OVERSEEING ADVERSE EVENT FOLLOWING IMMUNIZATION?	61	35.5%
	21.WOULD YOU HAPPEN TO USE/REPORT AN AEFI FORM?	45	26.2%
	22.WOULD YOU RECEIVE ANY ELECTRONIC UPDATE RELATED TO VACCINE SAFETY SURVEILLANCE?	61	35.5%
	23.WOULD YOU HAPPEN TO BE AWARE OF THE NATIONAL POISON INFORMATION CENTRE?	67	39.0%
	24.NATIONAL POISON INFORMATION CENTRE PROVIDES INFORMATION RELATED TO	120	69.8%

	25.WOULD YOU HAPPEN TO EVER CONTACT OR SOUGHT GUIDANCE FROM THE NATIONAL POISON INFORMATION CENTRE REGARDING POISON-RELATED CASES OR INQUIRIES?	34	19.8%
	26.NATIONAL POISON INFORMATION CENTRE IS BASED AT	95	55.2%
	27.ARE YOU FAMILAR WITH THE HOTLINE NUMBER OR CONTACT INFORMATION OF THE NATIONAL POISON INFORMATION CENTRE FOR IMMEDIATE POISON-RELATED EMERGENCIES OR CONSULTATIONS?	31	18.0%

Table 2 indicates the dichotomy group tabulated at value 1. For the question regarding the awareness towards PvPI (n=132, 76.7%) and regarding the H&FW department initiative (n=112,65.1%) responded positively. (n=140, 81.4%) gave correct response to 'pharmacovigilance is related?' to and (n=102, 59.3%) gave correct response to 'pharmacovigilance detects?'. (n=101, 58.7%) showed positive response that all healthcare professionals are responsible for reporting and (n=161, 93.6%) considered that reporting is necessary. (n=69, 40.1%) responded that IPC oversees the PvPI and (n=91, 52.9%) responded positively towards 'receiving electronic update related to PvPI? (n=82, 47.7%) responded positively that they were aware of the MvPI, (n=75, 43.6%) responded yes to 'aware of the initiative of H&FW department, Sikkim towards MvPI. (n=80, 46.5%) were aware of the process for reporting adverse events related to the medical devices. (n=68, 39.5%) responded that IPC oversees MvPI. (n=78,45.3%) were aware that Government Pharmacy College, Sajong is a medical device Adverse event monitoring centre. Only (n=74, 43.0%) responded positively to 'receiving to electronic update to MvPI?'(n=135,78.5%) were aware of the Vaccine safety surveillance. Only (n=84, 48.8%) responded correctly to 'vaccine safety surveillance is related to?'. (n=93,54.1%) were aware of the process for reporting an AEFI and (n=61,35.5%) were aware of the body responsible for overseeing AEFI. (n=61, 35.5%) responded yes to 'use/report an AEFI form?' and (n=61,35.5%) responded yes to 'receiving any electronic update to vaccine safety surveillance'. (n=67, 39.0%) were aware of the NPIC and (n=120,69.8%) responded correct to' NPIC provides information related to?'. (n=34, 19.8%) have sought guidance from the NPIC. (n=95,55.2%) were aware where the NPIC was based at and (n=31, 18.0%) were aware of the hotline number of the NPIC.

DISCUSSION

This study observed that the respondents was least aware of the National Poison Information Centre (39%) followed by Materiovigilance programme of India (47.7%), Pharmacovigilance programme of India (76.7%) and then the Vaccine safety surveillance (78.5%). Only (26.2%) had use/reported using an AEFI form even though the respondents were aware of the Vaccine safety surveillance (78.5%) which implies reporting culture is still lacking. Majority (93.6%) of the respondents considered reporting as necessary but approximately, only half of the majority were aware of the reporting process.

To overcome these concerns and to improve the spontaneous reporting system among healthcare professionals we can suggest:

1. Opening job vacancies for clinical pharmacist in hospitals for clinical integration of pharmacist in general practice.
2. Awareness is key to improve spontaneous reporting and awareness among general public is as necessary as in healthcare professionals.
3. Providing financial incentives, training courses, improvement of the computer system and regular publishing of the ADR information are also some of the few interventions that aid in improving spontaneous reporting.
4. Establishment of pharmacovigilance system in hospital and ensuring availability of ADR reporting forms.
5. Alerting the physician about the list of ADR to be reported and practice stimulated reporting.
6. KAP studies among healthcare professionals to provide insight about the status of their knowledge, attitude and practice towards reporting and taking appropriate interventions. [26,27,28]

Efforts to improve spontaneous reporting and addressing adverse drug reaction will not only mitigate country's economic burden but will also contribute to improving the quality of life and public health.

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