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A Prospective Observational Study On Assessment Of Knowledge, Attitude, Behavior, And Barrier Towards Pharmacovigilance Among Hospital Pharmacists In Suburban Areas Of Chennai.

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ABSTRACT:

BACKGROUND:

Pharmacovigilance is the scientific activity of identification, evaluation, understanding, and prevention of adverse drug reactions and other medication-related issues. An "adverse drug reaction" is any hazard, unwanted effect of a drug, which occurs in a normal dose used in humans for prophylaxis, diagnosis, therapy or modification of physiological functions.

METHOD:

A structured and validated KAP questionnaire was developed and validated clinically, statistically, and also by conducting a pilot study. The reliability was assessed based on Cronbach's alpha score using SPSS version 24. The Cronbach alpha score was found to be 0.773 and it was considered reliable to conduct further study. All the hospital pharmacists who participated in this study were educated about pharmacovigilance using a structured Pharmacovigilance leaflet.

RESULT:

Among more than 250 Hospital Pharmacist approached for their interest in participating in the study only 150 (60%) pharmacists responded, gave written informed consent and answered the questionnaire. When stated the definition of pharmacovigilance as the detection, assessment, understanding, and prevention of ADR, about 28.7% of respondents strongly agreed with the statement. Nearly 72% of respondents strongly disagree that they have been trained in reporting ADR. Around 53.3% of respondents strongly agree that they did not know how to get the reporting form.

CONCLUSION:

If trained properly in pharmacovigilance, Hospital pharmacists will improve in knowledge, overcome the barrier, and change their attitude and behavior towards pharmacovigilance and in reporting ADR. The study strongly recommends conducting an awareness program in pharmacovigilance among Hospital pharmacists in India.

KEYWORDS:Pharmacovigilance, Adverse drug reaction, PvPI, Health-care system, Pharmacist

ABBREVIATION:

PVPI – Pharmacovigilance Program of India
ADR – Adverse Drug Reaction
AMC- ADR monitoring center
NCC – National Coordination Committee
WHO - World Health Organization

INTRODUCTION:

Pharmacovigilance is the science of identification, evaluation, understanding, and prevention of adverse drug reactions and other drugs-related issues [1]. An "adverse drug reaction" is any hazard, unwanted effect of a drug, which occurs in a dose used in humans for prophylaxis, diagnosis, therapy or modification of physiological functions. [2] ADR is the sixth largest cause for death among the Indian population but most of the adverse effects of the drugs can be prevented and it can lead to optimal drug therapy [3]. Many Health care professionals think pharmacovigilance was only limited to the ADR of modern medicine but it also included herbals medicines, blood products, medical devices, vaccines.[4]. Pharmacovigilance plays a crucial role in clinical research and post-marketing surveillance. India is the second populated country in the world with 1.4 billion people and different ethnic groups[5]. The Incidence of ADR is more in India because of differences in prescribing patterns, malnutrition among peoples and lack drug safety data in special population groups like pediatrics, geriatrics and pregnant women[6]. The following reasons lead to a need ina pharmacovigilance programin India to watch the adverse reaction of drugs became undeniable.To overcome that India initiated a pharmacovigilance program of India in 2010 with the help of the World Health Organisation. It was created by the guidance of the Ministry of Health & Family Welfare of India and Indian Pharmacopeia Commission, and was named as the National coordination center for the Pharmacovigilance program of India[7]. The goal of PVPI is to make ADR reporting mandatory and to increase the practice of reporting ADR. Currently, more than 250 adverse drug monitoring centers (AMC)are established in India under PVPI. AMCs are important for the active reporting of ADRs to NCC and collect the ADR data to record in the WHO Vigibase software[8]. The lack of knowledge about pharmacovigilance and ADR among people is the most important barrier for the pharmacovigilance program of India. In the current scenario, PVPI attained success in establishing the pharmacovigilance system in our country but still, pharmacovigilance and ADR reporting are not widely spread among the Indian population. The under-reporting of ADR is a major concern for PVPI and it takes various steps to use major advancement in technologies for enhancing Pharmacovigilance activity[9]. In future PVPI has planned to introduce a course on pharmacovigilance to medical and paramedical students to promote drug safety. An advertisement about ADR reporting promotes PV activity in India. The tremendous growth of pharmaceutical industries and clinical research lead to the expansion of PVPI in India[10]. With the help of private sectors,the Indian pharmacovigilance program can achieve good ADR surveillance and ensure drug safety. Hospital pharmacists can play a crucial role in the PVPI since they have extensive knowledge about the drugs[11]. Hospital is the place were ADR occurs more commonlybecause the probability of using injectable drugs and narrow therapeutic drugs are high[12]. Hospital pharmacists can prevent avoidable ADR and monitor drug safety in the patients. They can educate other healthcare professionals about the importance of reporting ADR and pharmacovigilance [13].

METHODOLOGY

A structured and validated KAP questionnaire was developed and validated clinically, statistically, and also by conducting a pilot study. The questionnaire consists of four domains that comprise of 52 questions. After the questionnaire was designed a pilot study was carried out to check the reliability and feasibility of the developed questionnaire to be self-administered by the HospitalPharmacists. The reliability was assessed based on Cronbach's alpha score using SPSS version 24. The Cronbach alpha score was found to be 0.773 and it was considered reliable to conduct further study. The study was commenced after obtaining approval from the institutional ethics committee, Vels Institute of Science, Technology and Advanced Studies. Hospital Pharmacists interested to participate in the study were enrolled in the study after obtaining written informed consent from them. The Knowledge, Attitude, Behaviour, and Barrier were recorded using the questionnaire administered among the hospital pharmacist. All the hospital pharmacists who participated in this study were educated about pharmacovigilance using a structured Pharmacovigilance leaflet at the end of the study.

STATISTICAL ANALYSIS:
The collected data were entered into a spreadsheet to prepare the master chart using Microsoft Excel. The compiled data were statistically analyzed using SPSS version 24 for descriptive statistics and analytical statistics. Our participant's response was recorded on the Likert scale, hence chi-square test was used to assess the significant difference. [14]

RESULTS:
Among more than 250 Hospital Pharmacist approached for their interest in participating in the study, only 150 (60%) pharmacists responded, gave written informed consent and answered the questionnaire. The respondents included both male (47.3%) and female (52.6%) and the entire study population fell in the age group between 20-60 years. The majority of the study population were of age less than 30 year (61.3%). We observed that many of the respondents held a Diploma in Pharmacy (58%) and the rest were B.Pharm graduates (42%). When enquired about Pharmacovigilance training, only 4.7% of respondents have been trained in Pharmacovigilance and 95.3% of respondents did not undergo any training in Pharmacovigilance. In terms of professional experience, most of them had experience of fewer than 5 years (48.6%). Around 80% of the participants were pharmacy employees. The distribution based on the demographic data and clinical background information is presented in Table 1 and Figure 1-6.
There were 13 knowledge-based questions present in the questionnaire for which all the participants responded. When stated the definition of pharmacovigilance as the detection, assessment, understanding, and prevention of ADR about 28.7% of respondents strongly agreed with the statement. A significant difference in response between hospital pharmacists trained and untrained in pharmacovigilance (P=0.001) and participant based on their qualification was observed (P=0.001). Nearly 28.7% of study participants agreed that CDSCO is responsible for monitoring ADR in India significant difference (P=0.043) was observed between those who underwent as training in Pharmacovigilance and those who did not have. A majority of the participants (41.3%) disagreed that the National pharmacovigilance program of India was inaugurated in New Delhi, 2004 and there was a significant difference in this regard between gender (P=0.012) and between Pharmacovigilance trained and untrained hospital pharmacists (P=0.002). Around 31% of the population disagreed that Vigibase is the WHO online database for reporting ADR. A significant difference between Pharmacovigilance trained and untrained of Hospital pharmacist and between Diploma in pharmacy and B.pharm graduates was observed in this regard. Surprisingly a majority of the study participants (36%) disagreed and strongly disagreed (36.7%) that Post-marketing surveillance is commonly employed as a method to monitor ADR of new drug launched in the market and there is a significant difference among person trained in pharmacovigilance and untrained hospital pharmacist (P=0.029). About 43.3% of study participants strongly disagreed that the Naranjo scale is used for causality assessment of ADR. A significant difference was observed between participants trained in pharmacovigilance and untrained hospital pharmacist (P=0.001) and between diploma in pharmacy and B.pharm graduated hospital pharmacist (P=0.002). Around 36% of respondents disagreed that drugs can be withdrawn from the Indian market due to ADR. In this regard, a significant difference was observed between Diploma in pharmacy and B.pharm graduated hospital pharmacist (P=0.03) and also between the participants who underwent pharmacovigilance training and theuntrained hospital pharmacist (P=0.023). The majority of participants disagreed (35.3%) that renal failure is the major risk factor for the occurrence of ADR and here again was a significant difference in response between participants who underwent pharmacovigilance training and untrained hospital pharmacist (P=0.034). Surprisingly 48.7% of participants disagreed that pharmacovigilance also extended to herbal, traditional, and complementary medicine, biological, vaccines, blood products, and medical devices and a significant difference in response among participants who underwent pharmacovigilance training and untrained hospital pharmacist (P=0.005) was seen. The distribution of response to knowledge questionnaire is presented in Table 2 and Figure 7.
Total of 13 Attitude based questions were present in the questionnaire to assess the attitude of hospital pharmacists towards pharmacovigilance. Around 72% of the study participant strongly agreed that

ADR should be reported by a pharmacist and a significant difference was observed between participant trained in pharmacovigilance and untrained hospital pharmacist (P=0.007) and between Diploma in pharmacy and B.Pharmacy graduated hospital pharmacist (P=0.001) and also between gender (P=0.001), in this regard. Nearly 46% of respondents agreed that proper ADR reporting and monitoring will benefit the patients. A significant difference was observed between gender (P=0.05) for the same. Around 52% of respondents think pharmacovigilance should be taught in detail to healthcare professionals and we observed a significant difference in response between a participant who underwent pharmacovigilance training and untrained hospital pharmacist (P=0.000) and between D.pharm and B.Pharm qualified hospital pharmacist (P=0.003). Only 44% of respondent strongly agreed that ADR reporting must be made compulsory and there is a significant difference in response between gender (P=0.02) and between a participant who was trained and untrained in pharmacovigilance (P=0.058). Around 40% of the respondents were not sure whether the drugs available in the market are safe and a significant difference between a participant who was trained and untrained in pharmacovigilance (P=0.002). The majority of the hospital pharmacists (36%) agreed that they noticed ADR in the patient and there was a significant difference between D.pharm and B.pharm educated hospital pharmacists (P=0.046). Nearly 50% of the respondents strongly agreed that they need assistance in the area of ADR and a significant difference was observed between a participant who underwent pharmacovigilance training and untrained hospital pharmacist (P=0.036) and between D.pharm and B.Pharm qualified hospital pharmacist (0.041). About 42.7% of respondents disagreed that they have reported any ADR from their institution. A significant difference between a participant who underwent pharmacovigilance training and an untrained hospital pharmacist (P=0.009) and between D.pharm and B.Pharm qualified hospital pharmacists (P=0.042) was observed in this regard. Majority of respondents (38.7%) were not sure about visiting the ADR monitoring center and a significant difference in response between a participant who trained in pharmacovigilance training and untrained hospital pharmacist (P=0.004) and between D.pharm and B.Pharm educated hospital pharmacist (P=0.003). Surprisingly 44% of the respondents think that ADR reporting will increase patient safety and there was a significant difference between D.pharm and B.pharm qualified hospital pharmacists (P=0.003) and also between a trained participant in pharmacovigilance and untrained participants (P=0.033). The distribution of responses to the attitude questionnaire is presented in Table 3 and Figure 8.

There were 13 questions framed to assess the behavior of pharmacists towards pharmacovigilance for which all participants responded. About 47.3% of respondent pharmacists strongly agreed that they are willing to make ADR reporting. A significant difference was observed between the trained participant in pharmacovigilance and untrained hospital pharmacist (P=0.001) and the difference were also observed between B.pharm and D.pharm qualified hospital pharmacists (P=0.01). Most of the respondents (45.3%) strongly agreed to tell the patient what to do in case if the patient develops ADR. In this regard, there is a significant difference in response between participants who underwent training in pharmacovigilance and untrained hospital pharmacist (P=0.000) and also between B.pharm and D.pharm educated hospital pharmacist (P=0.003). Nearly 56.7% of participants strongly agree that expert feedback from the ADR monitoring center and the difference in response between untrained and trained hospital pharmacists in pharmacovigilance(P=0.0049). About 51.3% precipitant hospital pharmacists strongly agreed that it is difficult to report ADR and there is a significant difference in response among participants trained in Pharmacovigilance and untrained hospital pharmacists (P=0.006) and the difference between D.pharm and B.pharm graduated hospital pharmacist in response to the statement (P=0.015). Around 27.3% of participant disagreed that reporting is waste of time and difference in response among D.pharm and B.pharm educated hospital (P=0.003) and also the response differs between a trained participant in pharmacovigilance and untrained hospital pharmacist (P=0.036). Nearly 72% of respondents strongly disagree that they have been trained in reporting ADR and there is a significant difference between a participant who trained in pharmacovigilance and nontrained hospital pharmacists (P=0.001). The majority of respondents (50.7%) strongly agreed to help fellow pharmacists in identifying and reporting ADR anda difference in response was observed between trained and untrained hospital pharmacists in pharmacovigilance

(P=0.023). Nearly 52% of respondents strongly agreed to educate health care professionals about ADR reporting, there was a significant difference in response based onthe participant's pharmacovigilance training (P=0.002) and education qualification (P=0.04). Around 34.7% of respondents agreed to discuss with a physician before reporting ADR. In this regard a significant difference in response between the gender (P=0.020) was observed. The distribution of response to behavior questions is presented in Table 4 and Figure9.

The barrier for reporting ADR was evaluated based on 13 questions for which all the participants responded. Nearly 38% of respondents agreed that they did not know how to report ADR. In this regards there is a significant difference in response between trained and untrained hospital pharmacist in pharmacovigilance (P=0.001). Around 53.3% of respondents strongly agree that they did not know how to get the reporting form and a significant difference in response was observed between D.pharm and B.pharm educated hospital pharmacists (P=0.015) and the difference in this regards between gender (P=0.011). In regards there is a significant difference was observed between participants who were trained and not trained in pharmacovigilance(P=0.027). Almost 50% of pharmacists responded strongly agree that lack of time for reporting ADR. A significant difference response was observed between gender (P=0.005) and also between respondent who trained and not trained in pharmacovigilance (P=0.036). Surprisingly 36% of respondents strongly agreed that they did not feel ADR reporting would have benefited them. A significant deviation of response between trained and untrained hospital pharmacists in pharmacovigilance (P=0.045). The majority of respondents (39.3%) strongly agree that ADR reporting is extra work and a significant difference in response was observed between participants trained in pharmacovigilance and untrained hospital pharmacist (P=0.014) and also between D.pharm and B.pharm graduated hospital pharmacists (P=0.011). Around 38% agreed that it is difficult to pinpoint suspected drug which causes ADR and a significant difference in response were found between respondents trained in Pharmacovigilance and untrained hospital pharmacist (P=0.023). Around 34.7% of respondents strongly disagreed that they were not allowed to report ADR and a significant difference was observed between the trained participant and untrained participants (P=0.01). About 35.3% of the pharmacist strongly agreed that the patient does not inform about ADR to them and a significant difference in response was observed over Participants trained in pharmacovigilance and untrained participants. Over 41.3% of participants strongly agreed that they are not considering ADR as their duty to report. In this regard, a significant difference was observed between Hospital pharmacists trained and untrained in Pharmacovigilance. The distribution of response to the Barrier questionnaire is presented in Table 5 and Figures 10.

TABLE 1:
Distribution based on Demographic and Clinical background information.

PARAMETER		**Frequency (n=150)**	**Percentage (%)**
Age (years)	>30	92	61.3
	30-40	42	28
	41-60	16	10.7
Qualification	D.Pharm	87	58
	B.Phram	63	42
PV Training	Yes	7	4.7
	No	143	95.3
Gender	Male	71	47.3
	Female	79	52.6
Experience (Years)	0-5	73	48.6
	6-10	39	26
	<10	38	25.3
Designation	Pharmacy Employee	121	80.7
	Pharmacy Manager	29	19.3

Table 2:Distribution based on response to Knowledge questionnaire

Q. NO	Questions	Response					P-value		
		Strongly agree N(%)	Agree N(%)	Neither N(%)	Disagree N(%)	Strongly Disagree N(%)	GENDER	QUALIFICATION	PV TRAINING
1.	Pharmacovigilance is defined as the detection, assessment, understanding and prevention of ADR.	43(28.7)	36(24)	11(7.3)	34(22.7)	26(17.3)	0.121	0.001	0.001
2.	The important purpose of Pharmacovigilance is to identify safety of drugs.	19(12.7)	54(36)	18(12)	31(20.7)	28(18.7)	0.553	0.619	0.064
3.	CDSCO is responsible for monitoring ADR in India.	17(11.3)	42(28.7)	12(8)	41(27.3)	38(25.7)	0.385	0.426	0.043
4.	National Pharmacovigilance Program of India was inaugurated in New Delhi , 2004.	6(4)	36(24)	18(12)	62(41.3)	28(18.7)	0.012	0.338	0.002
5.	The chairman of National Pharmacovigilance program is DCGI (Drug Controller General of India).	29(19.3)	38(25.7)	15(10)	40(26.7)	28(18.7)	0.028	0.317	0.325
6.	Chennai is a Zonal CDSCO Pharmacovigilance centre.	14(9.3)	42(28)	16(10.7)	44(29.3)	34(22.7)	0.766	0.227	0.027
7.	Vigibase is the WHO online database for reporting ADR.	19(12.7)	29(19.3)	25(16.7)	47(31.3)	30(20)	0.123	0.014	0.014
8.	Post Marketing Surveillance (PMS) is a commonly employed method to monitor ADR of new drugs launched in the market.	13(8.7)	14(9.3)	20(13.3)	55(36.7)	48(32)	0.594	0.192	0.029
9.	Naranjo Scale is used for Casuality assessment of ADR	15(10)	15(10)	26(17.3)	29(19.3)	65(43.3)	0.154	0.002	0.001
10.	There are 28 Peripheral Pharmacovigilance centre in India.	10(6.7)	28(18.7)	16(10.7)	52(34.7)	27(18)	0.386	0.345	0.493
11.	Drugs can be withdrawn from Indian market due to ADR.	27(18)	28(18.7)	16(10.7)	54(36)	25(16.7)	0.402	0.03	0.023
12.	Renal Failure is the major risk factor for the occurrence of maximum ADR.	12(8)	42(28)	20(13.3)	53(35.3)	27(15.3)	0.048	0.243	0.034

13.	Pharmacovigilance also extended to herbal, traditional, and complementary medicines, biologicals, vaccines, blood products, and medical devices.	18(12)	14(9.3)	8(5.3)	73(48.7)	36(24)	0.449	0.06	0.05

TABLE3: Distribution based on response to an Attitude questionnaire

Q.No	**Questions**	**Responses**					**P-VALUE**		
		Strongly Agree	Agree	Neither	Disagree N(%)	Strongly Disagree N(%)	GENDER	QUALIFICATION	PV TRAINING
1	Should ADR be reported by a pharmacist?	108(72)	22(14.7)	0	8(5.3)	12(8)	0.001	0.008	0.007
2	Do you think proper ADR reporting and monitoring will benefit the patient?	63(42)	69(46)	17(11.3)	1(0.7)	0	0.050	0.562	0.052
3	Do you think pharmacovigilance should be taught in detail to healthcare professionals?	78(52)	37(24.2)	17(11.3)	12(8)	6(4)	0.213	0.003	0.000
4	Should ADR reporting made compulsory?	66(44)	44(28)	24(16)	11(7.3)	5(3.3)	0.022	0.147	0.058
5	Do you believe all drugs available in the market are safe?	48(32)	20(36.7)	60(40)	10(6.7)	12(8)	0.724	0.251	0.002
6	Have you ever noticed/experienced an ADR in patient?	54(36)	42(46.7)	31(20.7)	15(10)	8(5.3)	0.079	0.046	0.050
7	Do you think a pharmacist is the right person to assist the physician in reducing ADR?	41(27.3)	55(36.7)	21(14)	12(8)	9(6)	0.173	0.158	0.440
8	Do you think the pharmacist should consult the physician before reporting ADR?	40(26.7)	70(46.7)	19(12.7)	11(7.3)	8(5.3)	0.137	0.041	0.036
9	Do you feel that you need assistance in the area of ADR?	75(50)	40(26.7)	19(48.7)	10(6.7)	6(4)	0.129	0.067	0.039
10	Have you seen any	23(15.	50(3	8(5.3	58(5.	6(4)	0.879	0.073	0.073

	ADR reporting form?	3)	3.3)	)	3)				
11	Do you report any ADR from your Institution?	5(3.3)	18(12)	32(21.3)	64(42.7)	31(20.7)	0.985	0.042	0.009
12	Have you visited any ADR monitoring centre?	15(10)	16(10.7)	58(38.7)	25(16.7)	36(24)	0.548	0.003	0.004
13	Do you think ADR reporting will increase Patients safety?	66(44)	34(22.7)	37(24.7)	10(6.7)	3(2)	0.192	0.003	0.033

TABLE4:Distribution based on response to Behaviour questionnaire

S.No	**Questions**	**Responses**					**P-Value**		
		Strongly agree	Agree	Neither	Disagree	Strongly Disagree	Gender	Qualification	Pv Training
1	Do you think that information technology can improve ADR reporting and patient health?	109(72.7)	23(15.3)	5(3.3)	10(6.7)	3(2)	0.871	0.192	0.136
2	Are you willing to make ADR reporting?	71(47.3)	59(39.3)	12(8)	7(4.7)	1(0.7)	0.531	0.01*	0.001*
3	Have you reported any ADR that you have observed in the patient during your practice?	3(2)	4(2.7)	20(13.3)	56(34.7)	67(44.7)	0.204	0.078	0.081
4	Do you tell the patients what to do in case if he/she develops side effects?	68(45.3)	41(27.3)	31(20.7)	6(4)	4(2.7)	0.152	0.003*	0.000*
5	Do you expect feedback from ADR monitoring centers?	85(56.7)	24(16)	23(15.3)	13(18.7)	5(3.3)	0.145	0.252	0.0049
6	Do you find difficulty in reporting ADR?	77(51.3)	35(23.3)	18(12)	11(7.3)	9(6)	0.836	0.015*	0.006
7	Do you think ADR reporting is waste of time?	20(13.3)	27(18)	29(19.3)	41(27.3)	33(22)	0.408	0.003*	0.036
8	Do you think ADR reporting is necessary?	60(36.7)	52(34.7)	14(9.3)	34(22.7)	10(6.7)	0.287	0.237	0.074

9	Have you ever been trained on reporting ADR?	9(6)	0(0)	18(12)	15(10)	108(72)	0.923	0.160	0.001*
10	Do you update your knowledge in regard to drugs and its adverse effects?	82(54.7)	40(26.7)	22(14.7)	5(3.3)	1(0.7)	0.752	0.248	0.056
11	Do you help your fellow pharmacist in identifying and reporting the ADR?	76(50.7)	45(30)	19(12.7)	5(3.3)	5(3.3)	0.959	0.274	0.023
12	Do you educate the health care workers about ADR reporting?	78(52)	30(20)	17(11.3)	15(10)	10(6.7)	0.236	0.04	0.002
13	Do you discuss with the physician before reporting ADR?	39(26)	52(34.2)	39(26)	17(11.3)	3(2.0)	0.020	0.128	0.685

TABLE 5:Distribution based on response to Barrier questionnaire

S. No	Questions	Response					P-Value		
		Strongly agree	Agree	Neither	Disagree	Strongly Disagree	Gender	Qualification	PV Training
1	Did not know that ADRs needs to be reported?	90(60)	18(10)	10(6.7)	4(2.7)	38(25.3)	0.122	0.150	0.181
2	Did not know pharmacists can report?	28(18.7)	73(487)	42(28)	7(4.7)	0(0)	0.334	0.234	0.064
3	Did not know how to report?	33(22)	57(38)	22(14.7)	34(22.7)	4(2.7)	0.793	0.511	0.001
4	Did not know how to get the reporting forms?	80(53.3)	29(19.3)	15(10)	3(2)	23(15.3)	0.016	0.015	0.027
5	Lack of time to involve in such activities?	75(50)	24(16)	26(17.3)	6(4)	19(12.7)	0.005	0.262	0.036
6	Did not feel that ADR reporting would benefit?	54(36)	38(25.3)	24(16)	30(20)	4(2.7)	0.113	0.254	0.045
7	Because it is extra work?	59(37.3)	31(20.7)	8(5.3)	13(8.7)	39(26)	0.713	0.011	0.014
8	I don’t have any benefit by reporting the same?	25(16.7)	44(29.3)	20(13.3)	42(28)	19(12.7)	0.060	0.206	0.173
9	Difficult to pinpoint the suspected drug?	28(18.7)	32(21.3)	29(19.3)	57(38)	24(16)	0.395	0.195	0.023
10	Is ADR not allowed to report?	23(15.3)	18(12)	14(9.3)	43(28.7)	52(34.7)	0.112	0.299	0.010
11	Patient do not inform about the ADR.	31(20.7)	30(20)	53(35.3)	18(12)	18(12)	0.184	0.305	0.007

12	Did not consider reaction serious enough to report	26(17.3)	53(35.3)	36(24)	31(20.7)	4(2.7)	0.642	0.224	0.556
13	Did not consider the duty to report it	62 (41.3)	18 (12)	43(28.7)	13(8.7)	14(9.3)	0.280	0.248	0.021

DISCUSSION:

Pharmacovigilance is an integral part of the health care system. In this present study,a 60% response was received when nearly 250 hospital pharmacists were approached, which is similar to the study conducted by **Vora *et al,* [2015]**[15]. In the current study majority of participants were below 30years in age, which is similar to the previous study conducted by **Syed *et al,*[2018]**[16] in Pakistan and contrast to studies conducted in Iraq by **Sharrad et.al,[2016]**[17]. Female respondents (52%) were predominant in this study population when this is similar to study participants of **Mirdula *et al,* [2017]**[18]. The majority of the respondents have a professional experience of fewer than 5 years in this study which is in contrast to the study done by **Udoeye *et.al.*,[2018]**[19] in Nigeria. In our study, the majority of the participants are pharmacy employees (80%) which is identical to that conducted by **Syed *et.al.,*[2018]**[19]. Most of the respondents in this KAP study were D.Pharm graduates (58%) which is comparable with the KAP study conducted by **Amin *et.al.*,[2015]**[20]. Out of 150 participants, only 4.7% attended pharmacovigilance training. From our study, it is clear that hospital pharmacists have a lacuna in knowledge towards Pharmacovigilance. The study conducted by **Meher *et.al.*,[2018]**[21] in South India have also shown similar results. The majority of respondents gave a clear response to the definition and purpose of pharmacovigilance which corroborates with the finding of **Kumari *et al,*[2015]**[22]. About 11.3% of respondents show a correct response that CDSCO is responsible for monitoring ADR in India these findings coincide with the result concluded by **Vora *et al,*[2015]**[15]. In this study, respondents gave an incorrect answer about the vigibase which is an online database of WHO for ADR which is similar to the response received from study participants of **Vora B*et al,*[2015]**[15]. Totally 48% of participant's perception of including herbal, traditional medicine, biological, vaccine and medical device in pharmacovigilance was wrong, which isa contrast to the results of the study done by **Reddy *et al,* [2014]**[23]. The study results shows that hospital pharmacists gave an incorrect response towards knowledge questions. Around 72% of the respondents do not know that pharmacist can report ADR, 44% of the respondents think ADR reporting must be made compulsory and 32% respondents believed all drugs in the market are safe and 0.7% of the respondents only visited the ADR monitoring center, these findings are similar to the study conducted by **Sonowal *et al,*[2018]**[24]. About 44% of hospital pharmacists agreed that ADR reporting should be made compulsory and reporting ADR will increase patient safety, these findings have similarities with the study conducted by **Gupta *et al,* [2011]**[25]**.**The majority of the respondents have a positive response to the attitude and behavior towards pharmacovigilance and ADR reporting. Nearly 47.3% of respondents strongly agree that they were willing to report ADR. Only 4.7% of respondents gave a positive response on that they have trained in pharmacovigilance and 3.3% of hospital pharmacists have already reported an ADR, another study conducted by **Anbalagan K *et al,*[2018]**[26]showed similar results. The major barrier in reporting an ADR was found to be that Hospital pharmacist are unaware that ADR needs to be reported (60%), lack of time (50%), did not know how to get reporting form (53.3%) and considering it not serious to report an ADR (42.3%). This was similar to the study results of **Amin M *et.al.,*[2015][27]** and **Sonowal *et.al.,*[2018][24].** Several other studies have been carried out in various countries for finding barriers in pharmacovigilance and ADR reporting. In India**, Divyalasa *et al,*[2016]**[28] conducted KAP on pharmacovigilance towards prescribers and found out that Lack of time is the main reason for not reporting ADR in their study and the present study 50% Hospital pharmacist also accept that as a barrier. The current study has identified other barriers for reporting ADR as'the Patient not informing about ADR and considers it as an additional work'. In

this study hospital pharmacists showed considerable interest in pharmacovigilance and they have a positive attitude toward ADR reporting.

CONCLUSION:
ADR monitoring and reporting is highly essential to ensure patient medication safety. Hospital pharmacist play a major role in drug safety. They are trained in therapeutics and pharmacology of drugs. If trained properly in pharmacovigilance, Hospital pharmacists will improve in their knowledge towards pharmacovigilance, overcome the barrier, and change their attitude and behavior towards pharmacovigilance and in reporting ADR. The study strongly recommends conductingawareness programs in pharmacovigilance to Hospital pharmacists in India.

SUMMARY:
We assessed the Knowledge, Attitude, Behavior, and Barrier towards Pharmacovigilanceamong 150 Hospital pharmacists in and around Chennai. The key findings of the study are:

- Lacunae in Knowledge towards pharmacovigilance.
- Hospital pharmacist lacks in training towards pharmacovigilance.
- Assistance in reporting ADR will motivate Hospital pharmacists to report.
- Many considered ADR reporting as extra work and not their duty to report ADR.
- The Pharmacovigilance program of India (PVPI) is not famous among hospital pharmacists and does not know about the introduction and functioning of the pharmacovigilance program.
- Majority of respondents are interested in reporting ADR
- Hospital pharmacists lack knowledge in pharmacotherapeutics and adverse drugreaction. So, it's difficult to find the suspected drugs which cause ADR.
- Many believed that reporting ADR may affect their career and their confidentiality in reporting ADR is low.

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CONFLICT OF INTEREST:
The authors declare no conflict of interest.

SOURCE OF FUNDING: The authors declare no source of funding

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FIGURES

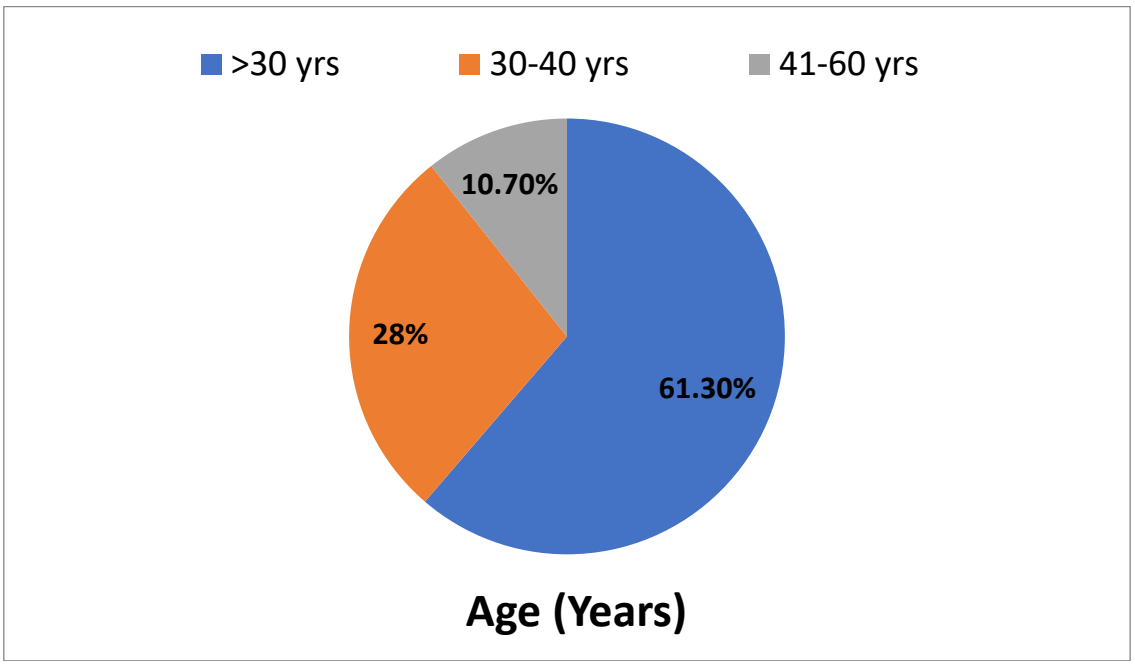

Figure 1 Age distribution

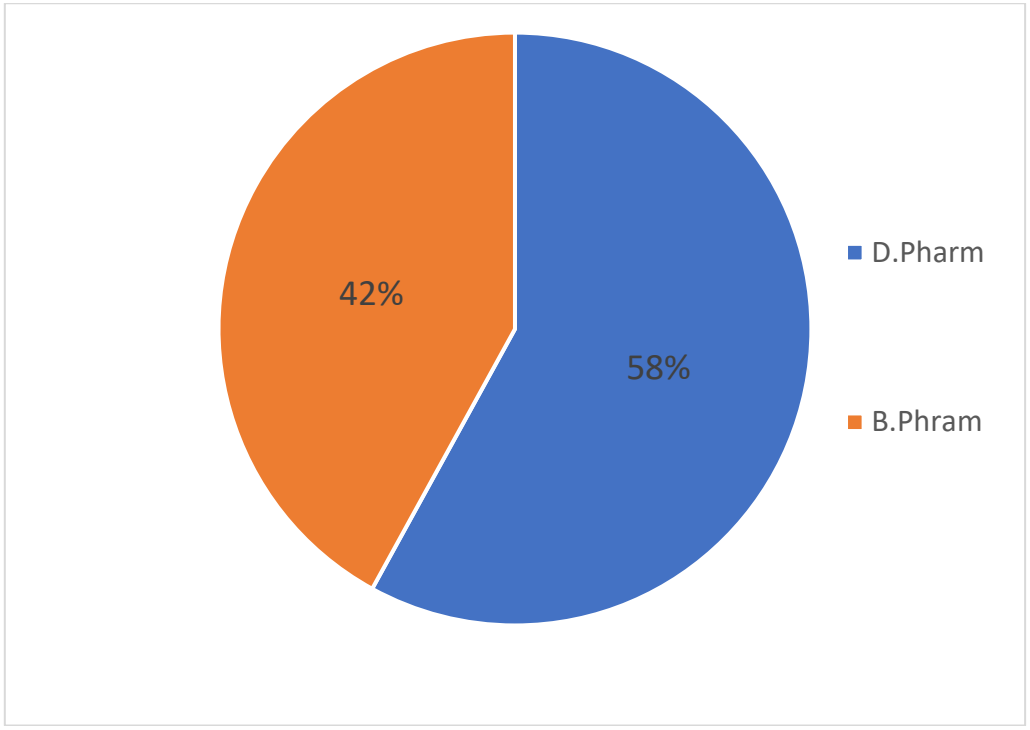

Figure 2 Distribution of education level of study participants

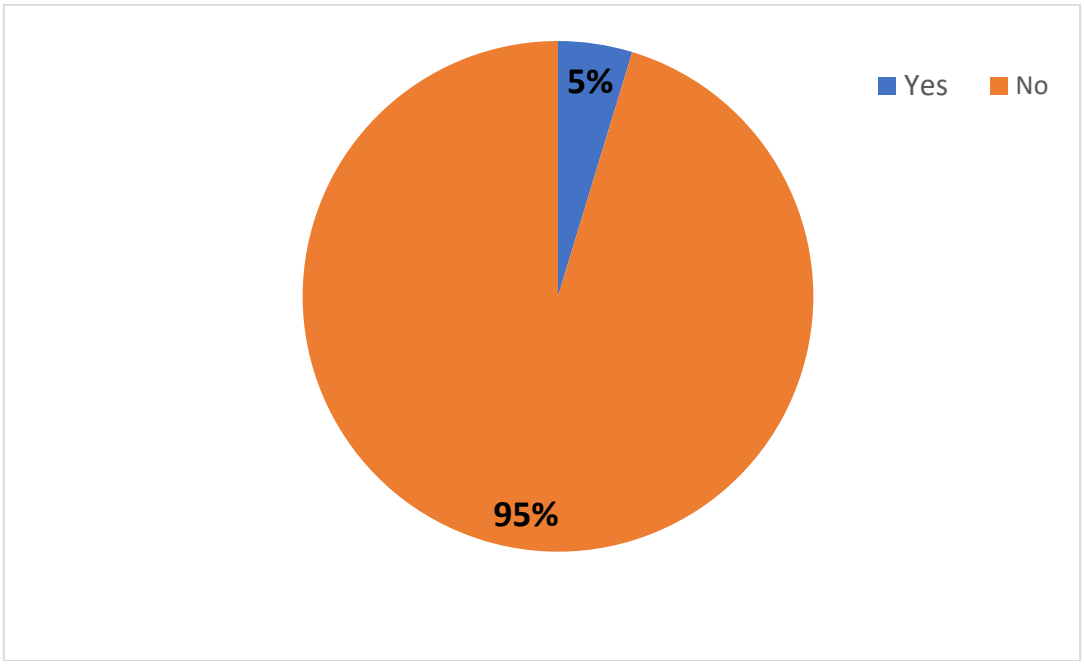

Figure 3 Status of Pharmacovigilance training

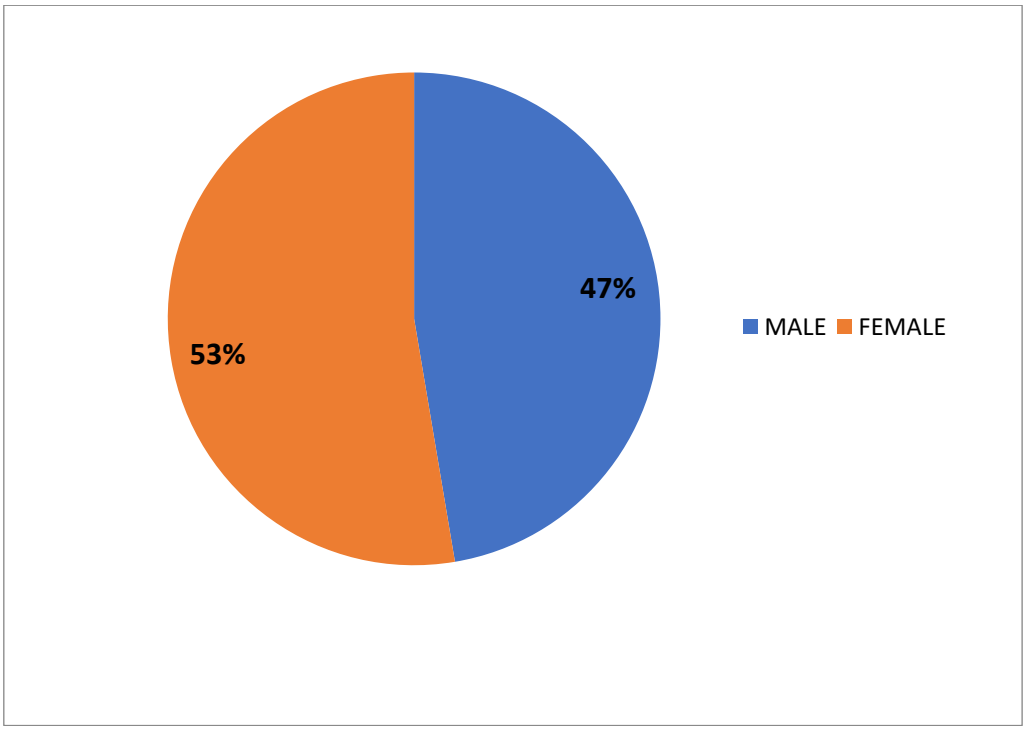

Figure 4 Gender Distribution

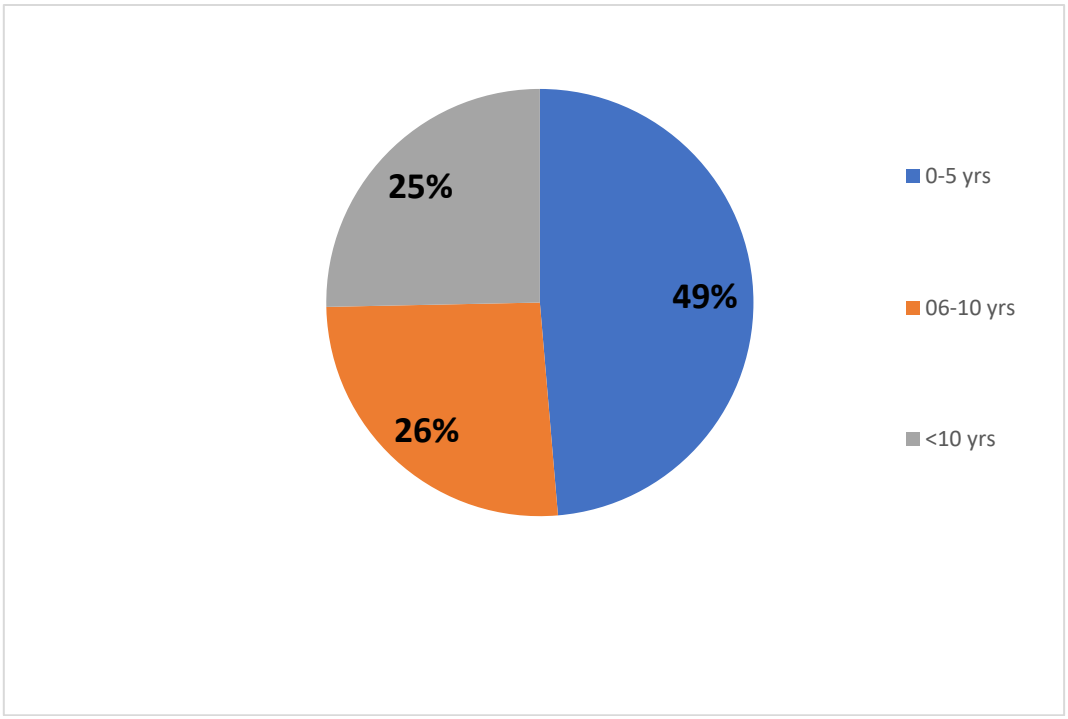

Figure 5 Distribution of professional experience as pharmacist

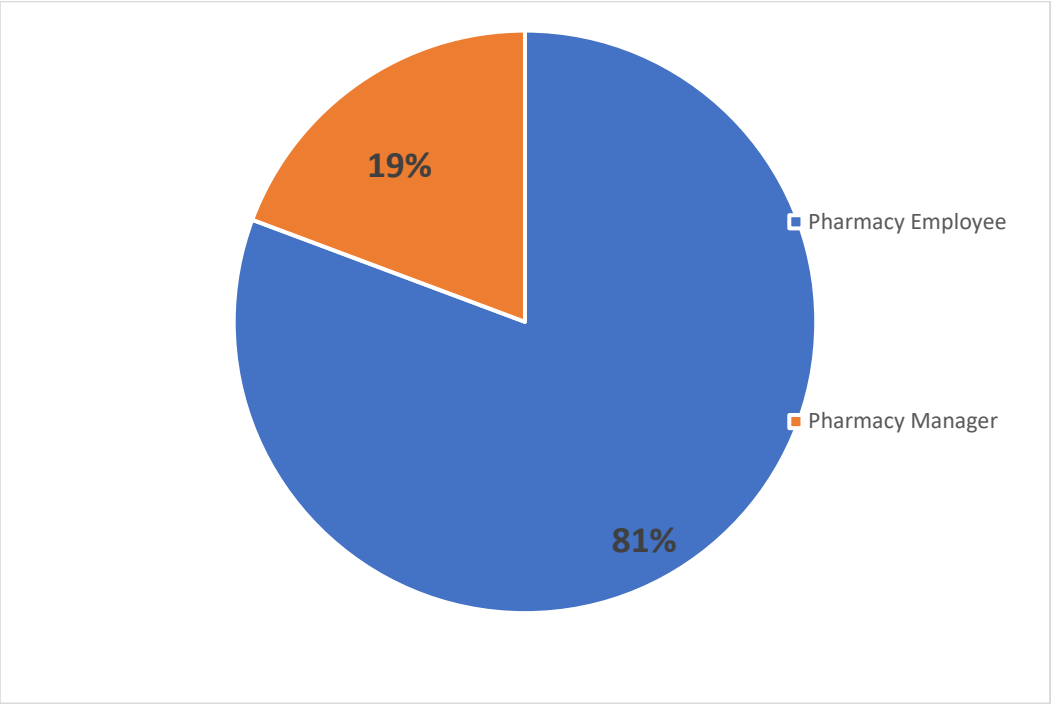

Figure 6 Designation wise distribution

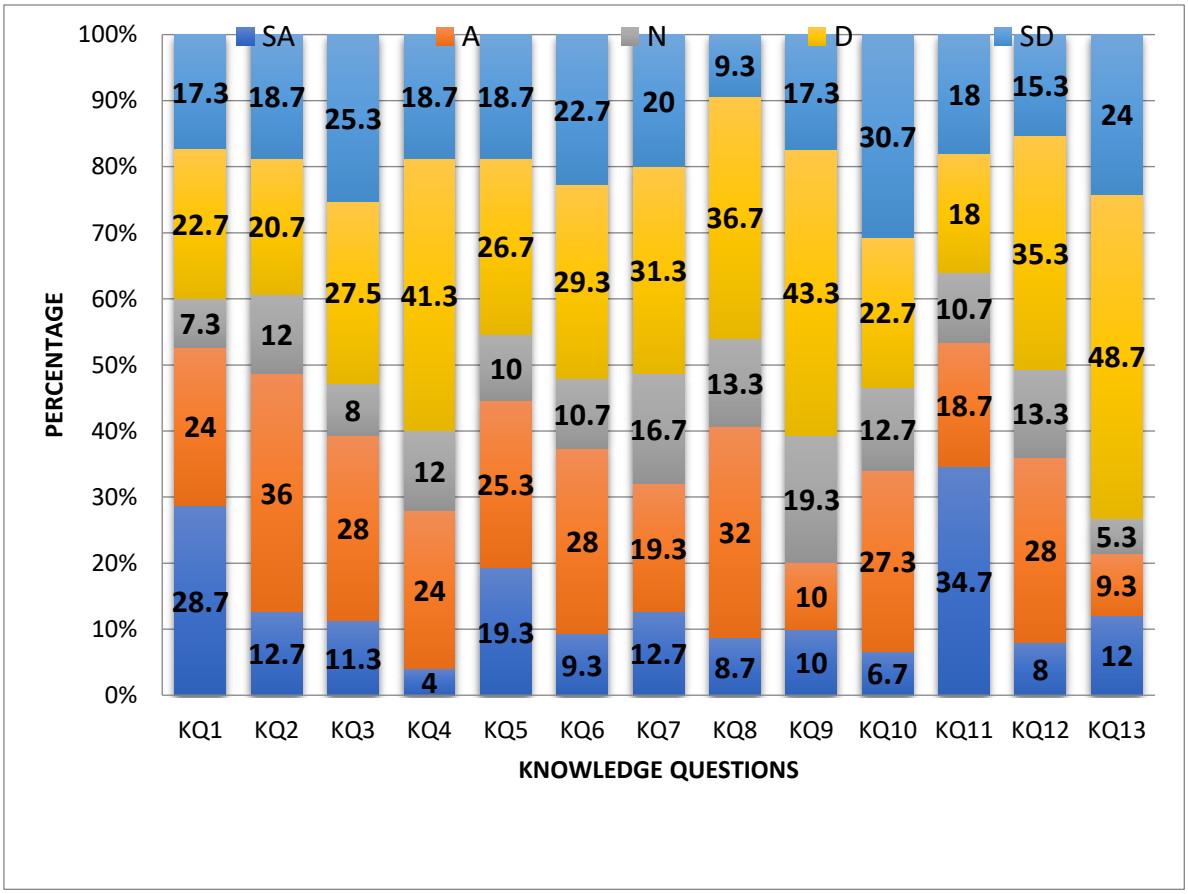

Figure 7 Distribution of response to knowledge questionnaire

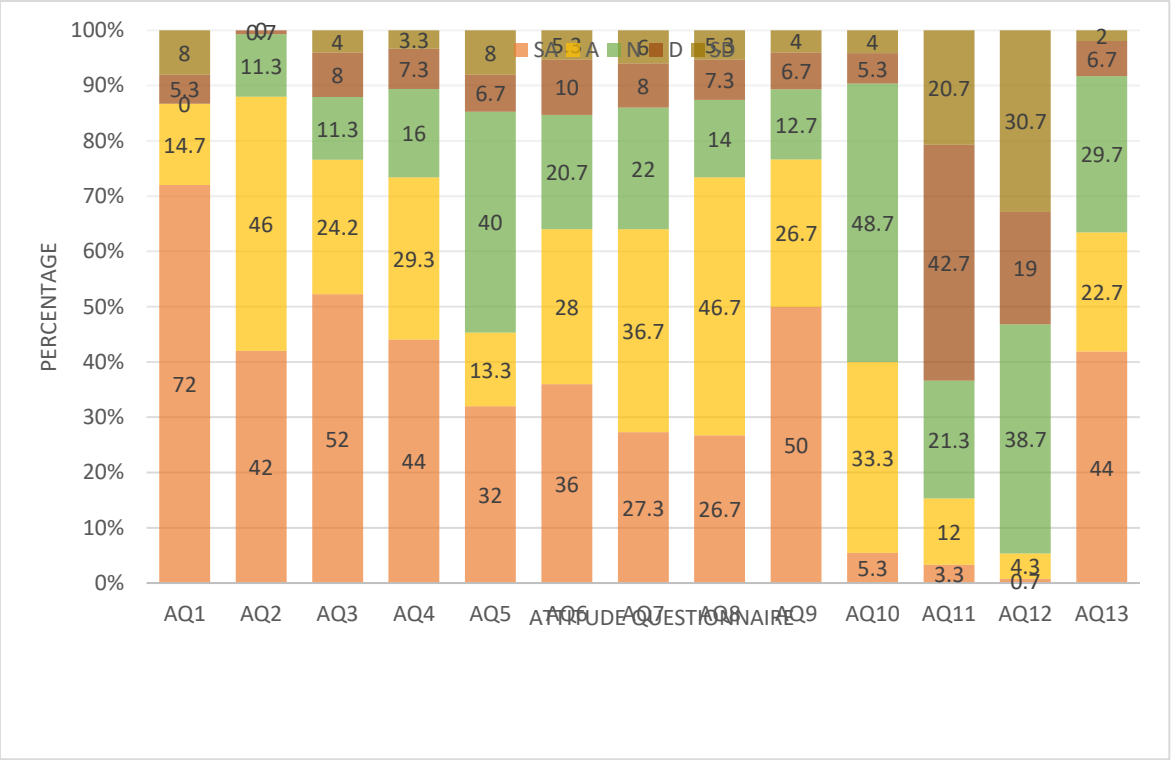

FIGURE 8 Distribution based on response to attitude questionnaire

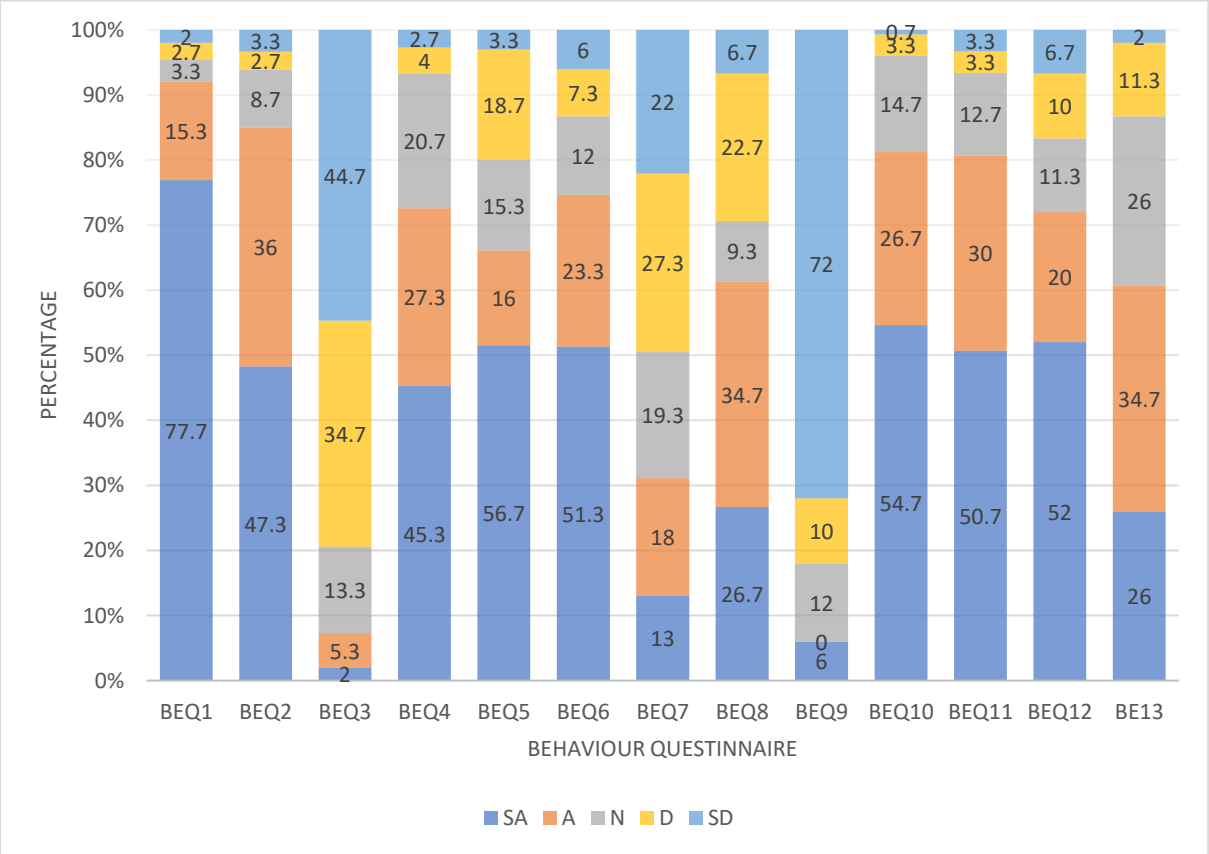

FIGURE 9 Behaviour response wise distributions

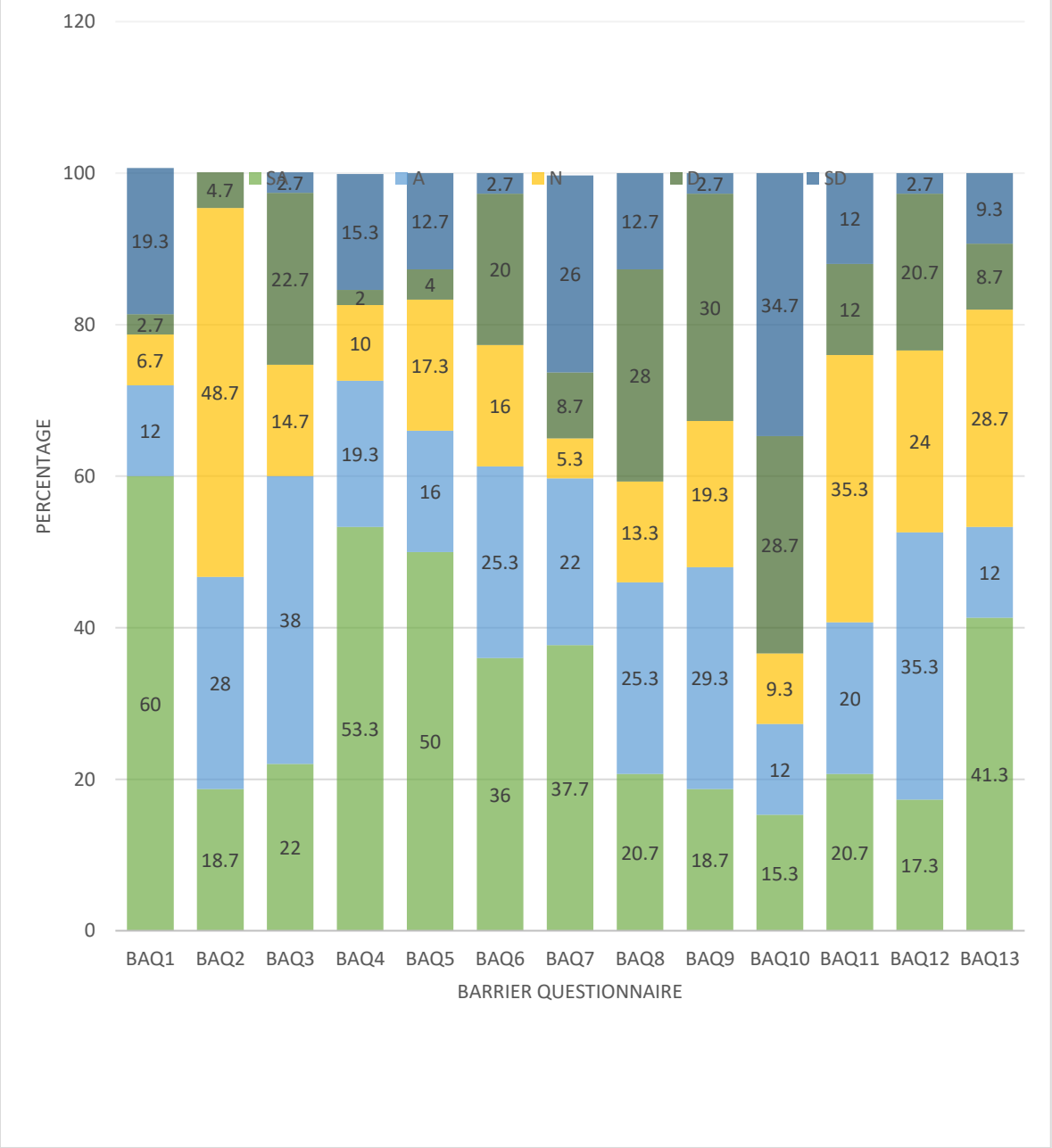

FIGURE10 Distribution based on response to barrier questionnaire