KNOWLEDGE AND PRACTICE OF PHARMACOVIGILANCE BY HEALTHCARE PROVIDERS IN TERTIARY HEALTH INSTITUTIONS IN LAGOS STATE, NIGERIA

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INTRODUCTION

- Pharmacovigilance (PV) programmes have been adopted by various countries in order to ensure safe use of drugs.

- Pharmacovigilance is commonly defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other related drug problems.



INTRODUCTION CONTINUED

- Healthcare providers comprise the professionals involved with health delivery services with the over all mandate of optimizing a patient's well being

- To date, the mainstay of pharmacovigilance has been spontaneous reporting by health care providers



OBJECTIVE OF STUDY

- The aim of this study was to assess the knowledge and practice of healthcare providers on Pharmacovigilance in Nigerian tertiary hospitals

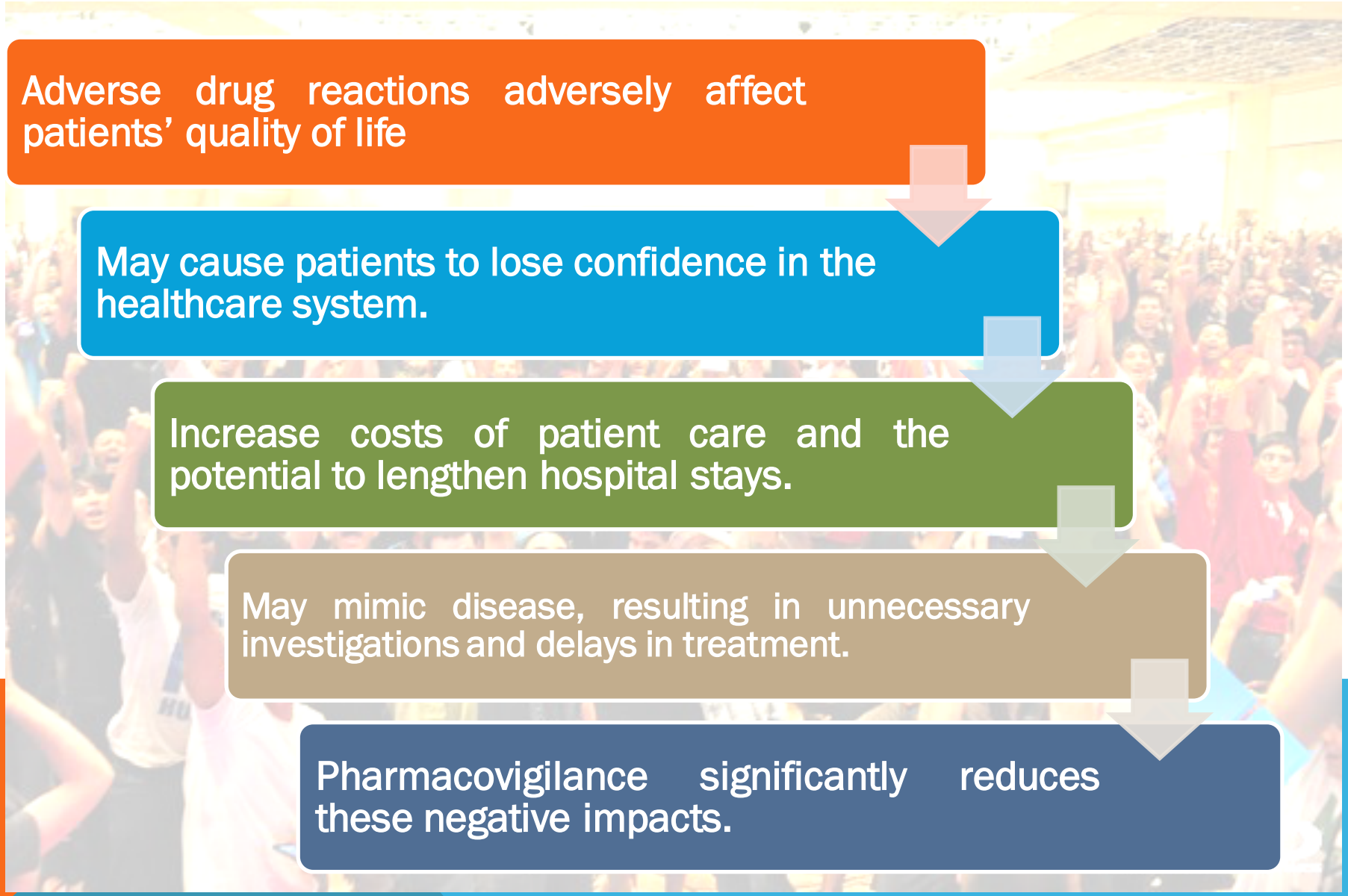


SPECIFIC OBJECTIVES

To identify healthcare providers' demographic characteristics, attributes and specialty in relation to the knowledge of PV.

To assess the healthcare providers' knowledge of Pharmacovigilance.

MOTIVATION FOR STUDY



Adverse drug reactions adversely affect patients' quality of life

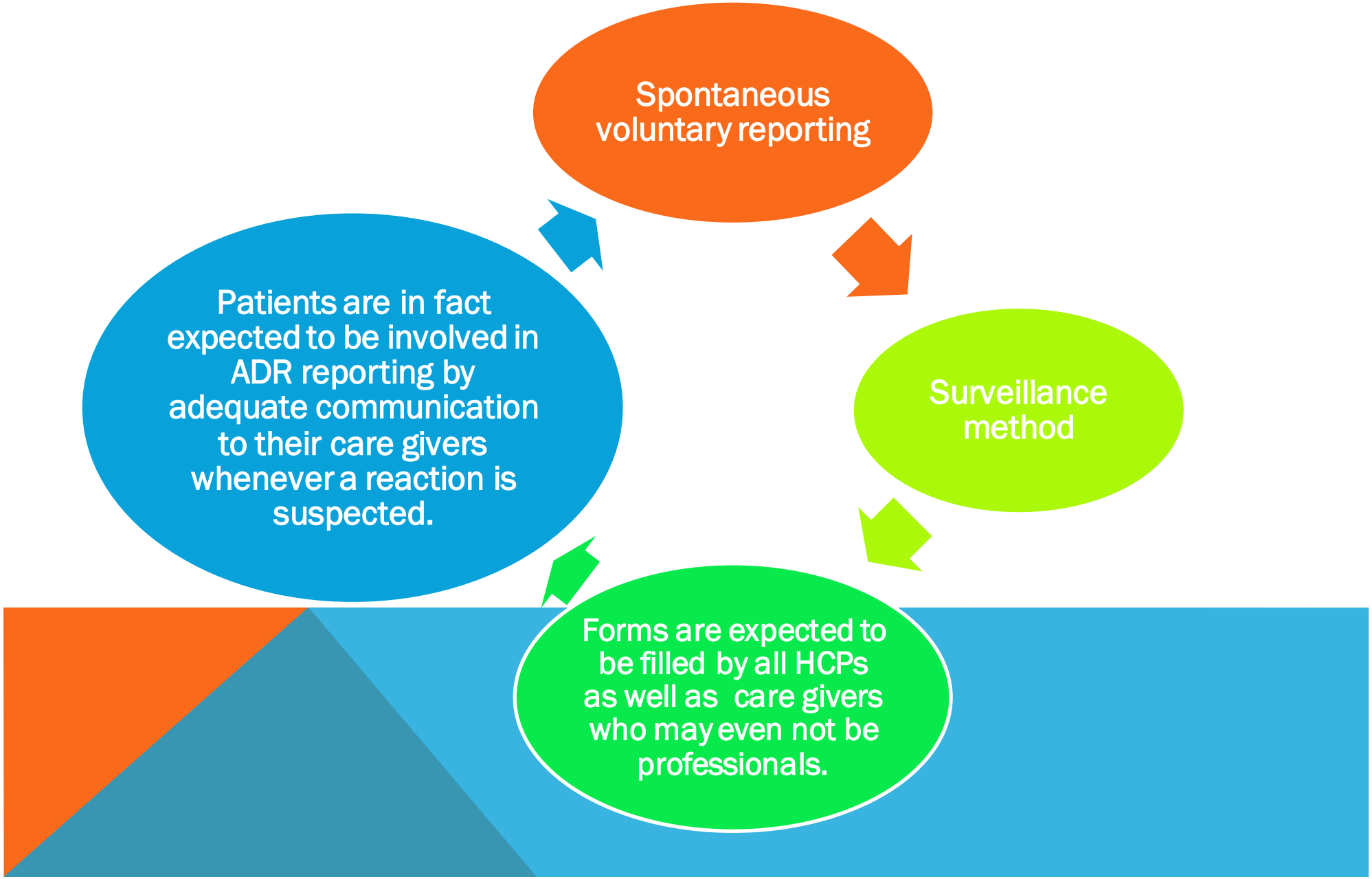
May cause patients to lose confidence in the healthcare system.

Increase costs of patient care and the potential to lengthen hospital stays.

May mimic disease, resulting in unnecessary investigations and delays in treatment.

Pharmacovigilance significantly reduces these negative impacts.

PHARMACOVIGILANCE IN NIGERIA



NATIONAL PHARMACOVIGILANCE CENTRE (NPC) NIGERIA

National Agency for Food and Drug Administration & Control (NAFDAC), Headquarters Office
Plot 2032 Olusegun Obasanjo Way
Wuse Zone 7 Abuja

Tel: 08086899571 or Fax: 09-5241108

FORM FOR REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS

IN STRICT CONFIDENCE

1. * PATIENT'S DETAILS

Full Name or Initials: _____ Patient Record No: _____

AGE/DATE OF BIRTH: _____ SEX: M ☐ F ☐ WEIGHT (kg): _____

HOSPITAL/Treatment Centre: _____

2. * ADVERSE DRUG REACTION (ADR)

A. DESCRIPTION

DATE Reaction Started	DATE Reaction Stopped

C. OUTCOME OF REACTION

TICK AS APPROPRIATE

☐ Recovered fully ☐ Recovered with disability (Specify) _____

☐ Congenital Abnormality (Specify) _____ ☐ Life Threatening (Specify) _____

☐ Death ☐ Others (specify) _____

B. Was Patient Admitted Due to ADR Yes ☐ No ☐

If Already Hospitalized, Was it Prolonged Due to ADR Yes ☐ No ☐

Duration of Admission (days) _____

Treatment of Reaction: _____

3. * SUSPECTED DRUG (Including Biologicals Traditional/Herbal Medicines & Cosmetics)

A. DRUG DETAILS (State name and other details if available / Attach product label / Sample (if available)

Brand Name: _____ Generic Name: _____ Batch No: _____

NAFDAC No: _____ Expiry Date: _____

Name & Address of Manufacturer: _____

B. Indications for Use	Dosage	Route of Administration	Date Started	Date Stopped

4. * CONCOMITANT MEDICINES (All medicines taken within the last 3months including herbal and self medication)

Brand or Generic Name	Dosage	Route	Date Started	Date Stopped	Reason for Use

5. * SOURCE OF REPORT:

Name of Reporter: _____

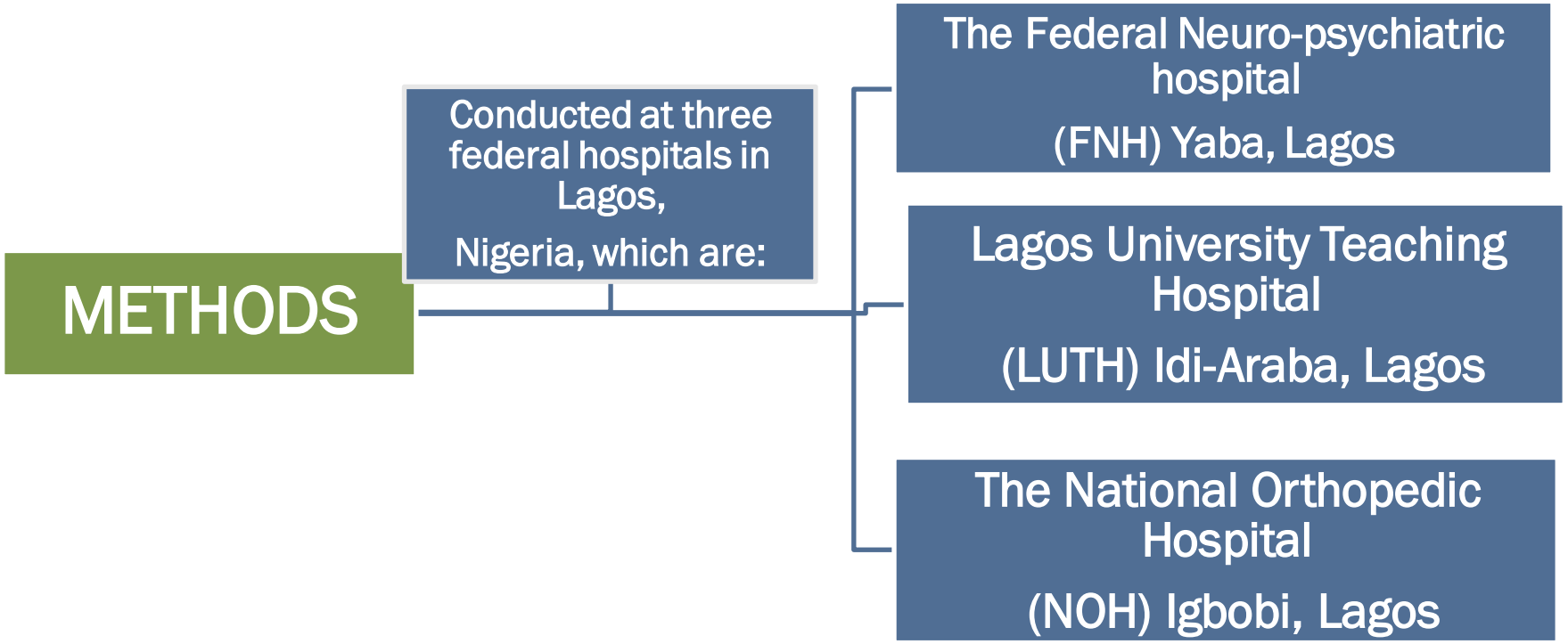
Address: _____

Profession: _____

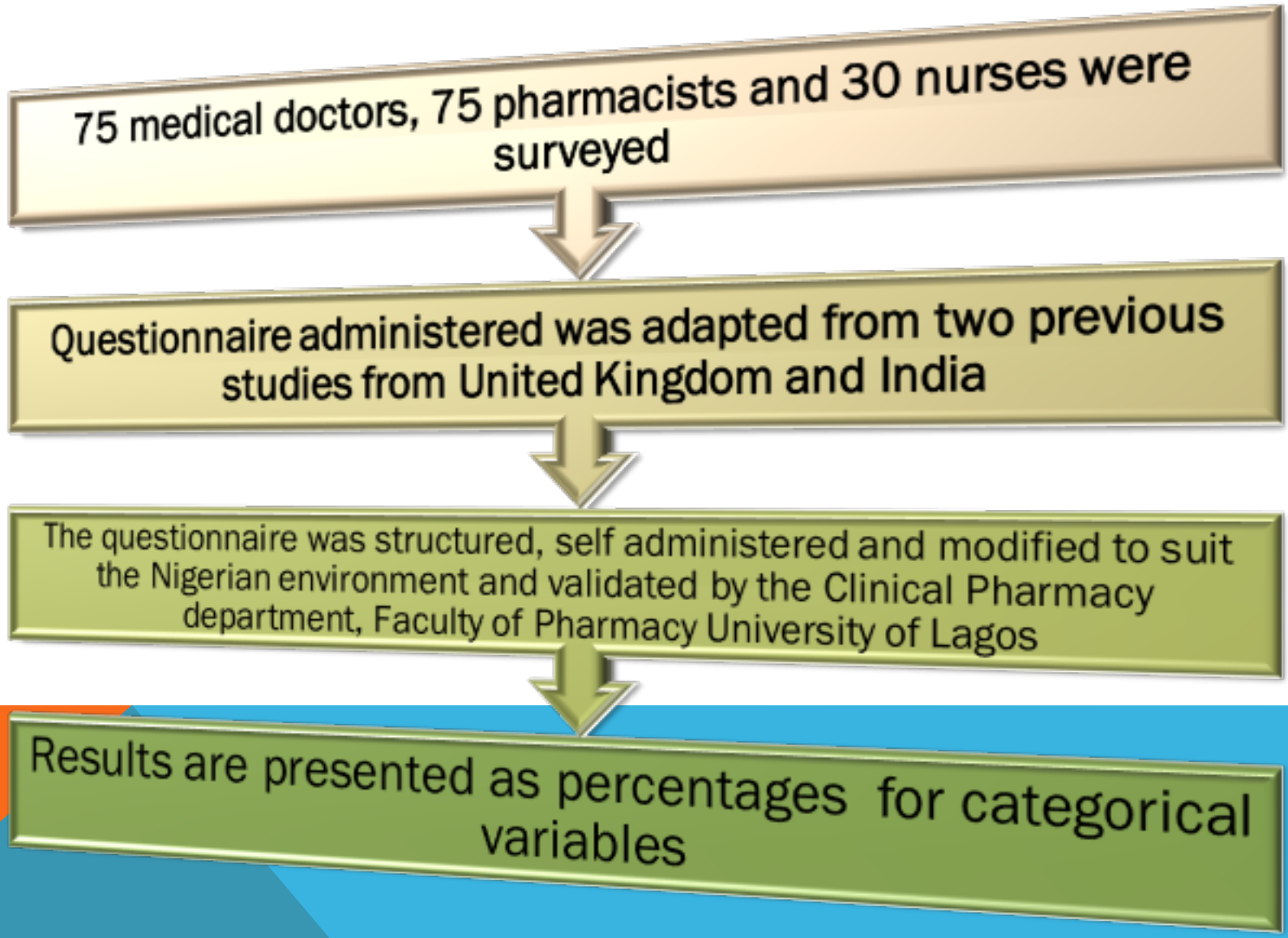
Signature: _____ Tel No/E-mail: _____

*: MANDATORY FIELDS

METHOD


METHODS
Conducted at three federal hospitals in Lagos,
Nigeria, which are:
The Federal Neuro-psychiatric hospital
(FNH) Yaba, Lagos
Lagos University Teaching Hospital
(LUTH) Idi-Araba, Lagos
The National Orthopedic Hospital
(NOH) Igbobi, Lagos

DESIGN AND STUDY POPULATION



RESULTS

TABLE 1: SOCIO-DEMOGRAPHIC DATA

POSITION	LUTH (n=60) Freq (%)	FNH (n=55) Freq (%)	NOH (n=57) Freq (%)	TOTAL (n=172) Freq (%)
Doctor	14(23.3)	14(25.5)	17(29.8)	45(78.6)
Pharmacists	12(20.0)	17(30.9)	22(38.6)	51(89.5)
House Officers	15(25.0)	6(10.9)	4(7.0)	25(42.9)
Pharmacy interns	11(18.3)	9(16.4)	7(12.3)	27(47.0)
Nurses	8(13.3)	9(16.4)	6(10.5)	25(40.2)
Others	0(0.0)	0(0.0)	1(1.8)	1(1.8)
NUMBER OF YEARS OF PRACTICE				
<10	49(81.8)	12(92.3)	27(77.14)	88(251.24)
11-20	6(10.1)	1(7.7)	6(17.14)	13(34.22)
21-30	10.1(5)	0(0.0)	2(5.71)	12.1(10.71)
GENDER				
Female	31(51.7)	26(47.3)	32(56.1)	89(155.1)
Male	29(48.3)	19(52.7)	25(43.9)	83(144.9)
AGE RANGE				
<25	19(31.7)	11(17.8)	9(15.8)	39(65.3)
26-35	26(43.3)	25(50.9)	33(57.9)	84(152.1)
36-45	8(13.3)	12(19.5)	10(17.5)	30 (50.3)
46-55	6(10.0)	7(11.8)	5(8.8)	18(30.6)
>55	1(1.7)	0(0.0)	0(0.0)	1(0.0)
MARITAL STATUS				
Married	25(41.7)	28(50.9)	22(38.6)	75(131.2)
Single	35(58.3)	27(49.1)	35(61.4)	97(168.8)
ETHNIC GROUP				
Yoruba	38(63.3)	24(43.6)	33(57.9)	95(164.8)
Igbo	20(33.3)	20(36.4)	21(36.8)	61(106.5)
Hausa	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Others	2(3.3)	11(20.0)	3(5.3)	16(28.6)
RELIGION				
Christianity	47(78.3)	39(70.9)	48(84.2)	134(233.4)
Islam	12(20.0)	14(25.5)	9(15.8)	35(61.3)
Others	1(1.7)	2(3.6)	0(0.0)	3(5.3)

RESPONDENTS KNOWLEDGE ON PHARMACOVIGILANCE

- Table 2: *Respondents knowledge on Pharmacovigilance*

ITEMS	LUTH	FNH	NOH
	Freq(%)	Freq(%)	Freq(%)
Pharmacovigilance definition			
✓ **Correct**	**41(68.3)**	**29(52.7)**	**32(56.1)**
✓ **Incorrect**	**19(31.7)**	**26(47.3)**	**25(43.8)**
Pharmacovigilance is an arm of….			
✓ **Correct**	**24(40.0)**	**21(42.1)**	**24(38.2)**
✓ **Incorrect**	**36(60)**	**34(61.8)**	**33(57.9)**
Aim of ADR reporting scheme in Nigeria			
✓ **Correct**	**40(69)**	**17(30.9)**	**48(84.2)**
✓ **Incorrect**	**20(31)**	**38(69.1)**	**9(15.8)**

TABLE 3: FURTHER KNOWLEDGE ASSESSMENT BY RESPONDENTS IN LUTH

	SA	A	D	SD
	Freq (%)	Freq (%)	Freq (%)	Freq (%)
Efficient identification and communication of medicine related adverse events	47(78.3)	11(18.3)	1(1.7)	1(1.7)
PV includes herbal, traditional and complementary medicines	15(25.0)	29(48.3)	13(21.7)	3(5.0)
PV includes food and drinks	16(26.7)	18(30.0)	25(41.7)	1(1.7)
A well implemented pharmacovigilance system results in reduced healthcare cost for patients.	27(45.0)	17(28.3)	13(21.7)	3(5.0)
In- patients and out-patients will spend more on healthcare if adverse drug reactions are reported and handled.	13(21.7)	15(25.0)	23(38.3)	9(15.0)
Unnecessary expenses during treatment of diseases, from adverse drug reactions will be reduced through Pharmacovigilance.	31(51.7)	25(41.7)	3(5.0)	1(1.7)
PV can reduce morbidity and mortality associated with major diseases	35(58.3)	23(38.3)	2(3.3)	-
Frequent hospital visits cannot be checked by a good Pharmacovigilance system.	12(20.0)	25(41.7)	20(33.3)	3(5.0)
The primary source of information for Pharmacovigilance is from spontaneous reporting by health care professionals.	21(35.0)	29(48.3)	6(10.0)	4(6.7)
Adverse Drug Reaction (ADR) Reporting and Pharmacovigilance is the same thing.	16(26.7)	20(33.3)	17(28.3)	7(11.7)

TABLE 4: FURTHER KNOWLEDGE ASSESSMENT BY RESPONDENTS IN FNH

	SA	A	D	SD
	Freq (%)	Freq (%)	Freq (%)	Freq (%)
Efficient identification and communication of medicine related adverse events	46(83.6)	8(14.5)	1(1.8)	-
PV includes herbal, traditional and complementary medicines	34(61.8)	19(34.5)	2(3.6)	-
PV includes food and drinks	33(60.0)	18(32.7)	3(5.5)	1(1.8)
A well implemented pharmacovigilance system results in reduced healthcare cost for patients.	33(60.0)	20(36.4)	2(3.6)	-
In- patients and out-patients will spend more on healthcare if adverse drug reactions are reported and handled.	27(49.1)	18(32.7)	6(10.9)	4(7.3)
Unnecessary expenses during treatment of diseases, from adverse drug reactions will be reduced through Pharmacovigilance.	28(50.9)	24(43.6)	3(5.5)	-
PV can reduce morbidity and mortality associated with major diseases	26(47.3)	26(47.3)	3(5.5)	-
Frequent hospital visits cannot be checked by a good Pharmacovigilance system.	19(34.5)	25(45.5)	7(12.7)	(7.3)
The primary source of information for Pharmacovigilance is from spontaneous reporting by health care professionals.	22(40.0)	23(41.8)	10(18.2)	-
Adverse Drug Reaction (ADR) Reporting and Pharmacovigilance is the same thing.	27(49.1)	22(40.0)	6(10.9)	-

TABLE 5: FURTHER KNOWLEDGE ASSESSMENT BY RESPONDENTS IN NOH

	SA	A	D	SD
	Freq (%)	Freq (%)	Freq (%)	Freq (%)
Efficient identification and communication of medicine related adverse events	21(36.8)	36(63.2)	-	-
PV includes herbal, traditional and complementary medicines	49(86.0)	6(10.5)	2(3.5)	-
PV includes food and drinks	11(19.3)	43(75.4)	-	-
A well implemented pharmacovigilance system results in reduced healthcare cost for patients.	51(89.5)	4(7.0)	2(3.5)	-
In- patients and out-patients will spend more on healthcare if adverse drug reactions are reported and handled.	6(10.5)	1(1.8)	4(7.0)	46(80.7)
Unnecessary expenses during treatment of diseases, from adverse drug reactions will be reduced through Pharmacovigilance.	55(96.5)	2(3.5)	-	-
PV can reduce morbidity and mortality associated with major diseases	51(89.5)	5(8.8)	1(1.8)	-
Frequent hospital visits cannot be checked by a good Pharmacovigilance system.	3(5.3)	6(10.5)	8(14.0)	40(70.2)
The primary source of information for Pharmacovigilance is from spontaneous reporting by health care professionals.	51(89.5)	4(7.0)	2(3.5)	-
Adverse Drug Reaction (ADR) Reporting and Pharmacovigilance is the same thing.	7(12.3)	8(14.0)	6(10.5)	36(63.2)

RESPONDENTS PHARMACOVIGILANCE PRACTICE IN LUTH

	SA	A	D	SD
	Freq (%)	Freq (%)	Freq (%)	Freq (%)
There is a functional pharmacovigilance or ADR reporting centre in this hospital.	19(31.7)	26(43.3)	14(23.3)	1(1.7)
ADR reporting is routinely done in this hospital.	14(23.7)	36(61.0)	9(15.3)	-
The facilities in the pharmacovigilance unit of this hospital are adequate.	7(11.7)	22(36.7)	29(48.3)	2(3.3)
Counseling to patients regarding ADR is often administered	19(31.7)	26(43.3)	13(21.7)	2(3.3)
The zonal pharmacovigilance centers initiative is ineffective.	6(10.0)	31(51.7)	14(23.3)	9(15.0)
Good communication skills are required in pharmacovigilance.	35(58.3)	24(40.0)	1(1.7)	-
Well known ADRs do not need to be reported.	5(8.3)	25(41.7)	17(28.3)	13(21.7)
There are usually hindrances during work hours to report Adverse Drug Reactions in the hospital.	18(30.0)	25(41.7)	9(15.0)	8(13.3)
No one is actually responsible for ADR reporting in this hospital.	8(13.3)	22(36.7)	23(38.3)	7(11.7)
ADRs in Nigeria cannot be curbed by pharmacovigilance activities.	2(3.3)	22(36.7)	27(45.0)	9(15.0)
In your opinion, ADRs should be reported to Senior personnel in the hospital.	15(25.0)	14(23.3)	18(30.0)	13(21.7)

RESPONDENTS PHARMACOVIGILANCE PRACTICE IN FNH

	SA	A	D	SD
	Freq (%)	Freq (%)	Freq (%)	Freq (%)
There is a functional pharmacovigilance or ADR reporting centre in this hospital.	11(20.0)	7(12.7)	36(65.5)	1(1.8)
ADR reporting is routinely done in this hospital.	13(23.6)	16(29.1)	26(47.3)	-
The facilities in the pharmacovigilance unit of this hospital are adequate.	8(14.5)	22(40.0)	25(45.5)	-
Counseling to patients regarding ADR is often administered	4(7.3)	36(65.5)	15(27.3)	-
The zonal pharmacovigilance centers initiative is ineffective.	9(16.4)	36(65.5)	10(18.2)	-
Good communication skills are required in pharmacovigilance.	12(21.8)	38(69.1)	5(9.1)	-
Well known ADRs do not need to be reported.	11(20.0)	34(61.8)	9(16.4)	1(1.8)
There are usually hindrances during work hours to report Adverse Drug Reactions in the hospital.	11(20.0)	35(63.6)	8(14.5)	54(98.2)
No one is actually responsible for ADR reporting in this hospital.	6(10.9)	31(56.4)	17(30.9)	54(98.2)
ADRs in Nigeria cannot be curbed by pharmacovigilance activities.	13(23.6)	20(36.4)	16(29.1)	6(10.9)
In your opinion, ADRs should be reported to Senior personnel in the hospital.	13(23.6)	27(49.1)	15(27.3)	-

RESPONDENTS PHARMACOVIGILANCE PRACTICE IN NOH

	SA	A	D	SD
	Freq (%)	Freq (%)	Freq (%)	Freq (%)
There is a functional pharmacovigilance or ADR reporting centre in this hospital.	11(20.0)	7(12.7)	36(65.5)	1(1.8)
ADR reporting is routinely done in this hospital.	13(23.6)	16(29.1)	26(47.3)	-
The facilities in the pharmacovigilance unit of this hospital are adequate.	8(14.5)	22(40.0)	25(45.5)	-
Counseling to patients regarding ADR is often administered	4(7.3)	36(65.5)	15(27.3)	-
The zonal pharmacovigilance centers initiative is ineffective.	9(16.4)	36(65.5)	10(18.2)	-
Good communication skills are required in pharmacovigilance.	12(21.8)	38(69.1)	5(9.1)	-
Well known ADRs do not need to be reported.	11(20.0)	34(61.8)	9(16.4)	1(1.8)
There are usually hindrances during work hours to report Adverse Drug Reactions in the hospital.	11(20.0)	35(63.6)	8(14.5)	54(98.2)
No one is actually responsible for ADR reporting in this hospital.	6(10.9)	31(56.4)	17(30.9)	54(98.2)
ADRs in Nigeria cannot be curbed by pharmacovigilance activities.	13(23.6)	20(36.4)	16(29.1)	6(10.9)
In your opinion, ADRs should be reported to Senior personnel in the hospital.	13(23.6)	27(49.1)	15(27.3)	-

HYPOTHETICAL CASES REPORTING ASSESSMENT OF RESPONDENTS

LUTH	YES	NO	Sometimes	Don't know
	Freq(%)	Freq(%)	Freq(%)	Freq(%)
Hiccup with Enalapril	32(53.3)	20(33.3)	4(6.7)	4(6.7)
G. I. bleeding with Diclofenac	29(48.3)	27(45.0)	4(6.7)	0(0.0)
Palpitation with Coartem	32(53.3)	21(35.0)	5(8.3)	2(3.3)
Jaundice with frusemide	51(85.0)	5(8.3)	1(1.7)	3(5.0)
Skin rashes with Roxithromycin	46(76.7)	6(10.0)	5(8.3)	3(5.0)
NOH				
Hiccup with Enalapril	17(30.4)	28(50.0)	7(12.5)	4(7.1)
G. I. bleeding with Diclofenac	47(83.9)	2(3.6)	3(5.4)	4(7.1)
Palpitation with Coartem	50(89.3)	1(1.8)		5(8.9)
Jaundice with frusemide	50(89.3)	0(0.0)	0(0.0)	0(0.0)
Skin rashes with Roxithromycin	47(83.9)	1(1.8)	2(3.6)	6(10.7)
FNH	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hiccup with Enalapril	49(90.7)	4(7.4)	0(0.0)	1(1.9)
G. I. bleeding with Diclofenac	47(87.0)	7(13.0)	0(0.0)	0(0.0)
Palpitation with Coartem	38(70.4)	16(29.6)	0(0.0)	0(0.0)
Jaundice with frusemide	34(63.0)	19(35.2)	0(0.0)	1(1.9)
Skin rashes with Roxithromycin	31(57.4)	21(38.9)	1(1.9)	1(1.9)

DISCUSSIONS

- Majority of respondents were able to identify the correct definition of Pharmacovigilance
- About 60% of HCPs in Nigerian tertiary hospitals have not embraced PV as an arm of patient care
- The patient's wellbeing as the focus for pharmacotherapy and PV has been eluded by the quest for profitability of healthcare services in health institutions (WHO 2008).
- Majority (over 90%) of the Respondents agreed that pharmacovigilance includes herbal, complementary and traditional medicines

DISCUSSIONS CONTINUED

- This shows that HCPs are aware of the significance of medicines that are unorthodox in ADEs and ADR reporting.
- The study abolishes the generally embraced but wrong notion that traditional medicines are devoid of ADRs
- The results also show a high level of agreement with PV being potentially instrumental in reducing morbidity and mortality associated with major diseases.
- Majority of HCPs from these tertiary hospitals correctly showed a high level of agreement with the statement that spontaneous reporting is the primary source of information for Pharmacovigilance

DISCUSSIONS CONTINUED

- This may be attributed to the fact that they are referral institutions and are located in the metropolitan Lagos city with an influx of professionals
- Results showed appreciable knowledge of HCPs on Pharmacovigilance thus corroborating Chinenye *et al* 2012
- 84.2% of NOH respondents agreed that a good PV system could reduce frequent hospital visits while 80% of those of FNH disagreed. This disparity could be due to their different patient base. NOH is an orthopaedic while FNH is a Neuropsychiatric specialist hospitals respectively
- This corroborates WHO publication on Safety monitoring of medicines where it stated that recurrent medical intervention due to ADRs were reduced by the incorporation of PV in public health programmes in Gambia.

DISCUSSIONS CONTINUED

- Majority of HCPs have adequate knowledge on the aim of ADR reporting scheme in Nigeria .

- FNH respondents indicated a higher priority (69.1%) on the comparison of ADRs rather than the identification of safe drugs and unrecognized reactions as indicated by 84.2% NOH respondents.

- A good percentage of the HCPs know that NAFDAC is host to the National Pharmacovigilance Center (NPC) where the filled ADR forms are sent to.

CONCLUSION

- ✓ Despite the high awareness level of Pharmacovigilance, ADR reporting is still low among healthcare providers in Nigerian tertiary hospitals.
- ✓ Contributing factors include inadequate reporting facilities in hospitals coupled with the tedious work conditions.
- ✓ These limiting factors can be allayed by :
- ✓ Incorporating Pharmacovigilance methods and strategies in the curriculum of medical, paramedical and pharmaceutical students;
- ✓ Regular trainings of hospital staff on ADR reporting as well as awareness campaigns.



RECOMMENDATIONS

- NAFDAC should synergise more closely with local health experts for training and information sharing to enhance their competence in Pharmacovigilance.

- The awareness of Pharmacovigilance created through the formal media could be further enhanced and extended to the emerging social media platforms to enhance the reach

Effort must be made to train staff who would flag off the monitoring and documentation of adverse effects of drugs.

- Commencement of public health and drug access campaigns in local languages and with regional surveillance systems.

- Finally, creation of a specific centre for Pharmacovigilance in all hospitals will help the advancement of Pharmacovigilance.

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