International Journal of Academic Research and Development
ISSN: 2455-4197; Impact Factor: RJIF 5.22
Received: 27-06-2019; Accepted: 29-07-2019
www.academicjournal.in
Volume 4; Issue 5; September 2019; Page No. 108-115

Factors influencing adverse drug reaction reporting among patients in selected hospitals within Kirinyaga County, Kenya

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Abstract
Background: Although medicines have outstanding edges to the wellbeing of the general public, they still have the potential of actuating adverse drug reactions which are a significant reason for morbidity and mortality. The study aims to determine factors influencing adverse drug reaction reporting among patients.
Method: This institutional based cross-sectional study was carried out within four selected health facilities in Kirinyaga County. Using a multistage sampling method, 360 patients were selected. A pretested interviewer-administered questionnaire was utilized for data collection. SPSS software was utilized to analyze data.
Results: Two hundred and sixty-four (73.3%) patients were unaware of the patient alert card. Two hundred and sixty-eight (74.4%) participants concurred that it was their responsibility to report ADRs. One hundred and fourteen (31.7%) respondents opined that reporting should be done to serious and life threatening ADRs. One hundred and sixty-six (46.1%) patients experienced ADRs. Among them, 145 (87.3%) reported ADRs to health professionals. Seriousness of the ADRs and change of regimen encouraged reporting whereas fear due to unfriendly doctors discouraged reporting.
Conclusion: The findings highlight gaps in knowledge and practice regarding ADR reporting. There is need for: regular sensitization, availing patient reporting tool in addition to implementing direct reporting by patients. Further investigations should be done at a national level to fully identify determinants of patient ADR reporting.

Keywords: Adverse drug reactions reporting**,** Pharmacovigilance**,** Knowledge, Attitude**,** Practice, Patients

1. Introduction

Pharmacovigilance (PV) is defined by World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem [1]. Adverse drug reaction (ADR) is defined as any response of a drug which is noxious and unintended, that occurs at doses used in humans for the prophylaxis, diagnosis or therapy of disease; or for the modification of physiologic function purposely excludes therapeutic failures, overdoses, drug abuse, non-compliance and medication errors [2].

ADRs are a public wellbeing burden. In the United Kingdom, ADRs account for 6.5% of all hospital affirmations with a case casualty rate of 0.15%. The charge incurred by the United Kingdom (UK) government to combat ADRs is approximately five hundred million Euros [3, 4]. In Singapore, 8.1% of ADRs caused hospitalization leading to 9,400 extra hospital days annually in the setting oversetting into 48,000 hospital days annually within the whole country. 11 ADRs caused permanent incapacity and death [5]. In South Africa, ADRs account for 16% of inpatient deaths and 1 in 12 people are hospitalized as a result of ADRs [6]. ADRs have contributed to delayed hospitalization, workers being truant from work, creating a monetary burden in Kenya's health framework, inability and death. The real magnitude of these detrimental impacts is as of now obscure due to our national PV system being recently built up [3].

The cutting edge of modern PV dates back to 1961 where a drug called Thalidomide caused Phocomelia, a congenital disorder affecting the appendages of the newborns. It was prescribed to manage morning afflictions among pregnant women. After intensive investigations, it was withdrawn from the market in 1962. In 1968, WHO started the global drug monitoring program. Originally, a trial was begun in ten nations (Australia, UK, USA, Germany, Canada, Ireland, Sweden, Denmark, New Zealand and Netherlands) where national ADR monitoring centers had already been instituted [7, 8]. The database currently holds more than 17 million case reports [9]. Right now, the program has 134 members and 29 associate nations [10].

By the conclusion of 2015, 35 African nations had procured full enrollment of the program. ADR reporting rate in Africa is exceptionally low, as the number of drug security concerns submitted to Uppsala monitoring center is 103,499 representing 0.88% of the world case reports [11]. Kenya joined the global drug monitoring program in 2010 as the 98th member. Since then, Kenya has detailed 11,017 case reports accounting for 0.06% of worldwide medicine security reports. The national PV program was introduced by the Pharmacy and Poisons Board (PPB) in June 2009. Out of 9000 health facilities listed in Kenya only 117 hospitals submitted ADR reports in 2018 [9]. Most ADR reporting studies are healthcare provider centered with constrained consideration paid to patients. Little is published on ADR reporting by patients. Quality of patients' reports has appeared to supplement those of healthcare workers [12]. ADRs reported by patients are detailed and give

a clear scenario on causality and effect on patient lives [13]. Patient reports represent 10% of all global results. Although, 46 nations have embraced direct patient reporting [14]. Kenya is yet to adopt the reporting system. Exceptionally few studies on ADR reporting among patients have been executed in Kenya. Therefore, the present study was conducted to determine factors influencing ADR reporting among patients in selected healthcare facilities in Kirinyaga County, Kenya.

2. Materials and methods

2.1 Description of study setting

The study was conducted within four selected hospitals in Kirinyaga County, Kenya. The county is divided into 4 Sub-Counties. According the County Integrated Development Plan 2018-2022 the 2019 population was projected to be 613, 511 people. There are 202 healthcare settings in the County of which 109 are public facilities. The region is situated North West to Nyeri County, West of Murang'a County and to the South and East of Embu County.

2.2 Study design

Facility based cross-sectional study was executed from April to September 2019 to determine patient–level factors influencing adverse drug reaction reporting in selected hospitals [Kerugoya Referral Hospital (level 5), Kianyaga, Kimbimbi and Sagana Sub-County hospitals (level 4)]. Patients enrolled in special clinics (HIV/AIDs, Hypertension and Diabetes) within the selected hospitals took part in the study.

2.3 Sample size determination

Cochran formula, Eq. (1) was utilized to generate the patients sample size [15]. Where: Z = 1.96 standard error (the standard deviation at a confidence interval of 95 %.), P = estimated proportion of patients in special clinics who ever experienced an ADR. Since the proportion of patients in special clinics experiencing ADRs in Kenya is not documented, P of 0.5 was used. Therefore Q (1- p) was 0.5. The degree of precision desired was 5%. The minimum sample size required was 385 patients. Correction for finite populations was done using Eq. (2). The calculated sample size (n_o) was 385 and the study population (N) was 5532 adjusting the sample size (n_f) to 360 patients.

$$n = \frac{Z^2 PQ}{d^2} \quad (1)$$

$$n = \frac{1.96^2 \times 0.5 \times 0.5}{0.05^2} = 385 \text{ patients}$$

$$n_f = \frac{no}{1+\frac{(no-1)}{N}} \quad (2)$$

$$n_f = \frac{385}{1+\frac{385-1}{5582}} = 360 \text{ patients}$$

2.4 Sampling technique

A multistage sampling method was used to select respondents. Patients were isolated into 3 special clinics: Diabetes, Hypertension and Comprehensive Care Clinic (Table 2). Proportionate assignment for patients in special clinics was calculated using a sampling fraction. Same calculations were done to assign HIV/AIDs, Hypertension and Diabetes patients proportionally to each hospital. Finally, random sampling was utilized to select respondents until the desired test estimate was acquired.

Table 1: Calculated sample size of patients in special clinics in each hospital by proportional allotment, with respect to population size in each facility, Kirinyaga County, 2018.

	Number of patients in selected hospitals (sample size)				
Special clinics	**Kerugoya**	**Kianyaga**	**Kimbimbi**	**Sagana**	**Total**
Comprehensive Care Clinic	1835(119)	419(27)	979(64)	767(50)	4000(260)
Hypertension	283(19)	562(37)	131(9)	237(15)	1213(80)
Diabetes	73(5)	155(3)	55(3)	36(2)	319(20)
Total	2191(143)	1136(74)	1165(76)	1040(67)	5532(360)

2.5 Data collection and procedures

An Interviewer-administered questionnaire was employed to collect data. The tool was borrowed with revisions from comparable studies assessing ADR reporting among patients [16, 17, 18, 19, 20]. The instruments were designed to capture: demographic characteristics, knowledge, attitude and practice on ADR reporting, challenges of reporting and measures towards a robust reporting culture. After thorough revision and scrutiny from peers and advisors the final drafts were prepared. It comprised of 23 items. Nine on social demographic characteristics, 6 on knowledge, 7 on attitude and 9 on ADR reporting practice.

2.6 Validity of the instruments

Pretesting of the instrument was conducted at ACK Mt Kenya hospital to check the congruity and precision of the research tools on subjects to whom the intention of the research was elaborated. After pretest results were reviewed and ambiguous issues addressed; the drafts underwent additional modification and refining.

2.7 Data analysis

Data was coded, cleaned and entered in a computerized database to scale back any mistakes and analyzed using SPSS version 20.0 computer program. Descriptive statistics were summarized by calculating the percentages, frequencies, means and standard deviation. Association between independent variables and outcome variables was determined by Chi-square test. Outcomes were considered significant at a p value of <0.05.

2.8 Ethical consideration

Ethical review and approval were procured from Kenyatta University - Ethical Review Committee. Permission was acquired from: The County commissioner, County Director of Education and County Director Medical Services Kirinyaga County. Before commencing data collection, all respondents signed the consent form. The purpose and importance of the research was explained to the respondents. Respondent's protection and secrecy was upheld. Respondents were allowed not to respond to

questions that made them uncomfortable and quit the study at any time without any consequences. Collected data was stored in a database guarded by a firewall and password.

3. Results

3.1 Demographic characteristics of patients on ADR reporting

Two hundred and forty-eight (68.9%; 95% CI 63.9 – 73.3) respondents were female and 112 (31.1%; 95% CI 26.7 – 36.1) were male. The most common age group was 46-55 years with 98 (27.2%; 95% CI 22.8 – 32.5) respondents. Two hundred and ten (58.3%; 95% CI 53.1 – 62.8) respondents were married. Farming was practiced by 199 (55.3%; 95% CI 49.7 – 60.6) patients with 268 (74.4%; 95% CI 70.3 – 79.7) respondents working full time. Primary school was the highest level of education attained by 205 (56.9%; 95% CI 52.0 – 61.9) respondents. The Majority of study participants 277 (76.9%; 95% CI 72.8 – 81.4) resided in the rural areas with majority of patients being Christians 345 (95.8%; 95% CI 93.9 – 97.8). Among the interviewed patients, 72.2% were HIV/AIDS patients, 22.2% were hypertension patients and 5.6% were diabetic patients (Table 2).

Table 2: Demographic characteristics of patients on ADR reporting, Kirinyaga County

Characteristics		Participants (n=360)	Percentage (%)
Gender of participants	Female	248	68.9
	Male	112	31.1
Age of participants (years)	>18	7	1.9
	19 – 24	12	3.3
	25 – 35	52	14.4
	36 – 45	93	25.8
	46 – 55	98	27.2
	56 – 65	51	14.2
	>66	47	13.1
Distribution of respondents by clinic	Comprehensive care clinic	260	72.2
	Hypertension	80	22.2
	Diabetes mellitus	20	5.6
Marital status	Single	78	21.7
	Married	210	58.3
	Widowed	34	9.4
	Separated	38	10.6
Occupation	Farming	199	55.3
	Skilled labor	19	5.3
	Civil servant	13	3.6
	Student	10	2.8
	Entrepreneur	79	21.9
	Unskilled labor	20	5.6
	Housewife	20	5.6
Work status	Full time	268	74.4
	Part time	84	23.3
	Pensioner retired	7	1.9
	N/A	1	0.3
Qualification	Primary school	205	56.9
	Secondary school	102	28.3
	Certificate	9	2.5
	Diploma	11	3.1
	University	6	1.7
	No formal education	27	7.5
Residence	Urban center	83	23.1
	Rural area	277	76.9
Religion	Christian	345	95.8
	Muslim	2	0.6
	Others	13	3.6

3.2 Patients knowledge on ADR reporting

More than half of the respondents 208 (57.8%) were uniformed of the medicines they were currently taking. Two hundred and eleven (58.6%) participants could not list at least 1 medication they were taking. The majority of respondents 264 (73.3%) didn't know of the ADR reporting mechanism for patients. A small proportion of patients 11 (3.1%) listed the patient alert card which is the standard reporting tool utilized to identify patients with ADRs (Table 3).

Table 3: Knowledge on ADR reporting among patients, Kirinyaga County, 2019

Knowledge item	Number (n=360)	Percent (%)
Aware of what an ADR is		
Yes	313	86.9
No	47	13.1
Duration of medication		
≤ 1995	6	1.7
1996 – 2000	14	3.9
2001 – 2005	17	4.7
2006 – 2010	110	30.6
2011 - 2015	93	25.8
≥ 2016	120	33.3
Aware of the names of the medicines you are taking		
Yes	152	42.2
No	208	57.8
List of the medicines you are taking		
None	211	58.6
1	123	34.2
2	23	6.4
3	3	0.8
Aware of an ADR reporting instrument for patients		
Yes	95	26.4
No	264	73.3
None	1	0.3
ADR reporting tool you are aware of		
Patient alert card	11	3.1
Telephone	8	2.2
consultation	92	25.6
No response	249	69.2
Sufficient knowledge	144	40.0
Insufficient knowledge	216	60.0

3.3 Patients' attitude on ADR reporting

Practically all respondents 359 (99.7%) concurred that ADR reporting is imperative, 357 (99.2%) patients felt that they should be included in the national ADR reporting scheme and 74.4% (268) of the participants concurred that it was their responsibility to report ADRs. One hundred and fourteen (31.7%) respondents opined that reporting should be done to serious and life threatening ADRs. Fear due to unfriendly doctors (33.9%) and unawareness (31.4%) discouraged reporting whereas change of medication (96.4%) spurred reporting. Sensitization campaigns through media were identified as the best strategy to reinforce ADR reporting by 275 (76.4%) respondents (Table 4).

Table 4: Attitude towards ADR reporting among patients, Kirinyaga County, 2019

Attitude item	Number (n=360)	Percent (%)
ADR reporting is important		
Yes	359	99.7
No	1	0.3
Patients to be included in the national ADR reporting scheme		
Yes	357	99.2
No	3	0.8
Who is responsible for reporting ADRs		
Medical doctor	42	11.7
Nurse	3	0.8
Pharmacist	7	1.9
Clinical officer	80	22.2
Patients	268	74.4
Challenges experienced in reporting ADRs		
Think it is not necessary	35	9.7
Fear due to unfriendly doctors	122	33.9
Unawareness	113	31.4
Lack of confidentiality	3	0.8
Long distance	16	4.4
ADR resolving themselves	18	5.0
Lack of feedback	40	11.1
Lack of reporting channels	12	3.3
Understaffing	1	0.3
Ways to enhance ADR reporting		
Sensitization campaigns	275	76.4

Toll free line	26	7.2
Better doctor-patient relationship	26	7.2
Checking patients' alert cards and giving timely response	9	2.5
Confidentiality	2	0.6
Government intervention	1	0.3
Better reporting channels	6	1.7
Follow-up by medics	14	3.9
Staffing of health cadres	1	0.3
Nature of ADRs to be reported		
Serous and life threatening	114	31.7
Sever and cause disability	59	16.4
Mild	33	9.2
caused by old drugs	28	7.8
caused by new drugs	43	11.9
caused by traditional/alternative medicine	1	0.3
all the above	82	22.8
Reason for ADR reporting		
To change regimen	347	96.4
To improve patient safety	12	3.3
No response	1	0.3

3.4 ADR reporting practice among patients

Less than ½ of the respondents 166 (46.1%) experienced ADRs from the medicine they were taking. ADRs that affected patients to a large extent included: dizziness (10.6%), headache (4.4%), rashes (3.6%) and ankle edema (3.6%). 43.3% (156) of respondents sourced medication that initiated ADRs from a hospital. A large number of respondents reported ADRs 145 (40.3%) they encountered. Among those who detailed ADRs, 20.8% (75) reported to clinical officers, 17.8% (64) reported to medical officers and 3.1% (11) reported to nurses. ADRs were reported verbally by 40.6% (146) of respondents. Of those who never reported ADRs, 1.9% (7) of participants found it not necessary to report. Most of the patients, 41.4% (149) agreed to receiving feedback after reporting. Feedback from the physician was given verbally to 147 (40.8%) respondents (Table 5).

Table 5: Practice towards ADR reporting among patients, Kirinyaga County, 2019

Practice	Number (n=360)	Percent (%)
Ever encountered adverse drug reactions		
Yes	166	46.1
No	194	53.9
Main ADRs experienced by patients		
Dizziness	38	10.6
Headache	16	4.4
Rashes	13	3.6
Legs swelling	13	3.6
Vomiting	12	3.3
Pruritus	11	3.1
Neuropathy	11	3.1
Source of medication that actuated the ADR		
From a hospital	156	43.3
From a pharmacy with a prescription	9	2.5
Over the counter at the pharmacy	1	0.3
Herbal/ alternative medicine	0	0.0
Can't recall/don't know	0	0.0
N/A	194	53.9
Ever reported the ADR		
Yes	145	40.3
No	21	5.8
N/A	194	53.9
To whom/where you reported		
Medical doctor	64	17.8
Clinical officer	75	20.8
Pharmacist	0	0.0
Nurse	11	3.1
Consultant	0	0.0
Pharmacy technician	1	0.3
Pharmacy and Poisons Board	0	0.0
N/A	209	58.1
How ADR was reported		
Telephone	1	0.8
Patient alert card	3	0.8
Email	0	0.0

Letter	0	0.0
Told someone about the issue	146	40.6
N/A	210	58.3
Reasons for not reporting		
The ADR was not life threatening	3	0.8
I discontinued taking the drug	1	0.3
It was not necessary	7	1.9
I am a general practitioner/health worker	2	0.6
I never knew the ADR was related to the medicine	1	0.3
I don't know	0	0.0
N/A	346	96.1
Feedback was given after reporting ADRs		
Yes	149	41.4
No	1	0.3
N/A	210	58.3
Method/channel you got feedback through		
Telephone	2	0.6
Drop off box	0	0.0
Mail	1	0.3
From the physician	147	40.8
Letter	0	0.0
N/A	210	58.3

4. Discussion

Concerning knowledge on ADR reporting, 86.9% of the patients comprehended what an ADR is. This discovery mirrors studies led in southwestern Nigeria and India where 81% and 74% of the patients knew what ADRs are [21, 18]. Greater part of the respondents couldn't recall when they began taking medication most of them reverted to their clinic cards and booklets. A dominant part of patients (33%) started to take medication ≥2016 followed by 30.6% between 2006 and 2010. A scarcity of knowledge was additionally found among CCC patients in Kiambu, Kenya as patients could not tell the duration they were on ARVs [16]. In the present investigation, only 42.2% knew the medicines they were taking whereas 34.2% listed at least 1 medicine they were taking. This negates discoveries from an Indian study where 78.6% of the patients knew about the drugs that caused ADRs anyway a greater part of them (86.4%) were from urban focuses. In this study, only 23.1% of the participants were from urban centers. A critical distinction on awareness (P=0.04) was seen between patients from urban and rural settlements [19]. Knowledge of names is indispensable when tracking ADRs initiated by a specific medication. Patient alert card is the official patient ADR reporting tool used to: apprehend, report and counteract future event of ADRs [3]. 73.3% of the respondents didn't know about the ADR detailing device used by patients. Among them only 3.1% listed patient alert card as the ADR reporting tool they were aware of. Low awareness on the ADR reporting mechanism was reported in an Australian study where only 12.5% of the patients knew of ADR reporting schemes for consumers. Of the 210 participants who encountered ADRs and were cognizant of the scheme, only 21.2% utilized the scheme when reporting [17]. A systematic review of published literature demonstrated that 75% of the patients were uninformed of the reporting mechanism [22]. Poor mindfulness on the ADR detailing instrument is an obstacle of patient ADR reporting [20]. An aggregate of 216 (60%) patients demonstrated poor knowledge on ADR reporting.

Patients' attitudes towards ADR reporting were positive. 99.7% of the patients concurred that it is imperative to report ADRs, 99.2 % felt that they ought to be involved in ADR reporting, 74.4% opined that it was their obligation to report ADRs and a greater part (31.7%) were inclined to report serious and life threatening ADRs. Similar positive attitudes were reported in comparable surveys conducted in India, Thailand and Poland [18, 19, 20, 23, 24]. Including patients as reporters adds to PV knowledge as patients are bound to detail outcomes of the events and non-recuperation from the events. Patient reports are more comprehensive, direct and overt. Permitting direct reporting will legitimately offset issues of underreporting [12, 24, 25]. To upgrade ADR reporting among patients, it was imperative to provide insight into the challenges and explanations behind patient ADR reporting. The fundamental hindrances uncovered by this study were: fear due to unfriendly doctors (33.9%), unawareness (31.4%) and lack of feedback (11.1%). A systematic review of published literature identified: poor awareness of the ADR reporting systems, lack of feedback and fear that reporting would be met with disapproval by their healthcare providers as key barriers patients experienced in reporting ADRs [22]. In a Netherlands study, 80% of the patients judged their doctor-patient relationship as unsatisfactory as doctors would not partake in discussions and gave negative responses [26]. The principal motive that impelled patient ADR reporting was to have their regimen changed as opined by 96.4% of the patients. A study conducted among hypertension patients in India dechallenged ACE inhibitors, beta blockers and diuretics to control ADRs [27]. Stopping to take the drug and medication cessation by healthcare workers have been utilized by patients to minimize ADRs in Netherlands [26]. Education/sensitization through media was laid out as the best strategy (76.4%) to enhance ADR reporting among respondents. Improving public awareness through media has been proposed by different published material [20, 26, 28, 29].

46.1% of the patients encountered ADRs from the medicine they were taking, similar to 46.3% encountering ADRs in Australia [17]. This is higher than discoveries from studies conducted in: India, Malaysia and New Zealand where 30.2%, 42.2% and 44% reported to encountering ADRs [28, 30, 31]. The distinction might be accounted for by methodological differences, sample population used or superior knowledge and practice with regards to ADR

reporting among the participants. 87.3% of the individuals who experienced ADRs reported them verbally to clinical officers (n=75) and doctors (n=64). A comparative proportion was reported by an Australian and Nigerian study where 84.6% and 83.1% reported ADRs to general practitioners (89.4%) and physicians (n=52) respectively [17, 21]. In Indian and Spanish studies, patients cited general practitioners (39.9%) and doctors (73.2%) as the right people to report ADRs [18, 32]. Clinical officers and doctors are the first healthcare workers patients encounter during consultation in these 4 hospitals. Telephone (63%) and online reporting (53.8%) was utilized to report ADRs among Australian and Indian patients respectively [17, 18] in opposition to verbal reporting (40.6%) utilized this study. Majority of the patients in this study were countryside farmers consequently, internet connection and calling expenses could be an issue. In the present study dizziness, headache, rash and ankle edema occurred frequently among the patients. Indian and Dutch studies have identified central nervous system disorders (dizziness and headache) and musculoskeletal disorders (ankle edema) as the most occurring ADRs [27, 33]. Rash has been reported as an often-occurring ADR by comparable studies across the globe [9, 16, 30, 31]. 41.4% of the patients received feedback on the reported ADRs. Verbal input from the doctor (40.8%) was the most utilized channel to rely feedback to patients. Lack of feedback after reporting is a principal hindrance to patient ADR reporting [22]. A dominant part of the patients (43.3%) sourced meds that activated ADRs from a hospital. This differs from an Australian study where a large proportion of patients (88.4%) obtained medicine that actuated ADRs from a pharmacy with a prescription [17]. In the present study, patients relied on hospitals to furnish them with medicine as majority are on multiple drug therapy subsequently obtaining them isn't cost effective. Of the individuals who never detailed ADRs, a greater part of them cited it was not necessary to report ADRs. This could be credited to low education level [23], side effect not being serious enough [17], ADRs resolved [22] and deciding not to report sensitive issues (e.g. sexual dysfunction) to healthcare providers [24].

5. Conclusion

Collectively patients demonstrate positive attitude and acceptable ADR reporting practice despite high ADR occurrence. However, patients' knowledge on ADR reporting is destitute. Patients are inclined to report serious and life threatening ADRs. The chief motive that impels ADR reporting among patients is to have their regimen changed. Fear due to the unfriendly healthcare providers/hostile nature of the health professionals and lack of awareness deter patients from reporting ADRs. Based on the results the following suggestions are recommended. All patients should be trained regularly on how and where to report ADRs. Patient alert cards should be made available in all hospital departments as it can boost reporting rates. Additionally, direct reporting by patients ought to be actualized, this will surge ADR reporting rate. Finally, baseline studies are recommended across all hospitals in the Country to harmonize the practice of ADR reporting.

6. Acknowledgment

The researchers are remarkably thankful to the hospital managers in the selected hospitals for allowing us to carry out the study in the facilities. The authors thank Dr. Milcah Nyaga for her consistent and colossal direction, participation and bolster she offered towards the preparation and proofreading of the manuscript. We wish to express our profound gratefulness to every respondent who willfully participated in this investigation.

7. Competing interests

None

8. Financial support

None to declare

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