


Compliance of Private Pharmacy Retail Outlets to Narcotic Drug Regulations in Ethiopia: A Cross-Sectional and Simulated Client Study Method

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Abstract

Background: Inappropriate use of narcotic drugs is a growing worldwide health challenge. The problem is even worse in Sub-Saharan Africa where organized supply chain regulations on dispensing and stock management are poor for controlling these global challenges.

Methods: A mixed method, descriptive cross-sectional and simulated client study design was used from September 10, 2020 to November 26, 2020 to assess the extent of utilization and compliance of narcotic drug dispensing in private pharmacy retail outlets of Gondar and Bahir Dar town of Amhara region, Ethiopia. A total of 107 private pharmacy outlets were on duty. But in simulated study, purposive sampling is a method that prioritizes study units having the data of interest.

Results: A total of 107 private pharmacy retail outlets were included in the survey. The average compliance to the controlled prescription regulation of Ethiopia in all pharmacy outlets (107) of the five drugs were calculated and found to be poor, 23.9% (SD = 18.3%). Compliance to strong narcotics is extremely low, 3.3 % for pethidine and 8% for morphine. Religion of the professionals has significant association with compliance to the prescription of narcotic drugs ($p < .001$).

Discussion: In the era of narcotic epidemics, as a result of growing global inappropriate use of controlled drugs, the finding of this study gives an insight for a serious and strict regulation in managing and controlling the overall distribution of the narcotic drugs.

Conclusions: The compliance of the private retail pharmacies of Ethiopia to the regulation of controlled drugs is low.

Keywords

compliance, simulated client study, narcotic drug, Ethiopia

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Highlights

-What do we already know about this topic?

The regulations and handling of psychoactive drugs like narcotics is poor in private pharmacies. In most cases, everybody has an access without narcotic prescriptions.

-How does your research contribute to the field?

This study tries to identify the gaps in appropriate utilizing of opioids. There are limited studies in this area especially in developed countries. Hence, it can be used as a source for further studies.

-What are your research's implications towards theory, practice, or policy?

The overall handling process of narcotics is poor and a regulatory authority should have a policy and standards to regulate and control narcotic use crises.

Introduction

Inappropriate use of narcotic drugs is a growing worldwide health challenge. This is also the problem of Sub-Saharan Africa where organized supply chain regulations on dispensing and stock management are poor for controlling these global challenges. The misuse of opioids by health professionals as well as other clients in the United States of America (U.S.A), Canada and Europe have also drawn the most attention.¹⁻⁶ However, recent trends in Africa and Asia suggest opioid use epidemic may be rapidly expanding. In Nigeria, a report in 2018 indicates that nearly 5% of its population (or 4.6 million people) engaged in non-medical use of prescription opioids in the past year.⁷

A study in USA for two decades (1991 to 2013) showed prescribing rates for opioids have increased around three-fold, from 76 million prescriptions in 1991 to approximately 207 million prescriptions in 2013. Similar study in 2016 shows there is an increase opioid use epidemic crisis, regardless of what policies were put in place. More than 2 million people have narcotic use disorder involving prescription opioids, and almost 600 000 have associated with use of heroin.⁸ This high volume of strong narcotic use is unique to the USA, where the amount consumed in 2015 were more than four times those in Europe. The worst side of this frequent use of addictive medications is connected to an epidemic of deaths related to abuse of strong narcotics and other drugs of abuse. Another recent study (2018) showed U.S. in the midst of narcotic use crisis that claimed nearly 70,000 lives.⁹ In this year, drug overdose deaths were a national emergency, mostly this overdose comes inappropriate use of strong narcotic drugs. Therefore, the abuse of opioids can be seen as the leading health care problems in the USA today.

For many people, private pharmacies are the first line of health care commonly the clients can get easy access for restricted abuse drugs because many of the private pharmacies may give first attention for their profit rather than patient safeties.

Although the availability of this strong opioids like heroin is expected to be low in developing countries, the abuse of

narcotic use like pethidine is high because of its fragile and poor handling practice especially in private pharmacy retail outlets. Developing countries like Ethiopia needs an organized, sustained, and vigilant effort to control the present opioid epidemic and ameliorate its harmful effects on society and to prevent new cases of addiction and associated overdose, and consequently death.

Recent studies clearly justified the COVID-19 effects such as lockdowns and social isolation have also impacted Psychoactive substance use rates. Cannabis and other psychoactive substance sales on illicit online markets have risen rapidly during the first few months of the pandemic. This may indicate an increase in misuse of drugs for addictive purpose, which may correspond to greater rates of drug use disorder.¹⁰ The National Institute on Drug Abuse in US, is also strongly announced, the raising concerns about peoples with substance use disorders with the effects of COVID-19. Psychoactive substances like opiates (e.g., heroin), synthetic opioids, and methamphetamine are invaluablely used.^{11,12}

International law and regulation on opioid control allow weak analgesics and cough syrups having low strengths of weak opiates like dextromethorphan and codeine phosphate alongside with other analgesics can be dispensed to clients without a prescription.¹³⁻¹⁵ But in many other studies private pharmacies in Ethiopia have a trend to dispense prescription only medications without prescription. Yet, little is known about the opioid dispensing practice of pharmacy professionals on retail outlets.¹⁶⁻¹⁸ This study was aimed at assessing the extent of compliance of private pharmacy retail outlets to narcotic drugs use regulations

Methods

Study Design and Area

A mixed method, descriptive cross-sectional and simulated client study design was used from September 10, 2020, to November 26, 2020, to assess the extent of utilization and compliance of narcotic drug dispensing in Private pharmacy

retail outlets of Gondar and Bahir Dar town of Amhara region, Ethiopia. Bahir Dar is a capital city for the Amhara region with an estimated population of 780 000 inhabitants. Bahir Dar has more than 70 pharmacy retail outlets. The second town for this study is Gondar which is the first capital city of Ethiopia before Addis Ababa. An estimation of 54 private pharmacy retail outlets is found according to the data obtained in September 2020.

Sampling and Sampling Procedures

The private pharmacy retail outlets in Ethiopia are divided into pharmacies, drug stores, and rural drug vendors based on the type of medications they allowed to dispense and the educational qualification of dispensers. Pharmacies are run only by pharmacists (with qualification of a university degree or above), drug shops by druggists (with qualification of diploma in pharmacy) and they are not allowed to have all drugs, for example, strong narcotic drugs are not supposed to be dispensed by drug stores. Very few drugs vended in both towns are available as such not included in this study. All private pharmacy outlets who were open during the study period were included in the survey study. A total of 107 private pharmacy outlets were on duty. Of which 45 are from Gondar town and the remaining 62 are from Bahir Dar town. But in simulated study, purposive sampling is a method that prioritizes study units having the data of interest.¹⁹ Therefore, for the pseudo-client sub-study, purposive sampling in which only private pharmacies retail outlets that acknowledged presence of opioids in their premises in the self-report survey were selected.

Data Collection and Management

Participants for the questionnaire-based survey in private pharmacies were recruited with the aim of getting enough of sample with those that stock narcotic drugs. First, the FMHACA of Ethiopia register of drugs as of September 2020 was examined to identify authorized private pharmacy outlets for narcotic drugs. Five data collectors (trained for 1 day) were assigned to a different sub city for data collection. During this time presence of narcotic were recorded for later simulation study.

Pharmacy professionals were recruited from among those that participated in the questionnaire survey and are willing to participate in a subsequent simulated client study. Private retail outlets that were recorded as “do not stock narcotic drugs” during the questionnaire survey were excluded from the simulated client study.

A pilot study was done on six private pharmacy outlets that were not included in the final study, to identify possible limitations of the study methods or data collection tools. All the six private pharmacy outlets were informed about the objective of the pretest and the aim of the study. All the study tools and the simulated clients were trained and tested.

Ethical Consideration

Ethical clearance was obtained from School of Pharmacy, College of medicine and health sciences, the University of Gondar ethical review board with an approval number of SoP 826/10. The caretakers were the legally authorized representative of minor subjects. Data were collected anonymously so that there were no personal identifiers. Furthermore, the collected data were kept confidential and used strictly for the study only.

Analyses

Data from the questionnaires and the simulated client guides was entered into excel and cleaned. Transcription from excel into SPSS 21 was done for last cleaning, categorization of continuous data, computation of compliance and prevalence of compliant pharmacies, and chi-square test was used to look the association independent variable with the predictors of compliance.

Results

A total of 107 private pharmacy retail outlets were included in the survey of which the majority are pharmacies (degree licensed) 81% and the rest 19% are drug stores (diploma licensed). Medication dispensers at these pharmacies and drug stores were primarily druggists (61%) and had less than 3 years of working experience in their current position (79%)(Table 1).

To gain further information into sickness of the professionals to the controlled drug regulation, especially in dispensing of strong opioids like pethidine injection was validated through a pseudo-client investigation. As shown in Figure 1, this data confirmed that many pharmacies are not compliant with the requirement of a valid and controlled prescription in dispensing of these drugs.

During pseudo-client analyses in 30 pharmacies there was pethidine surprisingly 29 of the dispensaries were ready to dispense it without controlled prescription (Figure 1). The simulated client analyses for the bulk sale of pethidine (more than 10 ampoules) with an invalid prescription order was seen in 9 private pharmacy dispensary units.

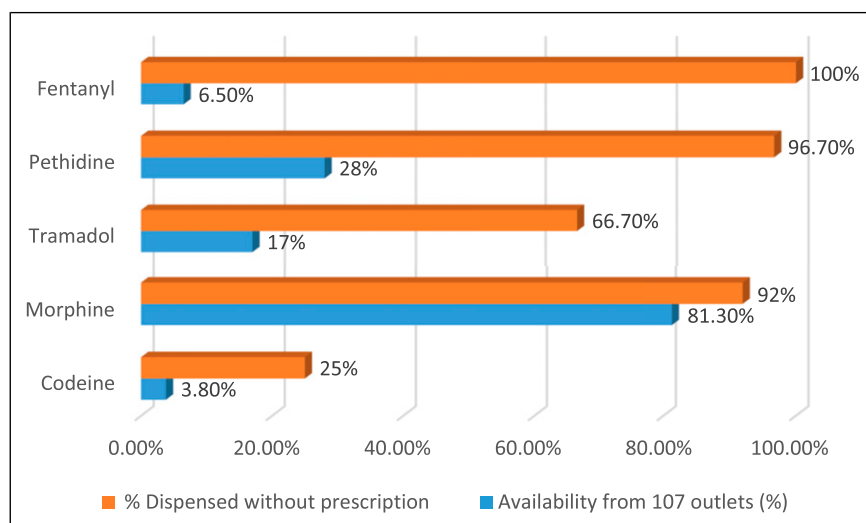
As shown in Figure 1, the proportion of pharmacies compliant with the requirement of controlled narcotic drugs is extremely poor. Even the strong opioid pethidine was dispensed like over-the-counter drugs. The average compliance to the controlled prescription regulation of Ethiopia in all pharmacy outlets (107) of the five drugs were calculated and found to be poor, 23.9% (SD=18.3%). Compliance to strong narcotics is extremely low, 3.3 % for pethidine and 8% for morphine.

All the private pharmacy retail outlets have no stock management system. There is no bin card and stock cards in all retail outlets. Although the FMHACA of Ethiopia strongly

Table 1. Socio-demographic characteristics of dispensaries who participated in the survey.

Characteristics	Category	Frequency n (%)
Retail	Pharmacies	87 (81%)
	Drug store	20 (19%)
Sex of dispense	Male	52 (49%)
	Female	55 (51%)
Work experience in the current position	<1 year	55 (51%)
	1–3 years	30 (28%)
	4–5 years	15 (14%)
	>5 years	7 (7%)
Religious background of dispenser	Orthodox	60 (56%)
	Muslim	39(36%)
	Protestant	8 (8%)
Dispenser's qualifications	Pharmacy technician	65 (61%)
	Pharmacist	38(37%)
	Nurse or midwife	2 (2%)
	Others	3 (3%)

Others include 2 Veterinary pharmacies and 1 health officer.

**Figure 1.** Availability of opioids and compliance of dispensaries for controlled prescription regulation

advice the use of locked storage system for strong opioids, only 8 retail outlets meet the requirements.

The associated factors with compliance to narcotic drugs dispensing regulation was done. Years of service at the pharmacy outlets and qualification (education level) have no any association ($p = .42$ and $p = .67$, respectively) with compliance the Ethiopian controlled drug regulation. But the religion of the professionals has significant association with compliance to the prescription of narcotic drugs ($p < .001$). Another factor associated with compliance to the prescription requirement was history of frequent previous Ethiopian drug control authority auditing and inspections (Table 2). Based on Ethiopian Narcotic drug control regulation every private whole seller or dispenser should report the stock status every three month. The presence of the owner pharmacist in the

pharmacy has no any association in the compliance ($p = .53$), and all of the participants in the questionnaire survey have no history of invitation for a workshop on handling narcotics by the Drug Control Authority of Ethiopia, (Table 2).

Two of the drug outlets have history of sanction by the control authority due to misconduct of the controlled drug regulation rules. Five (5%) of the professionals on private pharmacy know some of their friends who work in private pharmacy purchase or receive narcotic drugs without the regulated supply chain system, but they insist they are free of these misconducts. Simply in most pseudo-client observation anyone who want to purchase any type opioids can get easily, if they are available in pharmacy retail outlets.

Although the drug stores in Ethiopian regulation are not permitted to have strong narcotic drugs, during

Table 2. Inspection and compliance with the controlled drugs prescription requirements in dispensing of Narcotic drugs. Only result obtained from the survey study.

Factors	Category	Frequency (n)		x2	P value
		Pharmacy (87 total)	Drug stores (20 total)		
FMHACA has ever audited narcotic drugs	Yes	84 (96.5%)	19 (95%)	2.13	.34
	No	3 (3.5%)	1 (5%)		
FMHACA asked for reverse logistics of narcotic drugs	Yes	1 (1.2%)	0 (0%)	2.32	.67
	No	86 (98.8%)	20 (100%)		
Did you report stock status of strong ¹ narcotic drug every 3 Month	Yes	15 (68.2%)	0 (0%)	23.3	.01
	No	7 (31.8%)	20 (100%)		
Have you ever sanctioned due to misconduct of narcotic use	Yes	0 (0%)	2 (10%)	11.3	.03
	No	87 (100%)	18 (90%)		
Owner pharmacist is present in pharmacy premises	Yes	37 (42.5%)	7 (35%)	1.23	.78
	No	50 (57.5%)	13 (65%)		

¹Strong narcotic include only pethidine and morphine in this survey.

pseudo-patient assay 5 of the 20 drug stores have had pethidine and were dispense it without the controlled prescription.

This study was also tray to see the availability of naloxone in those private pharmacy outlets, none of them has naloxone on their premises. One of the most important pharmacist activities to reduce opioid related toxicities has been through increasing the availability of this drug, naloxone.

On questionnaire study some of the pharmacy professionals responded pethidine was sometimes dispensed for substance abuse purpose. "Before the current private pharmacy, I was working in another private pharmacy and during that time I had two customers for pethidine. The first one is medical doctor and the other is his friend. Both of them use pethidine for recreational purpose. They were totally addicted to this drug. They took more than 10 ampoules of pethidine each day. Finally, the first person died as claimed it was due to opioid toxicity" according to the response of one of the respondents during the questionnaires survey.

Discussion

In the era of narcotic epidemics as a result of growing global inappropriate use of controlled drugs, the finding of this study gives an insight for a serious and strict regulation in managing and controlling the overall distribution of the narcotic drugs. With a mixed study method: a descriptive cross-sectional and a simulated client methods the extent of compliance of private pharmacy retail outlets to the narcotic prescription regulations was too poor as revealed by this study. The simulated method can be considered a robust and more reliable methodological tool for pharmacy practice research, especially in cases where observed facts lead to behavioral change.^{20,21} The result of this study showed private pharmacy outlets who have strong narcotics during the study period did not have compliance with the controlled drug prescription regulations. If the drug is available, they dispense it without

having narcotic prescription as well in bulk doses for a single client. This makes an easy access of abused narcotic drugs. A similar study by Kamba et al. in Uganda shows the compliance of private pharmacies to the controlled prescription regulation is very poor.²² Compliance with purchasing and distribution regulations, especially pertaining to prescription and stock control requirements as well as frequent inspection by the regulatory authority is an important component in minimizing the errors and addressing the problem.

Previous study findings showed that naloxone availability and distribution programs significantly reduced opioid overdose risks. In the era of COVID-19 the supply of many drugs was significantly reduced as a result some psychoactive drug users shifted into the more dangerous parentally administered opioids like pethidine.^{23,12,24}

In a situation where substance abuse is out of control, overdose may happen especially in this class of drugs.^{13,25} The toxicity of narcotics due to overdose can be reversed with naloxone but the bad side is the stock of naloxone in all of the private pharmacy retail outlets in this study was zero.

Although the availability of some narcotics is limited (not representative sample) in PPRO, the non-compliance rate to controlled prescription is high. The non-compliance rate for 3 of the four drugs was more than 90%. The average proportion of non-compliant pharmacies with controlled drug prescription requirements 88.7%. Similar recent study in Uganda revealed varied rate of non-compliance from 20% to 41% for pethidine and diazepam tablets, respectively.²⁶ Previous studies in sub-Saharan Africa and Asia showed antibiotics dispensing practices without prescription have nearly similar proportions of non-compliance with the current study. Another study in 73 private retail pharmacies in Zambia showed that 100% dispensed antibiotics without a prescription.¹² In Ethiopia, a study in simulated patient approach showed 87.93% of the pharmacy who worked in private outlets dispense antibiotic medications without the need of prescription.¹⁶ The only thing that dispensers want most of the

time when requested for narcotic drugs was the presence and number of ampoules (doses) that clients wanted. As a result, anyone who has history of narcotic addiction can easily access even this strong opioid. If the responsible body remains silent to take any measure, the coming few years the number of new substance addicted cases significantly increase. As a result, the current narcotic epidemic of USA and other European countries will not be far in sub-Sahara region too. Many similar studies indicated an expanding new narcotic use case in Africa.¹⁻⁷

The effect of the current pandemic, COVID-19 on the rate of psychoactive substance abuse is significant, yet there are no studies that support the claim in Ethiopia. Fear, stress, and anxiety have affected people all over the world, exacerbating latent psychiatric and psychological disorders as a result the intention of peoples for use of these substances may increase.²⁷

Pharmacists have a professional responsibility in controlling and validating narcotic prescriptions and screening clients to assess potential for non-medical use before dispensing. But many pharmacy professionals are out of code of ethics and participated in many fraud activities as mentioned earlier. A study of how illegal drug suppliers in the U.S. obtain their controlled drug inventories found that pharmacy fraud by pharmacy professionals in which they undercount dispensed medications or inward inventories is an important channel for getting more illegal narcotic drugs.²⁸

FMHACA of Ethiopia has a responsibility to scale up the various regulatory activities that improve compliance to good narcotic drug dispensing and stock control practices. There should regular training of pharmacy professionals, owners and others on laws, regulations and good practices in monitoring and handling of narcotics. At the same time increase audits of pharmacies through regular inspection for these drugs is mandatory.

Limitation of the Study

As the study was cross-sectional and simulated client survey, the sample size may not be representative specially on cross-sectional sub-section. the other limitation of the current study was also devoid of making a temporal relationship (cause and effect relationship) between the outcome variable and the different independent variables.

Conclusions

The compliance of the private retail pharmacies of Ethiopia to the regulation of controlled drugs is low. The inspection and controlling of premises is also low. As a result, strong narcotics is found even in drug stores, though they are not allowed to have such drugs. Furthermore, pharmacist presence and educational qualification have no effect on compliance to the regulation. This is the first scientific study to report on compliance to narcotic drug regulations in Ethiopia. So, it

provides a platform for further studies and also provides useful evidence to the regulatory authorities to amend their policy and practice in the regulation of these drugs.

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Author's contributions

Kasahun

AE performed the Conceptualization, data collection and carried out the statistical analysis and interpretation and final revision. Woldeyohanins

AE and Kifle

ZD participated in the methodological selection, sequence alignment of the work. Demeke CA, Ergena

AE and Abebe RB participated in the data collection statistical analysis and draft of the manuscript.

Declaration of Conflicting Interests

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