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ORIGINAL RESEARCH

Simulated client study on the dispensing practices for narcotic and psychotropic medications in community drug outlets in Ethiopia

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Abstract

Background: Dispensing prescription-only medications without a valid prescription poses significant public health risks, including inappropriate drug use, adverse drug reactions and medication dependence. Narcotics and psychotropic drugs are particularly vulnerable to misuse. Despite this, limited data exist on the dispensing practices of these medications at community drug retail outlets in Ethiopia. This study aimed to assess the extent and factors of non-prescription dispensing of narcotic and psychotropic medications at community drug retail outlets in Ethiopia.

Methods: An observational cross-sectional study was conducted using the simulated client method from June 1, 2023, to September 30, 2023, in Debre Markos town, Ethiopia. Three trained volunteer pharmacy professionals acted as simulated clients. A validated simulated client approach was used to request medications through three different scenarios: symptom-based (depression), direct request by name and request by presenting a medication package.

Results: A total of 109 requests were made by the simulated clients at 38 community drug retail outlets during three rounds of observations. The rates of non-prescription dispensing were 28.9% for depression simulation, 60.5% for direct name requests and 81.6% for package-based requests. A total of nine types of narcotic and psychotropic medications were dispensed without prescription, the most common of which were amitriptyline, followed by tramadol, carbamazepine, pethidine and haloperidol.

Conclusion: This study revealed a high prevalence of non-prescription dispensing of narcotic and psychotropic medications, particularly in response to assertive client requests. Urgent regulatory measures are needed to ensure adherence to prescription-only policies, especially for frequently dispensed drugs such as amitriptyline, tramadol and chlorpromazine.

Keywords: community pharmacies, narcotic drugs, non-prescription dispensing, psychotropic medications, simulated client method.

Citation

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Introduction

Community drug retail outlets (CDROs) are private-sector healthcare facilities that are highly accessible to the general public.[1] They provide a range of basic healthcare services, including medication selection, patient counselling, medication monitoring, and the dispensing of medications with or without prescriptions, according to national regulations.[2,3] In developing countries like Ethiopia, CDROs play a vital role in healthcare services due to their accessibility and cost-effectiveness.[4] Globally, prescription-only medications are commonly accessed through CDROs.[5] Whilst medication dispensing is strictly regulated in most developed nations, inappropriate dispensing practices are frequently reported in low-income and middle-income countries.[6] These issues are often attributed to weak regulatory enforcement, high client demand and limited expertise amongst professionals.[7] In many cases, the failure of CDROs to adhere to regulations allows individuals to obtain medications without prescriptions, increasing the prevalence of self-medication.[8,9]

Psychotropic medications influence a person's thoughts, feelings and behaviour, whereas narcotics are referred to as medications that bind to opioid receptors and alter a person's mental and physical states by inducing sleep, changing mood or reducing pain. These include medications that cause sedation, muscle relaxation and reduce sensation. Psychotropic medications, such as antidepressants, mood stabilizers, antipsychotics and anxiolytics, are cornerstones to the treatment of mental illness.[10,11] Recently, the use of narcotic and psychotropic medications has increased significantly across many countries.[12–14] Self-medication is one of the reasons for the worsening of mental health conditions.[6] Narcotics and psychotropic are amongst the groups of medications that are prone to misuse.[15] Whilst developing nations have limited access to narcotic medications, the abuse of narcotics, such as pethidine, is more common, particularly at CDROs.[16] Prescription drug abuse for non-medical purposes is an under-recognized health concern that is exacerbated by easy access to medications.[17] Dispensing prescription-only medications without a valid prescription can have a drastic impact on people's well-being by increasing conditions such as the likelihood of harmful drug reactions.[18] Medications such as benzodiazepines and opioids, in particular, carry a high potential for misuse, and they may be taken alongside alcohol, illegal drugs or other medications, further compounding risks.[19,20] Community pharmacy professionals can affect mental health outcomes by counselling patients about psychotropic medications to increase adherence, recommending referrals to patients who may need them, and looking over medication histories for medications that might affect the mental state of an individual.[21]

In most developed countries, aside from over-the-counter products, medications are not dispensed without a valid prescription. However, this is not always the case in developing countries like Ethiopia, where numerous prescription-only medications are frequently dispensed without a prescription. Although a few studies have reported on this issue, there remains a lack of focused studies on the non-prescription dispensing of narcotic and psychotropic medications specifically. Therefore, the aim of this study was to assess the dispensing practices of narcotic and psychotropic medications without prescription at CDROs in Ethiopia using a simulated client method.

Methods

Study setting

The study was conducted at CDROs found in Debre Markos town, located approximately 300 km from Addis Ababa, the capital city of Ethiopia. The town has a total of 68 registered CDROs, consisting of 27 community pharmacies and 41 drug stores.

Study period and design

An observational, cross-sectional study using a simulated client method was carried out from July 1, 2023, to October 30, 2023.

Sampling technique and procedure

A complete list of 68 licensed and registered CDROS in Debre Markos was obtained from the town's health regulatory authority. A census-based approach was employed to assess dispensing practices in all eligible outlets. However, during the data collection period, only 38 CDROs were actively operating and accessible and were all included in the study without further selection criteria. Another 30 outlets in the town were excluded due to temporary closure (for renovations, staffing shortages or administrative issues like license renewal delays) or permanent closure.

Data collection materials and procedure

In Ethiopia, community pharmacies are typically managed by a licensed pharmacist with at least a Bachelor's degree in pharmacy, whilst drug stores are operated by qualified druggists or pharmacy technicians with a Diploma in pharmacy. For this study, three volunteer pharmacy professionals with a Bachelor's degree were recruited as simulated clients. A structured and comprehensive training programme and standardization process were conducted prior to data collection.[4] The simulated clients participated in a 2-day intensive workshop led by the principal investigator. The training included orientation on the study objectives, ethical considerations and

detailed instruction on delivering each of the three study scenarios. Simulated clients were instructed to avoid any language or behaviour that could influence the dispenser's decision, for example, pressuring, negotiating or suggesting the desired outcome. Instead, they were trained to behave as naturally as possible, reflecting typical client interactions in the real-world setting. Each scenario was practiced using role-play and feedback sessions to ensure consistency and standardization. Symptom narratives and communication scripts were developed and validated by clinical pharmacy and mental health experts. Moreover, mock visits were performed at five non-study CDROs in Amanuel town to pilot test the scenarios and data collection tools. Simulated clients completed all three scenarios and documented dispenser responses. These were reviewed for consistency, and calibration sessions were held to align data recording practices and address discrepancies. During the actual study period, each of the 38 CDROs was visited three times, once for each scenario. Visits were spaced at least 3 days apart to minimize detection and reduce bias. Simulated clients rotated between roles and outlets.

After each visit, simulated clients immediately completed a structured form documenting whether medications were dispensed and if questions were asked, counselling was provided or referrals were made. Regular debriefing sessions were conducted with the principal investigator to monitor data quality and adherence to protocol.

Disease simulation and scenarios

The study employed a structured simulated client approach using three distinct and realistic scenarios: (1) clinical presentation (disease simulation), (2) direct medication request by name and (3) request by showing an empty medication package. These scenarios were designed to reflect realistic client behaviours.

In the disease simulation scenario, two standardized clinical cases were used: depression and back pain. These were developed in collaboration with clinical pharmacy professionals and validated by a mental health specialist and a pain management physician. The depression scenario was reviewed by a licensed mental health specialist, whilst the back pain scenario was reviewed by a physician experienced in pain management. Feedback from these experts was used to refine the symptom descriptions and ensure the presentations reflected real-world patient experiences. In the depression simulation, a 31-year-old simulated client verbally reported symptoms consistent with moderate depression. These included persistent sadness, feeling of hopelessness, low self-esteem, mood instability and sleep disturbance, persisting over 2 weeks. In the severe back pain scenario, a 45-year-old simulated client described back pain characterized by an intense pain with burning sensations accompanied by tingling, which has lasted for 3 days. In both cases, no medication was requested directly; instead, symptoms were described to assess how dispensers would respond. Simulated clients recorded whether dispensers asked follow-up questions such as symptom duration, medication history, allergies and comorbid conditions, provided counselling, offered non-pharmacological advice, referred to a physician or dispensed prescription-only medications.

In the second scenario, the simulated clients requested a specific medication by name without a prescription. Requested medications included tramadol, morphine, fluoxetine, pethidine, lamotrigine, haloperidol and carbamazepine. These requests were made without additional clinical justification, reflecting a purely transactional inquiry. The third scenario involved presenting an empty package of one of the same medications and asking for refill. The simulated clients handed over the packaging and simply asked to receive the same medication, again without a prescription or clinical explanation. This shows a common real-life practice where patients return to CDROs for medication previously obtained without a prescription.

Each outlet was visited three times, once for each scenario, by one of the three trained simulated clients. Visits were spaced over 3 months to minimize recognition and influence. Simulated clients rotated across outlets and scenarios to further reduce familiarity with staff and avoid detection.

Data quality assurance

The principal investigator trained all simulated clients on the objectives, methodology and ethical aspects of the study. A pretest was conducted in five CDROs in Amanuel town to identify any potential issues with the procedures and data collection tools. Feedback from this pilot informed minor modifications to the final protocol.

Data entry and analysis

Data were coded, checked for accuracy and completeness, and entered into Epi-data 4.6. The data were then exported to SPSS 26 and Python for analysis. Descriptive statistics, including frequencies and percentages, were used to summarize the characteristics of dispensing practices. To assess associations between categorical variables, such as type of request (disease simulation, request by name and request by showing package), type of facility (pharmacy *versus* drug store) and the outcome variable (dispensing of narcotic or

psychotropic medications without a prescription), Pearson's χ^2 test was applied. A p value of <0.05 was considered statistically significant. In comparisons involving more than two groups, the disease simulation request was used as the reference group, as it represents the least assertive and most clinically driven type of interaction. To further quantify associations, adjusted odds ratios with 95% CIs were calculated using logistic regression to control for facility type. To present more reliable estimates of proportions (e.g. the percentage of visits resulting in dispensing or the frequency of specific drugs dispensed), 95% CIs were computed using the Wilson score method, which is particularly appropriate for small samples or extreme proportions.

Ethics consideration

Ethical approval for the study was obtained from the Institutional Review Board of the University of Gondar, Ethiopia. The Institutional Review Board approved the

Table 1. Pharmacy professional's response for medication request without prescription at community drug retail outlets.

Variables		Frequency (*n*)	Percentage (%)
Medication dispensed without a prescription			
	No	39	19.4
	Yes	162	80.6
Depression simulation	Recommend physician consultation	23	67.6
	Requested further information		
	About symptom details	11	32.4
	About medical history	17	50.0
	About medication history	8	23.5
	Dispensed medication	11	32.4
	Amitriptyline	9	81.8
	Fluoxetine	2	18.2
	Recommend non-pharmacological options	6	17.6
Back pain simulation	Dispensed medication	31	93.9
	Tramadol	16	51.6
	Paracetamol	14	45.2
	Pethidine	1	3.2
	Recommend physician consultation	3	9.1
	Requested further information		
	About symptom details	16	48.5
	About medical history	8	24.2
	About medication history	4	12.1
Request medication by name	Dispensed medication	56	83.6
	With counselling	49	87.5
	Without counselling	7	12.5
	Did not dispense medication	11	16.4
Request medication by showing package	Dispensed medication	64	95.5
	With counselling	17	26.6
	Without counselling	47	73.4
	Did not dispense medication	3	4.5

use of covert data collection on the basis that the study posed minimal risk to participants, did not involve the collection of any personal or identifiable information, and addressed a significant public health concern. All data were recorded anonymously, and the identity of dispensers and outlets was strictly protected throughout the study. No audio or video recordings were made, and the information was reported only in aggregate form to ensure confidentiality.

Results

The magnitude of narcotic and psychotropic medication dispensing

A total of 201 requests were made by the simulated clients at 38 CDROs. In 80.6% of visits, medications were dispensed without a prescription. Regarding specific modes of requests, 67 requests were made for each scenario. For the first scenario (disease simulation), there were two simulations, including depression simulation and severe back pain simulation, in 34 and 33 visits, respectively. Amongst the 34 requests, 67.6% of pharmacy professionals recommended consulting a physician for depression simulation, whilst most of the respondents (93.9%) dispensed medication for back pain simulation. For the second scenario (request medication by name), 83.6% of participants dispensed the medication, and 87.5% of dispensers provided medications with counselling. For the third scenario (medication requests by showing an empty container or package), 95.5% of the participants dispensed medications

Generally, in the three types of observation, namely simulation (depression simulation and severe back pain simulation), request by name and request by showing package, 50.7%, 83.6% and 95.5% of pharmacy professionals dispensed medications without a prescription (Figure 1).

The type of medications dispensed

From a total of 201 visits to CDROs, nine types of narcotic and psychotropic medications were requested, and prescription-only medications were dispensed without a prescription in 162 cases. Amongst these 162 dispensed encounters, amitriptyline was the most frequently dispensed medication, provided in 17.9% of visits (95% CI 12.6–24.8), followed by tramadol in 16.7% (95% CI 11.6–23.6), carbamazepine in 14.8% (95% CI 10.1–21.2), haloperidol in 11.1% (95% CI 7.1–17.0) and pethidine in 7.4% (95% CI 4.0–13.1) (Table 2).

From the total 201 requests, the overall rate of medication dispensing without prescription was high. When comparing dispensing practices by facility type, 80.3% of drug stores and 81.0% of pharmacies provided medications without a prescription. However, the difference was not statistically significant (χ^2=0.856, p=0.355). In contrast, a statistically significant association was found between the type of client request and the likelihood of dispensing without a prescription (χ^2=12.176, p=0.002). The rate of dispensing was lowest in the disease simulation scenario (62.7%), compared to 83.6% in direct name-based requests and 95.5% when clients presented an empty medication package (Table 3).

Figure 1. Distribution of medication dispensing without prescription across different types of requests.

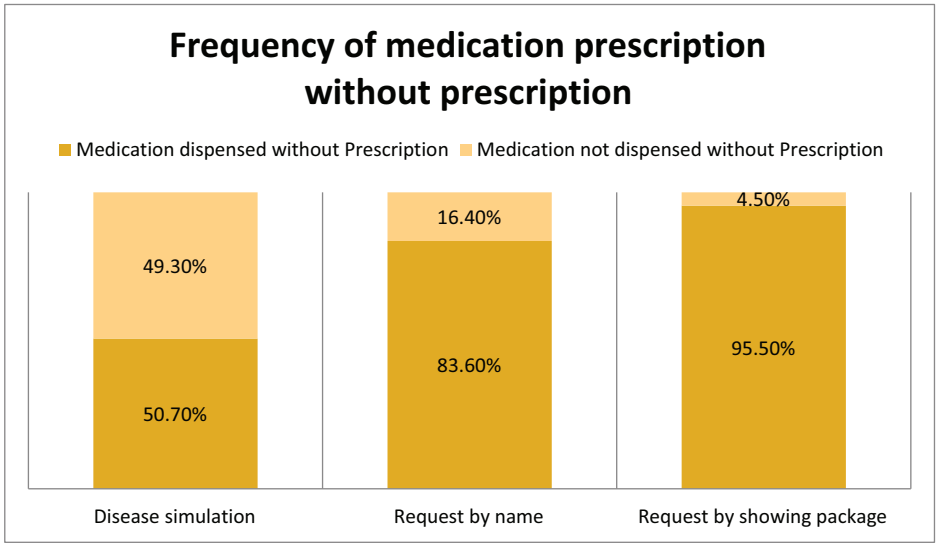

Table 2. Frequency of medication dispensing for narcotic and psychotropic medications dispensed without a prescription amongst dispensed visits (*n*=162).

Pharmacological class	Name of medication	Frequency	Percentage (%)	95% CI
Antidepressants	Amitriptyline	29	17.9	12.6–24.8
	Fluoxetine	14	8.6	5.1–14.1
Antipsychotics	Haloperidol	18	11.1	7.1–17.0
	Chlorpromazine	16	9.9	6.1–15.6
Anticonvulsants/mood stabilizers	Carbamazepine	24	14.8	10.1–21.2
	Lamotrigine	13	8.0	4.7–13.5
Opioid analgesics	Tramadol	27	16.7	11.6–23.6
	Pethidine	12	7.4	4.0–13.1
	Morphine	9	5.6	2.9–10.6

Table 3. Association between type of request and facility type with non-prescription dispensing of narcotic and psychotropic medications.

	Variable	Medication dispensed without prescription		χ^2 test	*p* value
		Yes	No		
Type of facility					
	Drug store	98 (80.3%)	24 (19.7%)	0.856	0.355
	Pharmacy	64 (81.0%)	15 (19.0%)		
Type of request					
	Disease simulation	42 (62.7%)	25 (37.3%)	12.176	0.002
	Request by name	56 (83.6%)	11 (16.4%)		
	Request by showing package	64 (95.5%)	3 (4.5%)		

Table 4. Logistic regression analysis for factors associated with dispensing medications without a prescription (n=201)

	Variables	Logistic regression analysis		
		Adjusted odds ratio	CI	*p* value
Type of facility				
	Drug store	1.27	0.63–2.55	0.51
	Pharmacy		1	
Type of request				
	Disease simulation	4.83	3.25–6.05	<0.001*
	Request by name	3.15	1.01–3.28	0.06
	Request by showing package		1	

*Statistically significant.

Factors associated with dispensing medications without a prescription

To further explore factors associated with the likelihood of dispensing medications without a prescription, a binary logistic regression analysis was conducted, adjusting for the type of request and facility type (Table 4). The analysis revealed that the type of request made by the client was significantly associated with the probability of receiving a medication without a prescription.

Clients who requested a medication by disease simulation were 4.83 times more likely to receive it without a prescription compared to those who requested by showing package (adjusted odds ratio 3.15, 95% CI 1.40–7.08). In contrast, facility type (pharmacy *versus* drug store) was not found to be a statistically significant predictor of non-prescription dispensing.

Discussion

To the best of our knowledge, there is a paucity of data on the non-prescription dispensing of narcotic and psychotropic medications in CDROs in Ethiopia. This study systematically investigated this issue using a simulated client methodology, which is recognized as a robust and realistic approach in clinical pharmacy research.[22] Our findings reveal a high prevalence of inappropriate dispensing, with 80.6% of CDRO visits resulting in the provision of prescription-only narcotic or psychotropic medications without a valid prescription. Notably, the type of request significantly influenced dispenser behaviour. Compared to symptom-based requests, clients who asked for medications by name were over three times more likely to be dispensed the drug, whilst those who presented an empty medication package had nearly 11 times greater odds to be dispensed the drug. This indicates the critical role of client behaviour in triggering non-compliant dispensing practices.

Although the use of psychotropic medications without a prescription entails a high risk of abuse and adverse outcomes,[6] such dispensing is common in Ethiopian CDROs as observed herein. Pharmacy professionals are expected to ensure rational medicine use and provide appropriate counselling.[23] However, in many low- and middle-income countries, adherence to standards is often compromised due to limited access to healthcare data, poor interprofessional communication and a shortage of adequately trained pharmacy professionals.[24]

Our findings are consistent with similar studies from developing countries where regulatory enforcement is weak and CDROs often serve as the first and only point of contact for many patients. In Nigeria and Pakistan, most pharmacies were found to dispense psychotropic medications without a prescription.[6,11] Similar findings have been reported in Saudi Arabia and Uganda, where high rates of non-compliance with controlled drug regulations were observed despite stricter policies.[25,26] In Ethiopia, although the Ethiopian Food and Drug Authority regulates prescription-only medications, enforcement mechanisms are often weak due to limited resources, infrequent inspections and inconsistent follow-up. Previous studies also found that CDROs frequently dispensed narcotics without requiring prescriptions when such drugs were available.[16] In contrast, countries like England and Australia demonstrate significantly lower levels of unauthorized dispensing due to stronger legal frameworks, clearer delineation of prescribing and dispensing roles, and the use of electronic prescription tracking systems.[5,27] Whilst financial incentives may partly explain non-adherence to regulations, our findings suggest multiple contributing factors, including patient pressure, fear of losing business, lack of awareness about legal restrictions and health risks, and minimal regulatory supervision. In our study, many dispensers complied with direct requests by name or packaging, which may reflect both economic pressures and weak enforcement. Likewise, as prior studies have shown, the majority of CDROs neglect the regulations governing the dispensing of medications, which permits and encourages individuals to obtain medications readily without a prescription and raises the rate of self-medication usage.[9,28] One serious consequence of the unauthorized sale of controlled medications is the rise in self-medication. This practice is strongly linked to the misuse of opioids and co-occurring substance use disorders, particularly in individuals with mental health conditions.[28,29]

In our study, antidepressants and opioids including amitriptyline and tramadol, were the most commonly dispensed drugs, echoing findings from Iran, where tramadol is also widely accessible without oversight.[30] This is especially concerning given that the Ethiopian Food and Drug Authority prohibits the non-prescription sale of tramadol, indicating a gap between regulatory intent and practice. Although, it is sometimes argued that access to medications without prescription reduces healthcare costs for minor conditions,[31] the uncontrolled availability of high-risk drugs, such as benzodiazepines, opioids and certain antidepressants, can lead to dependency, overdose, suicide and long-term public health burdens.[32]

With regards to the assessed clinical scenario that approximated depression, 67.6% of the professionals did not dispense any medication but rather advised the simulated client to consult physicians, which was

quite an encouraging finding. However, a significant proportion still dispensed antidepressants, mainly amitriptyline, without a prescription, which is troubling because depression may mask other psychiatric disorders, such as bipolar disorder, and inappropriate treatment may worsen the clinical condition. Psychotropic medications have been linked to adverse effects such as weight gain, an increased level of glucose, raised circulating lipid levels and abnormalities in ECG values,[33–35] necessitating proper diagnosis and monitoring prior to use.

In our study, most of the pharmacy professionals did not refuse to dispense for direct medication requests by name or showing the container. From an operational perspective, such practices may be influenced by financial pressures and the competitive nature of the retail pharmacy environment. The most common easily accessible medications in our study were antidepressants and opioids, which was similar with study conducted in Nigeria.[11] These findings underscore the need to balance business interests with public health responsibilities.

These findings reinforce the urgent need to strengthen regulatory oversight of CDROs in Ethiopia. Policy-makers should consider implementing regular inspections, enforcing penalties for unauthorized dispensing and introducing prescription verification tools such as electronic prescription tracking. In addition, ongoing training for dispensers on legal and ethical standards, psychotropic medication safety, and patient communication is essential. Public awareness campaigns are also needed to inform consumers about the dangers of self-medication and the importance of consulting licensed professionals.

Strengths and limitations

This study provides important insights into the non-prescription dispensing of narcotic and psychotropic medications in Ethiopian CDROs, using the simulated client method to capture real-world practices without observation bias. Including all operational CDROs in the study area enhances the representativeness of the findings. The use of pilot-tested scenarios and appropriate statistical analyses, including odds ratios with CIs, strengthens the study's methodological rigor. However, the covert nature of the methodology meant that prior consent was not obtained, which, although ethically approved, may raise concerns. Additionally, the lack of post hoc comparisons and adjustments for multiple testing may increase the risk of type I error. The observational design also limits causal interpretation. Future studies should explore the qualitative perspectives of dispensers and apply analytical methods that account for multiple comparisons, whilst also conducting in-depth investigations into the contextual factors influencing non-compliant dispensing behaviour.

Conclusion

This study revealed a high rate of non-prescription dispensing of narcotic and psychotropic medications in CDROs, with medications such as amitriptyline, tramadol and chlorpromazine frequently provided without valid prescriptions. The findings also indicate that some drug stores are dispensing medications that are legally restricted to pharmacies, suggesting regulatory gaps in enforcement. To address this, we recommend immediate policy action to strengthen regulatory oversight, conduct regular inspections of CDROs, and enforce prescription-only regulations. Additionally, targeted training for dispensers and public education campaigns are necessary to promote rational medicine use and reduce the risks associated with inappropriate access to controlled medications.

Contributions: Conceptualization: TKZ. Data curation: TKZ, RBA. Formal analysis: TKZ, MCW, SAW, RBA, MAA, TTA, KG, AT. Investigation: TKZ, BAT, FBT, GWG, SAW, AEF, MAA, RBA. Methodology: TKZ, BAT, RBA, MAA, AMT, AEF. Project administration: TKZ, BAT, RBA, TTA. Supervision: TKZ, MCW, RBA, MAA, GWG, TTA. Visualization: TKZ, BAT, FBT, GWG, MAA, RBA. Writing original draft preparation: TKZ, SAW, AMT, RBA, MAA, AEF, TTA. Review and editing: TKZ, SAW, MCW, FBT, AMT, RBA, TTA, KG, AT. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Data availability: All necessary data is included in the document. The corresponding author can provide you with additional data that has been used to support the results of the research on enquiry.

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