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A pilot study of the implementation of good pharmacy practice in private and public sector pharmacies in Nepal

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Abstract

Introduction: With limited awareness of good pharmacy practice (GPP) and weak regulatory enforcement in Nepal there is a need to investigate and assess adherence to GPP in private and public sector pharmacies. **Methods:** A cross-sectional pilot study assessed in 2021 adherence to GPP guidelines in selected private (n=20) and public (n=19) sector pharmacies in the capital district, and two districts within each two of seven provinces. Hospitals and primary health care centre were randomly selected while health posts and private pharmacies were selected based on their proximity to these. Trained data collectors and regulatory inspectors used two sector-specific, indicator-based electronic inspection tools aligned with World Health Organization best practices to uniformly assess GPP implementation in public and private facilities—58 joint indicators overlapped in the two sector tools. The indicators were classified by importance as critical, major, and minor. **Results and Discussion:** On average, public pharmacies passed slightly more (not significant) GPP indicators than private pharmacies—62% and 57% of the 58 joint indicators, respectively. The aggregated compliance percentage for critical, major and minor joint indicators was 72 vs. 75%, with outliers such as labelling and refrigerator monitoring which is around 90% noncompliance, 73 vs. 84% and 46 vs. 50% in the private and public sector respectively. The lowest compliance rate was found in the operating requirements domain with 10% for private and 15% for public sector facilities. **Conclusion:** Although private and public sector pharmacies have not yet fully implemented the new GPP guidelines, the government is moving forward with strengthening GPP legislation and regulations, building GPP capacity, and bolstering the GPP inspection function, which are needed to improve pharmaceutical services and thereby safeguard the people of Nepal.

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Introduction

Nepal has over 25,000 registered pharmacies, which are the country's de facto first line of primary health care and pharmaceutical services together with local level health facilities. The Drug Act mandates the Department of Drug Administration (DDA) (Department of Drug Administration, 1978) to regularly inspect all medicine outlets to ensure that premises, personnel, and practices meet the minimum standards described in the act and in the Code on Sales and Distribution of Drugs (Ministry of Health and Population, 2014). The World Health Organization (WHO) and International Pharmaceutical Federation jointly published good pharmacy practice (GPP) guidance that most countries use as a basis for their own national guidance (International Pharmacist Federation, 2011), (WHO, 2011). The Nepal Pharmacy Council formulated national GPP guidelines in 2005 (Nepal Pharmacy Council, 2005); however, those guidelines were neither formalized by the DDA, nor implemented. Earlier studies found GPP adherence in private sector to be 51-56% (Acharya & Khanal, 2020), (Shrestha & Ghale, 2018); weak prescription handling (36%) and dispensing (28%) and half of pharmacies dispensed antibiotics without a prescription, (Shrestha & Ghale, 2018), closely associated with pharmacy staff qualifications (Acharya & Khanal, 2020). Little is known about the GPP adherence in government facilities.

Poor GPP implementation is probably linked to the DDA's limited resources including inspectors; a chronic pharmacist shortage; regulatory focus on pharmaceutical companies and private sector pharmacies, but also by deeper systemic issues. Pharmacy inspections are focused on a few mandatory and critical regulatory requirements with low interest by pharmacy owners to implement GPP due to limited financial and low professional motivation for quality improvement.

Nepal has three cadres of pharmacy staff; Pharmacists are qualified as either a Bachelor or Master degree of Pharmacy (Ranjit, 2016); Assistant pharmacists qualified through a three-year diploma pharmacy education and vyabasahi (professionalists) having a three-month pharmacy training course recognized by Drug Advisory Committee. All three cadres can legally operate a pharmacy once the pharmacy, the owner and pharmacists are registered with the DDA and the Pharmacy Council. In 2021, there were 12,620 pharmacists, including 4,261 with bachelor or master level and 8,359 with diploma level (Nabin, 2021). The majority of private sector pharmacies are run by professionalists (Acharya & Khanal, 2020), (Shrestha & Ghale, 2018). In public facilities, pharmacy staff are only found at hospitals and higher-level facilities. Nurses and other health professionals without pharmacy training manage medicines at lower-level facilities.

The Government of Nepal has embarked on several strategies to strengthen the DDA's regulatory maturity in adherence to the WHO Global Benchmarking Tool (WHO, 2021). Recognizing the gaps in pharmacy services, the DDA has taken action in collaboration with the Medicines, Technologies, and Pharmaceutical Services (MTaPS) program to update the Drug Act, and approve the Code on Sales and Distribution including the new GPP guidelines (International Pharmacist Federation, 2011), (WHO, 2011). Additionally, the DDA embarked on a multi-pronged GPP strategy strengthening registration requirements and inspection, capacity-building, and strengthen regulatory oversight. The enhanced GPP inspection includes the development of electronic, indicator-based inspection tools for assessing GPP adherence. The indicators were customized to Nepal context based on the Nepal drafted GPP guidelines, WHO tools and GPP inspection tool applied in other countries (Stenson et al., 2001; Trap et al., 2010; Trap et al., 2016; WHO, 1993). There is limited awareness and knowledge of GPP standards and weak regulatory enforcement in Nepal (Pathak et al., 2025; Sankhi & Marasine, 2025; Sapkota & Shrestha, 2024; Shakya et al., 2025).

To help inform DDA's GPP implementation strategy, this pilot study used the electronic indicator-based inspection tools to identify key barriers to GPP implementation in a sample of private and public sector pharmacies. To date, there are no studies on GPP in Nepal, a unique setting

with diverse geographical terrain. This study will help identify current gaps in GPP implementation and help the DDA finalize the GPP guidelines for Nepal.

Materials and methods

This is a descriptive cross-sectional study using a sample of registered private and public pharmacies.

Sampling

We randomly selected two of Nepal's seven provinces from which we then randomly selected two districts. Each district has one district hospital pharmacy, 2 to 6 PHCCs and 29 to 47 health posts. All public health facilities—district hospitals, primary health care centres (PHCCs), or health posts—have a main pharmacy. From each district we included the district hospital and randomly selected one PHCC. We excluded one secondary wing of a hospital pharmacy because it was privately owned. We purposely sampled three health posts based on their proximity to the hospital and the PHCC and in two hilly districts with distance and accessibility challenges we sampled only one health post. We purposely sampled four to six private sector pharmacies per district based on their proximity to the sampled public sector facilities and their accessibility. The inspection tools was piloted in one PHCC, one health post, and one private pharmacy from Kathmandu district leading to sampling a total of 39 facilities—19 public and 20 private sector (Table 1).

Indicators included in the GPP Inspection Tools

The DDA, in collaboration with the MTaPS program, developed an indicator-based GPP inspection tool based on the Nepal GPP Guidelines 2005 (Nepal Pharmacy Council, 2005), the WHO GPP guidelines and prescribing indicators (WHO, 2011), the Codes on Sale and Distribution, and GPP indicator tools developed in other countries (Ministry of Health and Population, 2014). The GPP inspection tool consists of three indicator categories—critical, major, minor—covering six GPP domains. (Table 2). Not all domains include all three categories of indicators and few indicators differ between sectors- linked to staffing. The private and public sector tool has 66 and 60 indicators, respectively, with 58 joint indicators used for data analysis. The private and public sector tools include 19 and 14 critical indicators (14 joint), respectively, 10 major joint indicators and 37 and 36 minor indicators (34 joint), respectively. (Tables 2). The GPP inspection tools are included in Appendix Table 1. The tools align with the revised Code on the Sale and Distribution of Drugs, integrating the Good Pharmacy Practice (GPP) guidelines.

Five critical indicators are irrelevant in public facilities where pharmacists are seldom available, basic essential medicines are provided free of charge and may be prescribed and dispensed by a single healthcare provider and recorded in the dispensing log only.

Table 1: Study sample by province, district, and pharmacy type

Province		Province 1		Karnali		Bagmati	Total
District		Jhapa	Terhathum	Surkhet	Jajarkot	Kathmandu	
Public sector	Hospital	1	1	1	1	0	4
	PHCC	1	1	1	1	1	5
	Health post	3	3	2	1	1	10
Private sector		6	4	5	4	1	20

Three minor indicators apply only to private pharmacy inspection because public pharmacies only dispense free or insurance-covered medicines and patient sees the health care provider (prescriber) before going to the pharmacy or at health posts the same health care provider diagnoses, prescribes, and dispenses medicines. Two minor indicators were only monitored in the public sector as private sector pharmacies only dispense blister packs, and can dispense all registered medicines, not just those on the essential medicines list (Table 2).

In all, we excluded 10 non-joint indicators from the comparative analysis. For some indicators sample size was reduced as some pharmacies were missing values i.e., pharmacy has no refrigerator.

Data collection

DDA inspectors and MTaPS surveyors piloted and revised the tool in Bagmati Province. Surveyors attended a one-day data collection training session and a two-day practical training. The tool requires both retrospective and prospective data collection through direct observations, record reviews, and interviews with pharmacy staff and exiting patients (Appendix Table A 1). Data was collected between April and May 2021, and surveyors along with DDA inspectors collected data at all facilities. The tool allows offline data entry. Data was validated and cleaned, checking for inaccuracy and completeness before uploading to a central database that automatically generated inspection reports and data for analysis.

Data analysis

Microsoft Excel was used to compute the percentage of facilities that were in compliance with GPP indicators and tabulate and compare indicator compliance and scores by indicator type and domain between the two facility types. For each indicator, pharmacies were considered compliant when scored "yes," "acceptable," or "needs improvement." Twelve joint indicators were scored "not applicable" in some facilities, if for example, the facility did not have a refrigerator, did not use patient cards, did not store narcotics, or if the data collectors were unable to get the data from that health facility (i.e., there were no patients to interview at the time of the visit).

Confounders:

Possible indirect confounders are variation in inspection frequency, stock-outs of essential medicines, profit margin to procure medicines and insufficient funding in government pharmacies. Performing good practice assessment during the inspection might result in Hawthorne bias.

Results and discussion

Private pharmacies on average complied with fewer joint indicators than public pharmacies in all three indicator categories, overall (n=58) with 57% versus 62%, critical (n=14) with 72% versus 75%, major (n=10) with 73% versus 84% and minor (n=34) with 46% versus 50% (Figure 1). In the public sector indicator passing rate of 76-100% was 14(41%) of the indicators compared to 12 (35%) in the private sector. An indicator passing rate below 25% in private versus public sector was 47% versus 41%. We found that compliance with the 34 minor indicators to be challenging in both sectors.

Appendix Table A2 demonstrates the compliance disaggregated by indicator category and domain for all joint indicators.

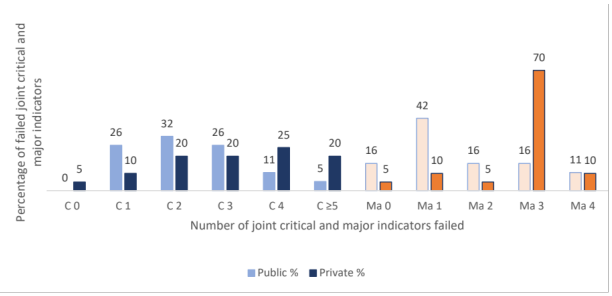


Fig. 1: Comparison of private (n=20) and public (n=19) sector facilities by the percentage of failed joint critical (C) and major (Ma) indicators.

To clarify Figure 1: More public sector pharmacies only failed one joint critical indicator (C1) compared to private sector facilities i.e. percentage of one failed joint critical was 26% versus 10%.

Table 1: GPP indicators by category and domain assessed in only the private sector or only in the public sector pharmacies or jointly in both sectors

Category	Domain	#	Indicator
Critical	Dispensing	1	A logbook for prescription for class A drugs (narcotics & psychotropics) are available in pharmacies /hospitals
		2	Appropriate labeling information (medicine name, strength, quantity, dispensing date, patient name, dosage, and facility name) of dispensed medicine
		3	Patient information/knowledge on dispensed antimicrobials is well understood
		4	*Prescription medicines are dispensed with prescriptions only*
	Operating requirement	5	Class A drugs (narcotics) are kept under lock
		6	*Banned drugs are not sold in the pharmacy*
		7	*Sample drugs are not sold in the pharmacy*
		8	*Unregistered drugs are not sold in the pharmacy*
	Pharmacy & staff	9	The daily manager/pharmacist was present in the pharmacy/health facility during inspection
		10	*The pharmacist's/professional's membership is valid*
	Premises	11	The medicines are protected from direct sunlight
		12	The roof is in good condition to avoid water penetration
		13	The walls are clean without holes and signs of humidity and degradation
		14	Handwashing facilities for staff are acceptable, hygienic, and functional
		15	The size of the dispensary is adequate, having enough shelves and layout for patients' information and dispensing
		16	The temperature of the refrigerator is monitored and recorded daily
		17	There is a functioning system for cold storage/refrigerator
		18	Toilet facilities are available to the staff and are hygienic and function well
	Storeroom management	19	The size of the storeroom is adequate, having enough shelves and layout so medicines can be organised systematically
Major	Dispensing	20	A dispensing log/prescription recording system is available
	Premises	21	Floors are made of a material that is easy to clean, free of holes and big cracks, and appears clean
		22	The pharmacy/store is lockable and access limited to authorised personnel
		23	Medicines and dispensing services are provided from an area separated from the storeroom
		24	There are no signs of pests, harmful insects, or rodents
	Storeroom management	25	Stock cards, ledger book, or electronic records are available
		26	Medicine packs are stored only on shelves and/or in cupboards, and they are not stored in disorganized stacks or boxes directly on the floor
		27	Stock cards, ledger book are kept next to the medicines on shelves (or organised in a folder in the storeroom)
		28	There is a designated area and box to store expired medicines clearly marked "expired goods not for sale"
		29	There is a record for expired medicines and health supplies
Minor	Dispensing	30	There is a table available for counseling and benches for customers/patients so they can sit while waiting for their medicines
		31	The pharmacy/health facility uses dispensing envelopes/bags for dispensing medicines
		32	Drinking water is available to the customer/patients
		33	Handwashing facilities and soap are available to the customer/patient
		34	If patient cards are used, they are returned to the patient after the pharmacy/health facility ticks off the dispensed medicine on the card
		35	It is possible to ensure product traceability

Table 2: GPP indicators by category and domain assessed in only the private sector or only in the public sector pharmacies or jointly in both sectors (cont.)

Category	Domain	#	Indicator
Minor	Dispensing	36	Privacy is achieved during dispensing and counseling (other waiting patients should be at least 2 meters away from dispensing window)
		37	**Pharmacy staff does not use bare hands to count tablets from a big container**
		38	The dispensing log/prescription recording system is used for all medicines dispensed
		39	Prescription completeness is systematically carried out before dispensing
		40	The medicine to be dispensed is double-checked with initials of the controller
	Operating requirement	41	**A list of free medicines is available**
		42	The latest version of the national list of essential medicine is available
		43	Other materials like training manuals are available
		44	Reference materials like British National Formulary, standard treatment guidelines, etc. are available
		45	The pharmacy has standard operating procedures for dispensing, labeling, stock management, and expiry in place
		46	*Retail prices are included in an updated product list **or** printed on the medicine*
	Pharmacy & staff	47	All pharmacy staff have a name tag with job title visible on their clothing
		48	All pharmacy staff wear an apron/coat
		49	The pharmacist is registered by the Nepal Pharmacy Council
		50	Pharmacy registration is verified for validity by the DDA
		51	*Patients are appropriately referred to a doctor if required*
		52	*The word "Pharmacy" is part of the facility name*
	Premises	53	The medicines are stored in the center of the refrigerator (not in door, top/bottom shelves)
		54	Fire safety equipment (fire extinguisher or bucket with sand or water) is available and accessible
		55	There is a power backup for the refrigerator
		56	Only medicines are stored in refrigerator (no food or drinking water)
		57	The premises appear clean and tidy with waste collection baskets available
		58	The temperature in the pharmacy is monitored and recorded daily and records are kept for two years
		59	There is a constant supply of electricity and a telephone is available
	Procurement	60	Proper procurement records are available (date, invoice, supplier, quantity received, batch number, expiry date, DDA ID, PAN ID, registered wholesaler)
	Storeroom management	61	Adherence to first expiry-first out (FEFO) is practiced (check for 5 randomly selected products)
		62	Procured medicines are put in a quarantine area until quality is checked and recorded before release
		63	Expired medicines in the pharmacy have been entered into the expired medicines log
		64	The pharmacy/drug outlet is computerized
		65	Medicine is stored in a systematic manner and prescription medicines are out of patients' reach
		66	Shelves in the pharmacy are labeled with medicine name or class in the pharmacy
		67	Stock card headers are filled correctly with medicine's name, strength, dosage form, special storage instructions
		68	Stock cards are correctly updated so physical count and actual balance are the same

Note: Gray *italics* indicates indicators only applied in the private sector GPP tool. **Bold** indicates indicators only applied in the public sector GPP tool.

Private pharmacies on average complied with fewer joint indicators than public pharmacies in all three indicator categories, overall (n=58) with 57% versus 62%, critical (n=14) with 72% versus 75%, major (n=10) with 73% versus 84% and minor (n=34) with 46% versus 50% (Figure 1). In the public sector indicator passing rate of 76-100% was 14(41%) of the indicators compared to 12 (35%) in the private

sector. An indicator passing rate below 25% in private versus public sector was 47% versus 41%. We found that compliance with the 34 minor indicators to be challenging in both sectors. The overall differences were not significantly different.

Appendix Table A2 demonstrates the compliance disaggregated by indicator category and domain for all joint indicators.

Domain compliance

The domain score calculated as a proportional score on a scale of 1-5 for each of the six domains shows that the overall compliance pattern was similar for both sectors, with lowest performance in the operating requirements domain and highest in the premises and procurement domains (Figure 2).

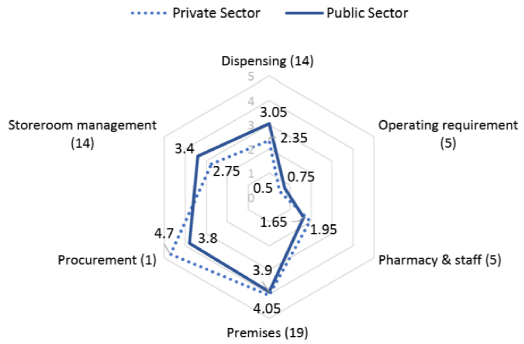


Fig. 2: Domain scores for public and private pharmacies for the 58 joint GPP indicator

The 1-5 scoring scale used in Figure 2 indicates 1 – very poor, 2 – Poor, 3 – Average, 4 – Good, 5 – Excellent.

Average compliance was highest in the public sector in all domains except for procurement, including only one indicator (Table 3). The lowest average performance in both sectors was in the operating requirement domain, relating to poor availability of resource materials and improper storage of class A drugs (narcotics and psychotropics).

Indicator scores

Given the high level of noncompliance among both public and private pharmacies, we identified which specific indicators were particularly challenging. We define challenging indicators as those having compliance rate of ≤75%. Of the 58 joint indicators, 33(57%) were classified as challenging, including 6(43%) of the critical indicators and 3(30%) of the major indicators being of most importance towards GPP implementation (Figure 3).

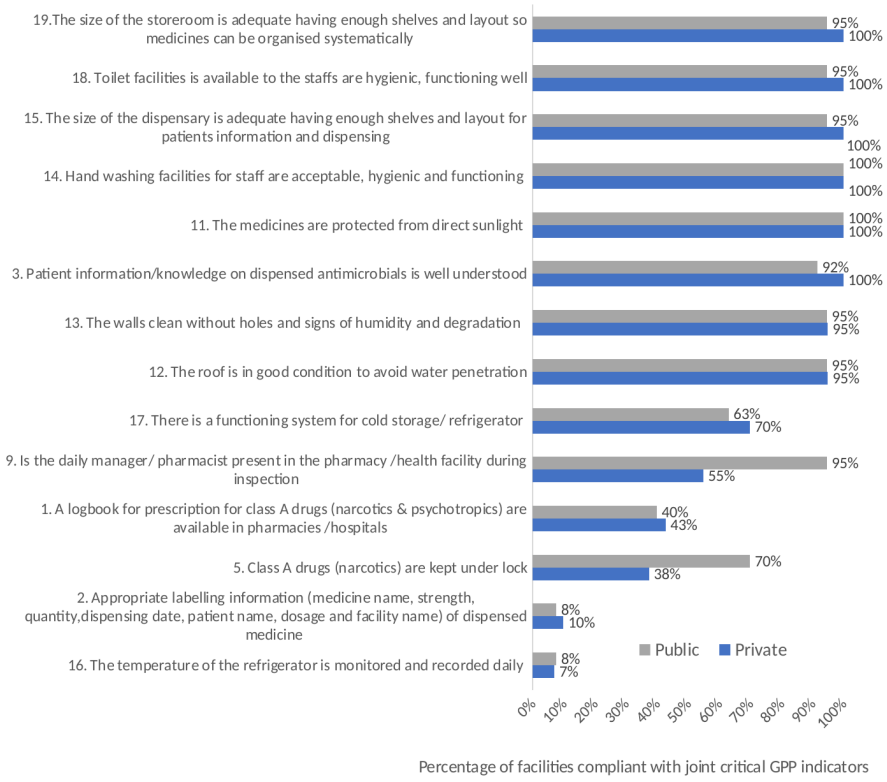
Critical joint indicators

Among the critical joint indicators, 'the temperature of the refrigerator is monitored and recorded daily was challenging in both sectors as only few pharmacies had a refrigerator. Only few pharmacies complied with the 'appropriate labelling information. Despite inadequate labelling, patients' knowledge on dispensed antimicrobials (when and how much to take, the reason for taking it, and the need to complete the full course) was good. Less than half of the pharmacies had logbooks for class A drug prescriptions, and 38% and 70% of private and public sector pharmacies, respectively, kept class A drugs under lock. The public sector was significantly better in one indicator, 'the daily manager or pharmacist was present in the pharmacy /health facility during inspection,' with all but one facility in compliance. In the private sector, the manager must have pharmaceutical training at a professional, diploma, Bachelor's, or Master's level.

Table 3. Average percentage of compliance by sector and domain for joint indicators

Domain and No. of indicators	Private sector (n=20)	Public sector (n=19)
Dispensing n=14	47%	61%
Operating requirement n=5	10%	15%
Pharmacy & staff n=5	39%	33%
Premises n=19	81%	78%
Procurement n=1	94%	76%
Storeroom management n=14	55%	68%
Total n=58	**57%**	**62%**

Note: Total is the average of all the 58 indicators



Note that indicators #1, #2, #5, and #16 were calculated based on lower denominators.

Fig. 3: Percentage of facilities compliant with 14 joint critical GPP indicators ranked by compliance.

That is not a public sector requirement due to Nepal's acute shortage of trained pharmacy personnel. All facilities ensured medicines are 'protected from direct sunlight' and 'the pharmacy has hygienic and functioning hand-washing facilities for staff.' Figure 3 shows their compliance for all the joint critical indicators.

Major joint indicators

Of the 10 major indicators, three were classified as challenging for the private sector pharmacies, with public sector pharmacies performing significantly better in all three. For the indicator, 'the dispensing log / prescription recording system is available,' 10% of private pharmacies and 37% of public sector pharmacies were compliant. Lack of a dispensing log or prescription recording system precludes product traceability or assessment of appropriate dispensing and prescribing practices.

' Stock cards, ledger book or electronic records are available' and 'kept next to the medicines on shelves or organized in a folder in the storeroom', were compliant for 15% of private sector facilities compared to 68% and 89% in the public sector for the two indicators. We also found that all private pharmacies kept a record for expired medicines, compared with 79% of public facilities. All other major indicators were comparable in the two sectors having compliance of 89%-100%. (Appendix Table A2)

Minor joint indicators

The minor indicators were the most challenging, with less than 20% pharmacies in both sectors complying with 24 (71%) of 34 joint minor indicators. For six of the challenging minor indicators, we found a significant difference between private and public sector performance; for example, the private sector scored significantly better in use of dispensing envelopes/bags, pharmacists registered with DDA, availability of procurement records, ensuring product traceability, double-checking with initials before medicine is dispensed, and appropriately filling stock cards (Appendix Table A2 and A3). For procurement record we assessed the invoice number, date, supplier, quantity received, batch number, expiry date, DDA ID, PAN ID. Private sector procured the items from the registered wholesalers and the invoice provided by the wholesalers contained most of the information complied with the procurement indicator. Whereas for the public sector pharmacies

they have procured through the local government, some through the provincial government and some medicines are directly supplied by the federal government. The proof of the procurement is the letter sent by the government which lacked most of the procurement information as indicated above. This was why private pharmacies scored higher in the procurement domain.

Discussion

This pilot study investigated adherence to GPP looking at 58 joint indicators stratified as critical, major, and minor in public and private sector pharmacies in Nepal and explored the adequacy of indicator-based inspection tools to assess GPP implementation in both sectors. To strengthen GPP implementation in both sectors towards GPP compliance, pharmacy owners must initially focus on complying with all indicators classified as critical followed by addressing lower-scoring major and then minor indicators to further strengthen their GPP implementation.

Our findings did not show significant differences between the two sectors but show both sectors' lack in GPP implementation, similar to other countries (Stenson et al., 2001a), (Syhakhang et al., 2001), (Stenson et al., 2001b), (Trap et al., 2016), (Butt et al., 2005) and (Wijesinghe et al., 2007). The overall compliance rate of 72%–75% refers to the aggregate performance across all critical indicators. However, when examining specific tasks such as labelling and refrigerator monitoring, compliance was much lower, with nearly 90% non-compliance observed. This difference highlights that while pharmacies may meet many critical indicators on average, certain indicators remain major weakness.

Due to the limited number of DDA inspectors and the very large number of pharmacies, current DDA inspections cover only few of the indicators included in the new GPP inspection tool. Our study reinforced that pharmacies in both sectors must build GPP capacity and GPP guidelines should be a mandatory requirement for operating a pharmacy. To successfully strengthen GPP implementation, formalized GPP guidelines must be combined with more frequent pharmacy inspections by strengthening the DDA's human resources and setting and enforcing a deadline for when all pharmacies need to meet the GPP requirements (Lluch & Kanavos, 2010). It is important to raise awareness on regulation to impact objectives, relevance, skills and knowledge on GPP principles and practices. In view of the DDA's very limited number of inspectors, an alternative solution to strengthen GPP implementation might be to look at South Africa, where the pharmacy council carries out fee-based pharmacy inspections (The South Africa Pharmacy Council, 2010) (The South Africa Pharmacy Council). The Nepal Code already regulate collaboration with the pharmacy council but that does not give the council mandate to regulate professionals (vyabasahi). It is DDA leading regulation and collaboration with council that is required to regulate the pharmacies run by pharmacists and professionals. Therefore, DDA and Nepal Pharmacy Council should work alongside to strengthen regulatory GPP enforcement. Alternative, is to give the DDA the organizational and financial autonomy that other regulatory bodies have (Briggs 2021), which would allow them to retain any funding they generate and thus increase and improve their services. Another possibility could be to restructure and decentralize DDA to address staffing constraints.

Challenging indicators

Just over half of all indicators were characterized as challenging, meaning that less than 75% of pharmacies complied with the indicator. Important for the GPP implementation is to address the challenging indicators that pharmacies struggled to pass. For example, less than 10% of pharmacies labelled medicines appropriately confirmed in other studies (Shrestha and Ghala, 2018). Often dose only was written on the blister pack as O-O (take morning and evening), and because dispensers rarely used labels or dispensing envelopes, important information such as patient name, date, dosage, and duration was missing.

Improving GPP implementation

Meeting GPP requirements calls for financial investments in roofing, refrigerators, computerization, and dispensing tools along with the strengthening of human resources. However, behavioural and procedural changes can address many challenging indicators at no or minimal cost. In the public sector, the district health office and municipal authorities oversee pharmacies, and GPP implementation falls under the Department of Health Services, Curative Services Division, who has already taken steps to improve GPP by piloting a supervision, performance assessment and

recognition strategy (SPARS) similar to i.e. Uganda (Trap et al., 2016), (Trap et al., 2018).

Inspection tool

Combining electronic data entry with the use of a central database is optimal for monitoring GPP inspections and generating regular performance reports. Inspectors were able to enter data while on site and see the results instantaneously important for data quality and completeness and allowed the inspector to ask clarifying questions at the site. Adding analytical and visualization features such as a spider graph or histogram would help facilities see their GPP status in real time and track improvements for their staff and lay the foundation for self-assessment (Trap et al., 2010; Trap et al., 2016; Petrushevska-Tozi et al., 2014; Alein et al., 2023).

Because some of the indicators differed between the two tools, we could not compare the sectors comprehensively; regardless, this data will serve as an important and quantifiable baseline for future interventions to improve GPP. In addition, a standardized tool makes the assessment process reproducible, transparent, and less dependent on assessors.

Some initiation to implement GPP was initiated decades back by Nepal Pharmacy Council but was not materialized. In July 2023 DDA drafted new updated GPP guidelines as part of the codes on sales on distribution of drugs. However, mandatory GPP implementation will require a significant increase in the number of trained pharmacists and a strategy that capacitates pharmacy owners and orients the community on accreditation and quality of pharmaceutical services. The regulatory authorities can revise the number and type of indicators as GPP capacity and facilities' ability to perform, improve and establish GPP accreditation criteria.

Study limitations

A key limitation of our study is the sample size. With only 20 private pharmacies sampled out of approximately 25,000 private pharmacies and a similarly small proportion of the approximately 7,800 public pharmacies assessed; external validity is a concern. Although we chose the sample size for pragmatic reasons, we did select the provinces and districts randomly. Despite the small sample size, the findings generally align with previous studies on GPP implementation (Acharya & Khanal, 2020) (Shrestha & Ghale, 2018).

In addition to limited sample size, this pilot study, for pragmatic and time-consuming reasons, only included pharmacies selected in the proximity of hospitals. To minimize sampling bias and give a full picture of pharmacy practices in different settings, future studies should include a wider range of pharmacies, such as rural and standalone sites.
We ensured data quality by selecting experienced inspectors and data collectors who were trained to use the data collection tool. Data completeness was occasionally problematic, especially because the small sample sizes in the two sectors did not allow us to exclude indicators or facilities with incomplete data. In addition, poor medicines management, such as stock cards not being used, which made it impossible to evaluate how well they were filled in; lack of refrigerators; or limited patients available for exit interviews contributed to low counts for some indicators.

Conclusion

Building a mature regulatory structure as part of an overall effort to strengthen the pharmaceutical system is critically important to improve good pharmacy practices in the public and private sectors. The DDA has taken significant steps to ensure the availability and appropriate use of good quality, safe medicines among the people of Nepal by introducing and enforcement of GPP guidelines and an electronic indicator-based GPP inspection tool that will increase inspection uniformity, quality, and transparency. Successful GPP implementation, particularly given the country's large number of pharmacies, will also require a substantial increase in the number of DDA inspectors who are capacitated in the GPP concept.

Authors contributions

BT, SN and NPD conceived of, designed, and oversaw the study. BT, SN, SKC and SB contributed to the development of study methods, training of data collectors, data analysis, and drafting of the manuscript. SSK, AR and SB contributed to data collection. BT, TH, SN, and AR contributed data analysis and drafting of the manuscript; BT, NPD, SSK, SKC and AR contributed to the data interpretation, discussion, and manuscript writing. All authors read and approved the final version.

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Ethical approval statement

Ethical clearance from the Nepal Research Council #2241/2022 was obtained. The study used secondary data and did not involve identifiable human subjects or clinical data.

Data Availability and Access Statement

The research data are hosted on the DDA and MTaPS data base servers. The data, data collection tool, interviews, analysis, and other materials either are provided in supplementary files or are available from the corresponding author. The authors had complete access to the study data enabling data analysis and manuscript development.

Conflict of interest

The authors declare that there are no conflict of interest

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors did not used AI (e.g. ChatGPT, Gemini and others).

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Appendix A

Appendix Table A1: The two GPP inspection tools

Appendix Table A2: Compliance disaggregated by indicator category and domain (joint indicators including 14 Critical, 10 Major and 34 Minor)

Appendix Table A3: Challenging critical, major, and minor GPP joint indicators and domains in private and public sector pharmacies

Appendix Table A1: The two GPP inspection tools

Domain	Type	#	Indicators	Private	Public	Joint
Pharmacy and Staffing	C	10	The pharmacists/professionalists membership valid	1	0	0
		9	The daily manager/ pharmacist was present in the pharmacy /health facility during inspection	1	1	1
	Mi	51	Patients are appropriately referred to a doctor if required	1	0	0
		52	The word "Pharmacy" is part of the facility name	1	0	0
		49	Pharmacist registered at Nepal Pharmacy Council	1	1	1
		50	The pharmacy registration is verified for validity by DDA	1	1	1
		48	All pharmacy staff wear an apron/coat	1	1	1
		47	All pharmacy staff have a name tag with job title visible on their clothing	1	1	1
Premises	C	13	The walls clean without holes and signs of humidity and degradation	1	1	1
		12	The roof is in good condition to avoid water penetration	1	1	1
		11	The medicines are protected from direct sunlight	1	1	1
		15	The size of the dispensary is adequate having enough shelves and layout for patients' information and dispensing	1	1	1
		17	There is a functioning system for cold storage/ refrigerator	1	1	1
		16	The temperature of the refrigerator is monitored and recorded daily	1	1	1
		18	Toilet facilities is available to the staffs are hygienic, functioning well	1	1	1
		14	Hand washing facilities for staff are acceptable, hygienic and functioning	1	1	1
	Ma	21	Floors are made of a material that is easy to clean, free of holes and big cracks and appears clean.	1	1	1
		23	Medicines and services (dispensing) are provided from an area separated from the storeroom.	1	1	1
		24	There are no signs of pests, harmful insects or rodents seen.	1	1	1
		22	The Pharmacy/Store is lockable, and access limited to authorized personnel	1	1	1
	Mi	57	The premises appear clean and tidy with the waste collection baskets available	1	1	1
		58	The temperature in the pharmacy is monitored daily, recorded and records kept for 2 years	1	1	1
		56	Only medicines stored in refrigerator (no food or/and drinking water).	1	1	1
		53	The medicines stored in the center of the refrigerator (not in door, top/bottom shelves)	1	1	1
		55	There is a power backup for the refrigerator	1	1	1
		54	Fire safety equipment (fire extinguisher or bucket with sand or water) is available and accessible.	1	1	1
		59	There is constant supply of electricity and a telephone is available.	1	1	1

Domain	Type	#	Indicators	Private	Public	Joint
Dispensing	C	4	Prescription medicines are dispensed with prescriptions only.	**1**	0	0
		1	A logbook for prescription for class A drugs (narcotics & psychotropics) are available in pharmacies /hospitals.	1	1	1
		2	Appropriate labelling information (medicine name, strength, quantity, dispensing date, patient name, dosage and facility name) of dispensed medicine	1	1	1
		3	Patient information/knowledge on dispensed antimicrobials	1	1	1
	Ma	20	A dispensing log / prescription recording system is available.	1	1	1
	Mi	37	Pharmacy staff does not use bare hands to count tablets from a big container	0	1	0
		32	Drinking water is available to the customer/patients.	1	1	1
		36	Privacy is achieved during dispensing and counseling (other waiting patients should be at least 2 meters away from dispensing window).	1	1	1
		30	There is a table for counselling and benches for customers/patients so they can sit while waiting for their medicines	1	1	1
		33	Hand washing facilities and soap available to customer/patient.	1	1	1
		31	The pharmacy/health facility use dispensing envelopes/bags for dispensing medicines	1	1	1
		39	Prescription completeness is systematically carried out before dispensing.	1	1	1
		40	The medicines to be dispensed is double checked with initials of the controller	1	1	1
		38	The dispensing log / prescription recording system is used for all medicines dispensed.	1	1	1
		35	It is possible to ensure traceability	1	1	1
		34	If patient cards are used & returned to the patient does the pharmacy/health facility tick the dispensed medicine on the card.	1	1	1
Storeroom management	C	19	The size of the storeroom is adequate having enough shelves and layout so medicines can be organized systematically	1	1	1
	Ma	26	Medicine packs are stored only on shelves and/or in cupboards and they are not stored in disorganized stacks or boxes directly on the floor.	1	1	1
		25	Stock cards, ledger book or electronic records are available.	1	1	1
		27	Stock cards, ledger book is kept next to the medicines on shelves (or organized in a folder in the storeroom).	1	1	1
		29	There is a record for expired medicines and health supplies.	1	1	1
		28	There is a designated area & box to store expired medicines clearly marked: expired goods not for sale.	1	1	1
	Mi	65	Medicine is stored in a systematic manner and prescription medicines out of reach for patients.	1	1	1
		66	Shelves are labelled with medicine name or class in the pharmacy	1	1	1
		62	Procured medicines put in a quarantine area until quality checked (order, batch no, quantities, medicines type, quantity, min. shelf live etc) and is it recorded before released.	1	1	1

Domain	Type	#	Indicators	Private	Public	Joint
		67	Stock card headers are filled correct with medicines name, strength, dosage form, special storage.	1	1	1
		68	Stock cards correctly updated so physical count and actual balance is the same.	1	1	1
		64	The pharmacy/drug outlet computerized	1	1	1
		63	Expired medicines in the pharmacy have been entered into the log	1	1	1
		61	Adherence to First Expiry First Out (FEFO) (check for 5 randomly selected products).	1	1	1
Operating requirements	C	5	Class A drugs (narcotics) kept under lock	1	1	1
		8	Unregistered drugs not sold in the pharmacy	1	0	0
		6	Banned drugs not sold in the pharmacy	1	0	0
		7	Any sample drugs not sold in the pharmacy	1	0	0
	Mi	44	Reference materials like British National Formulary, standard treatment guidelines, etc. are available	1	1	1
		42	The latest version of the national list of essential medicine is available	1	1	1
		41	A list of free medicine is available	0	1	0
		43	Other materials like training manuals are available	1	1	1
		45	The pharmacy has standard operating procedures for dispensing, labeling, stock management and expiry in place	1	1	1
		46	Retail prices are included in an updated product list **or** printed on the medicine	1	0	0
Procurement records	Mi	60	Procurement records are available (date, invoice no., Supplier, Quantity received, batch number, Expiry date, DDA ID, PAN ID, Registered wholesaler)	1	1	1
			Total Indicators	**66**	**60**	**58**

Note: C=Critical, Ma=Major, Mi= Minor

Appendix A2: Compliance disaggregated by indicator category and domain (joint indicators including 14 Critical, 10 Major and 34 Minor)

Indicator			Noncompliant				Compliant				Grand Total
			Private		Public		Private		Public		
Category	Domain	Indicator	Count	%	Count	%	Count	%	Count	%	Private/Public
Critical	Dispensing	1. A logbook for prescription for class A drugs (narcotics & psychotropics) are available in pharmacies /hospitals	8	57	5	56	6	43	4	44	14/9
		2. Appropriate labelling information (medicine name, strength, quantity, dispensing date, patient name, dosage and facility name) of dispensed medicine	9	90	12	92	1	10	1	8	10/13
		3. Patient information/knowledge on dispensed antimicrobials	0	0	1	8	4	100	11	92	4/12
	Pharmacy & staff	9. The daily manager/ pharmacist was present in the pharmacy /health facility during inspection	9	45	1	5	11	55	18	95	20/19
	Premises	11. The medicines are protected from direct sunlight	0	0	0	0	20	100	19	100	20|19
		12. The roof is in good condition to avoid water penetration	1	5	1	5	19	95	18	95	20|19
		13. The walls are clean without holes and signs of humidity and degradation	1	5	1	5	19	95	18	95	20|19
		14. Hand washing facilities for staff are acceptable, hygienic and functioning	0	0	0	0	20	100	19	100	20|19
		15. The size of the dispensary is adequate having enough shelves and layout for patients information	0	0	1	5	20	100	18	95	20|19
		16. The temperature of the refrigerator is monitored and recorded daily	13	93	12	92	1	7	1	8	14|13
		17. There is a functioning system for cold storage/ refrigerator	6	30	7	37	14	70	12	63	20|19
		18. Toilet facilities are available to the staffs and are hygienic, and functioning well	0	0	1	5	20	100	18	95	20|19
	Storeroom management	19. The size of the storeroom is adequate having enough shelves and layout so medicines can be organized systematically	0	0	1	5	20	100	18	95	20|19

Indicator			Noncompliant				Compliant				Grand Total
			Private		Public		Private		Public		
Category	Domain	Indicator	Count	%	Count	%	Count	%	Count	%	Private/Public
	Operating requirement	5. Class A drugs (narcotics) are kept under lock	10	62.5	3	30	6	37.5	7	70	16|10
Major	Dispensing	20. A dispensing log / prescription recording system is available	18	90	12	63	2	10	7	37	20|19
	Premises	21. Floors are made of a material that is easy to clean, free of holes and big cracks and appears clean	1	5	1	5	19	95	18	95	20|19
		22. The Pharmacy/Store is lockable, and access limited to authorized personnel	0	0	1	5	20	100	18	95	20|19
		23. Medicines and services (dispensing) are provided from an area separated from the storeroom	0	0	0	0	20	100	19	100	20|19
		24. There are no signs of pests, harmful insects or rodents seen	1	5	1	5	19	95	18	95	20|19
	Storeroom management	25. Stock cards, ledger book or electronic records are available	17	85	2	11	3	15	17	89	20|19
		26. Medicine packs are stored only on shelves and/or in cupboards and they are not stored in disorganised stacks or boxes directly on the floor	0	0	2	11	20	100	17	89	20|19
		27. Stock cards, ledger book is kept next to the medicines on shelves (or organized in a folder in the storeroom)	17	85	6	32	3	15	13	68	20|19
		28. There is a designated area & box to store expired medicines clearly marked: expired goods not for sale	1	5	2	11	19	95	17	89	20|19
		29.There is a record for expired medicines and health supplies	0	0	4	21	20	100	15	79	20|19
Minor	Dispensing	30. There is a table for counselling and benches for customers/patients so they can sit while waiting for their medicines	4	20	4	21	16	80	15	79	20|19
		31. The pharmacy/health facility uses dispensing envelopes/bags for strip/blister cutouts	14	70	18	95	6	30	1	5	20|19
		32. Drinking water is available to the customer/patients	0	0	2	11	20	100	17	89	20|19
		33. Hand washing facilities and soap available to customer/patient	1	5	2	11	19	95	17	89	20|19

Indicator			Noncompliant				Compliant				Grand Total
			Private		Public		Private		Public		
Category	Domain	Indicator	Count	%	Count	%	Count	%	Count	%	Private/Public
		34. If patient cards are used, they are returned to the patient after the pharmacy/health facility ticks off the dispensed medicine on the card	9	45	1	11	11	55	8	89	20|9
		35. It is possible to ensure product traceability	19	95	5	26	1	5	14	74	20|19
		36. Privacy is achieved during dispensing and counseling (other waiting patients should be at least 2 meters away from dispensing window)	5	25	5	26	15	75	14	74	20|19
		38. The dispensing log / prescription recording system is used for all medicines dispensed	17	85	12	63	3	15	7	37	20|19
		39. Prescription completeness is systematically carried out before dispensing	15	75	0	0	5	25	19	100	20|19
		40. The medicines to be dispensed is double checked with initials of the controller	17	85	12	63	3	15	7	37	20|19
	Operating requirements	42. The latest version of the national list of essential medicine is available	19	95	18	95	1	5	1	5	20|19
		43. Availability of other materials like training manuals	19	95	19	100	1	5	0	0	20|19
		44. Reference materials like the British National Formulary standard treatment guidelines etc are available	20	100	19	100	0	0	0	0	20|19
		45. The pharmacy has standard operating procedures for dispensing, labelling, stock management and expiry in place	20	100	19	100	0	0	0	0	20|19
	Pharmacy & staff	47. All pharmacy staff have a name tag with job title visible on their clothing	20	100	18	95	0	0	1	5	20|19
		48. All pharmacy staff wear an apron/coat	20	100	16	84	0	0	3	16	20|19
		49. The pharmacist is registered at Nepal Pharmacy Council	8	40	3	75	12	60	1	25	20|4
		50. The pharmacy registration is verified for validity by DDA	2	18	3	75	9	82	1	25	11|4
	Premises	53. The medicines are stored in the center of the refrigerator (not in door, top/bottom shelves)	2	14	2	22	12	86	7	78	14|9
		54. Fire safety equipment (fire extinguisher or bucket with sand or water) is available and accessible	0	0	2	11	20	100	17	89	20|19
		55. There is a power backup for the refrigerator	10	71	6	67	4	29	3	33	14|9
		56. Only medicines stored in refrigerator (no food or/and drinking water)	5	36	4	44	9	64	5	56	14|9
		57. The premises appear clean and tidy with the waste collection baskets available	1	5	1	5	19	95	18	95	20|19

Indicator			Noncompliant				Compliant				Grand Total
			Private		Public		Private		Public		
Category	Domain	Indicator	Count	%	Count	%	Count	%	Count	%	Private/Public
		58. The temperature in the pharmacy is monitored daily, recorded and records kept for 2 years	19	95	19	100	1	5	0	0	20|19
		59. There is constant supply of electricity, and a telephone is available	1	5	0	0	19	95	19	100	20|19
	Procure-ment	60. Procurement records are available (date, invoice, supplier, quantity received, batch number, Expiry date, DDA ID, PAN ID, Registered wholesaler)	1	6	4	24	17	94	13	76	18|17
	Storeroom management	61. Adherence to First Expiry First Out (FEFO) (check for 5 randomly selected products)	0	0	2	11	20	100	17	89	20|19
		62. Procured medicines are put in a quarantine area until quality checked and is it recorded before released	0	0	3	16	20	100	16	84	20|19
		63. Expired medicines in the pharmacy have been entered into the log	19	95	16	84	1	5	3	16	20|19
		64. The pharmacy/drug outlet computerized	17	85	16	84	3	15	3	16	20|19
		65. Medicine is stored in a systematic manner and prescription medicines out of reach for patients	0	0	0	0	20	100	19	100	20|19
		66. Shelves are labelled with medicine name or class in the pharmacy	20	100	17	89	0	0	2	11	20|19
		67. Stock card headers are filled correct with medicines name, strength, dosage form, special storage	17	85	0	0	3	15	19	100	20|19
		68. Stock cards correctly updated so physical count and actual balance is the same	18	90	15	79	2	10	4	21	20|19

Appendix Table A3. Challenging critical, major, and minor GPP joint indicators and domains in private and public sector pharmacies

Category	Domain	Indicator	Noncompliant		Compliant		p-value (Chi-squared)
			Private	Public	Private	Public	
			Count (%)	Count (%)	Count (%)	Count (%)	
Critical	Dispensing	1. A logbook for prescription for class A drugs (narcotics & psychotropics) are available in pharmacies /hospitals	8 (57)	5 (56)	6 (43)	4 (44)	0.94
		2. Appropriate labeling information (medicine name, strength, quantity, dispensing date, patient name, dosage and facility name) of dispensed medicine	9 (90)	12 (92)	1 (10)	1 (8)	0.85
	Pharmacy and staff	9. The daily manager/ pharmacist was present in the pharmacy /health facility during inspection	9 (45)	1 (5)	11 (55)	18 (95)	**0.00**
	Premises	16. The temperature of the refrigerator is monitored and recorded daily	13 (93)	12 (92)	1 (7)	1 (8)	0.17
		17. There is a functioning system for cold storage/ refrigerator	6 (30)	7 (37)	14 (70)	12 (63)	0.65
	Operating requirement	5. Class A drugs (narcotics) are kept under lock	10 (62.5)	3 (30)	6 (37.5)	7 (70)	0.11
Major	Dispensing	20. A dispensing log / prescription recording system is available	18 (90)	12 (63)	2 (10)	7 (37)	**0.00**
	Storeroom management	27. Stock cards, ledger book are kept next to the medicines on shelves (or organized in a folder in the storeroom)	17 (85)	6 (32)	3 (15)	13 (68)	**0.00**
	Storeroom management	25. Stock cards, ledger book or electronic records are available	17 (85)	2 (11)	3 (15)	17 (89)	**0.00**
Minor	Dispensing	31. The pharmacy/health facility uses dispensing envelopes/bags for dispensing medicines	14 (70)	18 (95)	6 (30)	1 (5)	**0.04**
		34. If patient cards are used, they are returned to the patient after the pharmacy/health facility ticks off the dispensed medicine on the card	9 (45)	1 (11)	11 (55)	8 (89)	0.06
		35. It is possible to ensure product traceability	19 (95)	5 (26)	1 (5)	14 (74)	**0.00**
		36. Privacy is achieved during dispensing and counseling (other waiting patients should be at least 2 meters away from dispensing window)	5 (25)	5 (26)	15 (75)	14 74)	0.92

Cate-gory	Domain	Indicator	Noncompliant		Compliant		p-value (Chi-squared)
			Private	Public	Private	Public	
			Count (%)	Count (%)	Count (%)	Count (%)	
		38. The dispensing log / prescription recording system is used for all medicines dispensed	17 (85)	12 (63)	3 (15)	7 (37)	0.12
		39. Prescription completeness is systematically carried out before dispensing	15 (75)	0 (0)	5 (25)	19 (100)	0.12
		40. The medicines to be dispensed is double checked with initials of the controller	17 (85)	12 (63)	3 (15)	7 (37)	**0.00**
	Operating requirement	42. The latest version of the national list of essential medicines is available	19 (95)	18 (95)	1 (5)	1 (5)	0.97
		43. Other materials like training manuals are available	19 (95)	19 (100)	1 (5)	0 (0)	0.32
		44. Reference materials like the British National Formulary, standard treatment guidelines, etc., are available	20 (100)	19 (100)	0 (0)	0 (0)	NA
		45. The pharmacy has standard operating procedures for dispensing, labeling, stock management and expiry in place	20 (100)	19 (100)	0 (0)	0 (0)	NA
	Pharmacy and staff	47. All pharmacy staff have a name tag with job title visible on their clothing	20 (100)	18 (95)	0 (0)	1 (5)	0.30
		48. All pharmacy staff wear an apron/coat	20 (100)	16 (84)	0 (0)	3 (16)	0.06
		49. The pharmacist is registered at Nepal Pharmacy Council	8 (40)	3 (75)	12 (60)	1 (25)	0.20
		50. The pharmacy registration is verified for validity by DDA	2 (18)	3 (75)	9 (82)	1 (25)	0.03
	Premises	55. There is power backup for the refrigerator	10 (71)	6 (67)	4 (29)	3 (33)	0.69
		56. Only medicines stored in refrigerator (no food or/and drinking water)	5 (36)	4 (44)	9 (64)	5 (56)	0.59
		58. The temperature in the pharmacy is monitored and recorded daily and records kept for 2 years	19 (95)	19 (100)	1 (5)	0 (0)	0.32
	Procurement	60. Procurement records are available (date, invoice, supplier, quantity received, batch number, Expiry date, DDA ID, PAN ID, Registered wholesaler)	1 (6)	4 (24)	17 (94)	13 (76)	0.00
	Storeroom	63. Expired medicines in the pharmacy	19 (95)	16 (84)	1 (5)	3 (16)	0.27

Cate-gory	Domain	Indicator	Noncompliant		Compliant		p-value (Chi-squared)
			Private	Public	Private	Public	
			Count (%)	Count (%)	Count (%)	Count (%)	
	management	have been entered into the expired medicines log					
		64. The pharmacy/drug outlet is computerized	17 (85)	16 (84)	3 (15)	3 (16)	0.94
		66. Shelves in the pharmacy are labeled with medicine name or class	20 (100)	17 (89)	0 (0)	2 (11)	0.14
		67. Stock card headers are filled correct with medicines name, strength, dosage form, special storage	17 (85)	0 (0)	3 (15)	19 (100)	**0.00**
		68. Stock cards correctly updated so physical count and actual balance is the same	18 (90)	15 (79)	2 (10)	4 (21)	0.34

Note: Challenging indicators are defined as those in which at least 25% of the pharmacies in at least one sector were noncompliant.

Denominators are reduced for critical and major indicator #1, #2, #3, #5 and #16 to include only facilities where patent interviews were possible, the facility managed Class A drugs and availability of a refrigerator. For minor indicators denominator is reduced for #34; # 49; #50; #55; #56 and #60.