Final Technical Report

for

Research Project

Knowledge, Attitudes and Practices on Substandard and Falsified Medical Products among Nursing Professionals in Bhutan

Principal Investigator: Gyelwa Kuenzom (ASEAN Institute for Health Development, Mahidol University)
Co-Investigator(s): Gyelwa Kuenzom (ASEAN Institute for Health Development, Mahidol University), Tarinee Buadit (ASEAN Institute for Health Development, Mahidol University), Cheerawit Rattanapan (ASEAN Institute for Health Development, Mahidol University), Orapin Laosee (ASEAN Institute for Health Development, Mahidol University)

2026.28.NNW

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Knowledge, attitudes and practices on substandard and falsified medical products among nursing professionals in Bhutan

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ABSTRACT

Background: Substandard and Falsified (SF) medical products pose a significant threat to patient safety and progress towards Universal Health Coverage. The World Health Organization has reported increasing SF medical product incidents worldwide, particularly in the South-East Asia region. Bhutan faces similar challenges, with evidence of SF medical products in the supply chain. Despite efforts to combat SF medical products, underreporting continues to hinder timely detection and response. While existing studies have largely focused on regulatory and supply chain aspects, relatively few have examined the role of healthcare professionals, particularly nurses, who are often first to identify and report SF medical products. Assessing their knowledge, attitudes, and practices can identify gaps in detection and reporting and inform interventions to strengthen surveillance systems.

Objective: To determine the levels of knowledge, attitudes and practices on SF medical products among nursing professionals in Bhutan and assess their associations.

Methods: A cross-sectional study was conducted among nursing professionals in Bhutan with more than 6 months of experience. Data were collected using online survey questionnaire (Google Forms). Stratified proportional allocation followed by purposive and voluntary sampling was employed. Descriptive analysis, chi-square test, bivariate and multiple logistic regression were performed using SPSS version 31.

Results: A total of 357 nurses participated. Overall, 50.4% demonstrated good knowledge, 54.3% positive attitudes, and 54.1% good practices toward SF medical products. However, gaps remained in reporting knowledge and practice. Only 57.4% were aware of reporting systems and 50.4% of reporting forms. Furthermore, 52.1% informed relevant authorities when SF medical products were suspected, while 66.9% rarely or never used the reporting form. A total of 71.7% had never received training. Multiple logistic regression identified years of professional experience, knowledge level and attitude level as significant factors associated with good practice. Respondents with 21-30 years of experience (AOR=2.860, 95% CI =1.235-6.626, p=0.014), good knowledge (AOR = 1.684, 95% CI = 1.065-2.662, P=0.026) and positive attitude (AOR=1.627, 95% CI = 1.023-2.589, p=0.040) were more likely to demonstrate good practice towards SF medical products.

Conclusion: Despite moderate levels of knowledge, attitudes and practices, regulatory knowledge and reporting practices were limited. These findings highlight the need for enhanced training, increased awareness programmes and integration of SF medical product related content into education and professional development programmes. The findings provide evidence to inform strategies for strengthening surveillance and reporting systems in Bhutan.

Keywords: Substandard and falsified medical products, Knowledge, attitude and practices, Nursing professional, Bhutan

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INTRODUCTION

The availability of safe and effective medical products is essential for global health and achieving Universal Health Coverage under Sustainable Development Goal (SDG) 3.8, which emphasizes on ensuring access to safe, quality and affordable medicines and vaccines (1-4). However, Substandard and Falsified (SF) medical products limit access to safe and effective medicines, pose a significant risk to patient safety and impede the progress towards achieving the SDGs (5, 6).

The World Health Organization (WHO) defines substandard medical products as those that fail to meet quality standards and falsified medical products as those that deliberately misrepresent their identity, composition, or origin (5-7). SF medical products have been reported across all income settings (3, 6, 8-11), affecting a wide range of medical products (3, 12, 13). Globally, reported incidents have increased by an average of 36.3% annually, with WHO South-East Asia Region accounting for over 20% of reported cases in 2021 (3). Furthermore, around one-tenth of medicines in low and middle income countries (LMIC) is substandard or falsified (5).

Bhutan, as a LMIC (14), also faces challenges related to SF medical products. A five-year trend analysis conducted by the Royal Centre for Disease Control revealed reported medicine quality non-compliance rates, peaking at 10.6% in 2020 (15). In addition, SF medical products are a leading cause of product recalls, with recalls increasing from five in 2021 to twelve in 2025 (16-18).

SF medical products increase morbidity and mortality rates, financial losses and socioeconomic repercussions (5-7, 19). Despite global efforts, their prevention, detection, and response remain major public health challenges, with underreporting hindering timely action (7, 10). Healthcare professionals serve as a key source of accurate and reliable reports given their daily engagement with medical products and observation of patient outcomes (3, 10, 19, 20).

Existing research on SF medical products is largely focused on the supply chain aspects, with limited studies focused on end users (11). A significant gap remains in studies evaluating the

knowledge, attitudes, and practices (KAP) of healthcare professionals regarding SF medical products (11, 21). While KAP studies have been conducted in other countries (12, 13, 19, 20, 22), no published studies have systematically examined this issue in Bhutan.

This study therefore aims to assess KAP on SF medical products among nursing professionals in Bhutan. Nurses play a pivotal role in patient care, medication management and health education (23-25). In Bhutan, nurses constitute more than half of the healthcare workforce, with a density of 20.22 per 10,000 population (23, 26). This provides a practical and representative baseline of the healthcare workforce. Identifying gaps in their KAP may inform targeted interventions to strengthen detection, reporting, and control of SF medical products in Bhutan.

METHODOLOGY

Study Design and population

A cross-sectional study was conducted among nurses in Bhutan with more than 6 months of professional experience to determine the levels of KAP on SF medical products and assess their associations. The sample size for this study was computed using Krejcie & Morgan, 1970 formula for finite population with a 95% confidence interval and a 5% margin of error. After adjusting for a 10% non-response rate, the calculated sample size was 356 participants.

The study area included 22 healthcare centers across Bhutan as shown in Figure 1. A stratified approach was used in this study to ensure adequate representation of nursing professionals across different levels of healthcare centers. The total nursing workforce in each stratum was used to determine proportional sample allocation.

Table 1: Proportional allocation of samples.

Level of healthcare centers	**Total number of nurses**	**Allocation**
Referral	1067	198
60 bedded	151	28
40 bedded	266	49
20 bedded	195	37
10 bedded	227	42
PHC/Sub-post	13	2

Within each stratum, healthcare centers were purposively selected based on the pharmacy-to-nursing ratio, as nurses have greater responsibility for medical product management in facilities with fewer pharmacists. Eligible nurses from the selected facilities were then invited to participate voluntarily through an online survey, facilitating participation across geographically dispersed healthcare centers.

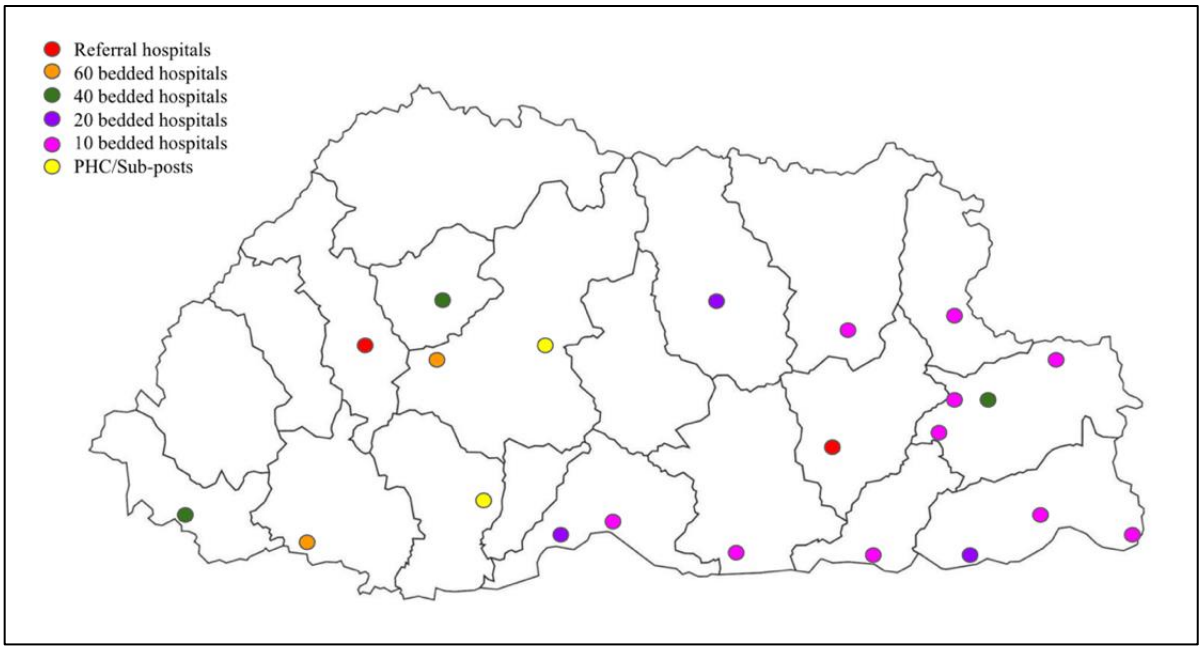


Figure 1: Map of Bhutan showing the selected study areas.

Research instrument

An online survey questionnaire was administered using Google Forms. The questionnaire was constructed based on the review of previous studies (12, 13, 19, 21, 22) and adapted to Bhutanese context. Knowledge section was assessed using 18 items scores as 1 for correct and 0 for incorrect response. Total knowledge scores were categorized as poor (< median) or good (≥ median). Attitude section was assessed using 16 items rated on a five-point Likert scale (1 = Strongly Disagree to 5 = Strongly Agree). Negatively worded items were reverse-coded. Overall attitude scores were classified as negative (< median) or positive (≥ median). Practice was assessed using 9 items rated on a five-point Likert scale, 1 (Not at all), 2 (Rarely), 3 (Sometimes), 4 (Often), and 5 (Always). Total practice scores were categorized as poor (< median) or good (≥ median). The median was used as the cut-off value because the knowledge, attitude, and practice scores were not normally distributed.

Content validity was evaluated by three experts for relevance and clarity. All items achieved an Item–Objective Congruence (IOC) value of ≥ 0.50. To assess reliability, the questionnaire was pretested among 37 nurses from healthcare centers not included in the study. Internal consistency, assessed using Cronbach's alpha, was 0.535 for knowledge, 0.751 for attitude, and 0.712 for practice. The relatively low reliability of the knowledge scale likely reflects the use of independent factual items and binary response options. Following pilot study, "Not sure" response option was added, and ambiguous or overly easy items were revised to improve response accuracy.

Data collection procedures

Data were collected after obtaining approval from Mahidol University – Central Institutional Review Board (MUCIRB) and Research Ethics Board of Health (REBH), Bhutan. After obtaining the necessary permissions, the online survey link was disseminated. The survey link included the participation information sheet and informed consent. Only participants who provided consent were directed to the questionnaire.

The survey link was distributed via email and messaging platforms (WeChat, WhatsApp, Messenger, and Telegram) within nurse groups. Data collection was monitored to achieve required sample size across healthcare center levels. Although the calculated sample size was 356, a total of 357 responses were received and included in the final analysis.

Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) software version 31. Data were cleaned, coded, checked and verified for completeness, consistency and accuracy. Descriptive analysis was used to summarize the socio-demographic characteristics. Categorical variables were presented as frequencies and percentages, while continuous variables were summarized using medians and interquartile ranges.

Associations were examined using Chi-square tests. Bivariate analysis to test a predictive effect of each independent variable on the dependent variable was conducted. Variables with P-value < 0.25 were included in Multiple Logistic Regression Analysis to identify independent factors of good practice. Multicollinearity was assessed using Spearman correlation. Adjusted odds ratios (AORs) with 95% confidence intervals were reported, with statistical significance set at $p<0.05$.

RESULTS

Characteristics of the respondents

Table 2 summarizes the respondents' socio-demographic characteristics. Most respondents were aged 30–39 years (41.2%), female (56.0%), held a diploma (63.6%), had 1–10 years of experience (63.0%), and worked at referral hospitals (55.5%).

Table 2: Socio-demographic characteristics (n=357)

Variable	Classification	Frequency (n)	Percentage (%)
Age			
	20-29 years	135	37.8
	30-39 years	147	41.2
	40-49 years	63	17.6
	50+ years	12	3.4
	Median=33, IQR=12, Min=20, Max=59		
Gender			

	Female	200	56.0
	Male	157	44.0
Highest Level of Education			
	Certificate	38	10.6
	Diploma	227	63.6
	Bachelor	87	24.4
	≥ Master's	5	1.4
Years of experience			
	1-10 years	225	63
	11-20 years	95	26.6
	21-30 years	37	10.4
	Median=7, IQR=11, Min=1, Max=30		
Level of healthcare facility			
	PHC	3	0.8
	10 bedded	42	11.8
	20 bedded	37	10.4
	40 bedded	49	13.7
	60 bedded	28	7.8
	Referral	198	55.5

Knowledge on SF medical products

The proportion of respondents with good level of knowledge was 50.4%. Figure 2 shows the correct response percentages for knowledge statements. Knowledge was high regarding the definitions of substandard (82.6%) and falsified (67.2%) products, health impacts (84.9%), product identification (84.9%), healthcare professionals' reporting responsibilities (82.4%), and the Bhutan Food and Drug Authority's (BFDA) regulatory role (82.6%). However, awareness of reported SF medical product cases in Bhutan was moderate (50.7%). Knowledge of reporting systems (57.4%), procedures (63.0%), and reporting forms (50.4%) was limited, with the lowest correct response for reporting form submission requirements (31.4%), indicating gaps in regulatory and reporting knowledge.

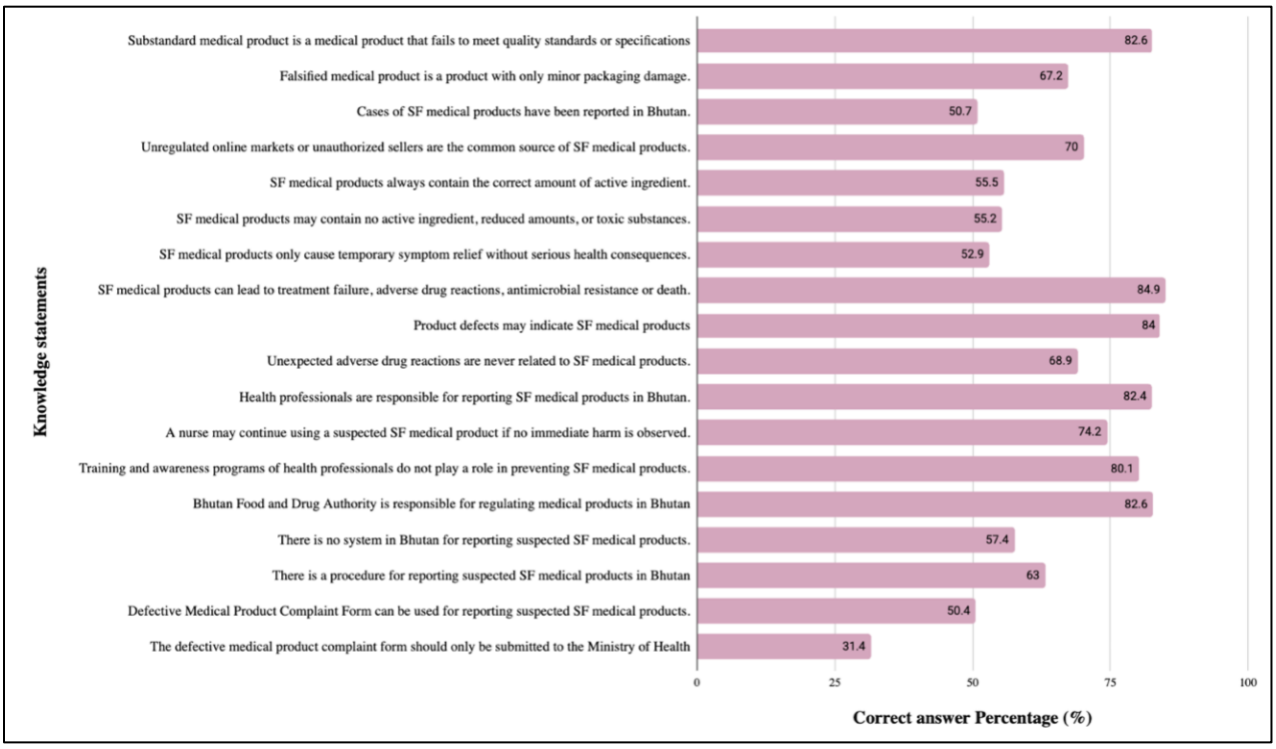


Figure 2: Correct response percentages for knowledge statements

Attitudes toward SF medical products

Overall, 54.3% of respondents demonstrated positive attitudes toward SF medical products, while 45.7% had negative attitudes. Figure 3 presents respondents' attitudes. 84.9% of respondents recognized SF medical products as a global public health concern. 75% rejected that SF medical products are not a concern in Bhutan. Respondents acknowledged the impacts of SF medical products and considered their use unethical. Majority agreed that nurses have a professional responsibility towards SF medical products. Strong support was expressed for regulatory enforcement and training. However, uncertainty remained regarding regulatory responsibilities and reporting burden, particularly the BFDA's role and the perceived workload associated with reporting.

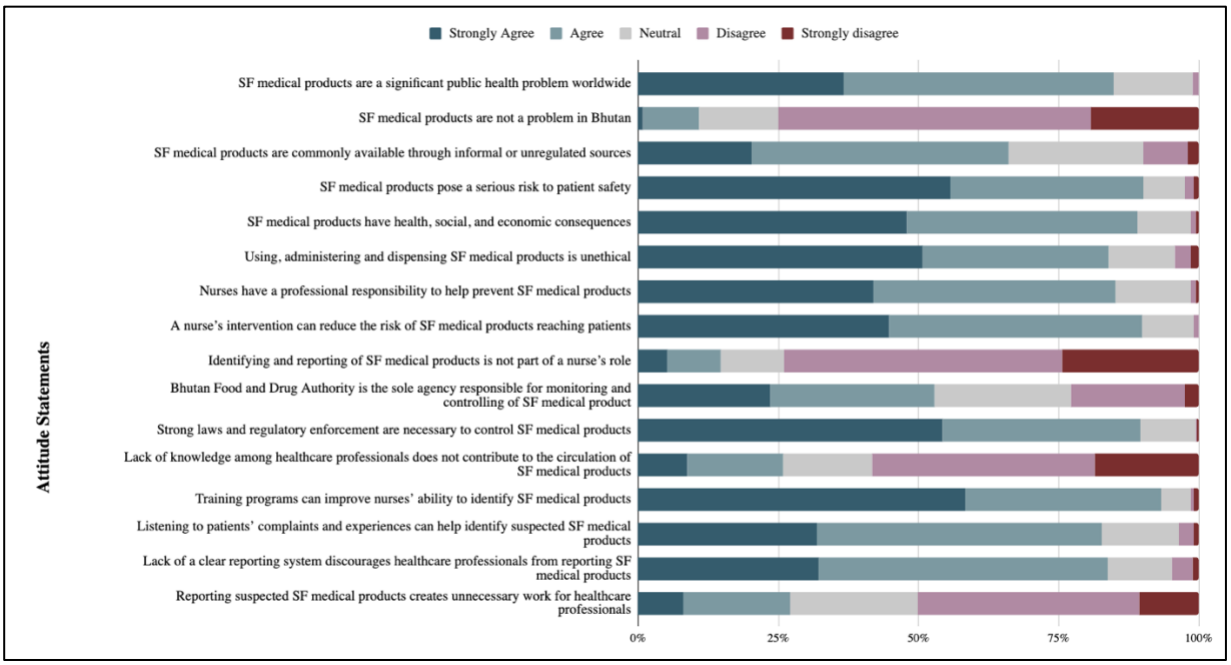


Figure 3: Respondents level of attitudes towards SF medical products.

Practices toward SF medical products

The proportion of respondents with good practice was 54.1%. Figure 4 presents respondents' practice levels. More than half of the respondents always checked product packaging and labeling (52.4%), assessed for unusual appearance (59.1%), and avoided using suspected SF medical products (54.9%). Patient education practices were also common, with 63.3% always or often advising patients against purchasing products from unlicensed sources. However, reporting practices were limited, with only 52.1% always or often informing relevant authorities upon encountering SF medical products. Furthermore, 66.9% had rarely or never used the defective medical product complaint form and 71.7% had never received training on SF medical products.

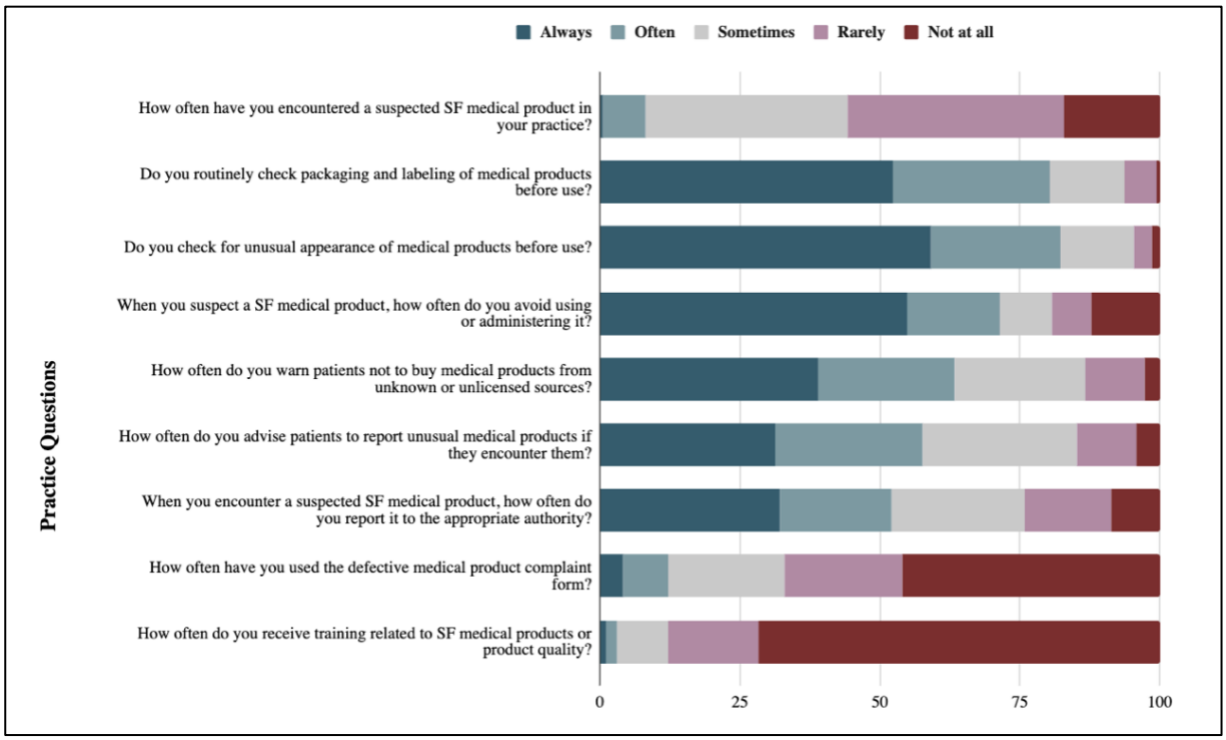


Figure 4: Respondents level of practices towards SF medical products.

Association between independent variables and practice towards SF medical products.

Table 3 presents the Chi-square analysis of factors associated with practices toward SF medical products. Good knowledge and positive attitudes were significantly associated with good practices. Respondents with good knowledge were more likely to demonstrate good practices than those with poor knowledge (62.8% vs. 45.2%, $p<0.001$). Similarly, positive attitudes were associated with better practices (60.8% vs. 45.7%, $p=0.005$).

Table 3: Chi-square analysis factors associated with practices toward SF medical products (n=357)

Variables	**Level of Practice**		**χ2**	**p-value (by Chi-square test)**
	Poor n (%)	**Good n (%)**		
Age Group			2.208	0.530
20-29 years	64 (47.4)	71 (52.6%)		
30-39 years	71 (48.3)	76 (51.7)		
40-49 years	25 (39.7)	38 (60.3)		
50 + years	4 (33.3)	8 (66.7)		
Gender			3.607	0.058
Female	83 (41.5)	117 (58.5)		
Male	81 (51.6)	76 (48.4)		
Education Level			0.258	0.879
Certificate	16 (42.1)	22 (57.9)		

Diploma	105 (46.3)	122 (53.7)		
≥ Bachelor's	43 (46.7)	49 (53.3)		
Years of Experience			5.630	0.060
1-10 years	103 (45.8)	122 (54.2)		
11-20 years	50 (52.6)	45 (47.4)		
21-30 years	11 (29.7)	26 (70.3)		
Healthcare facility level			1.997	0.736
≤ 10 bedded	20 (44.4)	25 (55.6)		
20 bedded	15 (40.5)	20 (59.5)		
40 bedded	26 (53.1)	23 (46.9)		
60 bedded	11 (39.3)	17 (60.7)		
Referral	92 (46.5)	107 (53.5)		
Knowledge Level			11.106	*<0.001**
Poor	97 (54.8)	80 (45.2)		
Good	67 (37.2)	113 (62.8)		
Attitude Level			7.825	*0.005**
Negative	88 (54.0)	75 (46.0)		
Positive	76 (39.2)	118 (60.8)		

**Variables that show significant association (P<0.05)*

Factors associated with practices towards SF medical products

Bivariate analysis identified four variables (gender, years of experience, knowledge level and attitude level) associated with good practices toward SF medical products ($p<0.25$). Spearman's correlation test was performed. It showed weak correlations among these variables ($r_s = -0.054$ to 0.373), indicating no evidence of multicollinearity. Multiple logistic regression using the Backward Likelihood Ratio (Backward: LR) identified years of experience, knowledge level and attitude level as significant factors associated with good practice. Table 4 presents the results of the multiple logistic regression analysis. Respondents with 21–30 years of experience were more likely to demonstrate good practice than those with 11–20 years (AOR=2.860, 95% CI: 1.235-6.626, p=0.014). Good knowledge (AOR=1.684, 95% CI: 1.065–2.662, p=0.026) and positive attitudes (AOR=1.627, 95% CI: 1.023–2.589, p=0.040) were also significantly associated with good practice. Gender was excluded from the final model.

Table 4: Multiple logistic regression analysis for factors associated with good practice towards SF medical products (n=357)

Variable	**Full Model**		**Final Model**	
	AOR (95% CI)	**p-value**	**AOR (95% CI)**	**p-value**
Gender (Ref: Male)				
Female	1.429 (0.912-2.239)	0.119		
Years of Experience (Ref: 11-20 years)				

1-10 years	1.231 (0.745-2.034)	0.417	1.337 (0.819-2.184)	0.246
21-30 years	2.439 (1.028-5.787)	0.043*	2.860 (1.236-6.626)	0.014*
Knowledge level (Ref: Poor knowledge)				
Good knowledge	1.740 (1.096-2.763)	0.019*	1.684 (1.065-2.662)	0.026*
Attitude Level (Ref: Negative attitude)				
Positive Attitude	1.611 (1.010-2.568)	0.045*	1.627 (1.023-2.589)	0.040*

Nagelkerke R Square =0.074; Hosmer and Lemeshow test chi-square = 4.358 (df = 7, p-value = 0.738); Omnibus test chi-square 20.418 (df = 4, p-value <0.001)
**Variables that show significant association (P<0.05),*
AOR (Adjusted odds ratio),

DISCUSSIONS

This study found that 54.1% of the respondents demonstrated good practice toward SF medical products. Although this proportion was higher than those reported in Bahir Dar City (46.3%) and Gondar City (35.29%), Ethiopia (13, 22), nearly half of nurses may still not consistently engage in optimal practices. Respondents in the present study reported relatively good preventive practices, such as checking packaging, labeling, and product appearance before use and educating patients on SF medical products. These practices likely reflect nurses' routine responsibilities in medical product management, particularly in Bhutan where nurses often assume additional responsibilities in facilities with limited pharmacy personnel. Similar preventive practices have been reported in India (20), Indonesia (27), Egypt (28) and Sweden (21), suggesting that frontline healthcare professionals generally recognize the importance of preventing SF medical products from reaching patients.

Despite good preventive practices, reporting of suspected SF medical products was limited, with majority of respondents rarely or never having used the complaint form. Similar underreporting was reported in Jordan, Egypt and Saudi Arabia (12, 28, 29). Furthermore, 71.7% of respondents in the present study had never received training on SF medical products, a finding comparable to Ethiopia (13). In Bhutan, these findings may reflect limited familiarity with reporting procedures rather than the inability to recognize suspected SF medical products. These highlight the need to strengthen reporting mechanisms, increase training, and improve awareness of reporting procedures to enhance surveillance and control of SF medical products.

Knowledge on SF medical products was moderate (50.4%), lower than that reported in Nigeria (70%) (30) but higher than findings from Ethiopia (18.24%) (13). While knowledge of definitions, impacts, sources, and professional responsibilities was generally good, awareness of reporting systems and procedures was limited. This may reflect the fact that nurses have fewer opportunities to participate in pharmacovigilance activities or receive regulatory training. Similar gaps have been

reported in Indonesia, India and Ethiopia (20, 22, 27), highlighting the importance of integrating pharmacovigilance and reporting procedures into nursing education and continuing professional development programs.

Slightly more than half of respondents (54.3%) demonstrated positive attitudes toward SF medical products, comparable to studies in Ethiopia (Gondar City – 50%, Bahir Dar City - 54.9%) but lower than in Nepal - 85.3% (13, 22, 31). Most recognized SF medical products as an important public health concern and supported stronger regulatory measures and training initiatives. However, uncertainty regarding stakeholder responsibilities and reporting obligations persisted, which may have contributed to the limited reporting practices observed. Clarifying the roles of healthcare professionals and regulatory authorities, together with regular awareness programmes, could foster a stronger culture of shared responsibility for medicine safety in Bhutan.

The analytical findings supported that respondents with greater experience, good knowledge and positive attitudes were more likely to demonstrate good practices. Comparable findings regarding years of experience were reported in studies conducted in India, Ethiopia and Nigeria (13, 20, 22, 32). More experienced nurses may have greater exposure to medical product management and institutional reporting processes, enabling them to identify and respond to suspected SF medical products. Likewise, nurses with better knowledge and positive attitudes are more likely to adopt appropriate preventive and reporting practices. These findings further highlight the importance of strengthening pre-service education, continuing professional development and pharmacovigilance training to enhance capacity to detect, report and prevent SF medical products.

RECOMMENDATIONS

The findings identified gaps in reporting practices, training and awareness of reporting system for SF medical products. Strengthening training and awareness programmes could improve healthcare professionals' knowledge, vigilance, and reporting practices. As many respondents had never used the reporting form, the reporting system could be simplified and made more accessible through enhanced dissemination of reporting procedures and digital reporting platforms. Additionally, monitoring and post-market surveillance activities could be reinforced through stronger regulatory implementation, stakeholder collaboration and timely dissemination of safety information. Future studies could include other healthcare professionals and use qualitative or longitudinal designs to explore reporting barriers and evaluate intervention effectiveness.

CONCLUSION

This study assessed the knowledge, attitudes, and practices toward SF medical products among 357 nursing professionals in Bhutan. It aimed to identify gaps in their preparedness to detect, report, and prevent SF medical products.

Although respondents demonstrated moderate knowledge, attitudes, and practices toward SF medical products, important gaps remained in regulatory knowledge, reporting systems, and reporting practices. These findings highlight the need for strengthened training, increased awareness, and integration of pharmacovigilance and SF medical product-related content into nursing education and continuing professional development to improve detection, reporting, and surveillance in Bhutan.

ETHICAL DECLARATION

Ethical approval was obtained from MUCIRB (Protocol No. MU-CIRB 2026/058.0902) and REBH, Bhutan (Approval No. PO/RL/2026.28.NNW) on 17 March 2026. Permission and clearance from the respective Heads/Chief Medical Officers/In-charges were sought prior to the dissemination of the survey questionnaire link. Consent to participate in the survey was obtained from participants prior to participation.

LIMITATIONS

This study was based on self-administered questionnaires and may be subject to recall and social desirability biases. Voluntary participation may have introduced voluntary response bias, as participants may have differed from non-participants in their knowledge or experience. Low internal consistency of the knowledge scale may have reduced measurement precision. As a cross-sectional study, causal relationships cannot be inferred, and the findings may not be generalizable beyond nursing professionals in Bhutan.

ACKNOWLEDGEMENT

The researcher would sincerely like to thank all study participants for their valuable time and contributions. Deep appreciation is extended to the academic advisor and committee members for their guidance and support, and to family and friends for their encouragement. We would also like to thank Thailand International Cooperation Agency for the scholarship and continued support.

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