Factors Influencing Pre-Purchase Decision-Making and Validation/Verification Practices for POCT among Clinical Laboratory Professionals: A Workshop-Based Cross-Sectional Study in Nepal

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ABSTRACT

Introduction

Point-of-care testing (POCT) is becoming more common in clinical environments; however, if devices are not chosen correctly and proper validation/verification is lacking, test quality and patient safety may be jeopardized. There is still limited evidence regarding pre-purchase decision-making and validation practices for POCT devices among clinical laboratory professionals in low- and middle-income countries, including Nepal. This study aimed to assess factors influencing pre-purchase decision-making and the validation/verification practices for POCT devices among clinical laboratory professionals in Nepal.

Methods

A cross-sectional study based on workshops was carried out with clinical laboratory professionals participating in a POCT-related workshop at a university hospital in Nepal. A structured, self-administered questionnaire was used to collect data on pre-purchase considerations, perceived importance of device-related factors, training exposure, and POCT validation/verification practices. Responses were summarized using descriptive statistics, and the relationship between training and validation practices was evaluated with odds ratios (ORs) accompanied by 95% confidence intervals (CIs).

Results

In the analysis, a total of 49 participants were included. During the selection of POCT devices, performance characteristics, analytical accuracy, and manufacturer support were often rated as highly important factors. Those who had undergone POCT-related training were significantly more likely to report performing POCT validation than those who had not received such training (OR = 10.85; 95% CI: 0.59–199.19; p = 0.047).

Conclusion

Clinical laboratory professionals in Nepal place strong emphasis on technical standards and quality when procuring POCT devices, however, gaps remain in how validation and verification are consistently carried out.

Keywords

Validation, Verification, POCT

Introduction

Point-of-Care Testing (POCT) brings laboratory diagnostics closer to the patient, promising quicker clinical decisions, improved patient flow, and better outcomes in resource-limited and critical care environments [1,2]. In low- and middle-income countries (LMICs) such as Nepal, POCT plays a crucial role in broadening diagnostic access for remote and underserved populations.

Nonetheless, the decentralized nature of POCT presents significant challenges for quality management. Two essential laboratory-driven processes, namely a thorough pre-purchase evaluation and an exhaustive post-purchase analytical validation/verification [3,4], are the foundation of any POCT result's accuracy and reliability. As stated in the International Vocabulary of Metrology 3 (VIM 3), verification is defined as provision of objective evidence that a given item fulfills specified requirements while validation means verification, where the specified requirements are suitable for the intended use [5,6].

It is required by international standards (e.g., ISO 22870) and guidelines from organizations such as the Clinical and Laboratory Standards Institute (CLSI). The laboratory professionals spearhead these processes to ensure that chosen devices align with clinical needs and function properly in their intended environments [4,7].

In many low- and middle-income country (LMIC) contexts, the procurement of point-of-care testing (POCT) can be influenced by factors such as user-vendor relationships or short-term costs, rather than by a thorough assessment of long-term operational expenses, connectivity issues, or the feasibility of validation [8]. Moreover, the absence of standardized protocols and training in validation methodologies (such as precision, accuracy, and interference testing) can result in the use of unverified devices, posing a direct risk to patient safety [9].

Although guidelines thoroughly document the significance of these processes, data on laboratory professionals' actual knowledge, attitudes, and practices concerning POCT procurement and validation process in LMICs is limited. The purpose of this study was to identify the factors that influences decision-making and validation/verification process among clinical laboratory professionals who participated in a dedicated POCT workshop in Nepal. The outcomes will identify major deficiencies and steer the development of targeted educational initiatives and protocols designed to strengthen the foundation of quality POCT services in similar healthcare environments.

Methods

A structured, self-administered questionnaire was used to conduct a descriptive, cross-sectional study. In 2023, the study was incorporated into a three-day POCT workshop organized by Dhulikhel Hospital-Kathmandu University Hospital. This context afforded a unique chance to survey a concentrated group of professionals who have a vested interest in POCT.

The clinical laboratory professionals (both trainees and trainers) attending the workshop constituted the target population. All participants who were willing to take part were included using a convenience sampling method. Informed consent was obtained. A structured, written questionnaire was administered to clinical laboratory professionals participating in a POCT workshop. A total of 55 printed questionnaires were distributed. Only those volunteers who provided informed consent and returned a fully completed questionnaire were included in the study. Only 49 questionnaires (89%) were fully completed and included in this study.

After reviewing standard guidelines and essential literature a structured questionnaire was created. The questionnaire addressed three domains: i) Demographics and general POCT experience. ii) Factors influencing pre-purchase decision-making and iii) Knowledge and practices regarding POCT validation/verification. The assessment of content validity was carried out by two experts in laboratory medicine with seniority. Five laboratory professionals were consulted to test the questionnaire, allowing for revisions to ensure clarity. To guarantee that participants had encountered fundamental POCT concepts, data gathering took place in person on the workshop's last day, before the session of validation process started.

Data from the filled-out questionnaires were input into Microsoft Excel and analyzed. Frequencies and percentages (%) were used to present descriptive statistics calculated for all variables. The decision-making factors were ranked according to the percentage of respondents who indicated “Very important” as their response.

Result

A total of 55 sets of questionnaires were distributed, but only 49 laboratory professionals returned well-completed sets. Male and female ratio of participants was very similar, 53% males and 47% females. The mean age was 33 years, while minimum was 25 and maximum was 45 years old. Every participant (100%) had utilized POCT, demonstrating a practical baseline of experience. Only 65.3% (n=32) considered POCT to be "really good for diagnostic lab," indicating that a considerable minority had doubts about its role or quality.

Table 1 indicates that the key elements affecting purchasing choices were connected to enduring sustainability and support: "After sales support, maintenance and warranty" (with 98% considering it very important) and "Long term efficiency and operating cost" (with 96% considering it very important). The software being user-friendly and having representative knowledge of the industry and technology were also rated highly (with 80% and 76% deeming them very important, respectively).

Table 1. Factors influence on decision making practices before purchasing POCT

Distribution of Importance Rating Factors			
Current or previous relationship with Vendor	**Very important**	**Somewhat important**	**Not important**
	10	24	15
Vendor's reputation and brand awareness	20	26	3
Vendor's online presence	25	18	6
Price of product	34	15	0
Representative knowledge of industry & technology	37	12	0
After sales support, maintenance and warranty	48	1	0
Long term efficiency and operating cost	47	2	0
User-friendly software	39	10	0
Vendor's representative sales skill	13	30	6
Extra features available in that POCT	13	31	5
Recommendation from Previous user	21	26	2

On the other hand, elements such as “Current or previous relationship with Vendor” (merely 20% regarded as very important) and “Vendor’s representative sales skill” (27% regarded as very important) were deemed least crucial, signifying a shift towards objective assessment (Figure 1).

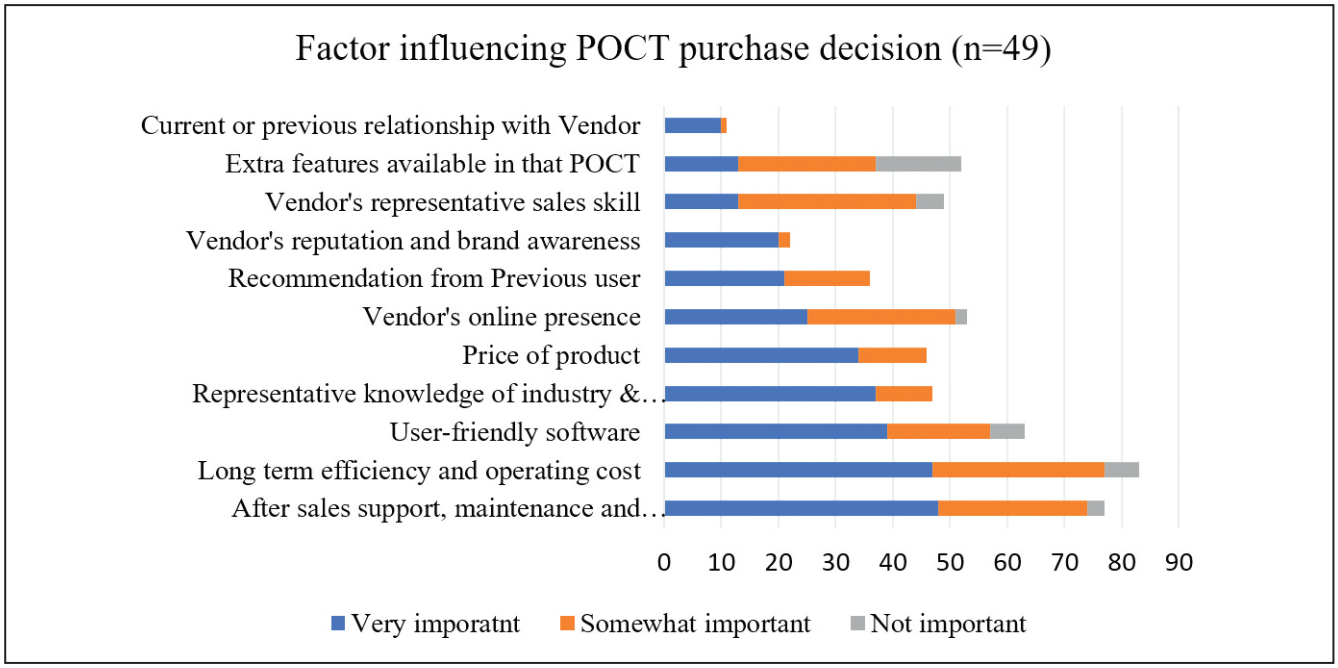

Figure 1: *Factors and frequency of pre-purchasing of POCT*

Only 49% (n=24) were involved in the procurement of POCT. Even more notable is the fact that just 22% (n=11) had ever confirmed or validated a POCT device, highlighting a significant discrepancy between usage and quality assurance. While 94% (n=46) understood the importance of reading the user manual, only 31% (n=15) were aware of the steps in the validation process (Table 2).

Table 2. Knowledge and practice of validation/verification process

SN	Questions	Answers	Frequency (%)
1.	Have you ever used POCT?	Yes	49 (100%)
		No	0
2.	Do you believe POCT is really good for diagnostic Lab?	Yes	32 (65.3%)
		No	17 (34.7%)
3.	Have you ever purchased any POCT?	Yes	24 (48.9)
		No	25 (51.0)
4.	Have you ever validated/ verified any POCT?	Yes	11 (22.4)
		No	38 (77.5)
5.	How much important to read and understand user manual before using POCT?	Very important	46 (93.8)
		Somewhat important	3 (6.1)
		Not important, I have used it before	0
6.	How will you validate/verify new POCT?	By running a same sample in an analyzer and POCT	28 (57.1)
		By using control material not specific for that POCT	8 (16.3)
		By repeating a test as an unknown sample for 3 times	3 (6.1)
		Not sure/don't know	10 (20.4)

SN	Questions	Answers	Frequency (%)
7.	Which regulatory agency provides guideline for POCT validation?	Food and drug administration (FDA)	15 (30.6)
		WHO	23 (46.93)
		European medicine agencies (EMA)	0
		Not sure/don't know	11 (22.4)
8.	Which is responsible for validation of	Manufacturing company	2 (4.0)
		Vendor	8 (16.3)
		Lab professional	33 (67.3)
		All user	6 (12.2)
9.	User has to generally do	Validation	6 (12.2)
		Verification	5 (10.2)
		Validation & Verification	34 (69.3)
		None of above	4 (8.1)
10.	How often do you perform validation/verification?	Whenever I have time	1 (2.0)
		Whenever needed	13 (26.5)
		As per guidelines	23 (46.9)
		Rarely	12 (24.4)
11.	Have you received any training for validation/verification process?	Yes	37 (75.5)
		No	12 (24.4)
12.	What challenges you faced for implementation of validation/ verification process?	Lack of resources	15 (30.6)
		Limited awareness	21 (42.8)
		No interests from healthcare service provider	5 (10.2)
		None	8 (16.3)
13.	Are you aware about steps of validation/verification process?	Yes	15 (30.6)
		No	34 (69.3)
14.	Are you willing to participate any kind of training related to POCT in future?	Yes, if it is free	18 (36.7)
		Yes, if get allowance	8 (16.3)
		Yes, even I can pay	21 (42.8)
		No	2 (4.0)

When asked how to validate a new POCT, 57% (n=28) correctly identified "running the same sample in an analyzer (previously verified) and POCT" for comparison results in verification process. However, 20% (n=10) answered "Not sure/don't know," and others chose incorrect methods. Knowledge of regulatory guidelines was poor. Only 31% (n=15) correctly identified the FDA (a key agency for device clearance); 47% (n=23) incorrectly selected WHO. Most participants (67%, n=33) correctly identified the "Lab professional" as primarily responsible for validation.

Although 76% (n=37) reported receiving some training, the major challenges cited were "Limited awareness" (43%, n=21) and "Lack of resources" (31%, n=15). Encouragingly, 96% (n=47) expressed willingness to participate in future POCT training, with 43% (n=21) willing to pay personally, highlighting a strong demand for capacity building.

A statistically significant relationship (Table 3) was identified between POCT related training and validation practices ($p = 0.047$). Laboratory professionals who had undergone training were more likely to engage in the validation of POCT devices compared to those without such training. Furthermore, previous training demonstrated a strong association with POCT purchasing practices ($p < 0.001$), indicating that trained professionals were substantially more involved in, or had greater influence over, decisions regarding the acquisition of POCT devices.

Table 3. Association between training and POCT practices (Fisher's exact test)

Comparison	p-value
Training × POCT validation	0.047
Training × POCT purchase	<0.001

Participants who had undergone POCT-related training were significantly more likely to report conducting validation procedures compared with those without training.

Discussion

This research uncovers a crucial paradox among laboratory professionals in Nepal: while POCT is widely used, there is a low level of direct involvement in its procurement and, alarmingly, a considerable lack of knowledge and adherence to essential validation procedures. Individuals who had undergone training related to POCT were about 11 times more likely to indicate that they performed validation procedures compared to those who had not received such training. However, this estimate was characterized by a notably wide 95% confidence interval (0.59–199.19), indicating considerable uncertainty, most likely attributable to the limited sample size.

It is a positive indication of mature, value-based procurement thinking that decision-making prioritizes long-term support and operational costs over vendor relationships. Similar findings were suggested by a research conducted in a medical center 10. It implies that professionals concentrate on sustainable outcomes when they are involved. Nonetheless, the involvement of only half in purchases illustrates that laboratory expertise is frequently overlooked in procurement committees, which poses a recognized risk to quality[11].

The most noteworthy discovery is the serious shortfall in both validation practice and knowledge. Even with total POCT usage, just 22% had carried out validation. Although most accurately attributed responsibility to the laboratory, practical knowledge was deficient: fewer than one-third were aware of the steps involved, and many were unclear about correct methodology or pertinent regulatory guidelines (e.g., confusing WHO with FDA). This corresponds with challenges observed in other LMIC environments, where logistical constraints and insufficient training overshadow quality assurance[12,13].

The main challenges identified in this study was "Limited awareness" and "Lack of resources" are connected to each other. Validation cannot be carried out without dedicated resources (time, money, control materials), which perpetuates the awareness gap. This leads to a perilous cycle in which POCT is adopted solely on the basis of assertions from manufacturers, which could endanger patient care[13].

A robust readiness to pursue additional training, despite incurring personal costs, represents a very encouraging discovery. It offers a clear mandate to health authorities, professional societies, and workshop organizers. Training should extend beyond merely learning to operate a device. It needs to concentrate on "Fitness-for-Purpose" evaluation, fundamental QC/QA statistics, and validation protocols that are practical and suitable for the available resources, as detailed by CLSI and the IFCC [14,15].

In spite of potential findings, this study has a few limitations. First, employing a convenience sample of workshop participants may result in the selection of individuals who have greater motivation or interest in the subject from the outset. This could skew the results toward more affirmative self-reports regarding practices and knowledge. Second, the sample size is suitable for initial exploratory analysis but is relatively small, which may restrict the generalizability of the findings and the ability to identify significant associations. All data regarding practices and knowledge were self-reported, making them susceptible to social desirability and recall biases.

Conclusion

This survey emphasizes a notable gap between the utilization of POCT and the implementation of fundamental quality assurance practices among laboratory professionals in Nepal. Even though the laboratory's key function is recognized, there is a lack of sufficient practical knowledge and implementation regarding pre-purchase evaluation and analytical validation. We strongly recommend laboratory professionals must be mandated members of all hospital POCT procurement committees. And national and institutional training programs should urgently address the gap in practical validation skills, focusing on guideline based, feasible methods.

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