Evidence based approach to implementing point of care testing (POCT) methods and practices in the Philippines

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Abstract *– Point of care tests (POCT) are performed using portable devices at the location of the patient and outside the main laboratory. It has the major advantage of shorter turn-around time and potential benefit for the patient. Stages of POCT development and implementation are still variable among institutions. Hence, this study was conducted to gather information on the status of POCT implementation in the Philippines. A descriptive design on the implementation and quality management methods and practices of POCT at different government and private hospitals was utilized in this study. Data were collected using an online questionnaire and responses were validated by an interview. Different practices in the implementation of POCT resulted in variations and inconsistencies from different healthcare institutions were identified. Seven Quality Systems Essentials (QSE) namely equipment, preanalytical process control, analytical process control, post analytical process control, external assessment, internal assessment, and occurrence management were significantly impacted by the presences or absence of a POCT Coordinator. In general, better adherence to QSEs were noted in institutions with POCT coordinators. A national policy on POCT is necessary to have a standardized and harmonized method and practices of POCT implementation in the Philippines.*

Keywords *– near patient testing, point of care testing, quality system essential*

INTRODUCTION

Point of Care Testing (POCT) refers to test performed at or near the patient's site and the result is used for possible changes in the management of patient care, as defined by International Organization for Standardization (ISO) 22870:2016 [1]-[2]. It is also known as near patient testing or bedside testing. POCT is usually performed by clinical personnel or non-laboratory staff who are not typically trained on laboratory practices [3], [4].

Application and use of Point of Care Testing has increased over the past decades [5], [6]. During the ancient times, there were reported practices of Point of Care Testing like tasting the patient's urine to detect the presence of glucose [7]. From the smallest and simplest point of care devices, POCT has now advanced in technology. Data management and connectivity options to the Laboratory Information System (LIS) and Health Information System (HIS) are also available in the market [8]. POCT has gone a long way from being a complementary test to the main laboratory and has moved further to the patients' bedside as part of the holistic patient care [9]. Clinical needs are a powerful tool to develop innovation in POCT [10]. Application of POCT increases overtime [11].

According to Abel [12] and Park [13], Point of Care Tests include glucose monitoring, blood chemistry, blood gas analysis, electrolytes, pregnancy test, urinalysis, cardiac markers, coagulation, hemoglobin, drug abuse, cholesterol, infectious disease, and tumor marker.

Guidelines and standards were developed by international organizations and applied when POCT is carried out in a hospital, clinic and healthcare organizations providing ambulatory care. ISO 22870-2016 is a set of specific requirements for quality and competence applicable to POCT [4], [14]. International Federation on Clinical Chemistry and Laboratory Medicine (IFCC) Committee on POCT is a network of specialists who are expert in POCT that promotes the quality in the use, performance, interpretation, and reporting of POCT and create a forum for high level discussion on POCT related topics. Clinical and Laboratory Standard Institute (CLSI) Quality System Essentials are guidelines used for

implementing, maintaining, and evaluating clinical laboratory's quality management system [15].

Although POCT was introduced in the Philippines more than 30 years ago, stages of development and implementation are still variable among hospitals or healthcare institutions. Formal structure is not in place yet even in most hospitals that have POCT facility [16]. Section VI-A.6 of the Administrative Order No. 2007-0027 from the Department of Health (DOH) states that management and supervision of POCT conducted in a hospital should be under the clinical laboratory [17]. A consensus guideline on the use of POCT in hospitals was proposed by the Philippine Council for Quality Assurance in Clinical Laboratory (PCQACL) in 2008.

OBJECTIVES OF THE STUDY

Even with the perceived increase in the use of POCT in the Philippines, there is no standardized policy and guidelines on how POCT is used in healthcare institutions, what parameters are measured, where in the clinical setting it is utilized, what are the key indicators being used and what is the role of the laboratory in POCT. Thus, this study was conducted to gather information on the status of POCT in the Philippines. It identified the gaps of the POCT program implementation in different healthcare institutions in the Philippines based on CLSI standards. The outcome of the study may be used in formulation of the policy and guidelines in POCT.

MATERIALS AND METHODS

Research Design

A descriptive design on the quality management, implementation of methods and practices on POCT at different government and private hospitals was utilized in this study which adapted the design of Nnakenyi et al. [4].

Participating Hospitals

The list of government and privately owned tertiary hospitals in the Philippines was taken from the Department of Health (DOH) website. There were 119 hospitals listed on the website (Table1). Khan, et al. [18] and Nnakenyi, et al. [4] conducted similar studies where the respondents were laboratory managers or supervisors from tertiary hospitals. These studies were used as the basis of this survey. Research laboratories and self-testing POCT were not included in this study [4].

Table 1. Number of hospitals per region

Region	*Private*	*Government*	*Total*
CAR	*1*	*1*	*2*
NCR	*31*	*26*	*57*
I	*1*	*3*	*4*
II	*0*	*3*	*3*
III	*5*	*6*	*11*
IV	*5*	*3*	*8*
V	*1*	*2*	*3*
VI	*6*	*3*	*9*
VII	*7*	*2*	*9*
VIII	*1*	*1*	*2*
IX	*0*	*1*	*1*
X	*1*	*1*	*2*
XI	*3*	*2*	*5*
XII	*1*	*2*	*3*
Total	**63 (53%)**	**56 (47%)**	**119 (100%)**

Data Gathering Instrument

The survey questionnaire has two parts, Part A includes Institutional Profile which described the healthcare organization and Part B is the Assessment that identified the gaps on the level of experience, methods, and practices in the implementation of POCT in the Philippines based on the twelve (12) Quality System Essentials (QSE) of Clinical and Laboratory Standards Institute (CLSI). The questionnaire was patterned from the studies conducted in Spain by Hernandez et al. [3], in Vietnam by Nyuyen and Kost [19], and from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)-Committee on POCT resources [19]. The 12 QSEs include organization, personnel, equipment, process control, internal assessment, external assessment, occurrence management, process improvement, documents and records, information management, facilities, and safety, and purchasing and inventory [5], [18]. This assessment was done to gather information regarding the pre analytical, analytical, and post analytical domains of point of care testing [3].

The questionnaire was subjected to face validation with the adviser, statistician, and panel of experts to achieve clarity and ease of administrability of the instrument. It was also sent to fifteen (15) respondents to determine the Cronbach Alpha using the SPSS software. The calculated Alpha value was 0.948.

Data Gathering Procedure

After the validation of survey questionnaire, it was made into Google forms. The questionnaire link was sent via email to 100 hospitals. There were 19

hospitals which were excluded in the study for they either refused to share their e-mail address or do not have valid e-mail address. There were 62 who responded to the e-mail; however, eight declined to answer the survey; thus, a total of 54 respondents, who came from all regions in the country, were included in the study as depicted in Table 2. The response rate was calculated at 62%

Table 2. Respondent per region

Region	Responded	Declined	Total
CAR	1	1	2
NCR	16	5	21
I	2	0	2
II	1	0	1
III	8	0	8
IV	6	1	7
V	2	0	2
VI	6	0	6
VII	4	0	4
VIII	1	1	2
IX	0	0	0
X	1	0	1
XI	4	0	4
XII	2	0	2
Total	54	8	62

Chief medical technologists or laboratory managers and POCT Coordinators of selected hospitals acted as respondents [20]. The respondents answered the survey questionnaire only once. An interview was conducted with selected respondents to validate their responses.

Ethical Consideration

Ethics approval was secured from Research and Ethics Review Committee of Mary Mediatrix Medical Center with study protocol code MMMC-RERC 0003-01-2021. Ethics approval was also secured from other healthcare institutions such as Silliman University Medical Center and Cotabato Regional and Medical Center for the purpose of conducting the survey in their respective institutions. Approval to conduct the survey was taken from the chief of hospitals and informed consent was obtained from the respondents before they answered the questionnaire.

Statistical Analysis

Results were entered into SPSS statistical package version 26 to compute for the counts, frequency, percentage and means. T test was used to assess the differences in the implementation POCT practices among institutions with and without POCT Coordinator. Values were assigned to scaled data to determine the weighted mean (WM). The following legends were used for verbal interpretation (VI) 1.00 – 1.49 = Never (N);1.50 – 2.49 = Sometimes (S); 2.50 – 3.00 = Always (A).

RESULTS

Hospital profile

From the 54 hospitals that were included in the survey, 33 (59%) were privately owned hospitals while 21 (41%) were government owned institutions (Figure 1). The private hospital respondents were 51% (29/63) of all the total private tertiary hospital while the government hospital respondents were 39% (18/56) of the total government tertiary hospitals.

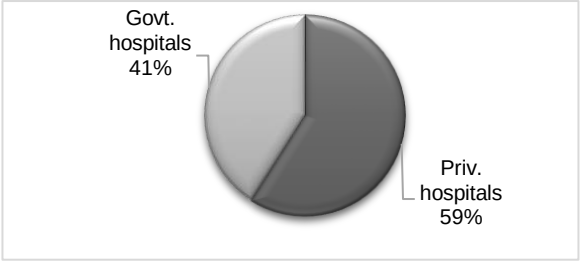

Figure 1. Respondents based on Hospital types

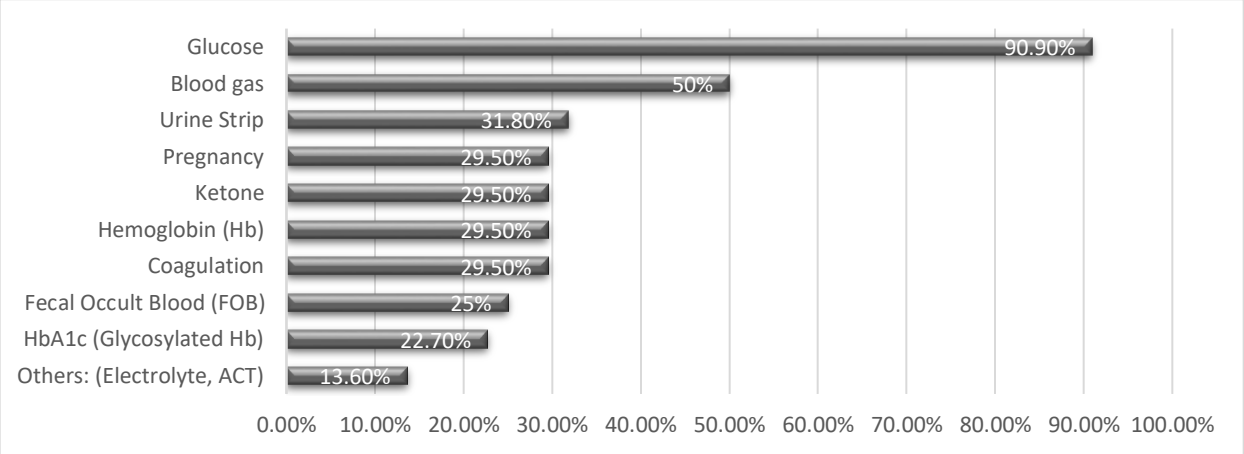

Figure 2. POC test

Figure 3. Personnel performing patient and QC test

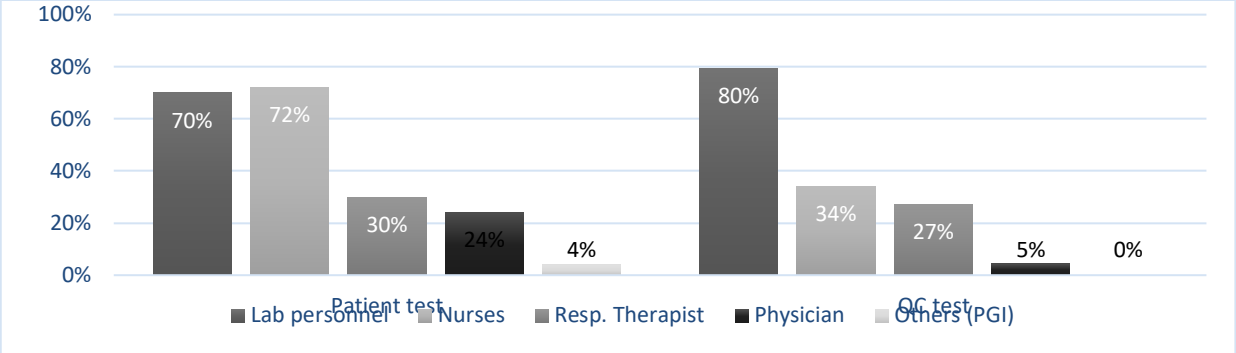

Figure 3. Personnel performing patient and QC test

All 54 hospitals were accredited and licensed by the Department of Health (DOH). Four private hospitals were accredited by Joint Commission (JCI). Five private hospitals and six government hospitals were accredited by International Organization for Standardization (ISO) and one with Accreditation Canada.

Table 3 described the hospitals based on the bed capacity. More than half (58%) of the private have 101-300 capacity. On the other hand, many government hospitals were 101-300 (33%) and 301-500 (33%). Overall, nearly half (48%) of the hospitals included in the study have 101-300 bed capacity.

Table 3. Hospital bed capacity

Bed capacity	Priv.	%	Govt.	%	Total	%
<100	8	24%	2	10%	10	19%
101-300	19	58%	7	33%	26	48%
301-500	1	3.%	7	33%	8	14%
>500	5	15%	5	24%	10	19%
Total	**33**	**100%**	**21**	**100%**	**54**	**100%**

Table 4 showed the hospitals with POCT. From the 54 hospitals, only 50 were found to have POCT. Thirty-two (32) were private hospitals and eighteen (18) were government hospitals. Most of the hospitals that have POCT belong to the 101-300 bed capacity group (Table 4).

Table 4. Hospitals with POCT based on bed capacity

Bed capacity	Priv.	%	Govt.	%	Total	%
<100	7	22%	2	11%	9	18%
101-300	19	59%	6	33%	25	50%
301-500	1	3.%	9	50%	10	20%
>500	5	16%	1	6%	6	12%
Total	**32**	**100%**	**18**	**100%**	**50**	**100%**

There were one private hospital and 3 government hospitals that do not have POCT yet. The reasons were due to lack of funds, lack of staff, lack of policies and/or standards and no clinical needs. Nevertheless, all four hospitals intended to implement POCT in the future.

With the hospitals offering POC tests, glucose is the commonly performed test as shown in Figure 2. It is followed by blood gas and urinalysis. Coagulation, hemoglobin, ketone, and pregnancy tests rank 4th followed by fecal occult blood (FOB) and HbA1C.

Most of the institutions use devices labelled for hospital use and a combination of devices labelled for home use and hospital use (Table 5). Off label use of devices or devices were utilized not according to the **intended** use as per manufacturer recommendation were observed. One of the respondents confirmed the findings during the interview.

> "*We have the small glucose meter similar from the one you can buy from the pharmacy. No patient ID is entered*"- R30

Table 5.
Type of POCT devices employed or used

Type of POCT devices	n	%
Devices labeled for hospital use	34	68%
Combined home and hospital labeled devices	16	32%
Total	**50**	**100%**

Assessment Organization

POCT Supervision

The POCT program in 27 private hospitals and 9 government hospitals or a total of 36 (72%) hospitals were supervised by the clinical laboratory and the program was under the clinical laboratory head or designee. POCT in 13 (26%) institutions were under the nursing department and one government hospital POCT was under the pharmacy department (Table 6).

Table 6. POCT Program Supervision

Department	Private	Government	Total	%
Laboratory	27	9	36	72%
Nursing	6	8	13	26%
Pharmacy		1	1	2%
Total	**32**	**18**	**50**	**100%**

POCT Committee

POCT committee was established in 32% or 16 out of 50 of the surveyed hospitals. Thirteen (13) were private hospitals and three (3) were government hospitals. Sixty-eight (68%) of the surveyed hospital do not have an established POCT committee yet (Table 7).

Table 7. POCT Committee (com)

Type of Hospital	With com	%	W/O com	%	Total
Private hospitals	13	42.%	18	58%	31
Govt. Hospitals	3	16%	16	84%	19
Total	**16**	**32%**	**34**	**68%**	**50**

POCT Coordinator (POCC)

There were 14 private and 7 government hospitals that have POCT Coordinators. More than half of the surveyed hospitals do not have POCT Coordinator (58%) as shown in Table 8.

Table 8. POCT Coordinator

Type of Hospital	With POCC	%	W/O POCC	%	Total
Private Hospitals	14	45%	17	55%	31
Govt. Hospitals	7	37%	12	63%	19
Total	**21**	**42%**	**29**	**58%**	**50**

Personnel

Laboratory personnel performed most of the patient and quality control tests as shown in Figure 3 which describe the percentages of patient and quality control tests performed by different healthcare providers. This was confirmed by two respondents during the interview conducted.

"Nurses perform the glucose test and lab personnel are performing other POCT like cardiac markers, electrolyte and D-dimers. QCs for glucometers are performed by nurses while QCs for other POCT are done by lab personnel." - R11

"Med techs are doing the blood glucose and other tests and RT are performing the blood gas. They also do the QC" - R8

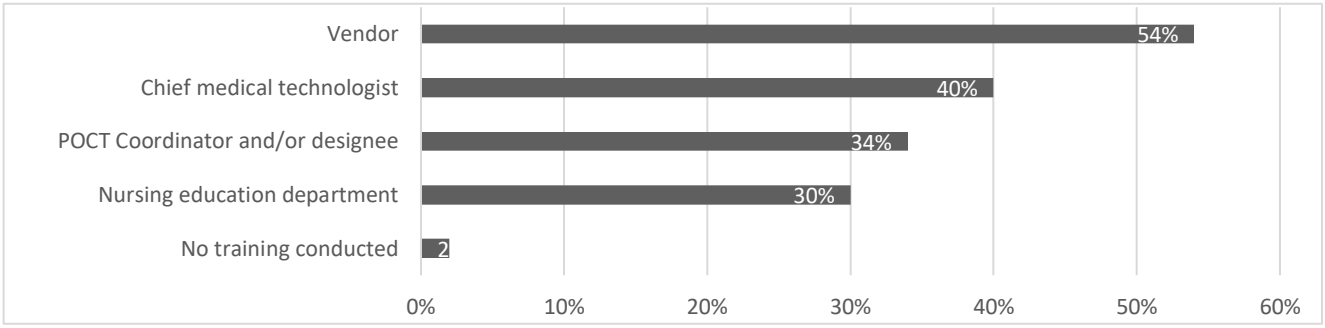

Figure 4. Personnel conducting the training

Training and Competency Assessment

Vendors or device suppliers conducted training to POCT end users or operators on most occasions which is equivalent to 54%. Chief or senior medical technologists, POCT coordinators and nursing department were conducting training in less than 50% of the times. No training was done for POCT operators from 2% of the respondents as shown in Figure 4. One of the respondents shared that:

"The supplier and the nursing department are in charge of the training". – R30

Competency assessment was conducted to POCT end users or operators in 48% of the hospitals with POCT program while 52% did not conduct competency assessment. It was also noted on this survey that the POCT program under the laboratory were conducting competency assessment more than those POCT program under nursing. The POCT program under the pharmacy department did not conduct competency assessment (Table 9).

Table 9. Department conducting competency assessment to end users

Departments	Assessment done	%	Assessment not done	%	Total
Laboratory	20	56%	16	44%	36
Nursing	4	31%	9	69%	13
Pharmacy	0	0%	1	100%	1
Total	24	48%	26	52%	50

Table 10 shows that annual competency assessments were done in 70% and 75% of programs under the laboratory and nursing, respectively.

Table 10. Competency assessment interval

Interval	Laboratory	%	Nursing	%
Biannually	6	30%	1	25%
Annually	14	70%	3	75%
Total	**20**	**100%**	**4**	**100%**

Equipment

POCT devices requirements like manufacturer recommendations on the utilization of the devices, tests or methods were validated before use, daily maintenance, periodic maintenance, maintenance documentation was always done by the respondents. However, strip test reading using a machine or device were not performed all the time as shown in Table 11. Manual or visual reading of test strips like the urine dipsticks was still practiced in few institutions that were surveyed.

Table 11. POCT devices requirements

Practices	WM	VI	Rank
Test/method validated before use	2.76	A	2
Manufacturer recommendation followed	2.88	A	1
Strip test read using machine	2.50	S	6
Daily maintenance done	2.56	A	5
Periodic maintenance	2.72	A	3.5
Maintenance documentation	2.72	A	3.5
Composite Mean	**2.69**	**A**	

Legend: 1.00 – 1.49 = Never (N); 1.50 – 2.49 = Sometimes (S); 2.50 – 3.00 = Always (A)

Process Control – Pre-Analytical

Preanalytical practices like reagent and quality control validation were carried out in almost all the institutions in this survey. Physician order was also in place before any POCT test was done to a patient as shown in Table 12.

Table 12. Preanalytical Processes

Preanalytical Practices	WM	VI	Rank
Reagent validated before use.	2.86	A	2
QC validated before use.	2.78	A	3
Physician order	2.90	A	1
Composite Mean	**2.85**	**A**	

Legend: 1.00 – 1.49 = Never (N); 1.50 – 2.49 = Sometimes (S); 2.50 – 3.00 = Always (A)

Process Control – Analytical

Among the analytical processes, the manufacturer recommendation on QC, establishment of acceptability criteria and performing daily QC were always performed by the respondents. Device comparison, patient ID entry, operator ID entry to the device, running linearity and establishment of analytical measurement range (AMR) and QC lock out were sometimes performed by the respondents (Table 13). One of the respondents mentioned that:

> *"For glucose, no ID is required. For blood gas patient number is entered before the test is run"* - R4

Table 13. Analytical Processes

Analytical Practices	WM	VI	Rank
Operator ID required	2.24	S	6
Patient ID required	2.68	A	5
QC done daily	2.00	S	3
QC Lock out	2.84	A	8
Manufacturer recommendation on QC	2.42	S	1
Device comparison	2.67	A	4
Acceptability criteria established	2.72	A	2
Linearity and AMR done	2.04	S	7
Composite Mean	**2.42**	**S**	

Legend: 1.50 – 2.49 = Sometimes (S); 2.50 – 3.00 = Always (A)

Table 14 outlined the frequency of performing comparison and linearity by the respondents. Most of the respondents were performing comparison between devices and linearity annually, however there were institutions that never performed comparison of devices and linearity at all.

Table 14. Comparison and Linearity Frequency

Practices	Biannually	Annually	Never	Total
Linearity	6 (12%)	31 (62%)	2(4%)	50
Comparison	15 (30%)	30 (60%)	5(10%)	50

Process Control – Post Analytical

Critical results were always acted upon and were always reported to the physician, repeated, always confirmed with a reference method and actions were documented by most of the respondents. Devices displayed alert to the operator when there were critical results; however, test results were not always traceable to the device (Table 15).

Table 15. Post Analytical Processes

Post Analytical Practices	WM	VI	Rank
Result traceable to the POC device	2.72	A	6
Critical result repeated before reporting	2.77	A	2
Critical result relayed to the physician	2.98	A	1
Critical result confirmed by use of reference method	2.70	A	4
No action done on critical result	1.16	N	7
Action/s on critical result documented	2.72	A	3
Alert is displayed on the POC device for critical result	2.84	A	5
Composite Mean	**2.55**	**A**	

Legend: 1.00 – 1.49 = Never (N); 1.50 – 2.49 = Sometimes (S); 2.50 – 3.00 = Always (A)

Internal Assessment

Table 16 showed that most of the respondents were not consistent in performing internal assessment practices related to POCT. Monthly review of devices maintenance and QC and internal audit were not always done by the respondents.

Table 16. Internal Assessment Practices

Practices	WM	VI	Rank
Internal audit done	2.27	S	3
QC results reviewed at least monthly	2.43	S	2
POC device maintenance reviewed at least monthly	2.50	S	1
Composite Mean	**2.38**	**S**	

Legend: 1.00 – 1.49 = Never (N); 1.50 – 2.49 = Sometimes (S); 2.50 – 3.00 = Always (A)

External Assessment

Proficiency Test (PT) or External Quality Assessment (EQA) was not performed in most of the hospitals. If it is done, POCT operators were the one performing the PT/EQA survey as described in Table 17.

Table 17. Performance of PT/EQA

PT/EQA Performance	WM	VI	Rank
PT/EQA done at least once a year	2.06	S	2
PT/EQA performed by POCT operators	2.74	A	1
Composite Mean	**2.05**	**S**	

Legend: 1.00 – 1.49 = Never (N); 1.50 – 2.49 = Sometimes (S); 2.50 – 3.00 = Always (A)

Occurrence Management

In this survey, respondents said that a mechanism was in placed to always report POCT-related issues; however, there were no persons available to troubleshoot the problem all the time as defected in Table 18. Troubleshooting of POCT-related issues was handled the by the vendors or the device suppliers as shown in Figure 5. Chief medical technologists or senior technologists were doing the trouble shooting more than the POCT coordinator since there were limited institutions that have a designated coordinator.

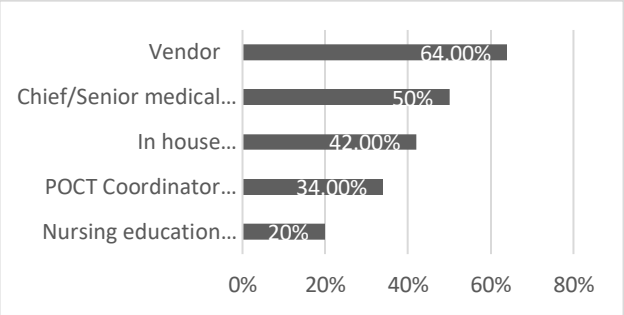

Figure 5. Person troubleshooting POCT devices

Table 18. Occurrence Management

Practice	WM	VI	Rank
Mechanism is in place to report POCT related issues	2.56	A	1
A person is available to troubleshoot problems at any shift	2.36	S	2
Composite Mean	**2.46**	**S**	

Legend: 1.00 – 1.49 = Never (N); 1.50 – 2.49 = Sometimes (S); 2.50 – 3.00 = Always (A)

Process Improvement

Key Performance Indicators (KPI) can identify areas for improvements. In this survey 62% of the respondents said that they have KPI (Figure 6). Among those with KPI, only 46% utilized such in implementing process and quality improvement projects.

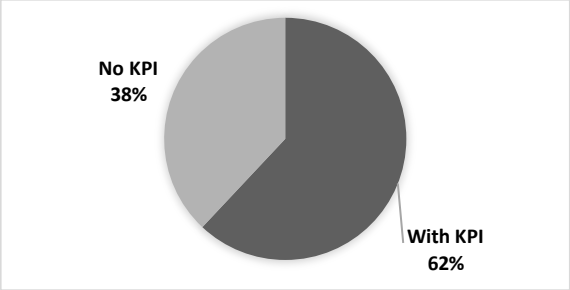

Figure 6. KPI

Documents and Records

Policy that outlined the extent of POCT implementation was available in 78% of the hospitals while 22% do not have policy in place. Written procedure or standard operating procedure (SOP) for every POC test performed was available in 86% of hospitals and 14% do not have procedure for every POC test (Table 19).

Table 19. Policy and Procedure (P/P)

Documents	With P/P	Without P/P	Total
Policy	39 (78%)	11 (22%)	50
Procedure	43 (86%)	7 (14%)	50

Legend: P/P- Policy/Procedure

Review of the policy was done annually in 60% of the hospitals while 37 % of them do it every two years. There also those that do not review their policy. Procedures were reviewed annually in 53%, every 2 years in 42% and 5% do not review their procedure (Table 20).

Table 20. Review of Policy and Procedure

Document	Annual	Biennial	Not done	Total
Policy	23 (60%)	14 (37%)	1 (3%)	38
Procedure	23 (53%)	18 (42%)	2(5%)	43

Training and competency records were kept for 5 years by 54%, for 2 years by 20%, for 1 year by 12% of the hospitals included in this survey. On the other hand, 14% do not keep training and competency records. QC and maintenance records were kept for 5 years by 48%, for 2 years by 20%, for 1 year by 22% and 6.8% do not keep records of QC and maintenance (Table 21).

Table 21. Record keeping

Records	1 year	2 years	5 years	Not kept
Training and competency	6 (12%)	10(20%)	27(54%)	7(14%)
QC and maintenance records	11(22%)	10(20%)	24(48%)	5 (10%)

Information Management

POCT test results should appear in the patient chart with corresponding unit of measurements, reference interval, date, time, and the person who performed the test. In this survey 64% of the hospitals were documenting their test results by manual entry into the patient chart while 14% used electronic transmission of test results to the patient chart. Moreover 22% of them used both methods (Table 22). One respondent confirmed that the glucose test result was entered by laboratory personnel from the test performed by nurses.

> *"Glucose test is performed by nurses and the result is phoned to the lab. The lab personnel enter the result to the patient chart."* R29

Table 22. POCT Test Result Documentation Method

Method	n	%
Manually entered to the patient record	32	64%
Electronically transferred	7	14%
Combined manual & electronic transfer	11	22%
Total	50	100%

Facility and Safety

Single-use devices for collecting blood samples for POCT top the safety practices among the respondents. POCT operators observed standard precautions when performing the test and disinfected the devices after each use. Procedure manuals/SOP and safety data sheets (SDS) were also available and accessible to operators on all POC sites as shown in Table 23.

Table 23. Facility and Safety

	WM	VI	R
Procedure/SOP/manual are accessible on all POC sites	2.60	A	4
SDS of all reagents are accessible on all POC sites	2.58	A	5
Operators observe standard precautions in performing POCT	2.88	A	2
Single use devices are used for collecting blood samples for POCT	2.94	A	1
POCT devices are disinfected after each use	2.82	A	3
Composite Mean	**2.76**	**A**	

Legend: 1.00 – 1.49 = Never (N); 1.50 – 2.49 = Sometimes (S); 2.50 – 3.00 = Always (A)

Purchasing and Inventory

Figure 7 described that 58% and 56% of the respondents said that the medical director or administrator and chief medical technologist respectively were responsible in selecting and approving purchases of POCT devices. Person in charge of monitoring POCT supplies and inventory varied in different institutions according to who supervises the POCT program. Figure 8 outlined the distribution of responsibility. In this survey, most of the POCT programs were under the laboratory. Most of the times it was the chief medical technologist who, was responsible for monitoring the POCT supplies. In institutions with POCT Coordinators, it was them who monitor the supplies.

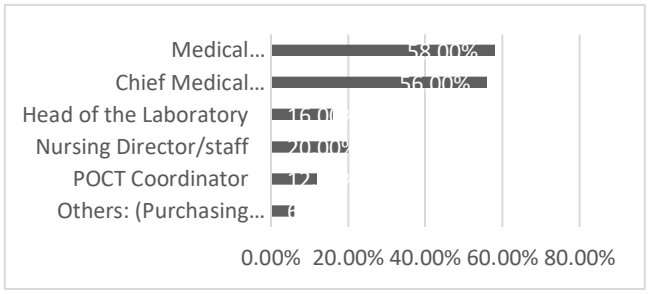

Figure 7. Selection of POCT device

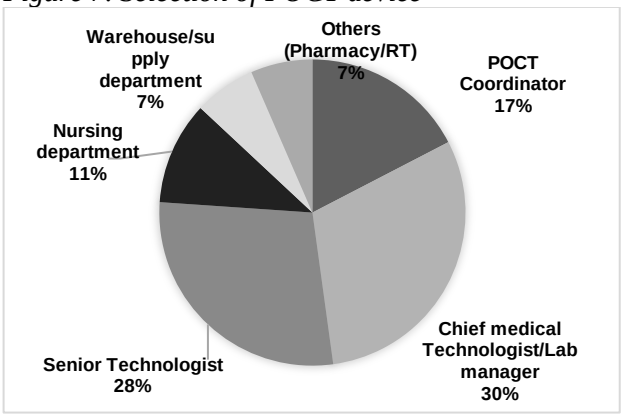

Figure 8. Monitoring of POCT Supplies

Table 24 summarized the variances that were identified in the implementation of POCT programs. Different practices were observed in the implementation of POCT in different healthcare institutions resulted to variations and inconsistencies. The Quality System Essentials (QSE) where variances were observed include organization, personnel, process control, internal assessment, external assessment, occurrence management and document and record.

Table 24. Summary of variances identified in the implementation of POCT programs

QSE	Variances identified
Organization	POCT supervision not under the laboratory Lack of POCT Committee Limited POCT Coordinators
Personnel	Limited operator training Limited competency assessment
Process control-analytical	Lack of device comparison Patient ID not required on POCT devices Linearity and AMR not done Lack of QC Lock out feature on POCT devices
Process control-post analytical	Manual entry of patient result Limited connectivity of POCT devices to LIS/HIS Lack of patient test traceability
Internal Assessment	Lack of audit QC results reviewed at least monthly POC device maintenance reviewed at least monthly
External Assessment	No participation in PT program
Occurrence management	No person available all the time to trouble shoot POCT devices
Document and records	Policy and procedure not available always Review of policy and procedure not reviewed regularly

Comparison of quality system essentials between hospitals with and without POCT Coordinators was described in Table 25. It was observed that there were a significant difference on quality systems essentials namely equipment ($p = 0.005$), process control-pre-analytical ($p = 0.004$), process control-analytical ($p = 0.035$), process control-post analytical $p = 0.017$), internal assessment ($p = 0.007$), external assessment ($p = 0.014$) and occurrence management ($p = 0.018$) since the obtained p-values were less than 0.05 alpha level. This means that the quality standards performed differs significantly. Furthermore, it revealed that the presence or absence of a POCT Coordinator greatly impacted the compliance with the QSE. This statistical analysis validated the observed variances in this survey.

Table 25. Comparison of hospitals with and without POCT Coordinator (POCC)

QSE	Group	Mean	SD	t-value	p-value
Equipment	W/ POCC	2.87	0.208	2.994	*0.005
	W/out POCC	2.56	0.485		
Process control-Preanalytical	W/ POCC	2.98	0.073	3.084	*0.004
	W/out POCC	2.75	0.405		
Process control-Analytical	W/ POCC	2.58	0.391	2.173	*0.035
	W/out POCC	2.31	0.454		
Process control-Post Analytical	W/ POCC	2.64	0.133	2.485	*0.017
	W/out POCC	2.49	0.275		
Internal Assessment	W/ POCC	2.63	0.407	2.843	*0.007
	W/out POCC	2.20	0.681		
External Assessment	W/ POCC	2.43	0.856	2.549	*0.014
	W/out POCC	1.77	0.928		
Occurrence management	W/ POCC	2.67	0.428	2.449	*0.018
	W/out POCC	2.31	0.558		
Facility and Safety	W/ POCC	2.82	0.244	1.02	0.313
	W/out POCC	2.72	0.372		

*Significant at p-value < *0.05; SD- Standard Deviation*

DISCUSSION

All the institutions that participated in this survey have valid license to operate by the Department of Health (DOH) at the time of this survey. It was observed in this survey that external accreditation like Joint Commission International (JCI) was common to private hospitals in the Philippines, a finding that was also seen in the study by Badrick et al. (2019) [16]. The cost and lengthy preparation of accreditation are contributing factors to this limitation. Accreditation by an independent body determine fulfilment of standards set by the accreditation agency ascertain the compliance of the institution to quality and provide universal recognition according to Mok et al. [1].

Utilization of POCT in the Philippines was common to hospitals with 100-300 bed capacity. It is noticeable that bigger capacity is observed in government hospitals. This is more likely due to a smaller number of government hospitals than privately owned hospitals; thus, it must offer more beds for the people. A survey with similar result was conducted by Hernandez et al. [3] in Spain where utilization of POCT is common to 100- 300 bed capacity hospitals. Sites that commonly use point of care testing are the Intensive Care Units (ICU), emergency department, operating rooms, dialysis units and even physicians' offices [21]. An increase in the integration of POCT in several medical procedures and specialties increased over the years has been documented [22]. Availability of test result or turnaround time (TAT) was a major advantage in POCT especially if time was a critical factor in clinical decision making [23], [24], [13]. Other advantages of POCT include elimination of sample transport resulting into better sample stability, reduced pre-analytical errors, and minimal sample volume requirements [5].

Although POCT was implemented in most of the hospitals that participated in this survey, there were institutions without POCT yet. There were several hospitals that were not capable of setting up POCT due to some limitations. Several factors like funds, training of health care force and efficiency of testing services contributed to this limitation as attested by the respondents. Accessibility to POCT in low and middle-income countries was limited as discussed by Kataba et al. [25]. The need to expand the use of POCT was recommended in a study conducted in Australia by Shephard and Shephard [8] and in Vietnam by Nyuyen and Kost [19]. Overcrowding in the emergency department was also a driver for the implementation of POCT. Introduction of POCT devices to the emergency department improved the turnaround of the patients [26]. Innovations in POCT reduces the length of stay of patients in the emergency department and in the hospital [27].

Glucose was identified as the most utilized test. Due to the alarming rise in diabetic cases especially in developing countries like the Philippines, the glucometer was the most widely used POCT device with usage varying from self-monitoring to hospital screening and intravenous insulin dosing in the ICU [28], [29]. This finding was very similar to the study conducted by Nyuyen and Kost [19], Hernandez et at. [3] and by Nnakenyi et al. [4].

Supervision of the POCT program varies between institutions. While most of the programs were under the clinical laboratory and the laboratory director as the head, there were still POCT programs that were under the nursing and pharmacy departments. This finding was not in compliance with Section VI-A.6 of

the Administrative Order No. 2007-0027 from the Department of Health (DOH) that states that management and supervision of POCT conducted in a hospital should be under the clinical laboratory. The general oversite of the POCT program should be the responsibility of the laboratory director or a designee.

POCT committees were not formed yet in most of the hospitals. A multidisciplinary team represented by all stakeholders from the laboratory, nursing, respiratory department, anesthesia, biomedical engineering, purchasing or material management and others should be formed and should meet on a regular basis. The absence of an oversight committee may have contributed to the variations in the implementation of POCT in the Philippines. The study by Khan et al. [18] in 2019 recommended the formation of a POCT committee to have a successful POCT program implementation. The AACC Guidance Document on Management of POCT stated that the interdisciplinary POCT committee has the responsibility to select and evaluate instruments or devices for POCT use.

POCT Coordinator has the primary responsibility to oversee, manage and synchronize all the activities related to POCT implementation. It is the responsibility of the POCT Coordinator to ensure that all devices and tests are in compliance with the existing licensing and accreditation regulations and requirements related to the selection and evaluation of devices, training and competency of end users, patient testing process, quality control and assurance procedures and resolving technical problems. The POCT Coordinator should be an experienced medical technologist as per recommendation from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and Philippine Council for Quality Assurance in Clinical Laboratory (PCQACL). Limited numbers of POCT Coordinators were observed in this survey even in institutions that have POCT committees. This may be due to limited awareness of hospital management on the benefits of having POCT coordinator and to the limited resources available to them [30]. In a study by Nyuyen et al. [19] in 2020, Vietnam has shortage in POCT Coordinators also. A limited number of POCT Coordinator in the Philippines was also documented in a study by Badrick, et al. [16]. It was mentioned that POCT coordinators were limited to private and internationally accredited institutions, a finding that was also seen in this survey.

POCT was commonly performed at patient's bedside by healthcare providers like nurses, respiratory therapists, and anesthesia technologists. The finding in this survey wherein most of the patients' tests and quality control tests were performed by laboratory personnel or medical technologist is in contrast with the common practice worldwide where in POCT is performed by non-laboratory personnel. Interview with the respondents confirmed this practice which was due to the lack of guidelines in some institutions that specifies the role of each healthcare personnel in relation to POCT activities. A similar result wherein laboratory personnel in the Philippines perform POCT was reported by Badrick, et al. [16].

Training of POCT operators was necessary to provide and develop knowledge, skills and behavior that is needed to meet the requirements for the job. ISO 22870:2016 subclause 5.3.1 specified that POCT devices must be operated only by trained and authorized personnel. In this survey, most of the training were conducted by POCT device vendors and representatives. Limited human resources like POCT Coordinators, was one of the reasons why institutions seek help from the vendors or device supplier to conduct training. Assessment of competence, knowledge and skills were specified in ISO 22870:2016 subclause 5.1.4. Competency is the ability to apply the knowledge and skills gained during the training to deliver the intended outcome or result or to perform a specific task or activity [1]. Having multiple devices and sizeable number of POCT operators make training and competency assessment a logistical challenge in many POCT program implementation. POCT devices may be simple and easy to use, but Clinical Laboratory Improvement Amendments' 88 (CLIA) and College of American Pathologist (CAP) states that training of POCT end users should be conducted by qualified personnel. A single training event is not sufficient to assess the competence of POCT operators. Continuing competency ensures and maintains the accuracy and reproducibility of test results. This survey result was also in agreement with the studies conducted by Shaw [31]and Nichols et al. [32].

Point of care testing processes include selection of the appropriate devices, validation of the devices, writing the policy and procedure, training of the operators and implementation. Several steps are involved in each of these processes. Results of this survey showed that preanalytical practices were always performed by the respondents, however analytical and post analytical processes were not consistently done. Accuracy and reliability of test results have some impact on patient care. Errors can occur throughout the pre-analytical, analytical, and post analytical testing stages [33]. Requirements on quality and competence

for POCT done in hospitals, clinics and other health care organizations were clearly stated on ISO 22870-2016, International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) -Committee on POCT recommendations and Clinical and Laboratory Standards Institute (CLSI) Twelve (12) Quality Systems Essentials (QSE) guidelines [4].

POCT devices should be validated before use. In the same way, manufacturer recommendations on the use and application of the devices should be followed. Manual or visual reading of test strips like the urine dipsticks was not a recommended practice in POCT. In this survey, most POCT devices were validated before use, manufacturer recommendations were followed, daily and periodic maintenance was carried out in most institutions. Since most POCT programs included in this survey were under the supervision of the clinical laboratory, the concept of POCT devices validation and maintenance is patterned from the practices done in the main laboratory. This finding was contrary to the outcome of the study conducted by Nnakenyi et al. [4] wherein validation was not performed before use of the POCT devices in 81% of their respondents because operators were not aware of this need.

Validation of reagents and quality control materials were integral parts of the internal quality assurance practices in POCT. Evaluation of reagents and quality control materials gives the confidence that the test results generated are reliable. Similarly, physician order was always in place before a POC test was carried out. Test results are communicated to the primary healthcare provider like a physician for appropriate action particularly in cases of critical or unexpected test result. The outcome of this survey confirmed the studies conducted by Blairon et al [34]and by Karon [29] wherein reagents and QC materials were validated before using as part of the quality assurance practices in POCT.

Unlike the central laboratory where the testing was done on few analyzers, POCT usually used multiple devices in different locations across the hospital. The use of several devices required POCT program to perform comparison and linearity on these devices and this imposed a big challenge to POCT coordinators. Comparison and linearity were done either twice or annually depending on the complexity classification of the device by CLIA. Accuracy, precision, comparison of test results and linearity were among the analytical performance assessment recommended by AACC Guidance Document on Management of Point of Care testing by Nichols et al. [32].

Quality control is mandatory to ensure that POCT devices are functioning properly, and tests are performed correctly. QC lock out feature allows the operator to perform patient test only if QC test was done and results were acceptable. In this survey, most of the devices used in POCT had no QC lock out feature. Some hospitals were using devices for home or personal use and QC lock out was not common to this device type. This feature is seen in newer models of devices and with devices labelled for hospital use. The result of this survey confirmed the finding of Nnakenyi et al. [4] that analytical practices varied among institutions surveyed.

Patient test result should be traceable to the POCT device, and this could be accomplished by entering a unique patient identifier into the POCT device before performing the test. Without unique patient ID, the test result could not be associated to a particular patient. In this survey patient identifiers were not always required when performing a patient test. Recalling test result from these POCT devices is not possible. This is a challenge if devices labelled for home use are utilized in health care institution and the device was used for several patients by different operators as the case in some hospitals included in this survey. This is also seen in the survey done by Nnakenyi et al. [4] where in 78% of the test results were not traceable to each patient.

In the same way that patient test result should be associated to a particular patient, patient's test result should be traceable to an operator as recommended by IFCC. Operator ID entry on POCT devices was required only on almost 50% of the devices used in hospitals included in this survey which means that more than 50% test results cannot be traced to an operator. Since POCT are usually performed by clinical personnel outside the clinical laboratory, entry of POCT operator ID into the devices serves as a "lock out" that only authorized operators can use the POCT devices. In the study conducted by CMS in the United States in 2017, 19% of POCT operators were not trained and were able to perform patient's test. This practice imposes a safety risk to the patient [4].

Manual entry of test results was still the most common method used by many of the respondents. Manual entry of test results is prone to transcription error. In a study conducted by Shaw [31] in 2016, approximately 30% of test results were entered incorrectly and 12% of the glucose test results were

never recorded in the patient chart. Repeat testing is usually performed when test result is not available in the patient chart which led to increase cost and discomfort to patient. Electronic transfer of test result is ideal. To achieve this, connectivity of POCT devices to the Laboratory Information (LIS), Hospital Information System (HIS) and Electronic Medical Record (EMR) is necessary; however, it is expensive and not a trivial undertaking.

Proficiency Test (PT) or External Quality Assessment (EQA) are samples that are treated like patient tests that could assess proficiency of the operator and detect procedural failure. As shown in Table 17, PT or EQA was not performed in most of the hospitals in this survey. Participation in PT/EQA programs enhanced POCT operator proficiency. Studies have shown that participation to PT/EQA improved POCT performance over time [32].

Similar with the central laboratory, critical results should be handled according to the established protocol. It is a recommended practice in POCT to repeat critical or unexpected results and/or to confirm this result by a reference method or by sending a sample to the central laboratory for confirmation of the result. POCT device design have evolved and most of the newer devices have alert displayed for critical result.

Post analytical practices on POCT in the institutions in this survey were similar with the common practices worldwide as shown in the study of Nichols et al. [32] and from the recommendations of the IFCC committee on Point of Care Testing.

Performing internal audit could detect problems that are unique to a particular institution. This will give an opportunity to improve the process or introduce measures to solve the problem or monitor an outcome of a process improvement initiative. Quality control results and device maintenance review gave assurance that the POCT devices were functioning properly. Performing internal audit, QC review and device maintenance are good laboratory practices that are also applicable in POCT as what was recommended by Nnakenyi et al. [4] in their study on quality management practices in Nigeria. These internal assessment practices were also recommended by Nichols et al. [32] in their paper Management of Point of Care testing.

Data gathered from KPI could be used to document effectiveness of the POCT methods and practices or it could also be used to develop quality initiatives to improve areas that were identified as problem prone. In this survey, although 62% of the hospitals have KPI, only 46% utilized such in implementing process and quality improvement projects. This implied that data gathered were not used to improve the practices in the hospitals that were surveyed. Nichols et al. [32] recommended in their paper that POCT programs should define KPI to identify opportunities for improvement and document program success and benefit to patient care. Common POCT performance indicators may include preanalytical variables like correct patient identification, redating expiry dates of reagents and quality control or device maintenance and disinfection. Analytical factors like troubleshooting of failed QC, successful proficiency testing or selecting appropriate QC level could be used. Documentation and reporting of critical result, clerical errors, and turnaround time (TAT) are few post-analytical indicators that could be monitored.

Multiple devices used by multiple operators imposed a big challenge on POCT services particularly when there are problems or issues related to the test results or the operation or use of the devices. Accreditation agency like CAP and JCI requires that a mechanism is in place to report issues related to POCT and a person is available to resolve issues or problems in any shift. Vendors or their representatives are oftentimes not available to respond immediately. In an emergency setting where a POCT device is needed to perform a patient test, down time of POCT devices is crucial. Institutions with well-established POCT services had resource persons often referred to a "super-user" who are usually nurses trained on simple troubleshooting activities whenever the POCT Coordinator is not available. Other option is to have remote access for the vendor representatives to check and maintain the device. This practice was implemented in Australia where POCT devices were used in remote areas but were remotely accessed by vendor representatives when problems were reported [8].

Records must be kept for certain period depending on the nature of the document. JCI and CAP required that records and documents were always kept and reviewed at regular intervals. Majority of the respondents kept their records for at least two years. This finding suggested that majority of the hospitals were following the accreditation regulatory requirements set by agencies like JCI and CAP.

Challenges encountered in the implementation of POCT program in this survey include compliance with regulatory requirements, organizational structure, training of non-laboratory personnel, quality assurance, documentation, and data management. These

challenges were brought about by the differences in the practices from the hospital included in this survey. Limited resources, lack of standard policy and experienced POCT Coordinators are few factors that contributed to the variation in practices. This is similar to the results of studies by Fitzmaurice, et al [35] in 2020, by Senggupta & Handoo [5] in 2020 and by Shaw [31]in 2016. It was found out in studies in other Asian countries like Vietnam, Malaysia, and Thailand that a national policy on POCT contributed to the successful implementation and improved outcomes [19] One of the recommendations in the study was to have a POCT committee and a POCT coordinator that oversees the program [5], [36]. Consistency is important in POCT; hence, quality management is necessary [37].

CONCLUSION AND RECOMMENDATION

There were gaps identified on the methods and practices of the POCT implementation in the Philippines. The challenges to set up POCT program varied between hospitals. Every institution followed its own internal POCT policy. This resulted in variations and differences in the practices of POCT in the Philippines. Variances identified in this survey include inconsistencies in organizational structure and supervision of POCT program, limited numbers of POCT Coordinators that were concentrated to private institutions, limited or lack of personnel training and competency assessment, lack of external quality assessment, use of devices labelled for home or personal use, limited use of electronic data management systems that resulted to manual entry of test results. Seven Quality Systems Essentials (QSE) namely equipment, process control on preanalytical, analytical and post analytical, external assessment, internal assessment and occurrence management were significantly impacted by the presences or absence of a POCT Coordinator. In general, better adherence to QSEs were noted in institutions with POCT coordinators, particularly in preanalytical process control.

The value of POCT to patient care had been well documented. A robust quality management system reduced the risk and complications arising from a poorly implemented POCT activities.

To have a standardized and harmonized practice in the implementation of POCT programs in the Philippines, a national policy is needed. The national policy should focus on certain quality system essentials primarily on organization, personnel training and competency pre-analytical, analytical, and post-analytical processes, internal and external quality practices. The policy should also cover the recommendations on selection and appropriate use of POCT devices for healthcare institutions and encourage connectivity and interface of POCT devices to Laboratory Information System (LIS) and Hospital Information System (HIS) to facilitate electronic transfer of data. Formation of interdisciplinary committee, having POCT Coordinators and establishing the role and responsibility of each team member are essential for a successful POCT program. Internal quality control, proficiency testing or external quality assessment, audits, equipment selection, method validation, standard operating procedure for each POCT, result reporting and documentation, critical result reporting procedure, device maintenance are necessary to ensure reliability of test results. Development of training curriculum for students and aspiring POCT Coordinators, training process, competency assessment are important components for the promotion and awareness of POCT in healthcare institutions. Formation of POCT Coordinator group or network to share interest, ideas, expertise, and best practices will help professionals and advance the career of POCT Coordinators. This will also pave the way for POCT to be recognize as a field in laboratory medicine. Competency enhancement of professional medical technologists or medical laboratory scientists by attending trainings and continuous professional development seminars (CPD) offered by professional organization and healthcare institutions must be strengthen.

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