The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine

eJIFCC

Catering for the point-of-care testing explosion

Adil I. Khan[1], Mazeeya Khan[1], Rosy Tirimacco[2]

[1] *Department of Pathology & Laboratory Medicine, Lewis Katz School of Medicine, Temple University, Philadelphia, PA, USA*

[2] *iCCnet SA, Rural Support Service, Government of South Australia, Australia*

ARTICLE INFO

Corresponding author:
Dr. Adil I. Khan
Department of Pathology &
Laboratory Medicine
Lewis Katz School of Medicine
Temple University
Philadelphia, PA 19140
USA
Phone: +1 215-707-0965
E-mail: adil.khan@temple.edu

Key words:
POCT, COVID-19, webinars, coordinator, education, quality

ABSTRACT

The ease of performing a laboratory test near to the patient, at the point-of-care, has resulted in the integration of point-of-care tests into healthcare treatment algorithms. However, their importance in patient care necessitates regular oversight and enforcement of best laboratory practices. This review discusses why this oversight is needed, it's importance in ensuring quality results and processes that can be placed to ensure point-of-care tests are chosen carefully so that both oversight can be maintained and patient care is improved. Furthermore, it highlights the importance of delivering focused webinars and continuing education in a variety of formats.

INTRODUCTION

Point-of-care diagnostics has grown at an unprecedented rate. The convenience of being able to test yourself or a patient by a small, portable point-of-care device, that is easy to use, requires very little trouble shooting and provides results within a matter of seconds to minutes has fueled the explosion in point-of-care testing instruments world-wide, enabling them to find a key role in managing patient health. Furthermore, the current COVID-19 pandemic has illustrated, more so to the general public at large, the importance of having a process in place for efficient diagnosis and triaging of patients for disease management [1]. However good POC technologies are, there is a need for governments with help from national societies to develop strategies for effective implementation [2].

A recent survey conducted by the International Federation of Clinical Chemistry and Laboratory Medicine Committee on Point-of-Care Testing (IFCC C-POCT) (Figure 1) showed that 62% of member societies did not have an official point-of-care testing committee (Figure 2A) and in 55% of member countries, point-of-care testing was performed without any formal regulation (Figure 2B). This data show that whilst point-of-care testing has become an important part of patient testing and diagnostic algorithms, it is still being performed in a significant number of countries without official hospital and regulatory oversight. This does not necessarily mean that it is being done incorrectly, however being performed in a non-standardized way, without official oversight does open up that possibility. This is important because having a POC testing committee and standardized POC testing guidelines mandated nationally leads to accountability in the management of POC testing. Moreover, these numbers gathered by the IFCC C-POCT, are actually an underestimation since only a very small number of countries represented South America, Africa, Asia and the Middle East (Figure 1).

Figure 1 World map showing the IFCC member countries that responded to the point-of-care testing survey

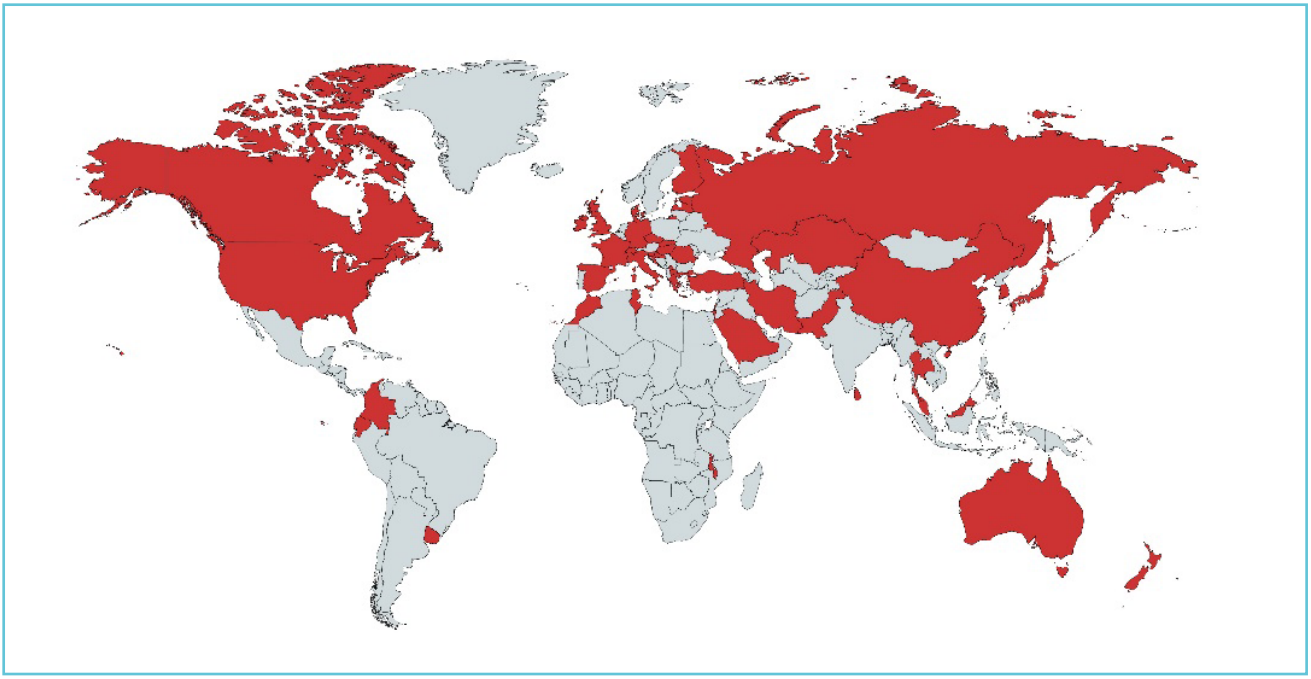


Figure 2A A. Does your society have a point-of-care testing committee?

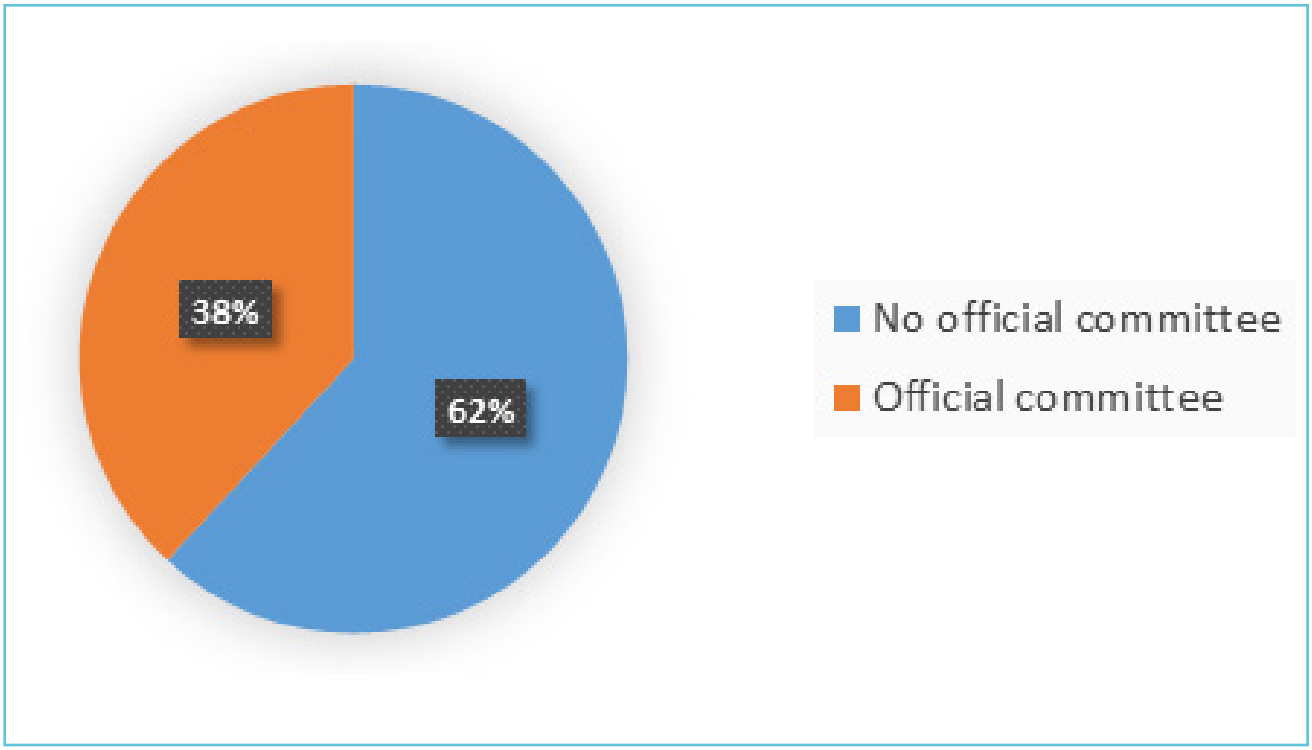


Figure 2B Is point-of-care testing regulated in your country?

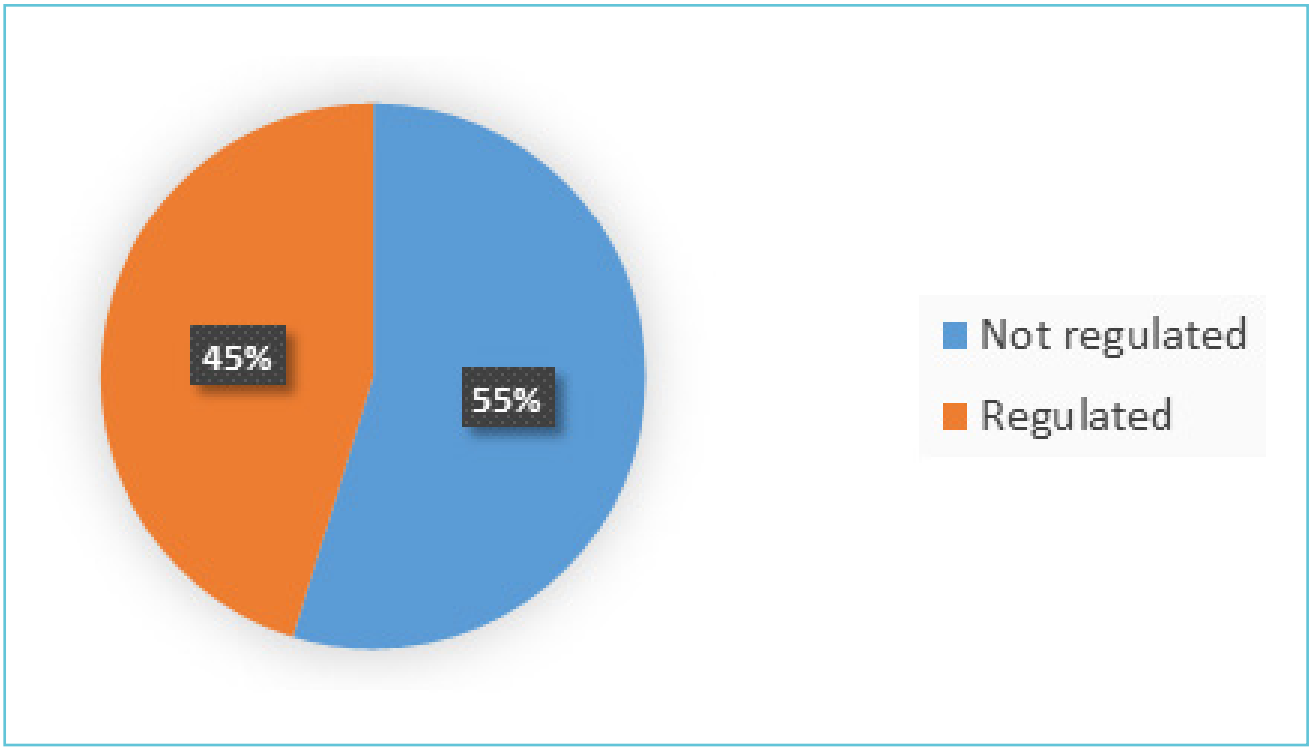
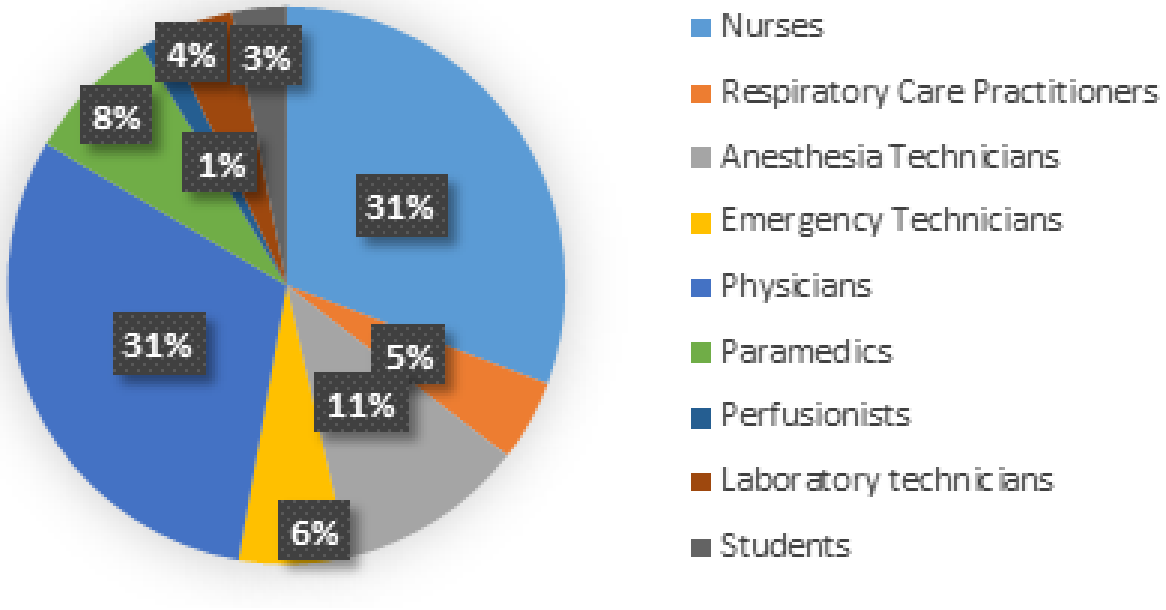


Figure 3 Point-of-care testing by job category



Performing POC testing in a non-standardized manner, without any official quality assurance program that includes performance improvement indicators, and regular audits, makes the POC testing program vulnerable to potential errors in the pre-analytical, analytical and post analytical stages and thus hinders potential benefits it can provide in patient management through the system. Simply following the manufacturer's instructions is not always sufficient to ensure quality results. Employing regulatory guidelines that have been developed through collaboration amongst experts within the field with a "best laboratory practices" mindset, using clinical and industry quality benchmarks, in addition to manufacturer recommendations is important.

For example, in 2016, a hospital in the United States found two patients with hepatitis C infections due to unsafe practices in a hemodialysis unit. Further investigation showed that there was a lack of compliance to infection control processes such as failure to change gloves when staff moved between equipment or using ungloved hands without proper hand hygiene. Lack of cleaning and disinfection of environmental surfaces (visible bloodstains on dialysis machine, on dialysis station televisions, and on patient chairs) [3].

The instruments being used for PT/INR patients are also potential sources of infection. In another United States study [4], nurse staff demonstrated a lack of infection control and best practices, despite training and competency in the use of the instruments. The staff were also not educated on the type of disinfectant to use, and the contact time for the disinfectant to remain wet on the surface of the prothrombin monitoring device [4].

Depending on the manufacturer, the package insert does not always fully address good laboratory practices. For example, when using glucose meters, the vendor may not always mention in their package inserts that glucose meters

needs to be disinfected when used between different patients. In a multicenter study of glucose meter usage in 12 hospitals in the United States, that were classified as urban, suburban, or rural, 30.2% ± 17.5% of the glucose meters studied had blood contamination, and the incidence was 2 times higher in the intensive care units. The number of operators per unit also correlated with higher incidences of blood contamination [5, 6], and another U.S. study found that hepatitis B infection outbreaks were increased in long-term care facilities [7, 8]. These examples highlight the importance of education associated with POC testing that goes beyond the package insert and regulation in the form of standardized policies that addresses the three phases of testing, in addition to regular audits and most importantly accountability corrective actions for deficiencies.

An important feature of POC testing that sets it apart from other healthcare disciplines is that the users can come from a wide variety of backgrounds, including, nurses, nurse aids, respiratory care practitioners, perfusionists, physicians, paramedics and other healthcare workers (Figure 3). As a result, training has to be geared to address the different educational backgrounds, often with no previous laboratory experience and a lack of familiarity with concepts such as quality control, quality assurance and root cause analysis [9].

Consequently, there is a requirement to have a robust POC testing program headed at a minimum by a director or equivalent to initiate institutional change and a POC coordinator that can implement the change [9]. The POC coordinator is the key to any successful POC testing program and is often a clinical laboratory professionals since they have both laboratory experience and knowledge. People-skills are equally important because they are constantly communicating to POC test users and involved in their training and education [10].

In the United States, the Clinical Laboratory Improvements Amendments of 1988 (CLIA'88) regulate laboratory testing through three federal agencies: the Food and Drug Administration (FDA), Center for Medicaid Services (CMS) and the Center for Disease Control (CDC). Each agency has a unique role in assuring quality in laboratory testing (See Table 1.)

The FDA categorizes tests according to their level of complexity [11]. There are three categories: waived, moderate complexity, and high complexity. A test that is classified as "waived" is simple to use, and will not cause harm to the patient if done incorrectly. Generally, over-the-counter and at-home use tests are given this category. The next classification, moderate and high complexity tests (also known as non-waived testing) is determined by the FDA committee, after reviewing the package insert and making the assessment based on 7 categories, with each being given a score of 1, 2, or 3. The lowest level of complexity is given a score of "1" and "3" to the highest level of complexity. When the 7 scores are added together if the sum is 12 or below it is a moderate complexity test and if above 12, a high complexity test. See Table 2, showing how FDA determines whether a test is categorized as moderate or high complexity and grades it accordingly by giving it a score of 1-3 [11].

In the United States, point-of-care tests used in hospitals usually belong to either waived or moderately complex category. This categorization can be effective in limiting the adoption of a POC tests in a hospital because each category is associated with different regulations, in terms of quality assurance practices, such as frequency of quality control, linearity, calibration, instrument correlations. For waived tests, manufacturer's instructions need to be followed, however, moderately complex tests in addition require linearities to be performed if applicable, instrument correlations, enrollment

into proficiency testing or external quality assessment programs and individual quality control plan (IQCP). In the absence of an IQCP, two levels of external quality control (QC) must be performed daily or if the manufacturer recommends, at the change of each shift for non-waived POC tests. If an IQCP is implemented, daily QC can be limited to the internal QC, (if this is available) and performance of external QC at the manufacturer frequency, with new lot/shipments of reagents, and at least monthly, whichever is more frequent. An IQCP is developed based upon guidelines published by the Clinical Standards Institute (CLSI) EP23-A, Laboratory Quality Control Based on Risk Management [12].

Table 1 In the U.S. three federal agencies have been designated to regulate different aspects of CLIA'88

Clinical Laboratory Improvements Amendments, 1988 (CLIA'88)		
Food and Drug Administration (FDA)	**Center for Medicaid Services (CMS)**	**Center for Disease Control (CDC)**
Categorizes tests based on complexity	Issues laboratory certificates	Provides analysis, research, and technical assistance
Reviews requests for Waiver by Application	Collects user fees	Develops technical standards and laboratory practice guidelines, including standards and guidelines for cytology
Develops rules/guidance for CLIA complexity categorization	Conducts inspections and enforces regulatory compliance	Conducts laboratory quality improvement studies
	Approves private accreditation organizations for performing inspections, and approves state exemptions	Monitors proficiency testing practices
	Monitors laboratory performance on Proficiency Testing (PT) and approves PT programs	Develops and distributes professional information and educational resources
	Publishes CLIA rules and regulations	Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)

Table 2 Showing how FDA determines whether a test is categorized as moderate or high complexity test and grades it accordingly by giving a score of 1-3)* (adapted from reference 11)

Categorization criteria
1 – Knowledge
• Score 1. (A) Minimal scientific and technical knowledge is required to perform the test; and (B) Knowledge required to perform the test may be obtained through on-the-job instruction.
• Score 3. Specialized scientific and technical knowledge is essential to perform pre-analytic, analytic or post-analytic phases of the testing.
2 - Training and experience
• Score 1. (A) Minimal training is required for pre-analytic, analytic and post-analytic phases of the testing process; and (B) Limited experience is required to perform the test.
• Score 3. (A) Specialized training is essential to perform the pre-analytic, analytic or post-analytic testing process; or Substantial experience may be necessary for analytic test performance.
3 - Reagents and materials preparation
• Score 1. (A) Reagents and materials are generally stable and reliable; and (B) Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions.
• Score 3. (A) Reagents and materials may be labile and may require special handling to assure reliability; or (B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.
4 - Characteristics of operational steps
• Score 1. Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.
• Score 3. Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.
5 - Calibration, quality control, and proficiency testing materials
• Score 1. (A) Calibration materials are stable and readily available; (B) Quality control materials are stable and readily available; and (C) External proficiency testing materials, when available, are stable.

- Score 3. (A) Calibration materials, if available, may be labile; (B) Quality control materials may be labile, or not available; or (C) External proficiency testing materials, if available, may be labile.

6 - Test system troubleshooting and equipment maintenance

- Score 1. (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and (B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.
- Score 3. (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or (B) Maintenance requires special knowledge, skills, and abilities.

7 - Interpretation and judgment

- Score 1. (A) Minimal interpretation and judgment are required to perform pre-analytic, analytic and post-analytic processes; and (B) Resolution of problems requires limited independent interpretation and judgment.
- Score 3. (A) Extensive independent interpretation and judgment are required to perform the pre-analytic, analytic or post-analytic processes; and (B) Resolution of problems requires extensive interpretation and judgment.

** Note: A score of 2 is assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of 1 and 3.*

There are three sections of an IQCP [13]:

(1) Risk assessment:

The purpose is to map the testing process so to identify procedural weaknesses. At a minimum it is made up of 5 components:

i. Specimen
ii. Test system
iii. Reagent
iv. Environment
v. Testing personnel

(2) Quality Control Plan (QCP)

The Quality Control Plan describes the processes that the point-of-care testing program has implemented to mitigate the procedural weaknesses identified in the risk assessment. The following is an example of what it may include:

i. Electronic controls
ii. Internal controls
iii. Proficiency testing (PT)
iv. Calibration Maintenance
v. Training and competency assessment

(3) Quality Assessment (QA)

This monitors the quality control plan to determine of the processes that have been put in place to reduce the weaknesses in the testing processes are effective and evaluates, but is not limited to the following:

i. QC reviews
ii. PT performance reviews
iii. Chart reviews

iv. Specimen rejection logs

v. Turnaround time reports

vi. Complaint reports

Webinars form an essential communication tool that has been increasingly used due to the social restrictions imposed by the COVID-19 pandemic. Their effectiveness can be seen in figure 5A-C which breaks down some of the data gathered from a recent Asia Pacific Point-of-Care Webinar on "The Role of Blood Gas in Overall Management of COVID-19 Patients."

CONCLUSION

Point-of-care testing will become increasingly intertwined with how healthcare systems manage acute and chronic diseases. Furthermore, a lack of reliance on healthcare infrastructure in resource limited settings makes POCT devices an attractive alternative to centralized laboratory testing [14]. Best laboratory practices are essential for meaningful results as is their appropriate use. However, the point-of-care diagnostics explosion outpaces global regulatory oversight that is needed in this sector and confirms the need to meet this demand with focused webinars, educational and practical workshops to ensure best laboratory practices are followed.

REFERENCES

1. Khan AI. Transforming Clinical Pathways. Arch Pathol Lab Med. 2020, 144(10):1164-1165.

2. Kost GJ. Geospatial Hotspots Need Point-of-Care Strategies to Stop Highly Infectious Outbreaks. Arch Pathol Lab Med. 2020, 144(10):1166-1190.

Figure 5A Registrants – by countries (640 registrants)

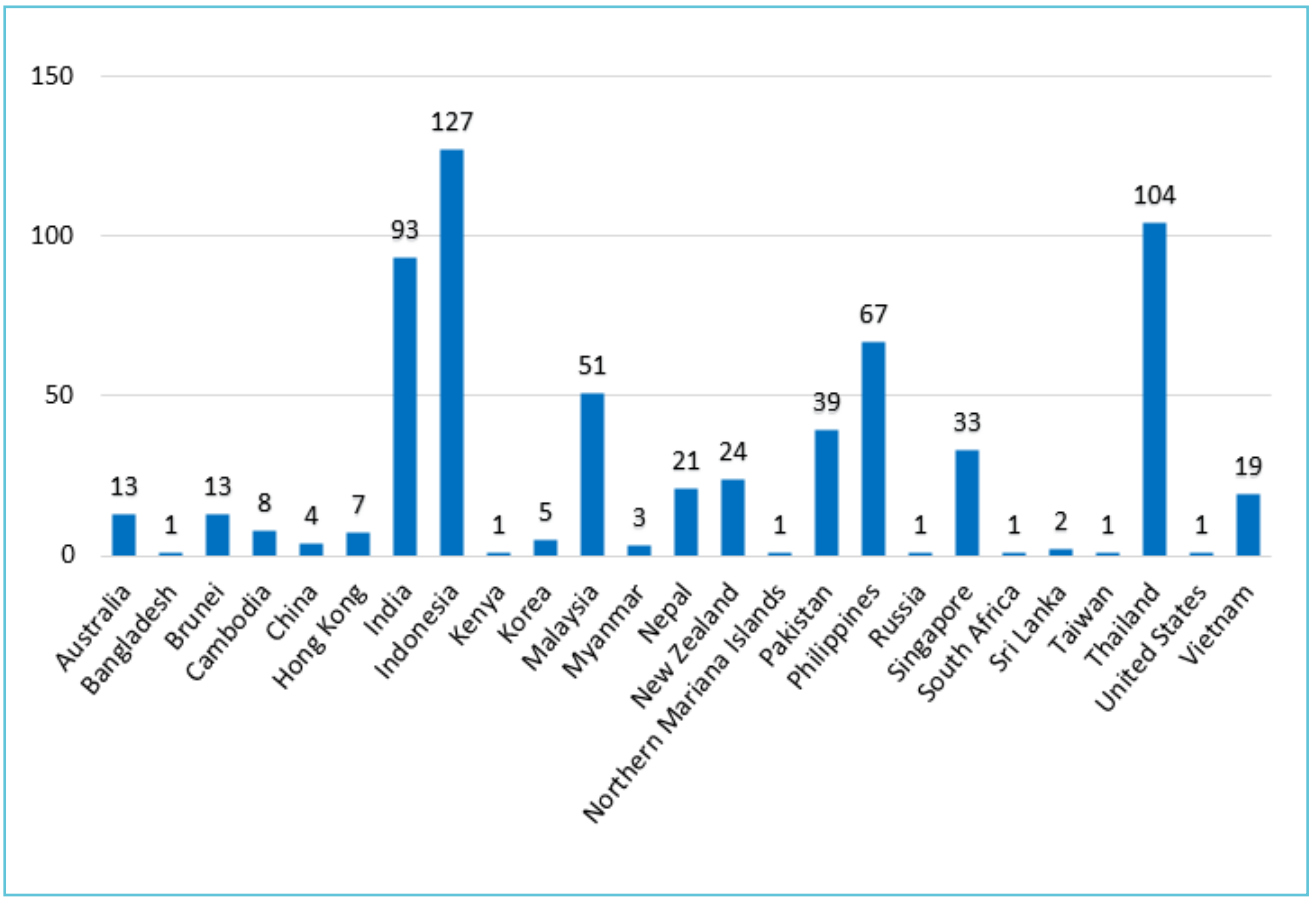


Figure 5B Live attendance by countries (219 registrants)

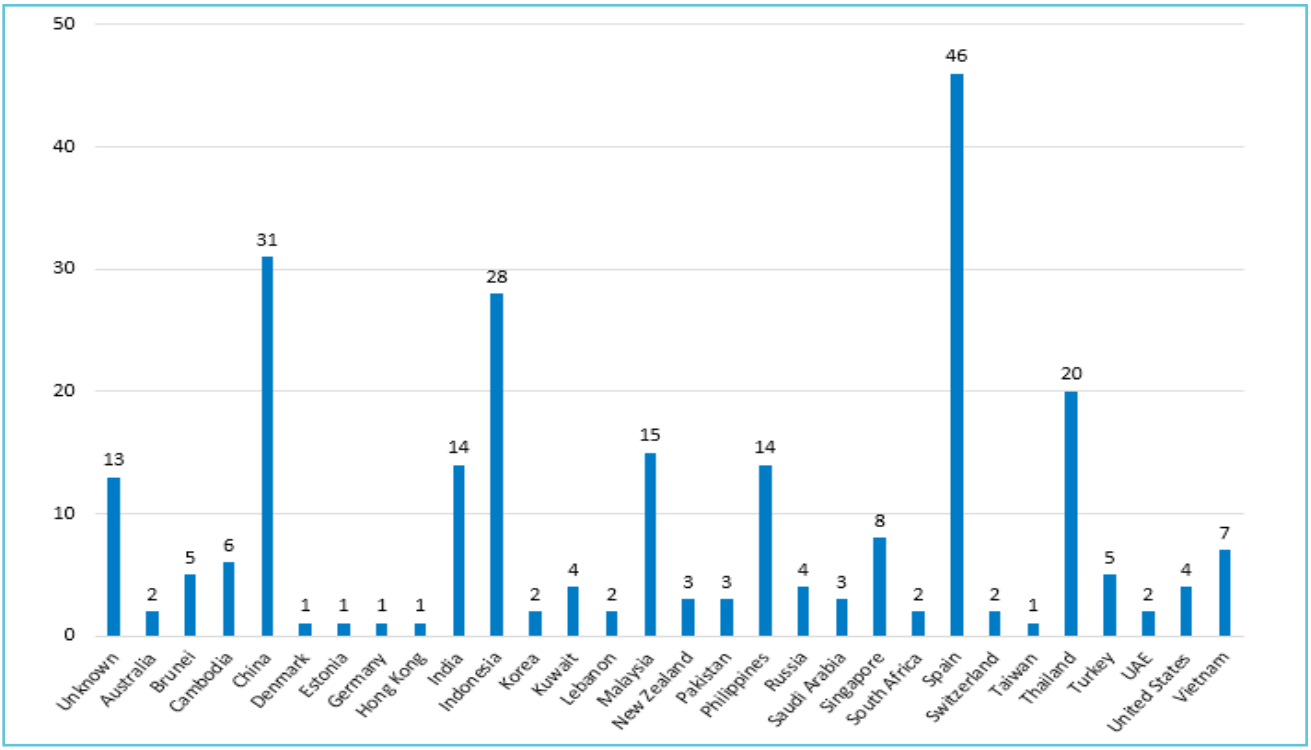
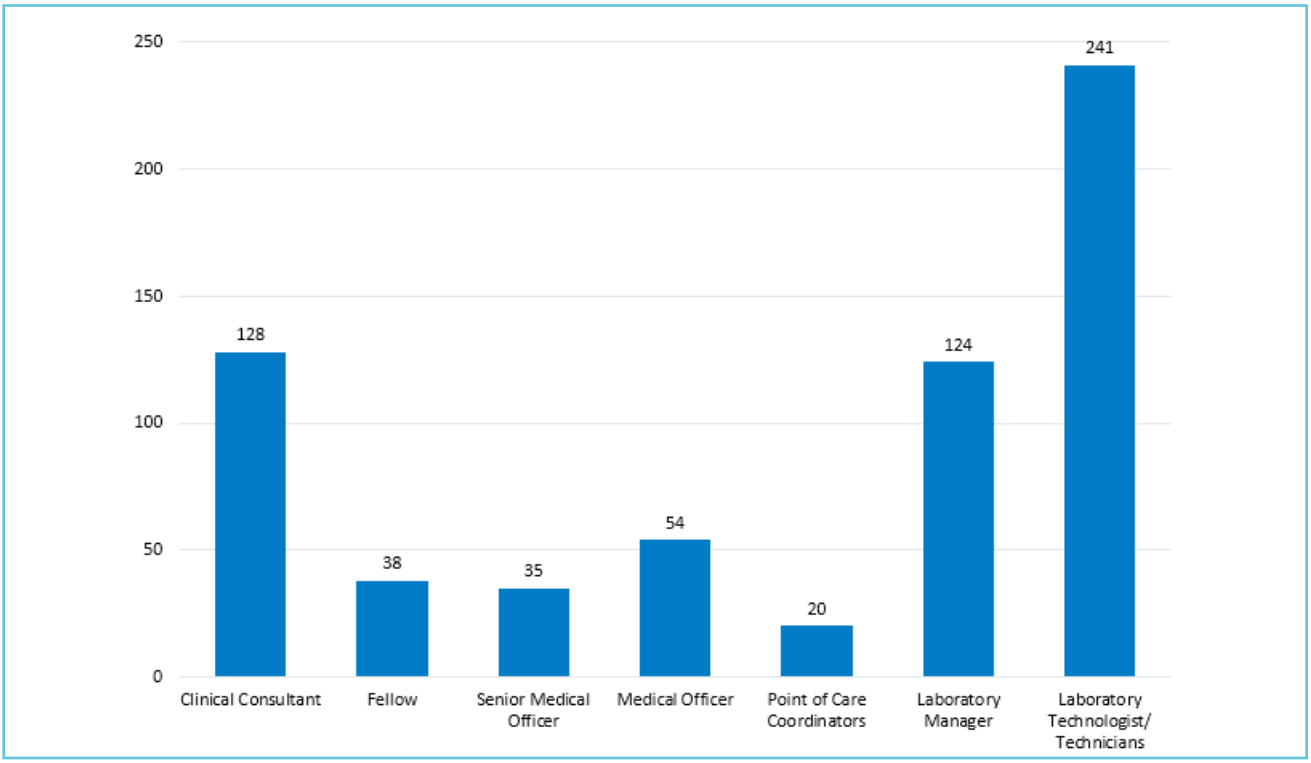


Figure 5C Registrants by job titles



3. Nguyen DB, Gutowski J, Ghiselli M, Cheng T, Bel Hamdounia S, Suryaprasad A, Xu F, Moulton-Meissner H, Hayden T, Forbi JC, Xia GL, Arduino MJ, Patel A, Patel PR. A Large Outbreak of Hepatitis C Virus Infections in a Hemodialysis Clinic. Infect Control Hosp Epidemiol. 2016, 37(2): 125-33.

4. McGoldrick M. Cleaning and Disinfecting Prothrombin Monitoring Equipment. Home Healthc Now. 2016, 34(10): 574.

5. Louie, Richard F BS; Lau, Matthew J BS; Lee, Judith H CLS, MT(ASCP); Tang, Zuping MD; Kost, Gerald J MD, PhD Multicenter Study of the Prevalence of Blood Contamination on Point-of-Care Glucose Meters and Recommendations for Controlling Contamination, Point of Care, 2005, 4(4): 158-163.

6. Khan, Adil I. MSc, PhD Using Glucose Meters in Hospital Environments: Some Challenges and Resolutions for Point-of-Care Testing, Point of Care, 2014, 13(3):97-100.

7. Thompson ND, Perz JF. Eliminating the blood: ongoing outbreaks of hepatitis B virus infection and the need for innovative glucose monitoring technologies. J Diabetes Sci Technol. 2009, 3(2):283-288.

8. Douvin C, Simon D, Zinelabidine H, et al. An outbreak of hepatitis B in an endocrinology unit traced to a capillary-blood-sampling device. N Engl J Med. 1990; 322 (1):57–58.

9. Khan AI: Quality Requirements for Point of Care Testing when Traditional Systems Fail. In: Global Point of Care: Strategies for Disasters, Emergencies, and Public Health Resilience, Editors: GJ Kost & CM Curtis, AACC Press 2015.

10. Khan, A. 2017. Choosing the right point-of-care coordinator. [online] Medical Laboratory Observer. Available at: <https://www.mlo-online.com/continuing-education/article/13009204/choosing-the-right-pointofcare-coordinator> [Accessed 11 April 2021.

11. https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations Accessed: 1/11/2020.

12. Clinical and Laboratory Standards Institute. Laboratory Quality Control Based on Risk Management; Approved Guideline. CLSI document. EP23-A Vol. 31, No. 18, 2011.

13. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

14. Sharma S, Zapatero-Rodríguez J, Estrela P, O'Kennedy R. Point-of-Care Diagnostics in Low Resource Settings: Present Status and Future Role of Microfluidics. Biosensors 2015, 13;5(3):577-601.