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POCT Testing and Importance of Operator Lock-out

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Point Of Care Testing and the Importance of Operator Lock-Out

By

Nuha Fadlalla

A culminating capstone project report submitted to the faculty of Dominican University
of California in partial fulfillment of the requirements for the degree of Master of Science
in Clinical Laboratory Sciences

Dominican University of California

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This capstone project paper, written under the direction of the candidate's thesis advisor and approved by the department chair, has been presented to and accepted by the department of Biological Sciences in partial fulfillment of the requirements for the degree of Masters of Science. The content and research methodologies presented in this work represent the work of the candidate alone.

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Abstract

Point-of-Care Testing (POCT) is usually performed at the patient's bedside by healthcare providers other than laboratory- trained professionals. Rapid growth of POCT is supported by numerous factors which include healthcare provider efficiency, improving diagnostic insight and better patient outcomes. This project study is done to make sure POCT users have adequate training to ensure and enhance the quality and patient safety. The individual performing these tests to be trained properly before he/she is approved to operate the POC devices. One method to ensure POCT operators have met the required training is the lock out approach which will not allow them to perform testing until they have completed the required training.

The more recent POCT devices have built in operator lock-out features. This added feature of lock-out alerts the user of the operational time lag. Non-competent users can be locked out with the help of this software and this will ensure an un-trained user will not perform testing. The operator lock-out minimizes error, ensures patient safety and is an important feature for quality control improvement.

In this study, we conducted surveys with health care providers who perform POCT in two hospitals: University of California at San Francisco (UCSF) and San Francisco General Hospital (SFGH). The result of the study showed operators of the POCT devices were interested in ensuring proper training and competency of the operators. They were interested in having a lock out process and the ability to use an emergency release code during an emergency situation so that the testing can be done in a timely method.

Maintaining a valid competency for all operators through a competency assessment plan and a continuous educational program will ensure un-interrupted services to the needed patients and avoid the use of the lock-out feature. Providing a special code to be used by locked-out operator during emergencies, is an added benefit to the patient care.

The future is promising with this technology, so it is important to have a good system in place. Operator lock-out is a safeguard to the patient care beside it is a compliance and one of the quality improvement tool.

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Abbreviations

POCT	Point Of Care Testing
POC	Point Of Care
CAP	College of American Pathologist t
QC	Quality Control
CLIA	Clinical Laboratory Improvement Amendments
FDA	Food and Drug Administration
QA	Quality Assurance

Situation

A concerning number of medical errors attributed to POCT, non- validated operators. Importance of Operator competency lock-out in critical units (ie, Emergency Rooms and Operating Rooms)

Objective

- Determine the feasibility of enabling operator competency lock-out in critical units.
- Ensure quality test results in POCT environment.
- Compare reality work flows vs. accreditation compliance.

Introduction to POCT

Definition of Point-of-care testing (POCT)

A medical diagnostic testing that occurs near the point of point of care, meaning the time and place of patient care, is defined as POCT also known as bedside testing (1). On the other hand the conventional testing method used to send samples to the main laboratory in which samples were sent off. Laboratory testing also involved a considerable waiting period. This has significantly shortened with the advancement of POCT that has led to obtaining result at the location of care thus allowing the treatment to go on with less delay.

In order to perform tests at the patients' bedside, technological advancement is required. An example of this would be ultrasonography-based tests that involved urine analysis, used to be an expensive matter but with the technological advancement now-a-days portable urine tests are widespread and considered as "simple tests". Another such example would be measuring oxygen saturation in the arteries. In olden days such measurements required a laboratory analysis after performing an intra-arterial needle puncture. Introduction of non-invasive pulse oximetry, has expedited such arterial oxygen saturation measurements and made it quick, simple and also inexpensive. Also recent advancements in the field of immunology-based testing methods has introduced several

rapid diagnostic tests, an example of which would be malaria antigen detection tests, such tests were non-existent before.

POCT has become the recent trend among physicians and health care provider across countries that include the United States, Belgium, Australia, the Netherlands and the United Kingdom. The goal is to perform the tests near the patient thus increasing the likelihood to obtain faster results, immediate and appropriate diagnosis and taking the right decision that is increasing the patient survival rate.

The Future of Point-of-Care Testing

Point-of-care approach is rapidly changing the way patient care is being delivered and managed. The rapidly expanding POCT market is making significant changes to the healthcare system, which is becoming more patient-driven and focused. This field will expand further and evolve our healthcare systems in futures to come so that POCT becomes more and more patient-driven and thus helping the physicians to gather more valuable data required to arrive at the right diagnosis at faster time by providing evidence-based medication to the patients.

It has potential to be used for early detection of cancer (e.g. cervical cancer) and it is expected that POCT will transform the field of infectious disease diagnosis and provide rapid treatment.

It can be utilized as an affordable diagnostic tool in remote, rural areas for infectious disease diagnosis such as HIV, Malaria and TB. In addition, molecular techniques such as polymerase chain reaction (PCR) and lab-on-a-chip system are incorporated into POCT.

Biosensors that can be worn in any part of the body and even development of tiny chips capable of running lab tests.

Establishing global POCT standardization to avoid results and ranges variations.

Developing accessible education materials and sufficient training.

Technological progress resulting in the invention of smaller devices & better gadgets and the availability of Internet across the planet have helped healthcare provider to reach out to patients and offer a much improved treatment.

POCT is being steered to a new era due to government and industry initiatives (13). POCT will find its application in home settings, in our smartphones. These devices will be able to constantly monitor our vital signs and various parameters.

POCT will play a role in the discovery of new tests for detection various types of malignancies and several chronic illnesses.

The fastest growing sector of POCT goes to the infectious disease that renders a speedy diagnosis of infections thus letting a timely treatment, containing the infection and eventually helping to prevent epidemic to take place. The various infectious diseases that can be handled by point-of-care methodology include diseases like influenza, to viral infections and resistant bacterial infections.

It is not possible to completely substitute laboratory testing with point-of-care testing but as the demand for more high quality and efficient healthcare will rise so will POCT play a vital role in this new expanding world of healthcare.

Disadvantage of POCT

Although POC tests have made considerable progress but it will be a grave mistake to assume that such tests can completely replace full range comprehensive tests performed in the laboratories since POC tests have limited range, specificity and also can be error-prone when performed by a non-professional.

The accuracy of performing a point-of-care test depends much on the individual performing the test. Familiarity with performing a certain POC test is extremely important as well as the ability to analyze and interpret the data obtained. It is also expected that the individual performing such a POC-based test be aware of the capability of such tests, which means that the test be only used for its intended purpose and not for measuring something beyond its ability. Also, it must be kept in mind that just like differences in test results are quite common among

different laboratories, so also there might exist variations in test results performed by a same POC test by different individuals at different locations.

It also extremely important to perform follow-up tests after an initial point-of-care test since lot of times POC tests can give false positive or negative results. An example of such a situation would be when in the year 2012 home-based POC HIV tests were approved by the U.S. Food and Drug Administration (FDA) with the intention that the benefit of increased HIV testing outweighed the risks (15). But home-based HIV POC tests have a major drawback, which is these tests can only detect the HIV antibody and not the HIV antigen. When an individual is exposed to HIV, it takes some time for the body to generate these antibodies and if a HIV-based POC is performed during these initial time of exposure then the POC kit can give a false negative result. Hence it is urged by FDA to always do a follow-up test after the initial HIV POC test to re-confirm the result.

Factors driving the POCT Market

The demand for POCT depends on several factors that include a rise in infectious diseases in developing countries, a significant number of individual s within the population being affected by lifestyle-based diseases like diabetes, hypertension and cardiac arrest and technological advancement that has made widespread use of home-based POC devices. There are however other factors that have contributed to this POCT revolution. Such additional factors are as follows:

- Healthcare improvement and patient-focused care
- Technological improvements (faster, user-friendly devices)
- Laboratory staff scarcities
- Increasing elder population and higher chronic disease
- Increasing tendency toward healthcare decentralization
- Long-term savings
- Remote locations with restricted lab services

The POCT devices are meant to be extremely user-friendly and requires a very small amount of sample to deliver result that is easy-to-interpret and at the same time reliable. POCT device manufacturing companies due to the increased demand of such tests are pouring lot of money and effort to make more reliable, faster and easier devices. The POCT market is growing on a world-wide basis and is estimated to grow at a compound annual growth rate (CAGR) of 9.3% between 2013 to 2018, and to reach \$27.5 billion by 2018 (2,4). Devices customized for use by both healthcare professionals and patient self-use include tests for monitoring blood glucose, lipid and electrolyte monitoring, kits detecting biomarkers for cardiac-based diseases, various infectious diseases, tumors, urinalysis, pregnancy and fertility related.

Benefits of POC testing

The following are few of the benefits the POCT technology has the potential to achieve: management of progressively ill patients. The list of different categories of patients and type of application keeps growing under the broad POCT heading and include patients at the advanced stage of a life-threatening disease who are admitted in the hospital emergency rooms or may include patients undergoing surgery or those who are victims of drug overdoses where a quick diagnosis can save life. This technology also has the potential to be used for early detection of cancer (e.g. cervical cancer). One aspect of rapidly growing area of POCT is the diagnosis of infectious disease diagnosis and provide rapid treatment. Such timely treatment will not only save patient lives but also restrict the outbreak of deadly infectious diseases like avian influenza (bird flu), Lyme disease, chikungunya virus and bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA).

Most POCT devices have a software interface via which allows the device to access an Electronic Medical Record (EMR) and share the results of a test with the entire medical team. This is a major benefit of POC testing since such communications reduces turnaround time (TAT) and also helps to reach a consensus decision regarding any particular test result. Such communications has resulted in significantly lower mortality rates among patients (8). POCT has been found to be beneficial to the patient-centered medical home (PCMH) by making tests more readily available to patients, better patient experience and offering more improved care

quality. Since POCT tests are user-friendly and less time consuming, patients seem to be more satisfied (6). This increase in patient satisfaction and engagement has also made it possible to achieve Meaning Use (MU) goals.

Efficiency Advantages

POCT offers several benefits in terms of bringing in efficiency to the healthcare system. These areas include the following: swift decision-making and the order of treatment of patients or casualties, less operating times, quick recovery and hence lower postoperative care requirement, reduction in emergency room time, lesser number of outpatient visits, fewer requirements of hospital beds and well ideal use of professional time. Benefits such as these ultimately result in faster medical decision-making and proper diagnosis, patients able to receive quick treatment. Proper integration & implementation of POCT systems into the healthcare systems result in more accurate outcomes due to quick and efficient clinical data collection, optimal patient engagement and getting better feedback from patients (8). Requirement for smaller sample size immensely benefits new-born babies and also in pediatric where the goal is to minimize use of invasive protocols. Also, patients whose medical condition makes it necessary for frequent testing is immensely benefitted by such POCT technique requiring smaller sample size. POCT eliminates the need for doctors to recapitulate a particular case once test results are back from the laboratory since POCT delivers results almost at the same time when a provider is examining a patient (17).

This rapid processing of result has also made it possible for physicians to provide on-site instructions that improves patient treatment. According to Gary M. Reisfield, M.D., of the Department of Psychiatry at the University of Florida College of Medicine, this rapid real-time POC drug testing has made real-time patient consultation possible and this is a massive improvement compared to the way treatment was offered back in the 1990-2000 decade, which was primarily laboratory-based. Dr. Reisfield points out that discussing face-to-face with patients with result in hand helps the physician to figure out the root cause of problem like patients are able to recall and remember the last time he/she took a certain drug. This helps the doctor the need to re-assign drug dosage requirement for a certain patient. Face-to-face conversation with result in hand has a much higher edge

over the conventional phone-to-phone conversation with patients with result still pending. This allows real-time analysis of results based on the current patient physical and emotional status of a patient (16).

Size and Portability Advantages

Underserved population, rural areas with minimum resources or having few trained personnel and with inadequate infrastructure (17), can be tested by POCT methods due to the fact that POCT is highly portable method and is very flexible that help to meet a wide range of medical requirements.

There are two broad categories into which POCT can be divided based on the level of complexity; these are waived and non-waived testing as shown below. This is in addition to provider-performed microscopy procedures (PPMP).

Waived testing: Under this category comes all the non-critical tests that FDA has approved for use at home. These POCT-based tests employ simple methodology and the results are mostly accurate as the probability to make errors is relatively much less and these tests possess no risk as such or any harm to the patient in case the tests are performed wrongly.

Non-waived Testing: (Also known as) **Moderately Complex testing:** Minimal scientific and technological knowledge is expected from the patient or individual performing this POCT is expected in order to perform this test accurately. These tests also require some basic level of judgment on the behalf of the test performing individual or the patient. **High Complex Testing:** Specialized technical and scientific knowledge is expected from the patient performing this test in order to perform this test accurately. The steps need to be follow with care and precision and close monitoring is recommended. These tests also require high level of judgment and analysis.

Provider-Performed Microscopy Procedures (PPMP): Microscopic examinations performed by a pro. Individuals Responsible for Test Performance a. Inside the hospital only licensed persons (MD, CLS, RN, NP, PA, Nurse Midwife, Respiratory Tech, Neurointerventional Radiology Tech, and Perfusionist) may execute Point of Care

testing. b. Within the Ambulatory practices, Medical Assistants may carry out waived point of care testing in addition to the above personnel categories. 3. Individuals Responsible for Direction/Supervision of Testing Activity: a. Overall direction of waived testing activity is provided by the Clinical Laboratory QA/POCT & Regulatory Compliance Section. The QA/POCT & Regulatory Compliance section and Laboratory Director appoints the Specialists of POC Testing. All POC testing is approved through the POCT Committee. b. The Nurse Manager or Ambulatory practice Manager of each individual area is responsible for the supervision of waived testing on that unit. The actual orientation and skill monitoring may be delegated to a specially trained RN, LVN or MA. 4. Orientation, Specific Training and Competency

Testing: a. All appropriate staff are trained in waived test procedures at time of orientation. b. Staff is assessed for competency on an annual basis. i. Initial orientation and training consists of acquisition of theoretical knowledge concerning the test as demonstrated by a score of 80% or better on the post-test and practical demonstration of technique to an authorized evaluator. ii. Ongoing annual competency assessment will consist of at least two of the following: 1. Performance of a test on a blind specimen 2. Periodic observation of routine work by the supervisor or qualified designee 3. Monitoring of each user's quality control performance 4. Use of a written test specific to the test assessed, attaining a score of 80% or better iii. Authorized evaluators are defined according to test complexity: 1. Waived tests: A specially trained individual competent to perform the test 2. Moderate complexity: A person meeting or exceeding the CLIA 88 requirements for a Technical Supervisor (in general a licensed Clinical Laboratory Scientist) iv. Physician competency: 1. Not required for: visual endpoint tests 2. Required for: device or instrument based tests 3. Required for: Provider Performed Microscopy (PPMP) c. Complete documentation of training and competency validation is maintained. i. Waived and non-waived testing documentation is maintained in the employee's unit based personnel file. ii. PPMP documentation is maintained in the Medical Staff Office (MSO). It is the responsibility of all the providers to complete the Annual PPMP Competency Checklist for each type of PPMP performed and to provide a copy of the form to the Medical Staff Office. 5. Provider on samples from patients in either the inpatient or ambulatory setting.

Test systems that have FDA clearance are included under the Waived tests and these can be performed at homes. It also includes tests that have been approved and verified for waiver under the CLIA-criteria that requires tests to be simple and having low risk of any future consequence in case the results are wrong.

Table 1 List of waived tests done at UCSF

Test	Use of result	Site
Blood glucose monitoring	Definitive	Hospital, Ambulatory practices
Urine dipstick	Screening	Hospital, Ambulatory practices
Fecal occult blood	Screening	Hospital, Ambulatory practices
Gastric occult blood	Screening	Hospital
Hemoglobin	Definitive	Hospital, Ambulatory practices
HemoglobinA1C	Definitive	Ambulatory practices
Urine pregnancy	Definitive	Hospital, Ambulatory practices
pH determination by pH paper/strip	Screening	Hospital, Ambulatory practices
RSV	Definitive	Hospital, Ambulatory practices
Strep A	Definitive	Ambulatory practices
Influenza	Definitive	Hospital, Ambulatory practices
Prothrombin time	Definitive	Ambulatory practices

Lipid analysis	Definitive	Ambulatory practices
Creatinine	Definitive	Hospital, Ambulatory practices
Micro albumin	Screening	Ambulatory practices
HIV	Screening	Hospital

Non waived testing in contrast to waived tests are relatively more complex to perform and individuals performing such tests need to be certified by CLIA and are required to be inspected and must meet the CLIA quality standards as explained in 42 CFR Subparts H, J, K and M.

POCT Competency

Point of Care Competency Challenges.

Users need to be properly trained before using such POCT devices and their competency needs to be evaluated. In addition to this an ongoing support needs to be provided all the time to build-up user confidence for the results generated from these POCT equipment. It is expected that the results of POCT are accurate and be able to be reproduced regardless of the experience and knowledge of the operators. Hence it becomes essential for close monitoring of POCT equipment along with evaluating the operator competency to operate the tests. Measures and instrument features that can minimize common mistake. Professional relationship is the key to effective management of point-of-care testing, and it also depends on the considerable effort by the POCT team in order to facilitate communication with professionals in the healthcare industry interacting on a regular basis that includes clinicians, staff members from the nursing team and other hospital-based professionals using the equipment. An understanding needs to be built-up among all parties which will ultimately result in good working practices eventually benefitting the patient and in obtaining accurate result and diagnosis.

Passwords needs to be protected in order to restrict access and this is one of the major criteria that need to be implemented for any point-of-care equipment. All operators handling POCT devices should have a unique password to access sensitive information and all these individuals should complete proper training of the instrument. Some of the day-to-day methods that establish access control include barcode identifiers and using RIF cards that comes under Biometric identification. It is important to weigh the pros and cons of every system access since each and every system of access control has its advantages and disadvantages and this is important during selection of the correct system to be used in boosting access control. For instance, although after training and competency testing are properly established and completed barcode identifiers are generated but they are still vulnerable to be mishandled when colleagues and coworker share such accesses among each other. Biometric identification which is based on RIF card is however not open to be duplicated and is under the control of hospital management systems. Such biometric applications can be quite expensive (17,18).

Users operating such POCT devices become aware that they don't have the liberty to make poor performance since their actions are constantly being monitored and such actions are not tolerated. Patient risk to mismanagement can be reduced significantly by highlighting barcode sharing at early stages to untrained staff. Frequency of various tasks can eventually make the operators competent and only after such training the user should be granted for POC instruments, failing to do this will result in diminishing competency over time. IT solutions can enable automatic user lockout once the user has finished operating the device after a given period thus this approach will be extremely helpful in alerting issue of time lag between training and use of device. Retraining can be offered to the individual in question by the POC team. An invaluable tool when evaluating competency is the frequency of monitoring and the issue of automatic reminders by the point-of-care team to operators to access online refresher training within a specified time frame would make it very useful (17,18).

At Surrey Pathology Services it currently is a challenge to monitor the frequency of system use by individuals and they are waiting for IT systems to provide a quick and easy solution to this problem. Thus until that happens it is important to settle for identifying issues retrospectively. As an indicator for retaining the importance of task frequency depend on the assay complexity that is in question. For example, urine dipsticks are simple, and usually have instructions written on the devices and several healthcare professionals might have carried out this test on several occasions during their career hence online training provided annually and competency evidence should be sufficient to guarantee optimal performance. Simplicity is the main factor since the POC devices will be eventually be used by non-professionals hence can result in misuse if not properly used. It is recommended to have not more than 6 steps for operating such devices when using a point-of-care instrument and this has been kept in mind by many manufacturers while designing such POC-based instruments making them user-friendly with wall charts or sometime even provided short video-based assistance on how to operate the device.

A lot of times the manufacturers fail to mention the various contradictions, shortcomings of the device and explanations in case certain error messages appear; and this reflects as a negative point on the behalf of the manufacture especially when such information holds a critical importance to the clinical taking care of the patient. The "decision maker" should be fully be aware of the device limitation and based on that will be able to

request for a confirmation of the result from the laboratory especially in situations when the result obtained does not match with the signs and symptoms shown by the patient (18).

By implementing an error logging system in the device that records any failure at different stages of the process, error tracking can be improved.

A point-of-care device should be able to collect information from the moment it detects an user has logged in and the moment the user makes a mistake the device should be able to detect it and be able to stop the test and offer adequate information and support to the user so that the user is able to successfully be able to conduct the procedure and get correct result. This is keep an accurate trail that will be very helpful during running an audit at the same time be able to guide the operator and this would have an educational value for those untrained users. When errors are made it is necessary to hold back the result and this feature should be enabled in all POC devices to reduce mismanagement (18).

IT systems should provide help to POC coordinators so that they are able to monitor and train thousands of healthcare professionals efficiently. Point-of-care testing devices should be able to connect to a software system in order to facilitate operator training to record operator identifiers, errors and task frequencies and this should bring every aspect of competency management together into one cohesive database that could then feed into the electronic staff record. The user competency issue of the can be determined based on the error rate frequency and it can also tell us whether this mistake was just a one-time incident (18).

Training and Competency Assessment

Both CLIA and CAP report mix-up between training requirements and ongoing fitness assessments. CAP deficiencies those that involve POCT, 20% are related to competency testing (19). Initial training is required previous to POC device operation for CLIA and accrediting agencies (CAP and CRI), and this is then followed by documented competency assessments at specific intervals. Among agencies and between waived and non-waived testing details of specific requirements vary. Annual competency testing is required by CAP and CRI for

waived testing. On the other hand annual only competency assessments for personnel performing non-waived testing is required by CLIA (13).

According to CLIA, elements of competency assessment include but are not limited to: 1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing, 2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results, 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records, 4. Direct observation of performance of instrument maintenance and function checks, 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6. Evaluation of problem-solving skills (13).

CLIA recommends the following measures to be taken in case satisfactory performance is not met in order to guarantee that staff is re-trained and is ready to be operate POC testing equipment: 1. Review of proficiency testing procedures with laboratory Medical Director or designee, 2. Review of test procedures with Laboratory Medical Director or designee, 3. Retraining of procedures with Laboratory Medical Director or designee, 4. Performance, reviewing, and/or retraining of other procedural steps as determined necessary by Laboratory Medical Director (13).

Analytical Quality and Regulatory Aspects

When it comes to POC testing inconsistency of results from different analyzers and testing devices is of a concern. There have been instances of differences between POCT obtained results from those derived from central laboratories. Since POCT does not use standard methods hence it may not be possible to compare variant methodologies. POCT and core lab methods differences can occur due to variations in specimen types (e.g., serum, plasma, or whole blood). In addition to this, FDA might not have approved several POCT kits and devices whereas similar tests run in the centralized laboratories have been approved by FDA. Also the fact that a test has been labeled as waived does not ensure its proper usage and reliability.

Just because a waived test is deceptively simple to perform there are many ways that staff can unintentionally generate an incorrect result when performing waived testing.

The laboratory should take primary responsibility although the POCT is performed by a non-professional individual. Vital to best-test performance and proper regulatory compliance are factors such as specimen acquisition and labeling, documentation, QC, proficiency testing, infection control, etc.

The top three CLIA deficiencies for certificate-of-waiver labs are listed in figure 4 (14). More than 55 standards are included in CAP and these directly apply to POCT, and in the common checklist another 75 are present, and the number of lab generated checklist are more than 300 in count and all these are relating to POCT. For each of the following categories CAP has POCT standards: Quality management, results reporting, instruments and equipment, personnel, quality control, instrument calibration, safety, and provider performed testing (19).

An increasingly large number of waived laboratories could contribute to errors and patient harm due to the lack of oversight and requirements for personnel qualifications and training. 10 criteria especially recommended for waived testing are added by COLA Resources, Inc. (CRI). The requirements to include competency testing for staff performing testing at all levels of complexity, and proficiency testing for waived tests have been updated in CRI's January 2015 accreditation manual (20, 21).

The issue of "off-label" testing to the forefront has been brought by the use of blood glucose meters. "Off-label" testing are tests that are used outside the FDA's approved, intended parameters, and outside of what is indicated by the manufacturer.

Current standards are drastically changed based on the new proposed guidance from the FDA on hospital use of glucose meters by classifying all glucose meters coming onto the market as CLIA non-waived compared to the previously the same tests being waived. In order for operators to perform the tests, plus additional requirements in proficiency testing, training, quality assurance, and other areas an higher education level for operators is required (13).

Data Management & EHR Connectivity

In POC testing absence of electronic capture of results is a challenge since it means accessibility becomes a challenge and just because accessibility is paramount in POCT this is a concern. Integrating POCT results in the EHR can add another level of complexity although the benefits of having POCT results in the EHR outweigh the concerns. A computer interface or middleware needs to be required in order to connect POCT devices to an HER. Via a proprietary data manager into the LIS and then into the HER some POCT devices must pass results. Correct display of results in the EHR has to be verified which are applicable to any test tests. It is also important to monitor IT staff who might not understand POCT and therefore would try to include all methods into one general test display (e.g. glucose). Based on methodology it is important to keep results separated since for those where analyzers may give different results for the same sample and involve different reference ranges (22).

Costs & Billing

For introduction of any new product in all areas of healthcare, it is important to demonstrate the economic benefits and enhanced patient outcomes. Due to their faster turnaround time (TAT) and consumable costs, most often POC tests are associated with higher costs per test. It is hard to achieve patient satisfaction to justify a faster TAT that is more expensive. Confusion about proper coding in terms of billing can emerge by having more than one methodology and CPT code for the same test. This can potentially contribute to billing errors.

Reimbursement of each test may not be possible for POCT devices that test many tests on one cartridge or cassette. Manufactures are working on making changes so that reimbursement can be achieved (3). Cost of POCT can be offset in appropriate situations against the greater savings in other areas (15). Finances might play a major role for reconsideration of the location in which testing is most effective, which can be either in a laboratory or near a patient bedside.

POCT Operator lock-out in critical units (Emergency room and Operating room) Install

to prevent medical errors, improve user performance, and enhance the quality and patient safety.

Definition of POCT Operator lock-out

ID deactivation of POCT operator who has not completely fulfilled the required training

and competencies (i.e only trained and competent operator are allowed to perform specific tasks aligned with their job functions).

I created surveys and distributed them within the UCSF Parnassus, Mission Bay, Mount Zion and San Francisco General (SFGH) hospitals.

Objective and goals of this survey:

1. Determine if the operators understand the importance of completing competency for POCT.
2. Assess the operator's knowledge about regulation and compliance standards.
3. Gain an understanding of operators opinions about operator lock-out in critical versus routine situations.

Method

Survey

Q1-What is your current job title?

- A. Physician.
- B. Physician assistant.
- C. Nurse.
- D. Nurse practitioner.
- E. Other.

Q2-Please grade your response to the following statement:

Completing competency training is important for patient care.

- A. Strongly agree.
- B. Somewhat agree.
- C. Neither agree nor disagree.
- D. Somewhat disagree.
- E. Strongly disagree.

Q3-Please grade your response to the following statement:

Completing competency assessment increases the operator's ability to obtain valid test results.

- A. Strongly agree.
- B. Somewhat agree.
- C. Neither agree nor disagree.
- D. Somewhat disagree.
- E. Strongly disagree.

Q4-Please grade your response to the following statement:

Only operators who have completed competency assessment should conduct testing.

- A. Strongly agree.
- B. Somewhat agree.
- C. Neither agree nor disagree.
- D. Somewhat disagree.
- E. Strongly disagree.

Q5-Please grade your response to the following statement:

Completion of competency assessment increases operator testing efficiency.

- A. Strongly agree.
- B. Somewhat agree.
- C. Neither agree nor disagree.
- D. Somewhat disagree.
- E. Strongly disagree.

Q6-In a critical situation would you perform patient testing if your competency expired?

- A. Yes.
- B. No.
- C. Maybe.

Q7-How would you rate your knowledge about regulation and compliance standards?

- A. Above average.
- B. Average.
- C. Below average.

Q8-Which of the following are a part of competency assessment? Check all that apply

- A. Assessment of problem solving skills.
- B. Review of QC and reporting test result
- C. Inventory.
- D. Direct observation Of QC and Sample handling.
- E. Preventive Maintenance.
- F. Receiving of delivered reagent.

Q9-Please grade your response to the following statement:

Implementation of operator lock-out will help reduce error to ensure patient safety.

- A. Strongly agree.
- B. Somewhat agree.
- C. Neither agree nor disagree.
- D. Somewhat disagree.
- E. Strongly disagree.

Q10-Please grade your response to the following statement:

Lock-out exception should be made during emergencies by providing an emergency code.

- A. Strongly agree.
- B. Somewhat agree.
- C. Neither agree nor disagree.
- D. Somewhat disagree.
- E. Strongly disagree.

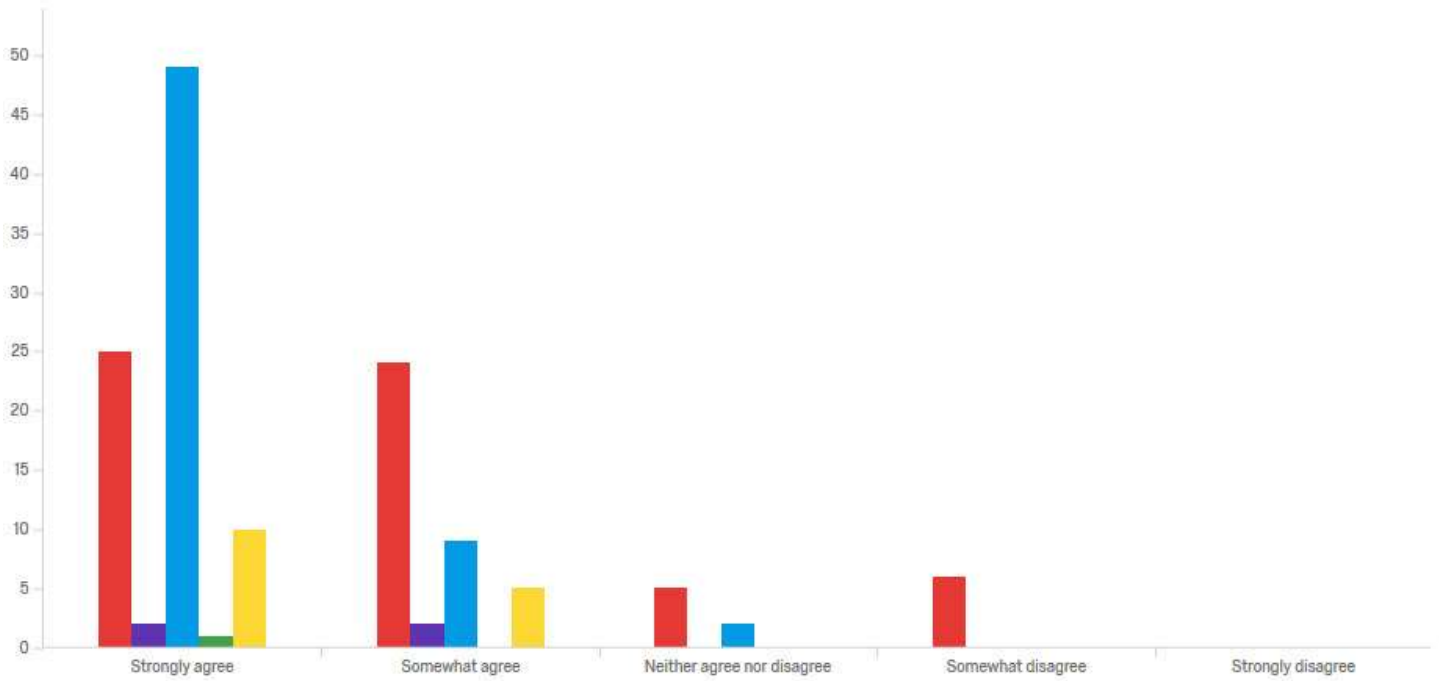
Q11-Please grade your response to the following statement:

Operator lock-out feature is an important element for quality control improvement.

- A. Strongly agree.
- B. Somewhat agree.
- C. Neither agree nor disagree.
- D. Somewhat disagree.
- E. Strongly disagree.

Results

Figure 1 Results of Q1 - What is your current job title?



#	Field	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
1	Physician	41.67% 25	40.00% 24	8.33% 5	10.00% 6	0.00% 0	60
2	Physician Assistant	50.00% 2	50.00% 2	0.00% 0	0.00% 0	0.00% 0	4
3	Nurse	81.67% 49	15.00% 9	3.33% 2	0.00% 0	0.00% 0	60
4	Nurse practitioner	100.00% 1	0.00% 0	0.00% 0	0.00% 0	0.00% 0	1
5	Other	66.67% 10	33.33% 5	0.00% 0	0.00% 0	0.00% 0	15

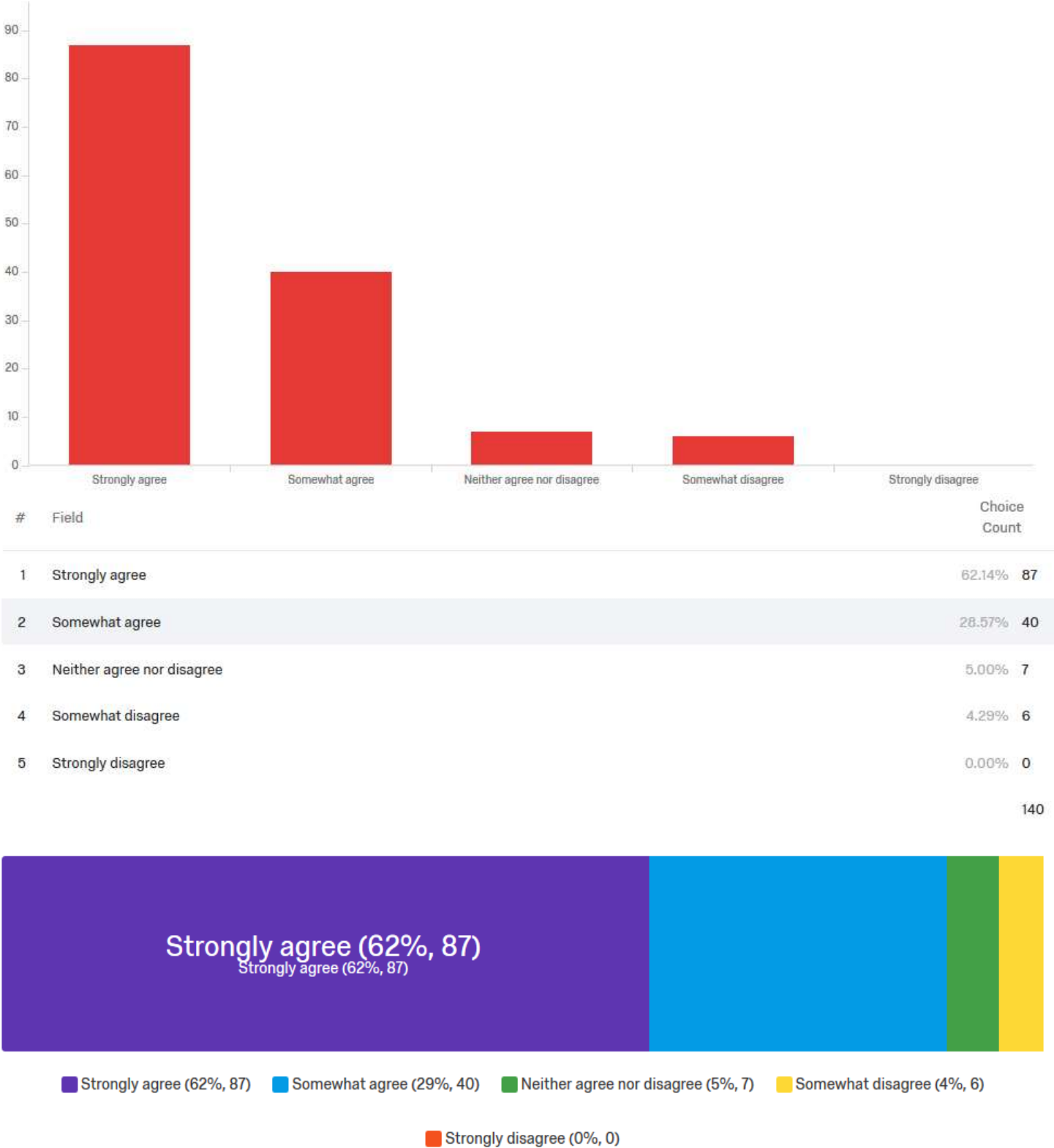
Showing Rows: 1 - 5 Of 5



■ Physician (43%, 61) ■ Physician Assistant (3%, 4) ■ Nurse (43%, 60) ■ Nurse practitioner (1%, 1) ■ Other (11%, 15)

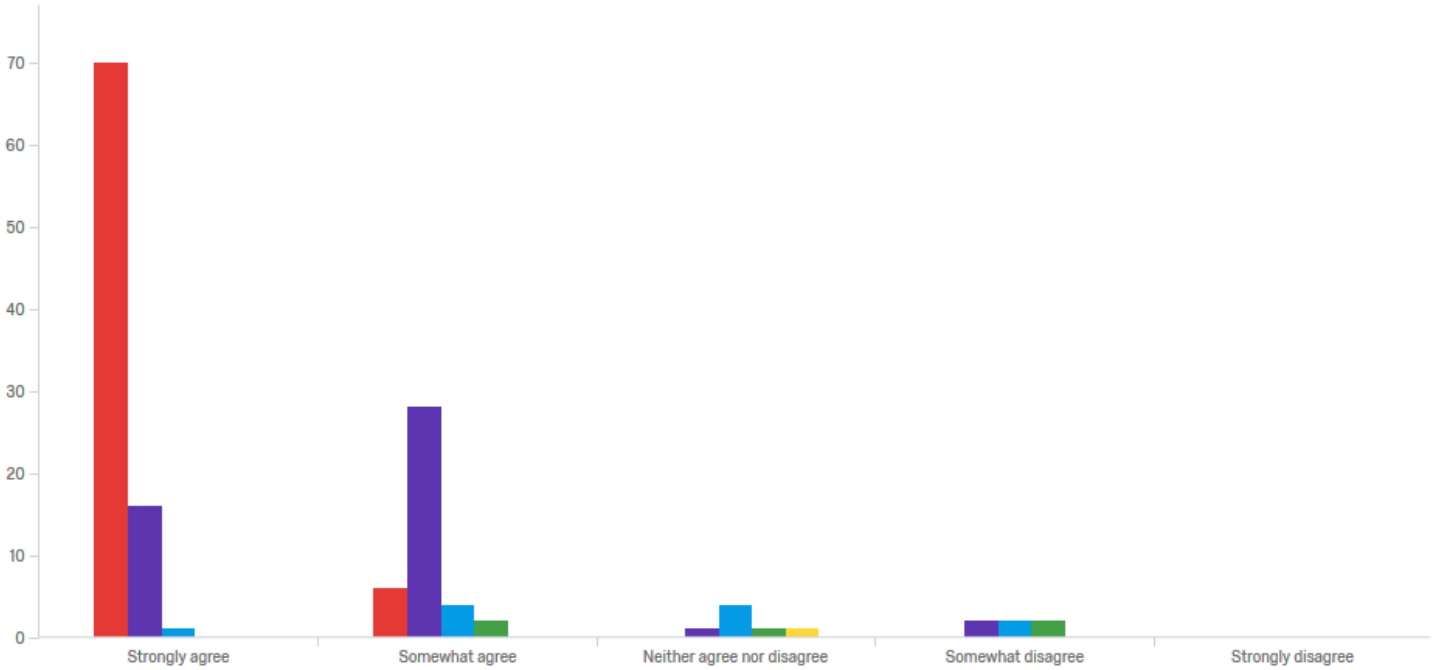
A sample group of 140 health care professionals other than laboratory-trained professionals in California (UCSF and SFGH) were questioned regarding their profession in the hospital. The graph above shows the result of this survey.

Figure 2 Results of Q2 - Please grade your response to the following statement: Completing competency training is important for patient care



POCT is used in patient care by staff that are not trained in the laboratory when rapid results are required and many believe that completion of training would make their role more efficient.

Figure 3 Results for Q3 - Please grade your response to the following statement: Completing competency assessment increases the operator's ability to obtain valid test results



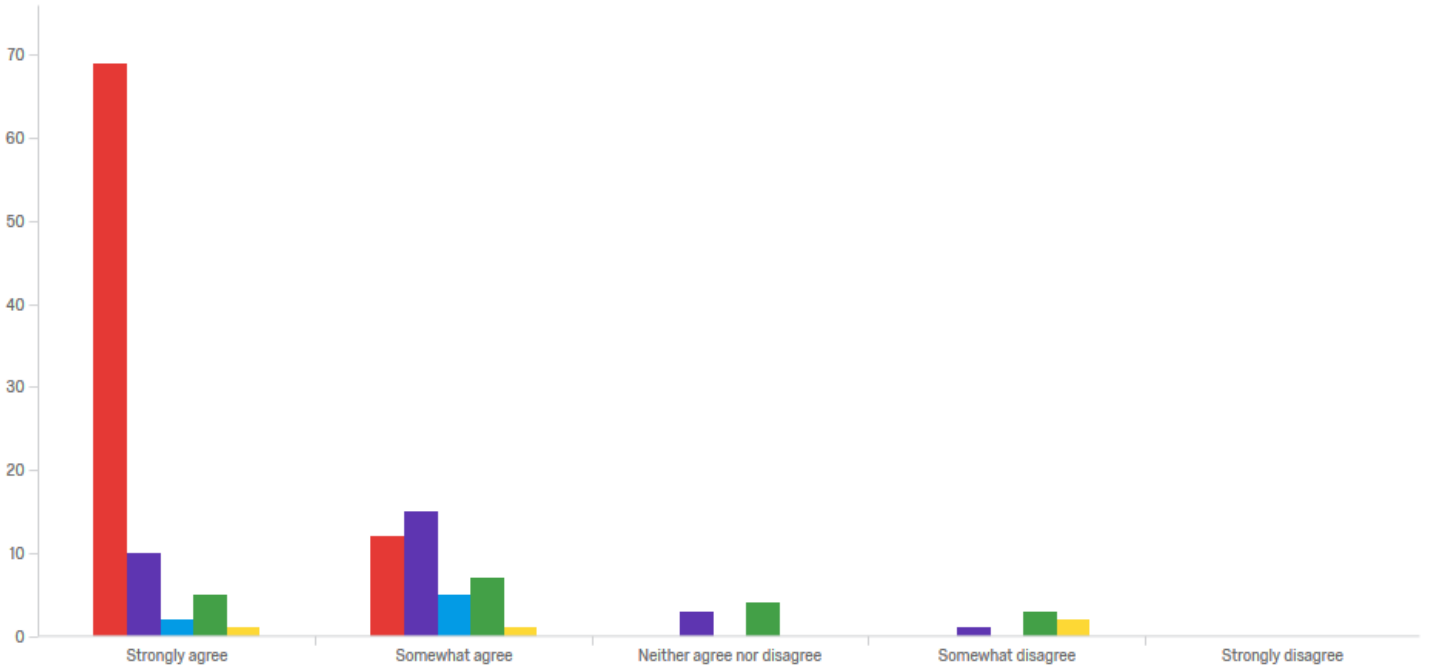
#	Field	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
1	Strongly agree	92.11% 70	7.89% 6	0.00% 0	0.00% 0	0.00% 0	76
2	Somewhat agree	34.04% 16	59.57% 28	2.13% 1	4.26% 2	0.00% 0	47
3	Neither agree nor disagree	9.09% 1	36.36% 4	36.36% 4	18.18% 2	0.00% 0	11
4	Somewhat disagree	0.00% 0	40.00% 2	20.00% 1	40.00% 2	0.00% 0	5
5	Strongly disagree	0.00% 0	0.00% 0	100.00% 1	0.00% 0	0.00% 0	1



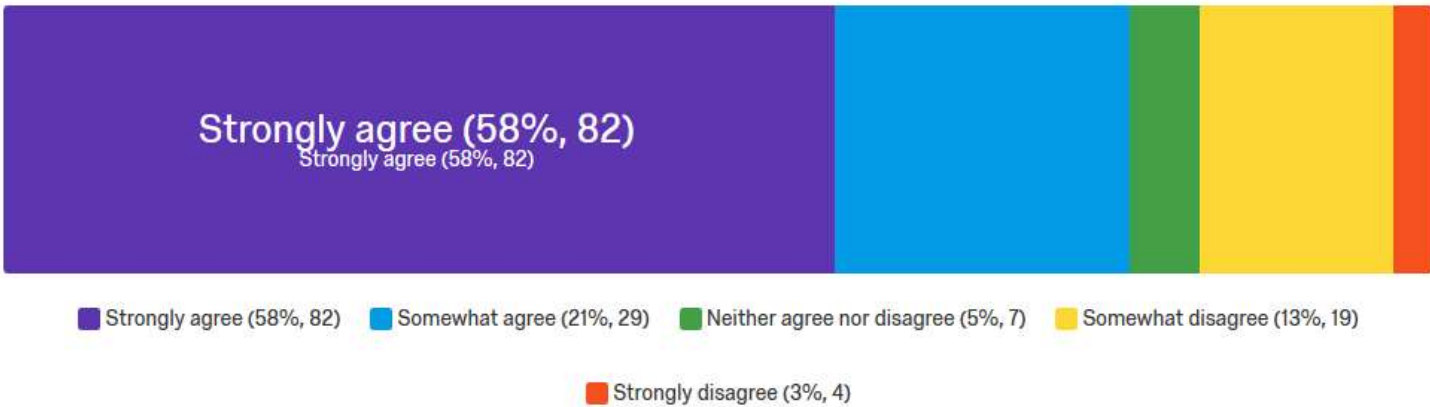
■ Strongly agree (55%, 77)
 ■ Somewhat agree (33%, 47)
 ■ Neither agree nor disagree (8%, 11)
 ■ Somewhat disagree (4%, 5)
 ■ Strongly disagree (1%, 1)

By focusing on the patient, most agree that it creates a higher chance of receiving valid test results.

Figure 4 Results for Q4 - Please grade your response to the following statement: Only operators who have completed competency assessment should conduct testing

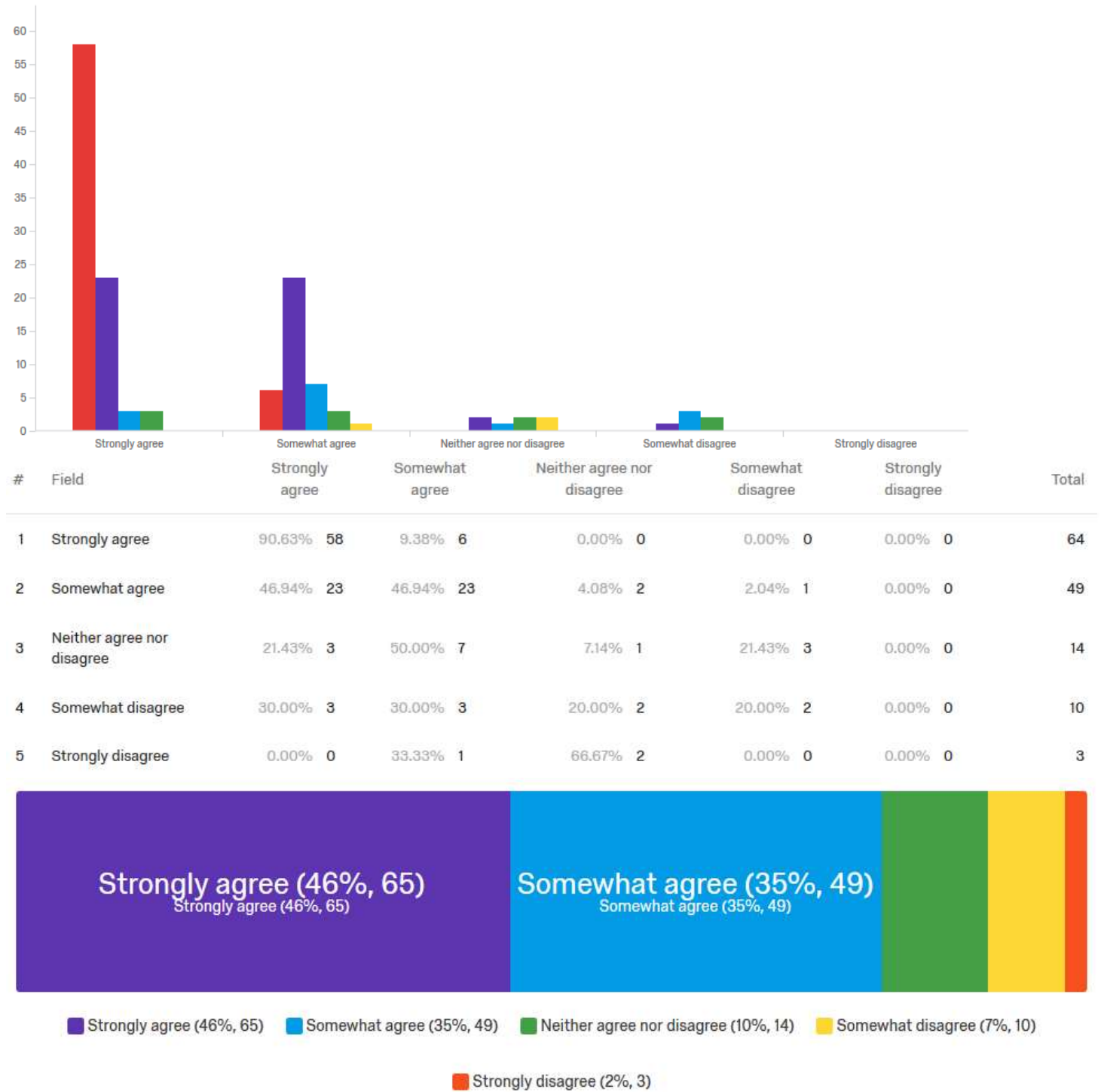


#	Field	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
1	Strongly agree	85.19% 69	14.81% 12	0.00% 0	0.00% 0	0.00% 0	81
2	Somewhat agree	34.48% 10	51.72% 15	10.34% 3	3.45% 1	0.00% 0	29
3	Neither agree nor disagree	28.57% 2	71.43% 5	0.00% 0	0.00% 0	0.00% 0	7
4	Somewhat disagree	26.32% 5	36.84% 7	21.05% 4	15.79% 3	0.00% 0	19
5	Strongly disagree	25.00% 1	25.00% 1	0.00% 0	50.00% 2	0.00% 0	4



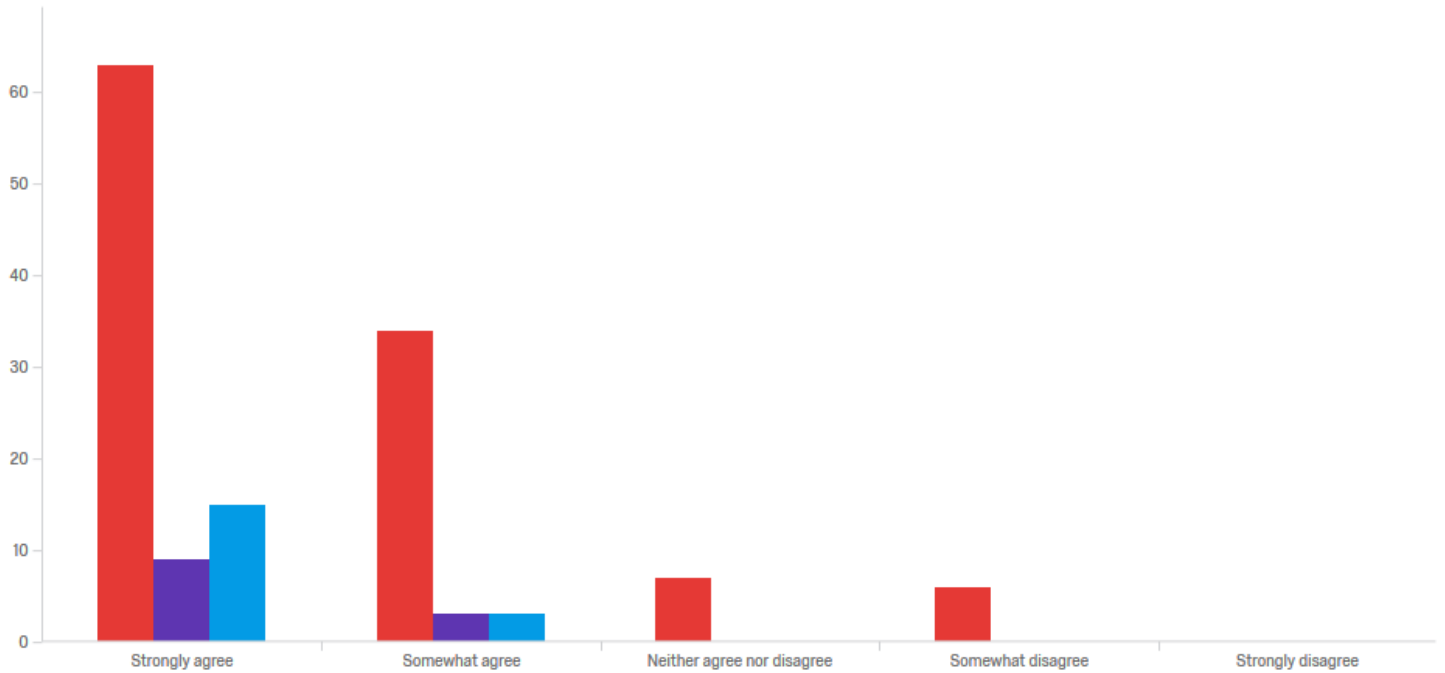
Over half of the professionals from the survey acknowledge the importance of completing competency to be able to conduct POCT. Healthcare providers must follow the manufacturer’s instructions.

Figure 5 Results for Q5 - Please grade your response to the following statement: Completion of competency assessment increases operator testing efficiency

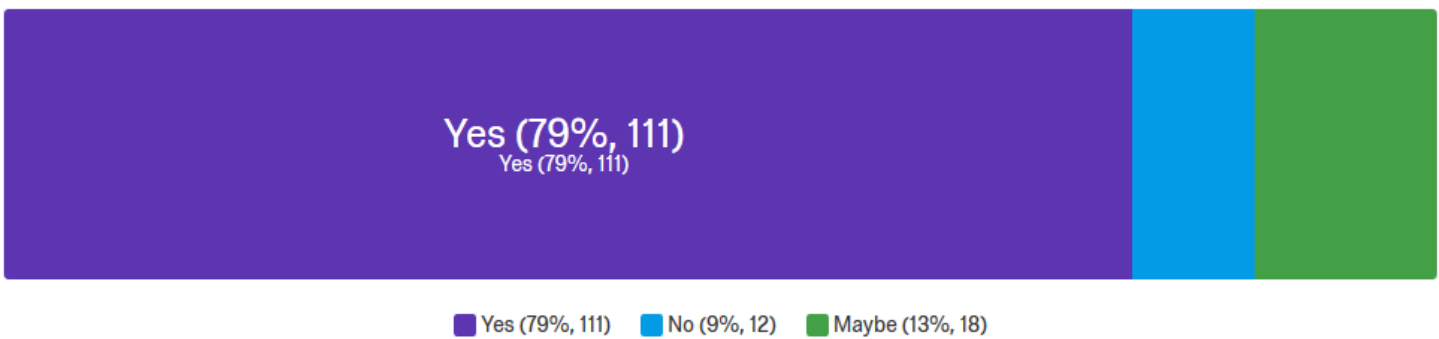


Over 80% of the group agrees that training prevents delay of testing.

Figure 6 Results for Q6 - In a critical situation would you perform patient testing if your competency expired?

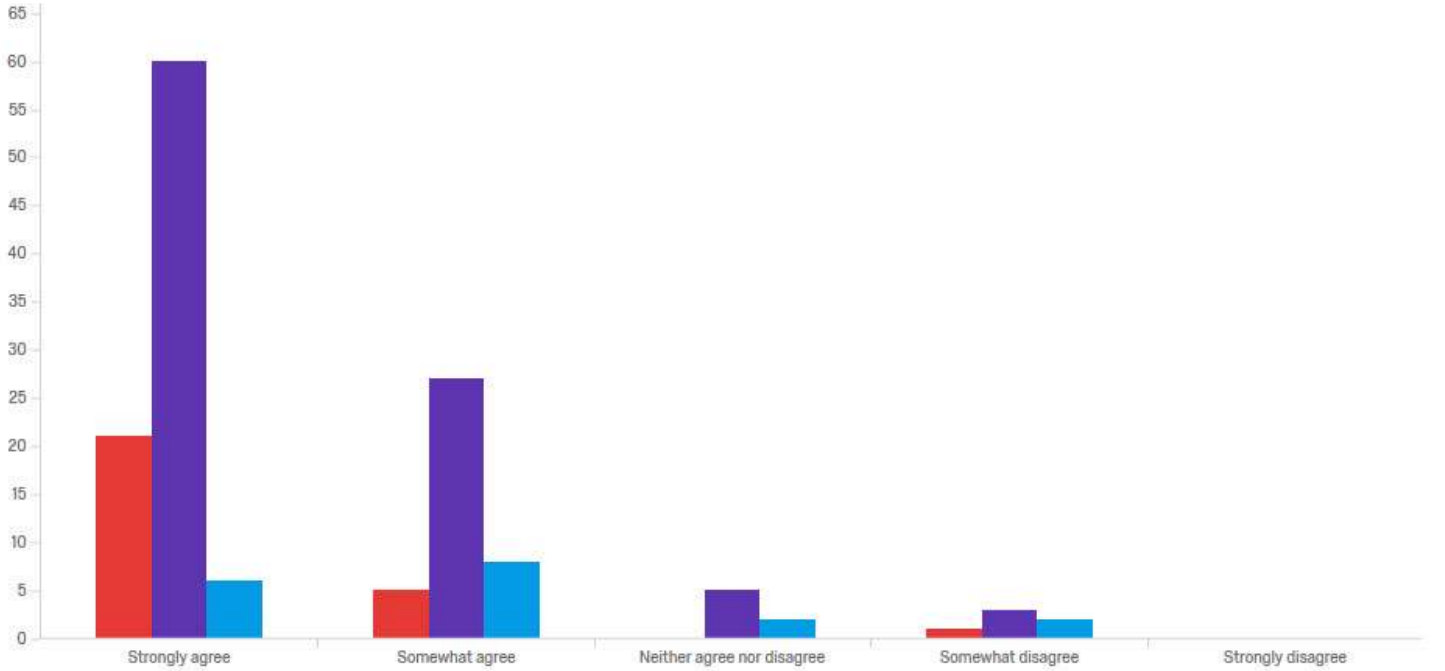


#	Field	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
1	Yes	57.27% 63	30.91% 34	6.36% 7	5.45% 6	0.00% 0	110
2	No	75.00% 9	25.00% 3	0.00% 0	0.00% 0	0.00% 0	12
3	Maybe	83.33% 15	16.67% 3	0.00% 0	0.00% 0	0.00% 0	18

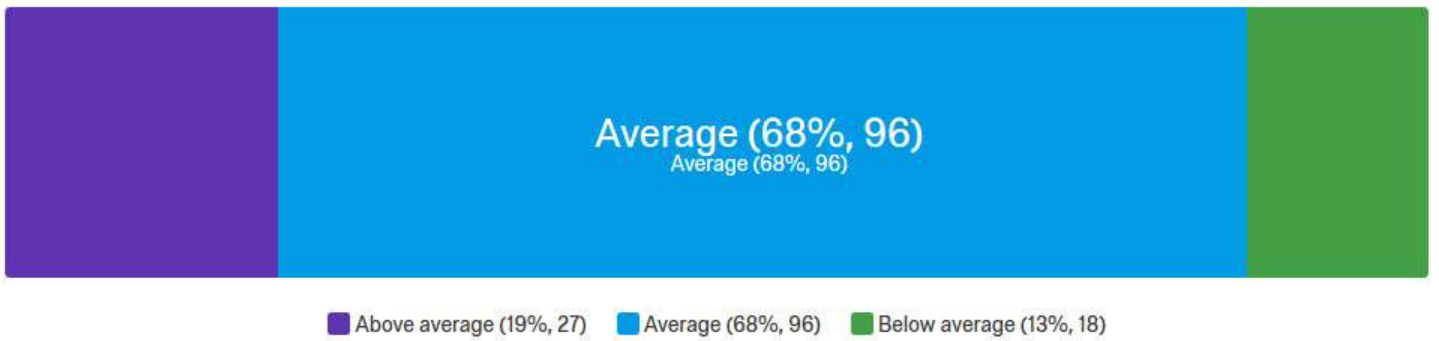


Ideally if someone’s competency expires he/she should not be allowed to perform POCT test. Many are aware of how time can change the fate of a patient and would take a risk to make sure the patient lives.

Figure 7 Results for Q7 - How would you rate your knowledge about regulation and compliance standards?

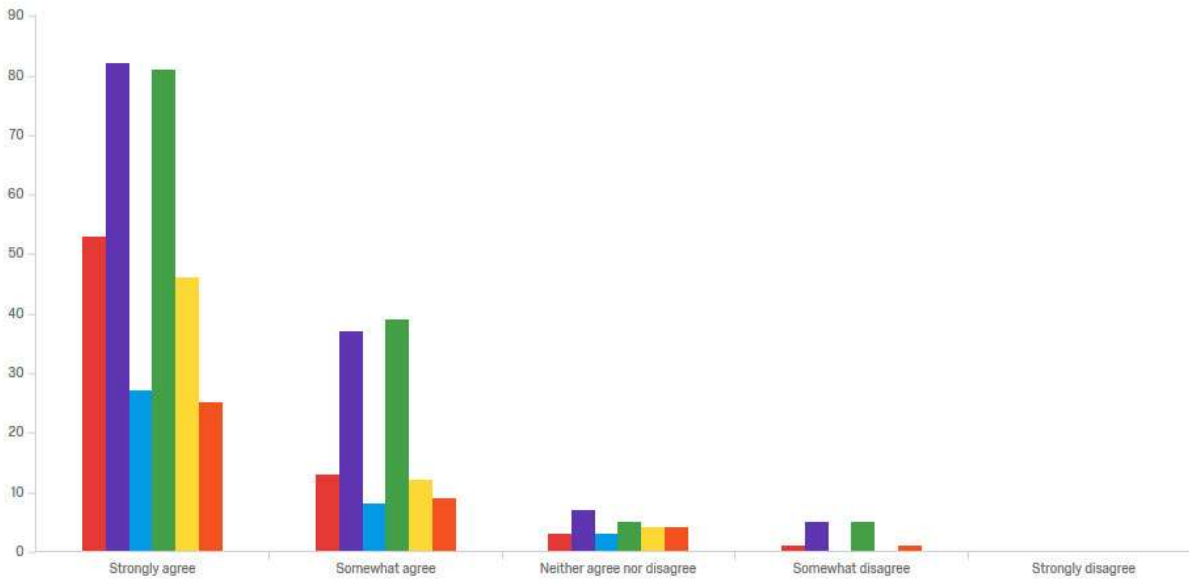


#	Field	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
1	Above average	24.14% 21	12.50% 5	0.00% 0	16.67% 1	0.00% 0
2	Average	68.97% 60	67.50% 27	71.43% 5	50.00% 3	0.00% 0
3	Below average	6.90% 6	20.00% 8	28.57% 2	33.33% 2	0.00% 0
		87	40	7	6	0

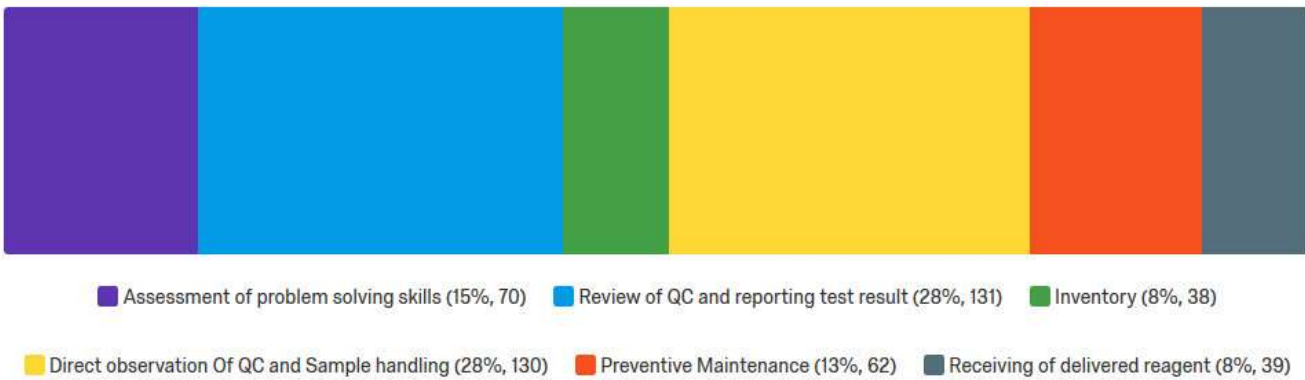


.The graph above shows that most people have an average knowledge regarding regulation and compliance standards.

Figure 8 Results for Q8 - Which of the following are a part of competency assessment ? Check all that apply

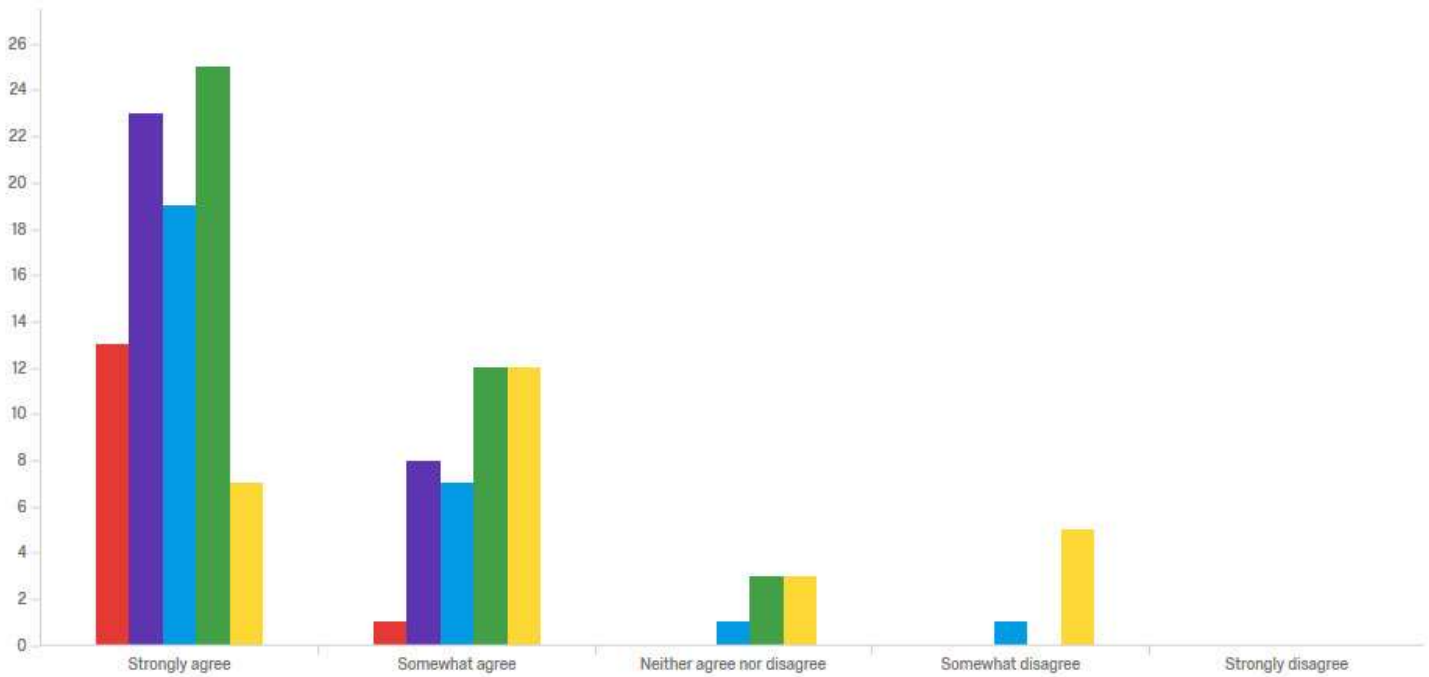


#	Field	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
1	Assessment of problem solving skills	75.71% 53	18.57% 13	4.29% 3	1.43% 1	0.00% 0	70
2	Review of QC and reporting test result	62.60% 82	28.24% 37	5.34% 7	3.82% 5	0.00% 0	131
3	Inventory	71.05% 27	21.05% 8	7.89% 3	0.00% 0	0.00% 0	38
4	Direct observation Of QC and Sample handling	62.31% 81	30.00% 39	3.85% 5	3.85% 5	0.00% 0	130
5	Preventive Maintenance	74.19% 46	19.35% 12	6.45% 4	0.00% 0	0.00% 0	62
6	Receiving of delivered reagent	64.10% 25	23.08% 9	10.26% 4	2.56% 1	0.00% 0	39

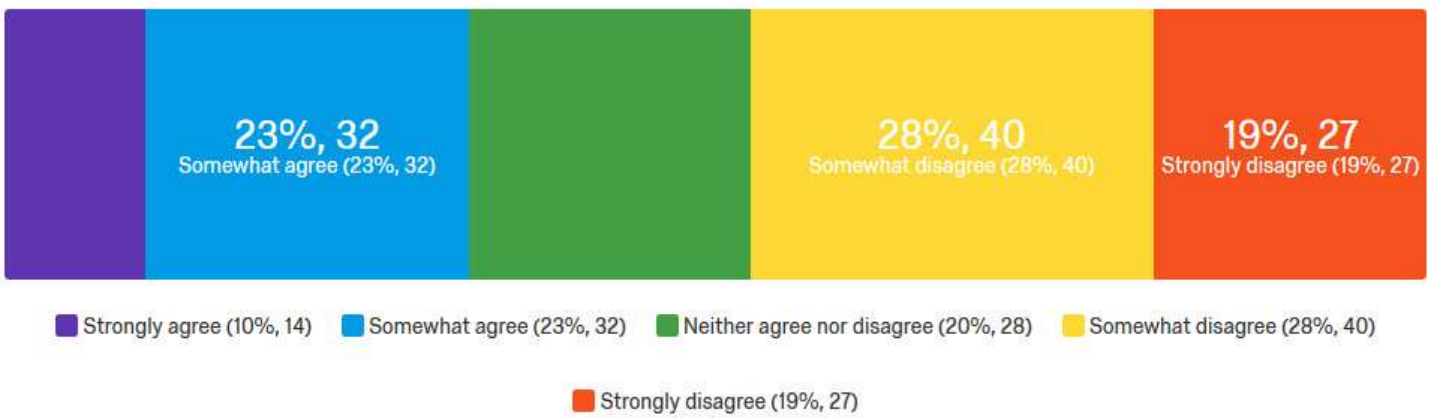


The above graph shows the response of the POCT staff regarding their knowledge about regulation and compliance.

Figure 9 Results for Q9 - Please grade your response to the following statement: Implementation of operator lock-out will help reduce error to ensure patient safety.

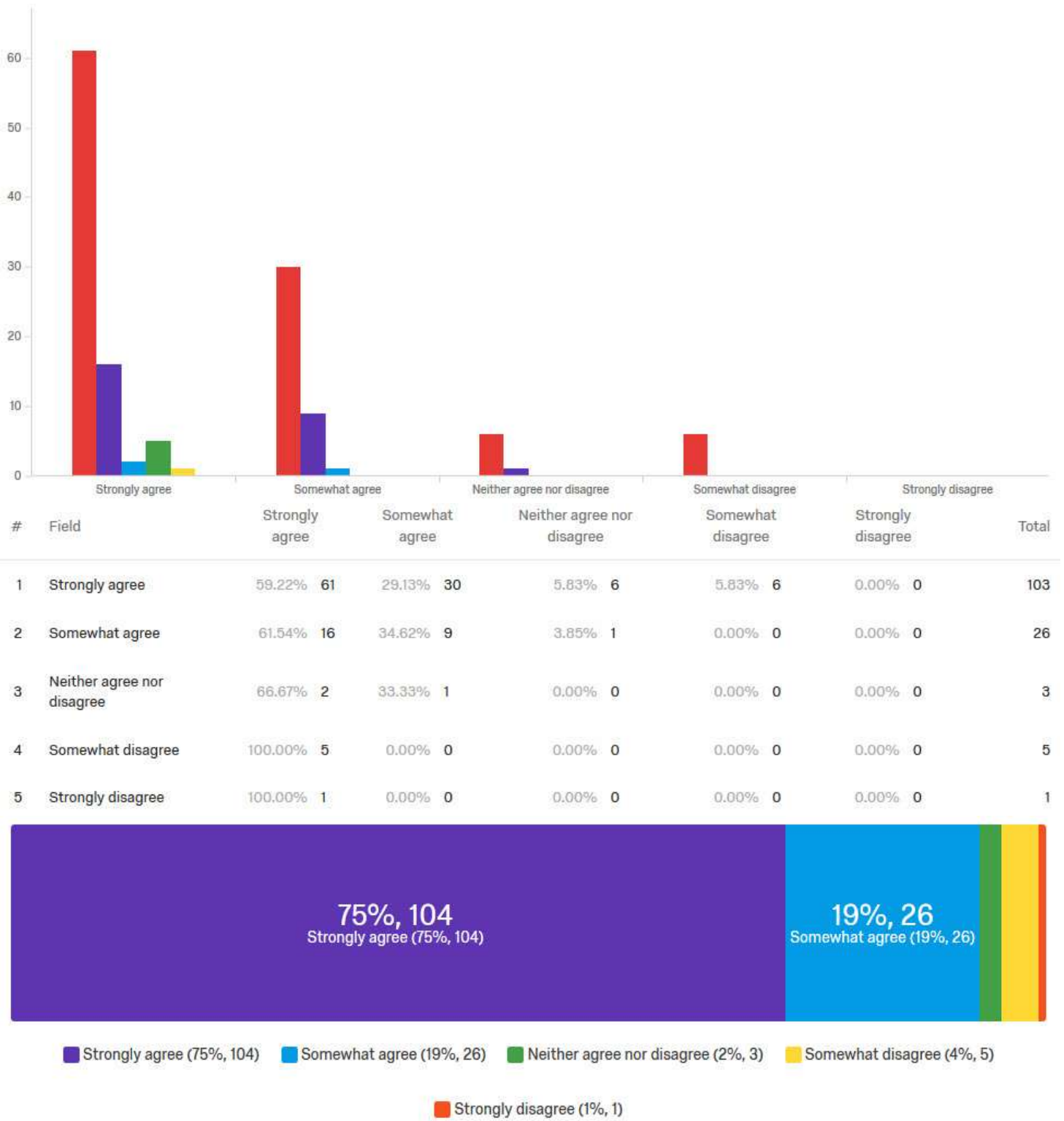


#	Field	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
1	Strongly agree	92.86% 13	7.14% 1	0.00% 0	0.00% 0	0.00% 0	14
2	Somewhat agree	74.19% 23	25.81% 8	0.00% 0	0.00% 0	0.00% 0	31
3	Neither agree nor disagree	67.86% 19	25.00% 7	3.57% 1	3.57% 1	0.00% 0	28
4	Somewhat disagree	62.50% 25	30.00% 12	7.50% 3	0.00% 0	0.00% 0	40
5	Strongly disagree	25.93% 7	44.44% 12	11.11% 3	18.52% 5	0.00% 0	27



Many believe that external factors that are not in the control of the staff do not improve patient safety. The graph shows that most people are not supporting the implementation of operator lock-out as a patient safety feature and improve patient safety. The graph shows that most people are not supporting the implementation of operator lock-out as a patient safety feature.

Figure 10 Results for Q10 - Please grade your response to the following statement: Lock-out exception should be made during emergencies by providing an emergency code.



Most agree that during emergencies codes should be provided to disable lock-out.

Figure 11 Results for Q11 - Please grade your response to the following statement: Operator lock-out feature is an important element for quality control improvement.



The graph showing that operator lock-out is not a very popular feature since very few strongly agree about the positive effect in quality control offered by the operator lock-out.

Figure 12 Completion of competency increases operator testing efficiency and gives valid result

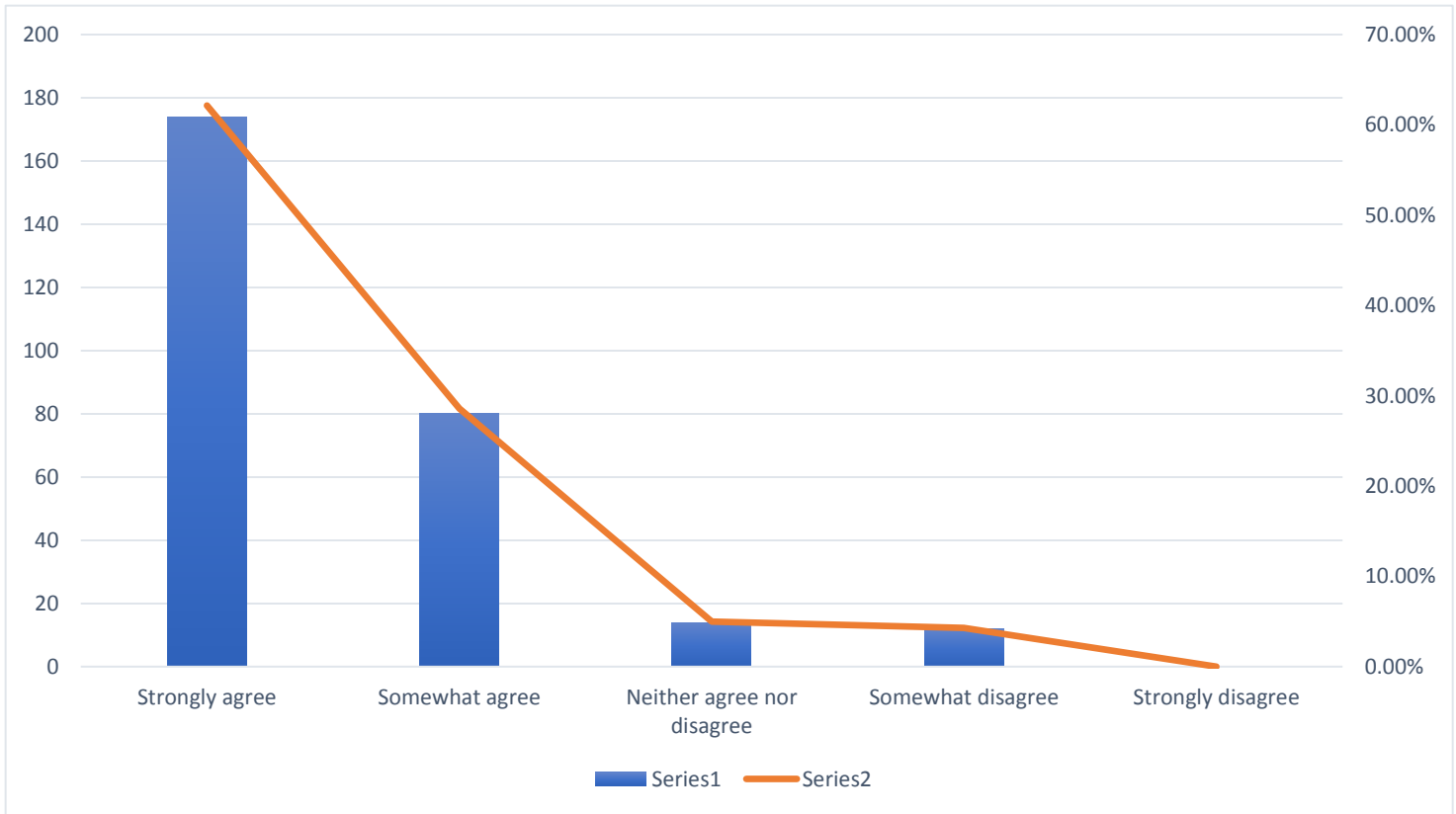
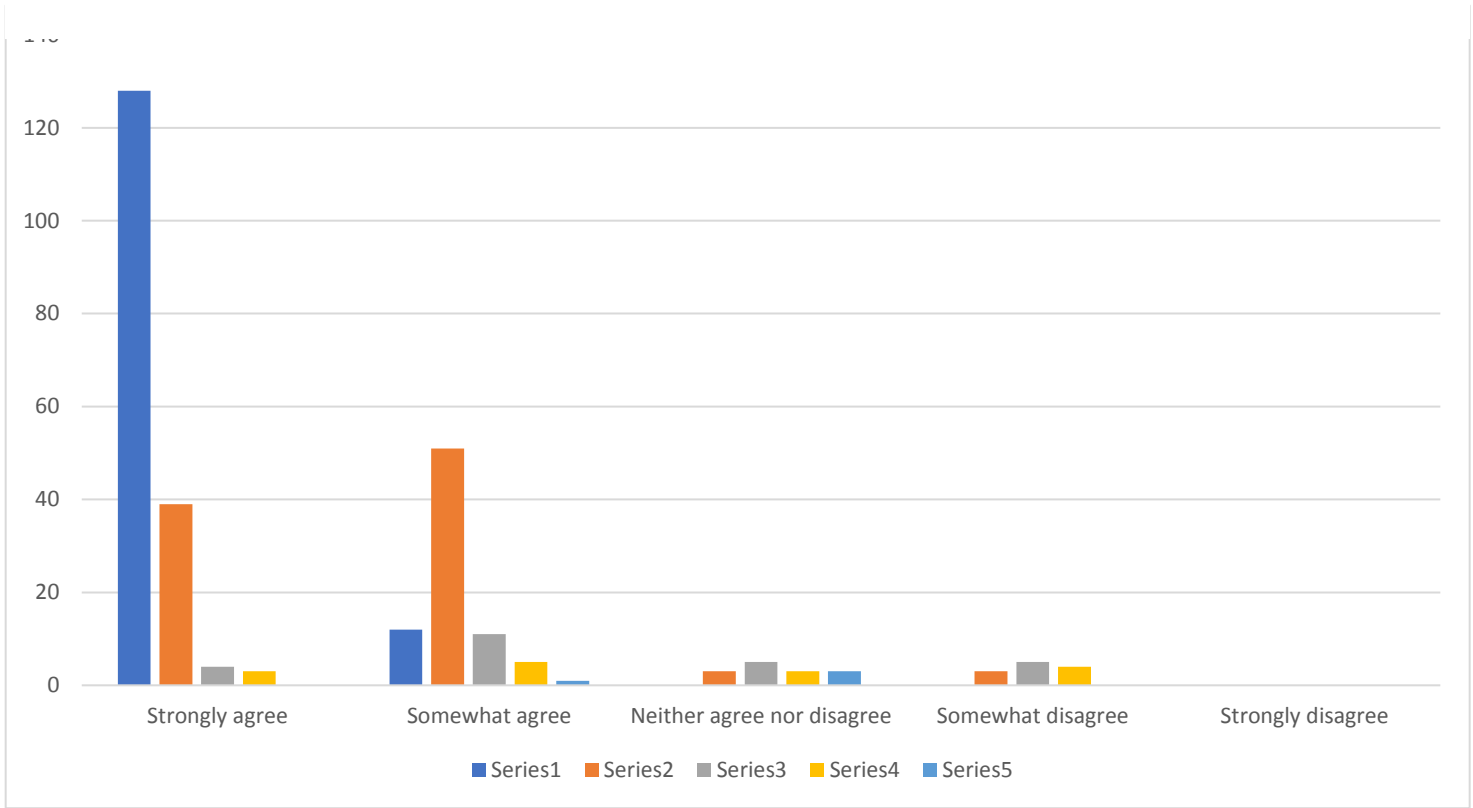
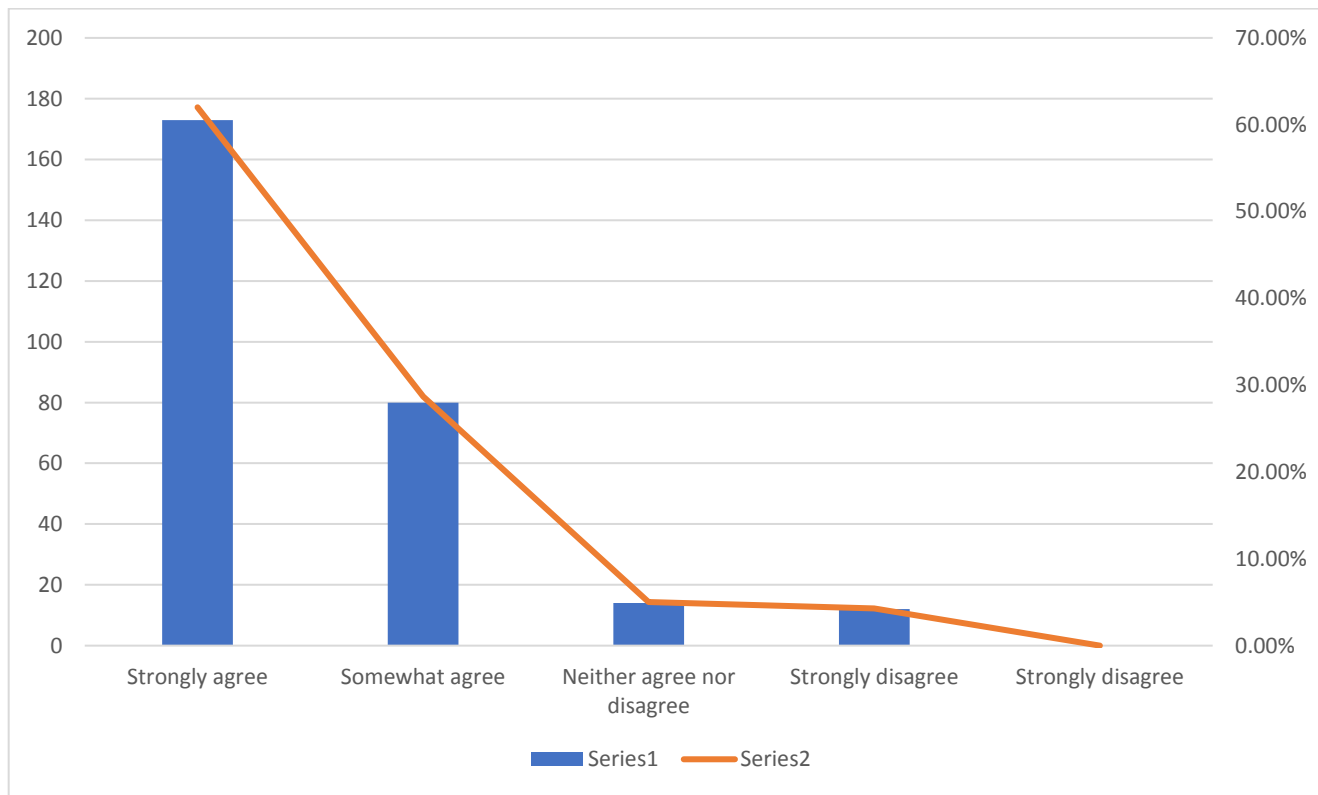
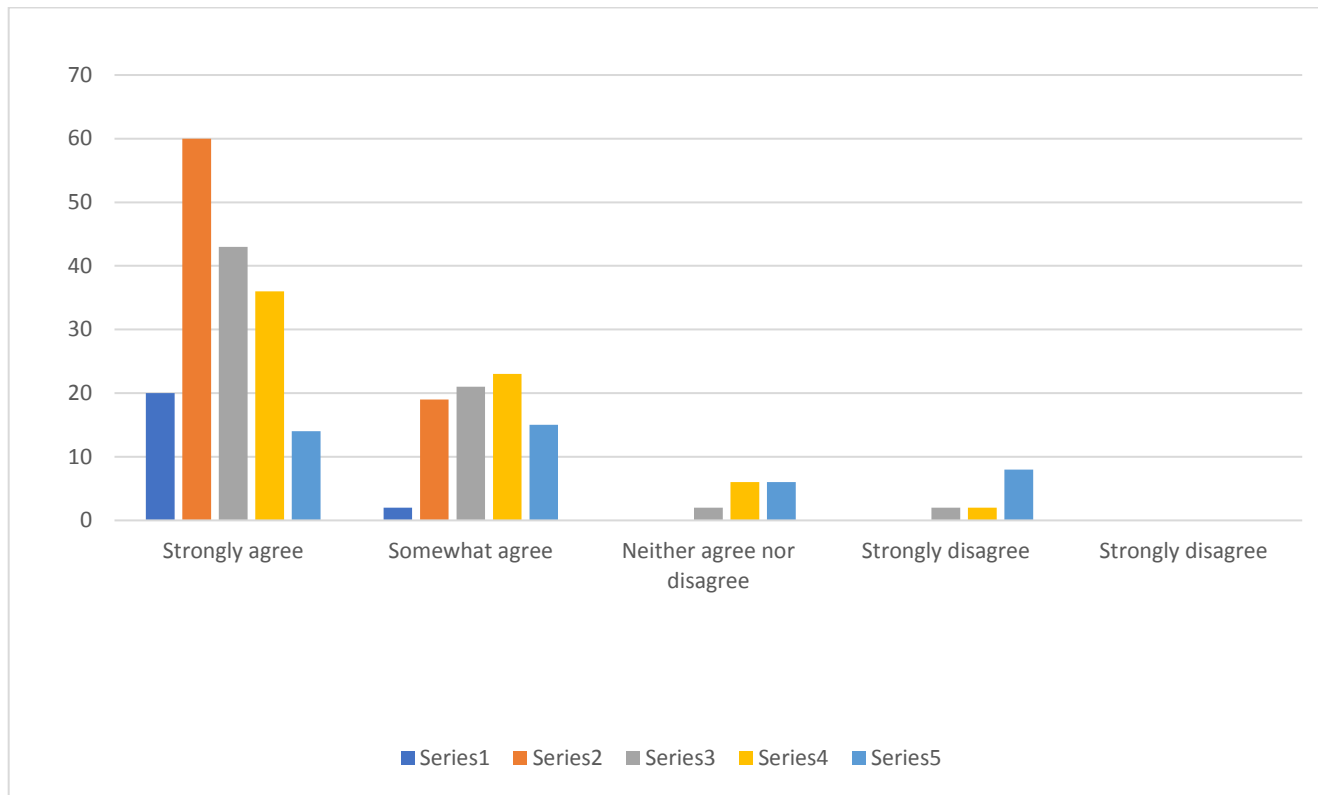


Figure 13 Implementation of operator lock-out will help reduce error to ensure patient safety and an important element for quality control improvement.



Discussion

A sample group of 140 health care professionals other than laboratory-trained professionals in California were questioned regarding their profession in the hospital: Participant Group A included Physicians 61(44.20%), Group B included Nurse and Nurse practitioner 60 (43.47 %), Group C included Physician assistants and others 16 (12.32 %).

POCT is used in patient care by staff that are not trained in the laboratory when rapid results are required and many believe that completion of training would make their role more efficient. By focusing on the patient, most agree that it creates a higher chance of receiving valid test results. Over half of the professionals from the survey acknowledge the importance of completing competency to be able to conduct POCT. Healthcare providers must follow the manufacturer's instructions. Over 80% of the group agrees that training prevents delay of testing. Ideally if someone's competency expires he/she should not be allowed to perform POCT test but in emergency situation when a patient life is in danger then most agree its ok to perform the test.

Even though POCT is more expensive than performing tests in the laboratory, many are aware of how time can change the fate of a patient and would take a risk to make sure the patient lives. Most people have an average knowledge regarding regulation and compliance standards .Many believe that external factors that are not in the control of the staff do not improve patient safety. The result of the study showed operators of the POCT devices were interested in ensuring proper training and competency of the operators. They were interested in having a lock out process and the ability to use an emergency release code during an emergency situation so that the testing can be done in a timely method.

Recommendation obtained from survey results

I. Validating Certified Point-of-Care Testing Operators

- A. Operators who been locked not approved to use instruments
 - i. Assign users appropriate levels based on competency and responsibility
 - ii. Time out access after instrument is idle for defined interval
 - iii. Include a special entry code for instrument set-up

- iv. Monitor rate of invalid operator use for performance improvement

B. Exceptions would make during medical emergencies

- i. An option to override operator lockout during emergencies should be included
- ii. Provide emergency access with a special code
- iii. Assure testing does not shut down during emergencies
- iv. Flag and track test results and operators for follow-up

C. Integrate competency requirements for accreditation

- i. Fulfill accreditation requirements for operator credentials, certification, and documentation
- ii. Lock out user after expiration of certification or too few tests performed in time interval
- iii. Lock or prevent operators who are not complete their competency or not recertified from using instrument
- iv. Notify operator of why locked out, corrective action, and contact person

D. More frequent training and evidence of in-department knowledge might be required to attain the required standard in situations where device is complex or is open to subjectivity. For successful outcomes.

II. Emergency Override System

Hospital defines conditions for emergency access to testing, which is flagged and tracked, following mandatory entry of operator's PIN.

- A. During emergencies, operator is warned, initiates testing, and is accountable for recovery actions.

- B. For instruments with override capability and those used during disasters, QC is performed in advance as part of daily workflow to assure that each instrument is prepared for critical patient testing.

Conclusion

Operator's competency improves the outcome of the Point-of-Care-Testing and the quality of patient care and therefore, lock-out feature during emergencies might affect patient's management. Maintaining a valid competency for all operators annually through a competency assessment plan and a continuous educational program will ensure un-interrupted services to the needed patients and avoid the use of the lock-out feature and providing a special code to be used by locked-out operator during emergencies, is an added benefit to the patient care.

Findings show responders indicate and acknowledge the importance of competency. POCT future is promising, so is important to have good system in place Operator Lock -Out is a safe guard to the patient care beside it is a compliance and one of the quality improvement tool.

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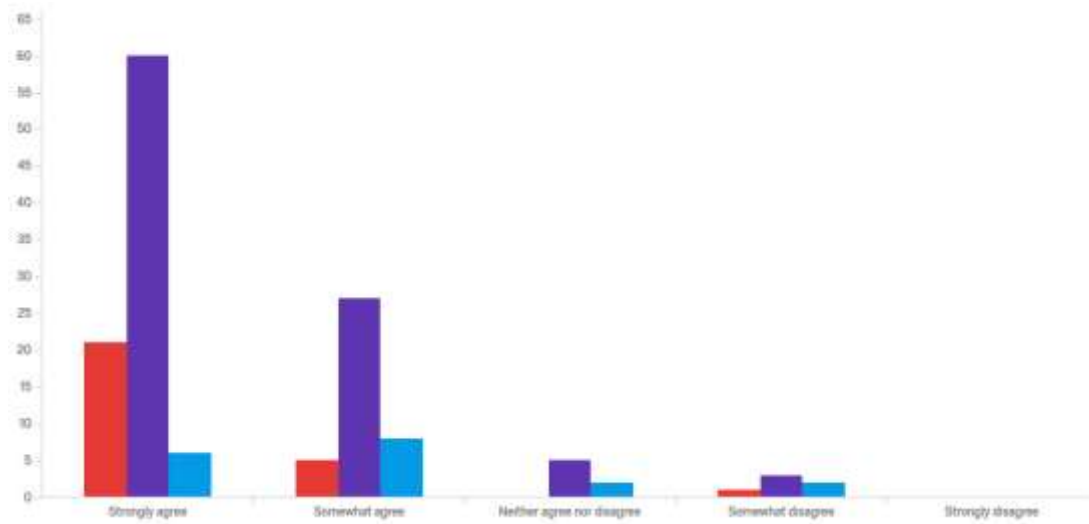
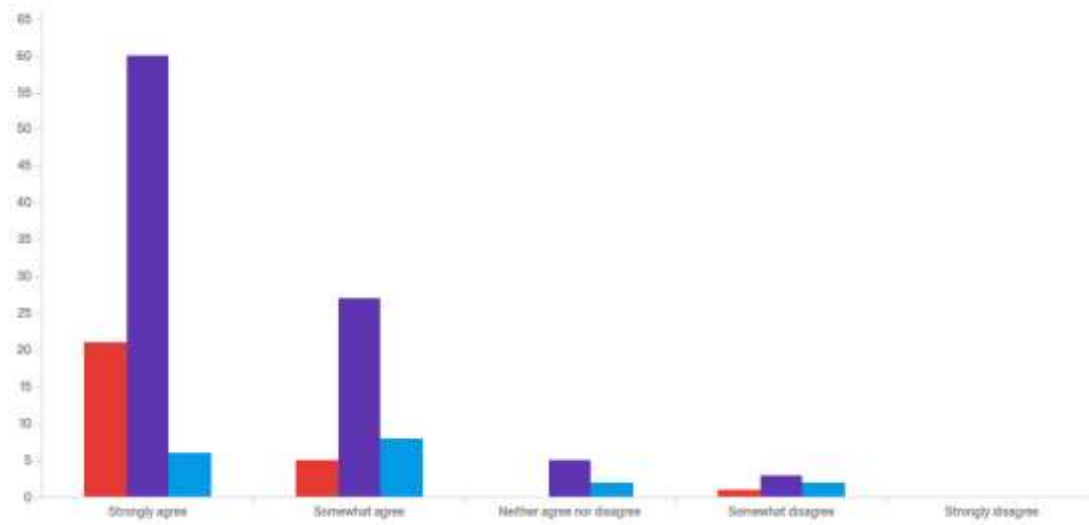
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