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Recommendations for the integration of standardized quality indicators for glucose point-of-care testing

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Abstract

Objectives: Quality indicator (QI) monitoring is essential to quality assurance for point of care testing (POCT). QI standardization is needed in the POCT field to provide clear guidance to hospitals and produce National and International benchmarks. A central aim was to standardize POCT QIs with existing QIs of the MQI program recommended by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) for central laboratory testing for integration in Comparison programs.

Methods: Process mapping and risk assessment of the POC glucose testing process were used to establish potential QI. Group consensus was used to rank each potential QI based on the ability to retrieve data for the specific QI. Higher scores were attributed to QI where data could be retrieved electronically and automatically. The highest scoring QI were chosen for follow-up. Members of the working group (authors) were asked to submit data from their own institutions for each QI to evaluate the feasibility of monitoring each QI and to develop preliminary benchmarks.

Results: Five QI recommendations are provided for glucose POCT, including: positive patient identification, operator training, internal quality control monitoring, external quality assessment and critical results follow-up. Preliminary QI data are presented along with implementation strategies and challenges associated with each recommended QI.

Conclusions: This study builds upon previous work by the Canadian Society of Clinical Chemists in developing a process to establish QIs for POCT based on process mapping

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and risk assessment. The recommended QIs are applicable to most other types of POCT, in addition to glucose testing.

Keywords: glucose monitoring; point-of-care testing; quality indicators

Introduction

Quality indicator (QI) monitoring is an important component of laboratory quality assurance, as it identifies areas for potential improvement [1, 2]. Previously, QIs were established for glucose testing at the point of care (POC) and promoted quality assurance standardization in the field [3]. This work further elaborates on five recommended QIs that should be regularly monitored to assess quality of the total testing process for POC glucose testing. These QIs were established using the previously presented framework, which involves process mapping, risk assessment and ease of detection through software analysis [3]. Standardization of the existing QIs from the Models of Quality Indicators (MQI) program of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) was also prioritized when possible, to facilitate their implementation in national and international QI comparison programs. The rationale for each recommended QI is discussed in detail, including calculations required, strategies for implementation and potential challenges. Point of care testing (POCT) program leaders are encouraged to review the list of indicators to decide which are most applicable to their test/device.

Materials and methods

A process for establishing QIs for POC glucose testing was previously described by our group [3]. Briefly, group consensus was used to map out potentially error-prone steps in the POC glucose testing process. The working group represented a group of 21 Clinical Biochemists from across Canada that are members of the Canadian Society of Clinical Chemists (CSCC), with experience providing oversight to POCT programs. Process mapping was followed by a risk assessment for each step, where the relative ease of detecting nonconformances and the severity of the impact of an error are evaluated for each step. The steps are then ranked based on their risk scores to identify the highest risk steps in the process.

QI data collection and analysis

Members of the working group (authors) were asked to submit data from their own institution(s) for three QI: internal QC, operator certification and EQA. Internal QC and operator certification data were requested for a one-month period and EQA data was requested for the 2024 calendar year. The data requested for each QI is outlined below. The performance of each QI was calculated following IFCC recommendations.

Internal QC QI

- Total number of QC points
- Number of QC points outside acceptability limits
- QC acceptability limits
- Source of QC acceptability limits
- Number of glucose meters
- Number of test strip lots
- Number of QC lots

Operator certification QI

- Total number of operators
- Total certified operators
- Total operators with pending certification
- Total expired operators
- Total soon to expire operators

EQA QI

- Number of EQA tests performed
- Number of EQA flags

Field validation of the two other QIs, positive patient identification critical results follow-up was conducted in our previous manuscript [3].

Results

Adapting the Failure Mode and Effects Analysis (FMEA) analysis model published previously [3], we refined our scoring strategy for the capacity of detection to clearly distinguish between process steps that can be monitored using extractable QIs and those assessed through internal audit. This step was essential to ensure successful integration in QIs comparison programs and for effective field monitoring. To do so, each potential QI was scored on ease of data accessibility using a score of: 3 for QI that can be extracted from software in an automated manner, 2 for QIs that can be extracted from software that required significant manual data processing and 1 for QIs that require a manual process to evaluate compliance. A total score was attributed to each QI, considering the probability of occurrence, the consequence

for patients of the occurrence and the attributed data accessibility score. A list of potential QIs were then classified based on the phase of the total laboratory testing process (pre-analytical, analytical and post-analytical) and total risk score that was calculated as the probability multiplied by consequence for patients and the data accessibility score (Table 1).

For the pre-analytical phase, the rate of positive patient identification (ID) was the highest ranked QI, with a score of 84.3. This was in line with the working groups previous findings [3] and the QI was also compatible with the (pre-analytical percentage of misidentified requests (Pre-MisR) QI of the IFCC Working Group on Laboratory Errors and Patient Safety (WG-LEPS) ([4] that focused on the pre-analytical phase for central laboratory testing. The second highest scoring QI in the pre-analytical phase was patient hand washing prior to testing with a score of 23.7. However, with a data accessibility score of 1, this QI was eliminated and deemed more suitable for monitoring by internal audits. With a total score of 22.5, operator training was the third highest ranked QI. With a data accessibility score of 3, this QI was selected as a pre-analytical QI for POCT. There is no equivalent IFCC WG-LEPS QI, however there are two related IFCC WG-LEPS QI, Training events (Supp-Train) and Training credits (Supp-Cred) [4].

For the analytical phase, potential QI with the highest data accessibility and risk scores were related to processes

Table 1: Process map for steps deemed most error prone for POC glucose testing based on group consensus. Steps are divided into pre-analytical, analytical and post-analytical stages of the total testing process. Risk is calculated as the consequence of the error multiplied by the probability of the error. Data accessibility refers to the ability to retrieve data automatically for monitoring (3, is completely automated, 2 is partially automated, 1 is a manual process).

Step of the process	Phase	Risk (CxP)	Data accessibility	Total score (risk X data)
Positive patient ID	Pre-analytical	28.1	3.0	84.3
Washing of patient hands	Pre-analytical	23.7	1.0	23.7
Operator training – does a formal program exist?	Pre-analytical	7.5	3.0	22.5
Sharing of operator IDs/inappropriate use of emergency operator ID (if applicable)	Pre-analytical	19.0	1.0	19.0
Wiping away first drop	Pre-analytical	18.3	1.0	18.3
Choice of specimen – is there awareness by operators of when a capillary specimen may not be appropriate?	Pre-analytical	16.3	1.0	16.3
Proper PPE practices (wearing gloves etc.)	Pre-analytical	15.5	1.0	15.5
Reagent expiry date labeling	Pre-analytical	14.7	1.0	14.7
Storage of reagent strips	Pre-analytical	12.0	1.0	12.0
Storage of QC solutions on the clinical units	Pre-analytical	10.6	1.0	10.6
Storage of meters on the clinical units	Pre-analytical	8.5	1.0	8.5
Validation of QC material – is there a process for this?	Pre-analytical	3.2	2.0	6.4
Meter validation – is there a process for this?	Pre-analytical	1.6	2.0	3.2
Validation of reagents – is there a process for this?	Pre-analytical	2.9	1.0	2.9
Inventory of management/lot sequestering	Pre-analytical	2.1	1.0	2.1
Operator lock-out – can only trained operators use the instrument?	Pre-analytical	9.0		0.0
Follow-up on QC failures by clinical area. Is the follow-up appropriate?	Analytical	14.5	2.0	29.0
Meter interferences – are operators aware of interferences?	Analytical	20.7	1.0	20.7
Testing procedure – is there a procedure and is it followed by the operators?	Analytical	17.6	1.0	17.6
Regular comparisons with the lab – are instruments regularly compared to the lab?	Analytical	8.5	2.0	17.0
QC – are operators performing QC according to the procedure?	Analytical	8.3	2.0	16.6
EQA – is there a formal EQA program?	Analytical	0.7	3.0	2.1
QC lock-out – do the instruments have QC lock-out and is it on?	Analytical	1.5		0.0
Critical results follow-up – are processes adhered to if they exist?	Post-analytical	23.5	3.0	70.5
Lab confirmation for discrepant results. Do clinical areas confirm suspicious results?	Post-analytical	27.2	1.0	27.2
Meter communication with middleware/LIS – are there challenges?	Post-analytical	10.3	2.0	20.6
Critical results reporting – is there a process for reporting?	Post-analytical	17.3	1.0	17.3
Cleaning of instrument	Post-analytical	14.7	1.0	14.7
Results reporting – are operators compliant with charting requirements?	Post-analytical	13.0	1.0	13.0
Proper disposal of samples/lancets	Post-analytical	7.8	1.0	7.8
Docking of meters (if applicable). Clinical compliance with docking for charging and results transmission.	Post-analytical	7.8	1.0	7.8
Periodic review of reference ranges and/or critical values	Post-analytical	3.6	1.0	3.6

Table 2: Proposed QIs for POC glucose testing based on process mapping and risk assessment.

QI	Phase	Calculation	Note	IFCC QIs
Positive patient ID	Pre-analytical	%: number of glucose tests performed without PPID/total number of glucose tests performed	Proper PPID refers to the operator following the defined process for PPID and using the prescribed patient identifier.	Related to Pre-MisR
Internal QC	Analytical	%: number of IQC results outside defined limits/total number of IQC results	Combine data from all QC levels and like devices	Equivalent to Intra-UniQC POCT and device specific
External quality assesment	Analytical	%: number of unacceptable performances in EQAS-PT schemes per year/total number of EQA schemes performed per year	Combine data from all like devices	Equivalent to Intra-Unac POCT and device specific
Critical results follow-up – repeats	Post-analytical	%: number of critically high glucose results repeated within 10 min/total number of critically high glucose results	Repeat can by POCT or by sample collection for central lab testing within 10 min	Related to Post-InsCR
Operator training	Pre-analytical	%: number of operators certified/total number of operators certified or with pending certification	Includes new users pending and current users who have expired and not completed recertification training	n/a

for internal and external quality control. To promote standardization with the international guidelines of the IFCC WG-LEPS, Intra-UniQC (the rate of internal quality control results outside of the range) [5] and percentage of unacceptable external quality assessment (EQA) performance (Intra-Unac) [4] were selected as they were also adaptable to POCT.

For the post-analytical phase, critical results follow up had the highest total risk score of 70.5 and a data accessibility score of 3. This QI was also related to the IFCC WG-LEPS QI for notification of critical results (Post-InsCR) [4], thus also promoting standardization. The five chosen QIs for POC glucose testing are summarized in Table 2.

Initial implementation data

Four of the five proposed five QIs have been further investigated here from an initial implementation perspective. Preliminary data for the critical results follow-up QI was presented previously [3] Information on challenges related to implementation of this QI can be found in the discussion section below.

PPID QI

This indicator has been discussed in detail previously [3] and is now included in the Canadian QI comparison program initiated by the Quebec Society of Clinical Biology [6] in collaboration with the Canadian Society of Clinical Chemists and the Working Group on Laboratory Errors and Patient Safety (WG-LEPS) of the IFCC. Figure 1 summarizes the findings from the past six QI data submission events from the Canadian program between February 2022 and January 2024.

Operator certification QI

Data on operator certification status for glucose were submitted by 13 sites and are summarized in Table 3 below. Not all sites were able to separate expired from pending certifications and some sites were not able to identify operators that were soon to expire. The total operators are defined as the operators that are currently certified and including operators with pending certification and soon to expire. The percentage of certified operators was calculated for each site, ranging from 50–100 %. The 25th percentile was calculated as 81 % and the 75th percentile as 99 %.

Internal QC QI

Preliminary data for this QI were obtained from the working group members over a one-month period. Data were submitted from 22 hospital sites across Canada, including sites using both the Nova StatStrip (n=12) and Roche Inform II (n=10) glucose meters. The data are shown in Table 3. As per the IFCC WG-LEPS recommended process, the 25th and 75th percentiles were calculated for each meter type based on the submitted data [7]. For the Nova StatStrip meter, the 25th and 75th percentiles of performance were 0.40 % and 0.57 %, respectively. For the Roche Inform II, the 25th and 75th percentiles were calculated as 0.38 % and 0.81 %, respectively. Most sites indicated using the QC limits provided by the manufacturer with one site using limits calculated from

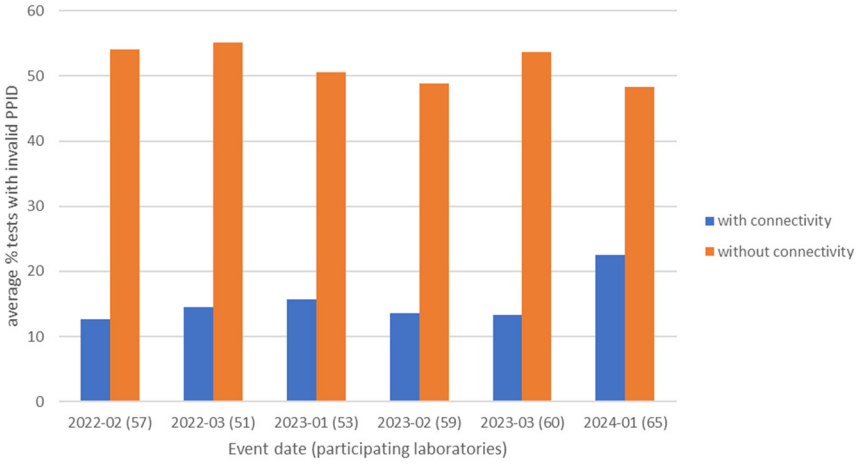

Figure 1: Average % of POC glucose tests performed without valid PPID across six data submission events. The number of laboratories included for each event is indicated in brackets next to the event date. Data are divided by sites that have admission, discharge and transfer system (ADT) connectivity for patient demographics with the glucose meters and sites that do not.

in-house performance of the glucose meters (N4). The number of test strip lots and QC lots included in the analysis is indicated in Table 4 for each site. One month of QC data was extracted from POCT data management software by glucose meter for one submitting site as an example for further investigation, with the data summarized in Table 5 as an example report. Obvious QC vial switches are noted for meters 1 and 7. QC were performed at least 31 times on each meter for the month, indicating QC performed at least every 24 h as per the provided site operating procedure.

EQA QI

EQA data were submitted from 20 sites and are summarized in Table 6 below. The percentage of EQA failures was calculated for each site. Given the low number of failures, the 25th and 75th percentiles for performance could not be calculated.

Discussion

The goal of this current study was to use findings from previous work by the CSCC [3] to identify a panel of five key QIs that would allow for regular monitoring of the total POC glucose testing process, with the potential of integration into National and International laboratory QI comparison programs. The 32 potential QI identified previously by our group were considered [3].

Based on the definition from the IFCC Working Group on Laboratory Errors and Patient Safety (WG-LEPS), state of the art QI should cover the total testing process, be applicable to a wide range of testing sites, be calculated and extracted

Table 3: Operator certification data for each submitting site.

Site	Total operators (certified, pending, soon to expire)	Operators with pending certification	Certified operators	Expired operators	Soon to expire operators	% certified operators
1	5,306	731	4,293	0	282	81
2	4,078	1,601	2,433	1,554	44	60
3	10,725	81	10,644	4,876		99
4	2,263	39	2,185	1,847	39	97
5	3,136	80	3,056	3,705		97
6	2,234	44	2,146	1,529	44	96
7	507	19	469	622	19	93
8	4,735	31	4,673	0	31	99
9	2,179		1,096	7	1,083	50
10	886		655	6	231	74
11	924	11	913	314		99
12	2,625		2,625	42		100
13	1,977	36	1,905	1,330	36	96

Table 4: % QC failures by site for the Nova StatStrip (A) and Roche Inform II (B) glucose meters.

A	Nova StatStrip						
Site	**QC outside limits**	**Total QC points**	**% points outside limits**	**Limits**	**# strip lots included**	**# QC lots included**	**# of meters**
N1	60	6,661	0.90	Manufacturer	1	4	160
N2	6	7,098	0.08	Manufacturer	1	2	230
N3	87	15,972	0.54	Manufacturer	1	4	380
N4	179	12,448	1.44	In-house	1	4	281
N5	59	12,366	0.48	Manufacturer	1	5	220
N6	56	17,577	0.32	Manufacturer	1	2	375
N7	70	10,711	0.65	Manufacturer	1	4	306
N8	212	44,739	0.47	Manufacturer	2	2	853
N9	43	11,044	0.39	Manufacturer	2	2	203
N10	31	5,785	0.54	Manufacturer	2	2	107
N11	19	4,715	0.40	Manufacturer	2	2	88
N12	206	45,045	0.46	Manufacturer	2	2	88
B	**Roche Accuchek Inform II**						
Site	**QC outside limits**	**Total QC points**	**% points outside limits**	**Limits**	**# strip lots included**	**# QC lots included**	**# of meters**
R1	14	4,647	0.30	Manufacturer	2	1	110
R2	12	3,744	0.32	Manufacturer	2	1	76
R3	25	7,978	0.31	Manufacturer	1	2	167
R4	29	9,084	0.32	Manufacturer	1	2	174
R5	18	4,826	0.37	Manufacturer	1	3	446
R6	44	6,382	0.69	Manufacturer	1	2	416
R7	58	7,833	0.74	Manufacturer	1	2	644
R8	30	5,909	0.51	Manufacturer	1	4	472
R9	66	15,847	0.42	Manufacturer	1	1	361
R10	147	16,799	0.88	Manufacturer	2	4	330

Green indicates sites with relatively low QC failure rates, yellow indicates sites with a moderate QC failure rate and red indicates sites with high QC failure rates, relative to the 25th and 75th percentiles calculated.

Table 5: One month worth of QC data from 10 glucose meters at a single site.

Device	Acceptable: 1.9–2.9 mmol/L			L1 count	Device	Acceptable: 15.4–17.6 mmol/L			L1 count
	Average	Min	Max			Average	Min	Max	
1	2.4	2.2	2.6	38	1	16.0	2.5	17	32
2	2.4	2.2	2.5	29	2	16.4	11.4	17	31
3	2.4	2.2	2.6	32	3	16.3	13.2	17.4	34
4	2.3	2.2	2.4	31	4	16.3	13.3	16.9	38
5	2.4	2.3	2.5	31	5	16.3	14.2	17.3	32
6	2.4	2.3	2.6	34	6	16.4	14.3	16.9	36
7	2.8	2.3	17	36	7	16.9	14.3	22.9	36
8	2.5	2.3	3.2	32	8	16.6	14.3	17.2	33
9	2.4	2.3	3.3	34	9	16.4	14.7	17	32
10	2.4	2.3	2.6	32	10	16.3	14.7	16.8	33

The average, maximum and minimum QC measurements are shown for each meter as well as the total number of measurements for the month on each device.

with scientific robustness and able to assess quality improvement. Very importantly, QI data needs to be easily extractable to encourage and allow for monitoring by all types of sites that complete the testing [1, 7].

The five key QI identified in this study cover the three testing phases for POC glucose testing, pre-analytical, analytical and post-analytical. The QIs also align with recommendations from the IFCC WG LEPS for central laboratory testing QIs.

Table 6: External quality assessment (EQA) data from submitting sites for the 2024 calendar year. Most sites participated in the Institute for Quality Management in Healthcare (IQMH) EQA program with one site participating in a program from the American Proficiency Institute (API).

Site	Year	EQA scheme	Total # glucose EQA performed	Total # glucose EQA flags	% EQA failures	Comments
1	2024	IQMH	546	0	0.0	
2	2024	IQMH	567	0	0.0	
3	2024	API	690	3	0.4	Wrong sample scanned. Repeat result was okay.
4	2024	IQMH	747	2	0.3	Unknown cause, typically we label this as “pre-analytical” without evidence of EQA material mishandling.
5	2024	IQMH	123	0	0.0	
6	2024	IQMH	729	0	0.0	
7	2024	IQMH	495	0	0.0	
8	2024	IQMH	183	0	0.0	
9	2024	IQMH	9	0	0.0	
10	2024	IQMH	6	0	0.0	
11	2024	IQMH	1,308	0	0.0	
12	2024	IQMH	324	0	0.0	
13	2024	IQMH	1,281	2	0.2	Random error- repeat testing was okay.
14	2024	IQMH	671	0	0.0	
15	2024	IQMH	417	0	0.0	
16	2024	IQMH	292	0	0.0	
17	2024	IQMH	435	0	0.0	
18	2024	IQMH	576	0	0.0	
19	2024	IQMH	75	0	0.0	
20	2024	IQMH	690	0	0.0	

Implementation of QI for POCT

PPID QI

The PPID QI was discussed in detail previously [3] This QI has been successfully integrated into the Canadian QI comparison program, with an average of 58 sites across Canada submitting data for each event. We have previously identified that sites with admission, discharge transfer (ADT) system connectivity for POCT glucose meters had less PPID errors than sites without ADT connectivity. This trend has been consistent across six QI submission events with the Canadian QI comparison program. This demonstrates the importance of connectivity for POCT devices to improve quality of results documentation.

Operator training QI

For devices that have connectivity to a POCT data management software, certification reports can be generated on a routine basis to calculate the QI using the number of operators with different certification status, including certified, expired and pending. Based on the data submitted for this QI, most sites show a high number of certified operators for POC glucose testing. A couple of sites had a relatively high number of operators with pending certifications. This may be related to different certification processes used by sites. For example, some sites may have one certification period for all operators whereas other sites may have rolling certifications. For devices that have operator lock-out capabilities, non-certified users will not be able to perform testing. It also highlights the risk of testing not being possible when required in an urgent situation, as when users’ certifications have expired or are pending. For manual POCT or devices that do not have operator lock-out capabilities, including manual POCT, monitoring of this QI may be important to understand the risk of testing by non-certified individuals. QI data may also prompt discussions around minimum recertification criteria and auto-certification based on testing frequencies. Many expired certifications may indicate high staff turnover rates and may suggest the need for alternative training opportunities to better support the program.

Internal QC QI

The rate of QC failure was higher in sites with Roche meters (75th percentile 0.81 %) compared to sites with Nova meters (75th percentile 0.57 %). This may be related to the number of QC points reported from Roche sites vs. Nova sites with twice as many points reported, on average, for Nova sites. This QI was chosen to ensure monitoring of the analytical testing process. QC testing is typically performed by clinical staff

performing POC glucose testing, and QC failures can indicate errors associated with the testing process that may require follow-up with a clinical area or operator. Data from obvious QC vials switches was removed from the analysis. Vial switches represented 33–72 % of all QC failures across the sites. Aggregate data from all glucose meters in an institution may not be meaningful, particularly in institutions with large numbers of devices or variety of inpatient units as workflows specific to different specialties may impact successful QC differently. Analysis of data with more granularity (i.e. by glucose meter, unit, operator etc.) can identify more nuanced issues with the POCT device or program. Table 5 shows an example QC report by glucose meter for one site. Analysis by individual glucose meter allows for identification of specific meters with QC outside the acceptability limits, as well as instances with obvious QC vial switches. It can also recognize areas where infrequent QC is performed, which can prompt discussions with clinical areas about utilization.

EQA QI

EQA is a key component of laboratory quality assurance practices, including POCT. Similarly to EQA for central laboratory tests, EQA for POCT can help identify gaps in the testing processes. Data from submitting sites here showed a low rate of EQA failure. Where there were failures, only one site could explain the cause of the failure. Failures at other sites were deemed random. Ideally, clinical staff who perform patient testing are the ones also performing testing for EQA challenges. If laboratory staff observe clinical staff performing testing, this is an opportunity to identify errors with the process of testing technique, which could explain EQA failures. Otherwise, it can be difficult to identify a root cause. For programs with a very large number of devices (e.g. blood glucose monitoring) it may pose a challenge to enroll every device in an EQA program due to cost or logistical challenges. However, the advantage of including every device allows for complete intra-instrument comparisons.

Critical Results Follow-up QI. Preliminary findings for this QI were presented previously [3]. Briefly, this indicator monitors compliance with repeat of critical POCT glucose measurements within a defined period for confirmation. Based on experience in their respective sites, authors in the working group have indicated challenges with implementation of this QI. A recurring challenge is the fact that clinical staff and leadership do not agree with the laboratory questioning (critical) results without knowledge of the clinical context. However, clinical staff are not always cognizant of, or they do not always appreciate or recognize the impact of pre-analytical factors on results. The timing required for valid repeat of measurement has also been questioned. Sites planning to implement this QI are advised to provide data to clinical staff on the historical rate of discordant glucose results when critical results are repeated, if available. Based on data provided by the authors and published previously [3] the average rate of discordant repeat was 36 %. Studies in the literature have demonstrated that the majority of erroneously high POC glucose results are due to insufficient hand washing prior to testing or testing of specimens that are contaminated after being taken from a contaminated line [8].

Limitations

One limitation of this study is that data are only available for two models of hospital grade glucose meters. Furthermore, except for the PPID QI, the Quality Specifications are preliminary, and their accuracy can be limited by the number of sites included in the calculation. State-of-the-art Quality Specifications will require the integration of these QIs into comparison programs including at least a year of data.

Conclusions

QI monitoring is a key component of POCT quality assurance. Five key QI for POC glucose testing are recommended here, which are applicable to other POCT programs, especially for quantitative measures. QI monitoring for POCT will aid in identifying areas for process improvement that will impact quality of testing and patient safety.

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