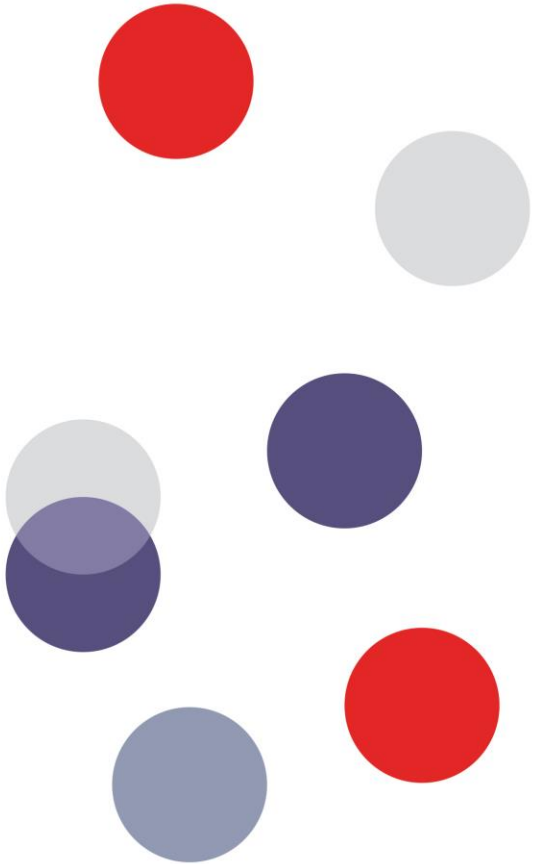
EQALM Workshop

18 October 2023



RCPAQAP

The Royal College of Pathologists of Australasia
Quality Assurance Programs

Questions

1. Is there a reason for the frequency of rounds and the number of samples per round?

2. Do you choose Analytical Performance Specifications based on clinical outcome goals, BV or state of the art?

3. Are there any consequences for labs if they have outlying values?

1. Is there a reason for a certain frequency of rounds, or the number of samples per round? Is this risk driven?

Historic	Objective logic?	Frequency of analysis clinical use	Availability of sample material	External factors e.g. legal	Need of participants or feedback	Comments
Yes	Yes	Yes			Yes	Partially historic. Programs covering high volume testing (e.g. routine chemical pathology) warrant more frequent rounds as most laboratories want to know sooner rather than later about a problem that their internal QC may not have detected.
	Yes					Based on the trade-off cq. balance between enough for multi sample statistics and feasibility and costs. Optimal is not scientifically investigated but educated estimate.
	Yes	Yes	Yes			In most schemes the frequency and number of samples is decided based on clinical use of the test, quality of the test and performer. In some cases, we are restricted to fewer rounds and/or less number of sample per round due to lack of sample material.
	Yes			Yes		We have legal requirements for a minimum of rounds and wishes of accredited labs to organise more rounds than required. There is also a legal requirement for a minimum of samples per round. This is not risk driven.
	Yes		Yes			Some of our programs run monthly, quarterly and bimonthly. Participants analyse one sample each round, but during the year there's a total of 4 batches repeated 3 times. The frequency of the programs is studied prior to its implementation and depends on sample preparation conditions, but there's no risk assessment itself.
	Yes	Yes			Yes	Yes , we consider that the frequency, number of samples should be in agreement as the needs of participants.
	Yes	Yes				One round per month for frequent analysis, six/year for less frequent analysis to replicate the routine.
Yes	Yes	Yes	Yes	Yes		At that time no reason, except some regulations for a low number of analyses, generally it is a survey per quarter, historical choice. The scarcity of the raw material, the cost of the laboratory analysis sometimes influences the choice.

Historic	Objective logic?	Frequency of analysis clinical use	Availability of sample material	External factors e.g. legal	Need of participants or feedback
	Yes				
	No				
	Yes				
	Yes				
	Yes	Yes			
	Yes	Yes			
	No				

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Historic	Objective logic?	Frequency of analysis clinical use	Availability of sample material	External factors e.g. legal	Need of participants or feedback
	No				
	Yes				
Yes					
	No				
		Yes			
	No			Yes	
	Yes				
	Yes			Yes	Yes
		Yes		Yes	

2. Do you choose performance specifications based on clinical outcome goals, biological variation or state of the art ?

Clinical outcomes	Biological variation	State of the art	Expert opinion	Different for low concentrations	Comments
Yes	Yes		Yes		Our Analytical Performance Specifications (APSs) are mainly based on clinical outcomes and biological variation and in some cases "Professional Opinion" (e.g. where Biological Variation data isn't available).
Yes	Yes	Yes			Yes, clinical outome where available else bio var where available, else State of the art. Next to outcome and bio var state of the art is reported always next to it in order to: 1. show how current state of the art compares to other APS 2. make sure participants are not punished for not reaching unreachable goals in case state of the art methods cannot comply with outcome ore bio var APS
Yes	Yes	Yes			We use all the above - it depends on the scheme. Most used are biological variation. Sometimes we use state of the art and sometimes clinical outcome. We also, for some analysis, use a mix of state of the art and clinical outcome. Proposals for APS, based on state of the art, are presented to an advisory board for discussion and decision. Sometimes the APS gets tougher and sometimes kinder based on the discussion in the board.
	Yes				First performance specification: All of these reasons. It is a choice of the specific scientific society, and it has to find acceptance of the authorities. Second performance specification: All of these reasons. It is a choice of the specific scientific society.
	Yes	Yes			We use APS based on biological variation or state of the art (if BV data is not available).
	Yes	Yes			Preferably biological variation.
	Yes				Biological variation or state of the art
Yes	Yes	Yes			State of the art is almost always given but we give also performance specifications based on clinical outcome goals, biological variation when they exists in the literature data as they are more useful
			Yes		Depends on the expert behind the schemes ...

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Clinical outcomes	Biological variation	State of the art	Expert opinion	Different for low concentrations
	Yes	Yes		
	Yes	Yes		
Yes	Yes	Yes		
	Yes			
Yes	Yes	Yes	Yes	Yes
Yes	Yes	Yes		
	Yes	Yes		
Yes	Yes	Yes		
Yes	Yes	Yes		
Yes	Yes	Yes		
	Yes	Yes	Yes	
Yes	Yes	Yes		
		Yes		
	Yes	Yes		

Basis for difference Glucose				
BioVar	Clin Guide	SOTA	Expert opinion	Other
No	No	No	No	Yes
Yes	No	No	No	No
Yes	No	Yes	No	Yes
No	No	Yes	Yes	No
Yes	No	Yes	No	Yes
No	Yes	No	No	No
No	Yes	Yes	Yes	No
Yes	No	Yes	No	No
No	No	Yes	No	No

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Letter to the Editor

Why do different EQA schemes have apparently different limits of acceptability?

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Keywords: acceptance limit; external quality assessment (EQA); Six Sigma; successfulness.

sometimes seen? There is essentially no globally applicable consensus concerning the setting of limits. The methods for establishing acceptance limits have been recently described by Klee (5). Establishing acceptance limits can be based on the state of the art of an analytical measurement; derivation from biological variability values; based on data provided by international medical recommendations; obtained by means of Horwitz relationship, and by various other means. Sometimes the acceptance limits may be legalized by governmental organizations (Clinical Laboratory Improvement

Table 1 Comparison of some acceptance limits in different EQA programmes.

No.	Analyte	Acceptance limits					
1	Na^+	3 mmol/L	0.9	3	5	5	4 mmol/L
2	K^+	0.2 mmol/L	6	4.5	8	8	0.5 mmol/L
3	Cl^-	3 mmol/L	1.5	4.5	8	7	5%
4	Ca^{2+}	0.1 mmol/L	2.4	6	10	10	0.25 mmol/L
9	Protein	5 g/L	3.4	6	10	9	10%
10	Albumin	10%	4	12.5	20	12	10%
13	Bilirubin	10%	31	13	22	21	20%
15	Cholesterol	0.5 mmol/L	8.5	7	13	10	10%
16	Glucose	10%	6.9	11	15	10	10%
17	Uric acid	50 μmol/L	12	7	13	14	17%
18	Urea	10%	16	10.5	20	15	9%
19	Creatinine	10%	8.2	11.5	20	15	15%
20	Triglycerides	10%	28	9	16	15	25%
22	α-AMS	15%	15	–	–	21	20%
23	AST	15%	15	11.5	21	21	20%
24	ALT	15%	32	11.5	21	21	20%

GE-RSMD, Root Mean Square Deviation (new quality metric defined in German RiliBÄK 2007 for internal assessments). RiliBÄK practically – deviation from assigned values (%). RCPA-QAP, The Royal College of Pathologists of Australasia quality assurance programs.

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DE GRUYTER Clin Chem Lab Med 2017; 55(7): 949–955

Opinion Paper

Graham R.D. Jones*, Stephanie Albarede, Dagmar Kesseler, Finlay MacKenzie, Joy Mammen, Morten Pedersen, Anne Stavelin, Marc Thelen, Annette Thomas, Patrick J. Twomey, Emma Ventura and Mauro Panteghini, for the EFLM Task Finish Group – Analytical Performance Specifications for EQAS (TFG-APSEQA)

Analytical performance specifications for external quality assessment – definitions and descriptions

At this time there are wide differences in the APS used in different EQA schemes for the same measurands. Contributing factors to this variation are that the APS in different schemes are established using different criteria, applied to different types of data (e.g. single datapoints, multiple data points), used for different goals (e.g. improvement of analytical quality; licensing), and with the aim of eliciting different responses from participants.

There are a number of steps that can be taken to improve the situation. A major advance could include further development of global programs. Even within the current practise of many smaller programs, improvements can be made with the use of commutable material, value assignment with higher order references, common data analysis and performance specifications and harmonized method classification.

In practice, these will only happen with co-ordinated action amongst EQA programs allowing adoption of common practices and detailed review of the results produced from the many programs currently available.

Special issue: External Quality Assessment in Laboratory Medicine

Review

The role of EQA in harmonization in laboratory medicine – a global effort

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Critical Reviews in Clinical Laboratory Sciences

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/ilab20

Analytical performance specifications and quality assurance of point-of-care testing in primary healthcare

Anne Stavelin & Sverre Sandberg

To cite this article: Anne Stavelin & Sverre Sandberg (01 Oct 2023): Analytical performance specifications and quality assurance of point-of-care testing in primary healthcare, Critical Reviews in Clinical Laboratory Sciences, DOI: 10.1080/10408363.2023.2262029

To link to this article: https://doi.org/10.1080/10408363.2023.2262029

4. Is there any specific consequence for labs if they have outlying values?

Lab initiative expected	Consequences for certificate	Escalation to authorities	Comments
Yes			Results are flagged when outside the APS limits for their method group. The expectation is that they review their reports and follow up on non-conformances.
			We indicate outliers as outliers, but still include them in calculations for lab performance, which would have been better without these outliers.
Yes			In most cases not. But we have exceptions - for example wrong mutation detected, missing a HIV-positive sample.
	Yes		75 % of the annual results have to fit the performance specifications. It is written in the annual certificate if this performance is reached or not. Accredited labs have to show what they undertake to improve. The authorities do not yet specifically survey the performance, only the participation. But the lab has to sign an annual self-declaration for the authorities, that they look for the reasons of any outlying value in order to improve.
Yes			The outlying values are reflected in the lab evaluation as poor performance (in the monthly reports the lab gets its iDE score and DP% values and in the biannual reports those poor performance results are scored as unsatisfactory). If needed, labs are provided with a guide helping them find the causes of their deviations.
Yes			No, we just advice them
		Yes	Signal to institutional Institute control
		Yes	Yes, they have to be declared to the competent health authority. For the moment, it is not done because the French Health EQA organizers (5 EQAO) are working to define a list of analysis for which the patient impact is critical and the common performance specifications. You can see this list on https://www.faeeq.fr/Information_criteres_acceptabilite_clinique_V05.pdf
No			No
No			No
No			No
Yes			There is no consequence for labs with outlying values. For the primary healthcare service, we have a follow-up system of all poor results in all surveys. For larger laboratories with laboratory technical staff, we assist if they ask for help.
		Yes	They are excluded from the statistical analysis, the result is not compliant and, depending on the analyte, a report to legal instance may be made if the problem is recurrent.
Yes			Most are accredited and will have to act in accordance with their quality system.

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f Australasia

Lab initiative expected	Consequences for certificate	Escalation to authorities
No		
No		
Yes		
		Yes
		Yes
Yes		
Yes		
	Yes	
		Yes
Yes		

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What now?

- Go to group

- Discuss what we do with the information - 20 minutes
  - What is the situation in the group members' organization?
  - Try to identify good practices or difficulties, reasons, and implications.
  - Try to collect suggestions for improvements.
  - How could EQALM help? e.g., by sharing good practices or working out guidelines.

Questions

1. Is there a reason for the frequency of rounds and the number of samples per round?

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3. Are there any consequences for labs if they have outlying values?

Why?

- Role of EQA – patient advocate
  - Risk that labs are not aware of
  - QA incidents of concern
  - Poorly performing assays
  - Post-market surveillance of kits/reagents

- Reputation of EQA
  - Why different