EQA– future challenges and opportunities

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Advances in the last decade

- More breadth and depth of analytes and design
- Commutable and challenging samples
- Milan criteria performance specifications
- Educational emphasis
- Assessment of total testing process - Pre and post analytical programmes / elements
- Iso 17043 accreditation
- Post market vigilance
- Harmonisation monitoring

Expectations of EQA Provider has changed

Accreditation status – 17043	• If not accredited, labs should justify why
Clinically relevant Distribution frequency	•Variable across Schemes (EQALM study 2009) * •Where EQA used to assess IVDs, minimum of 6 distributions p.a. (BS EN 14136:2004) •For core tests - monthly
Clinically relevant material, range and number of samples	•Evidence of reproducibility •Cover clinically appropriate range •"Blinded" •Commutable materials •Challenging samples
Clinically relevant performance criteria	• Based on clinical outcomes • Based on biological variation
Scheme designed and overseen by appropriately competent professionals	•Clinical Scientist or medically qualified •Independent Scientific or Medical Advisory group.
Reporting to Professional body / Regulatory body.	•Mechanism for identification and reporting of Persistent Poor performance issues
Education	•Training •Helpline •Pre analytical •Post Analytical
Post-marketing surveillance	•Alerts manufacturers •Alerts competent authority •Alerts laboratories •Alerts professional bodies

* A Thomas, Accred Qual Assur (2009) 14: 439-444

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Objectives of EQA

- Provide a measure of the quality of a test
- To supplement internal quality control procedures
- Provide a measure of the “state of the art” of a test
- To obtain consensus values when true values are unknown
- To investigate factors in performance (methods, staff etc) IFCC 1977
- To act as an educational stimulus to improvement in performance
- To provide a Post market vigilance service
- To provide evidence and monitoring of harmonisation strategies
- Provide an assessment of the whole testing process

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Expectations of EQA Provider

Clinically relevant Distribution frequency

- Variable across Schemes (EQALM study 2009) *
- Where EQA used to assess IVDs, minimum of 6 distributions p.a. (BS EN 14136:2004)
- For core tests - monthly

Clinically relevant target, range, material and number of samples

- Assessment of reproducibility
- Assessment of trueness, traceability
- Clinically appropriate range
- Commutable materials
- Challenging samples

* A Thomas, Accred Qual Assur (2009) 14: 439-444

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Clinically appropriate Target value

- Improvements in the assessment of the analytical phase includes evaluation of trueness using target vales assigned with high order reference methods, utilising performance criteria that are appropriate for the clinical utility of the analyte and the use of clinically challenging samples.

Advantage of Reference Measurement Targets

- Traceable to higher order
- Establishes method traceability for the lab– requirement of ISO 15189
- Independent assessment of manufacturer traceability claims.
- Highlights the pitfalls of using the trimmed overall mean as an accuracy target in EQA Schemes
- Overall mean and method mean may not be traceable, may not be stable, may be influenced by large numbers from one manufacturer.
- Useful in the post market vigilance of the IVD - Directive
- Promotes standardisation/ Harmonisation

Reference Measurement service provided as part of Weqas EQA programmes

Flame Atomic Absorption/ Emission Spectrometry

- Sodium, Potassium, Calcium
- Magnesium, Lithium

IFCC Enzymes

- AST, ALT, LDH, GGT

HPLC

- HbA1c **

** Provided by IFCC Ref lab, Netherlands

IDGC-MS & ID-LC-MS/MS

- 17ß-Oestradiol
- Progesterone
- Testosterone
- Cortisol
- Bile Acids
- Creatinine
- Cholesterol
- Glucose
- Urate
- Triglyceride
- HDL *

* Currently provided by CDC lab Rotterdam and WEQAS

Traceability From EQA reports

Scheme: Serum Chemistry. Distribution Code: RH.
Distribution Date: 2/01/18. Final. Report Issued: 24/01/18

Glucose (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		11.4	8.1	20.7	1.8	
Method Corrected Result		11.40	8.10	20.70	1.80	
Hexokinase	Mean	11.42	8.21	21.11	1.85	
	SD	0.20	0.15	0.41	0.05	
	Number	170	172	169	168	
	Uncert.	0.015	0.012	0.032	0.004	
Cobas C Module	Mean	11.45	8.26	21.13	1.88	
	SD	0.17	0.13	0.31	0.04	
	Number	91	95	92	91	
	Uncert.	0.018	0.013	0.033	0.004	
Overall	Mean	11.39	8.21	21.05	1.86	
	SD	0.22	0.15	0.46	0.06	
	Number	191	188	188	186	
	Uncert.	0.016	0.011	0.033	0.004	
Reference Values ID-GCMS		11.40	8.15	20.95	1.76	
Ref. Value Uncertainty		0.100	0.070	0.190	0.020	
Non-scoring Reference Values						
WeQas SD		0.34	0.25	0.65	0.12	
SDI		**0.00**	**-0.20**	**-0.38**	**0.34**	**0.23**

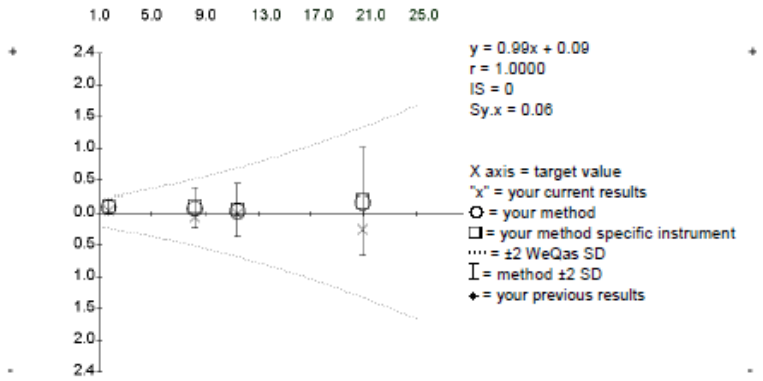
Sigma Metrics

Critical Level 1: 7 mmol/l

Minimum Acceptable score	1.62	Critical Level 1 Sigma score	7.4
MAPS Allowable TE	6.9%		
MAPS Allowable bias %	2.20%	Lab |bias| %	0.2%
MAPS Allowable CV %	2.90%	Lab CV %	0.9%

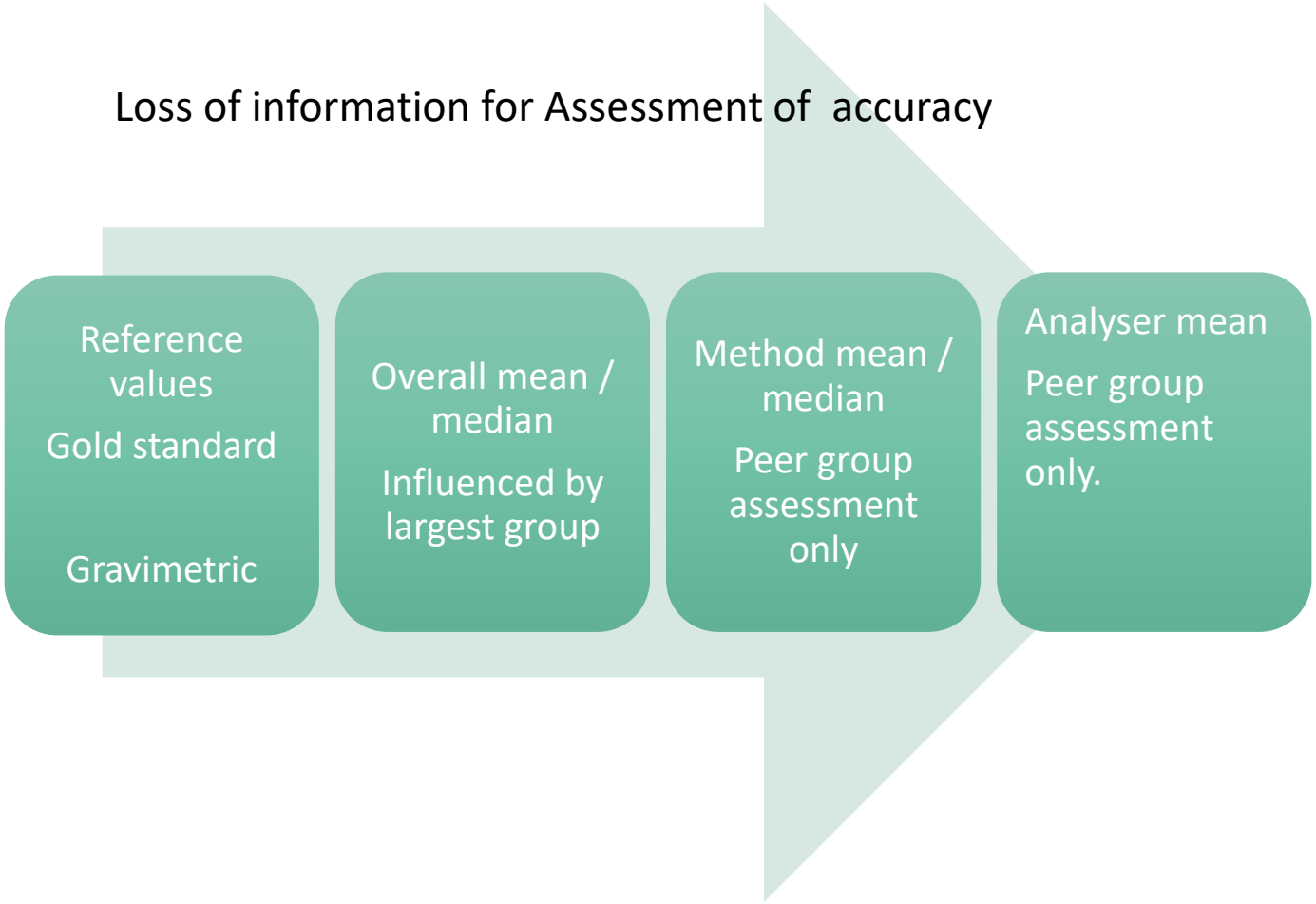
Please note: Linear regression uses CF corrected data.

This Distribution *RH* Prev



- Reference measurement values shown on report (and reference value uncertainty). Full traceability chain to SI units available.
- Lab results compared directly to reference values
- SDI scores, Sigma scores and bias plot based on reference values

Target values used in Quantitative EQA



Clinically Relevant Range and number of samples

- Sample numbers for each scheme assessed on an individual basis – still wide variation amongst EQALM members
- Appropriate sample matrices, endogenous, commutable, challenging, linear panels to assess method linearity, specificity and sensitivity (to assist with ISO15189).
- Covering pathological and analytical ranges. Careful selection of endogenous material to ensure range is covered, selected sources of patient material
- Cover critical “diagnostic cut points” e.g. high sensitivity Troponin, urine hCG, HbA1c, POCT CRP
- For Qualitative scheme, provide an appropriate number positive and negative pools, underpinned with known quantitative concentrations.

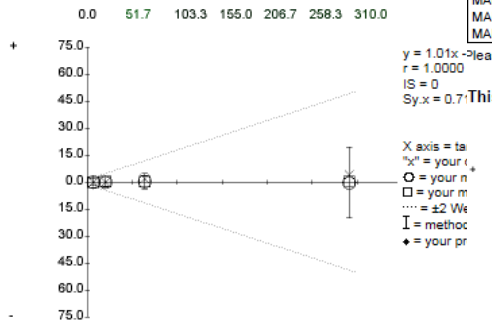
Clinically relevant samples

Scheme: Cardiac Marker. Distribution Code: N207.
Distribution Date: 24/10/17. Final. Report Issued: 23/11/17

Troponin T (ng/L)		1	2	3	4	Analyte SDI
Reported Result		7.0	305.0	21.0	68.0	
Method Corrected Result		7.00	305.00	21.		
Roche High Sensitivity	Mean	7.31	300.39	21.		
	SD	0.97	9.86	1.		
	Number	54	57			
	Uncert.	0.166	1.632	0.1		
Cobas E Module	Mean	7.31	300.98	21.		
	SD	1.00	9.81	1.		
	Number	50	53			
	Uncert.	0.177	1.684	0.2		
Overall	Mean	7.32	300.96	21.		
	SD	0.99	10.34	1.		
	Number	56	59			
	Uncert.	0.165	1.682	0.2		
Reference Values						
Ref. Value Uncertainty						
Non-scoring Reference Values						
WeQas SD		1.29	24.78	2.4		
SDI		**-0.24**	**0.19**	**-0.**		

Please note: Linear regression uses CF corrected data.

This Distribution *N207*



Scheme: Glycated Haemoglobin. Distribution Code: H264.
Distribution Date: 24/04/18. Final. Report Issued: 21/05/18

HbA1c IFCC (mmol/mol)		1	2	3	Analyte SDI
Reported Result		58.0	46.0		
Method Corrected Result		58.00	46.00		
Affinity	Mean	59.35	47.51	38.92	
	SD	2.67	1.65	1.44	
	Number	17	17	10	
	Uncert.	0.811	0.501	0.570	
Afinion AS100	Mean	56.86	46.26	NNR	
	SD	1.02	1.01		
	Number	7	7		
	Uncert.	0.482	0.478		
Overall	Mean	59.99	47.80	38.82	
	SD	2.24	2.21	2.89	
	Number	147	145	123	
	Uncert.	0.231	0.229	0.326	
Reference Values IFCC		59.60	48.40		
Ref. Value Uncertainty		1.400	1.400		
Non-scoring Reference Values					
WeQas SD		2.92	2.50	2.18	
SDI		**-0.46**	**-0.60**		**0.53**

Sigma Metrics

Critical Level 1: 50 mmol/mol

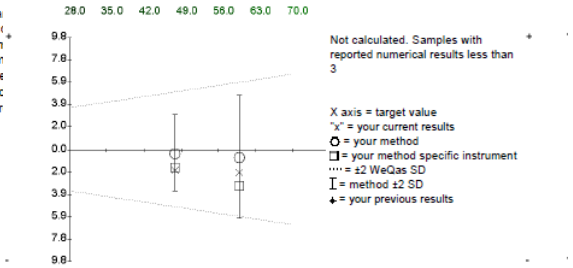
Minimum Acceptable score	1.64	Critical Level 1 Sigma score	2.1
MAPS Allowable TE	7.7%		
MAPS Allowable bias %	3.6%	Lab |bias| %	3.4%
MAPS Allowable CV %	2.5%	Lab CV %	2.1%

Please note: Linear regression uses CF corrected data.

y = 1.01x -
r = 1.0000
IS = 0
Sy.x = 0.7

This Distribution *H264*

Previc

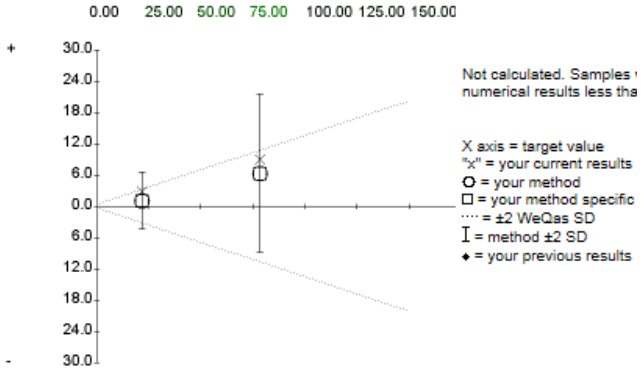


Scheme: PoCT CRP. Distribution Code: R7.
Distribution Date: 17/04/18. Final. Report Issued: 4/05/18

CRP (mg/L)		1	2	Analyte SDI
Reported Result		88.00	25.00	
Method Corrected Result		88.000	25.000	
QuikRead go	Mean	85.156	23.000	
	SD	8.054	2.875	
	Number	7	8	
	Uncert.	3.8053	1.2704	
QuikRead go	Mean	85.156	23.000	
	SD	8.054	2.875	
	Number	7	8	
	Uncert.	3.8053	1.2704	
Overall	Mean	78.617	22.000	
	SD	6.204	1.574	
	Number	35	36	
	Uncert.	1.3108	0.3279	
Reference Values				
Ref. Value Uncertainty				
Non-scoring Reference Values				
WeQas SD		5.703	1.740	
SDI		**0.50**	**1.15**	**0.82**

Please note: Linear regression uses CF corrected data.

This Distribution *R7*



Assessment of Total testing process

Pre analytical, analytical and Post analytical exercises – number of EQA provides now provide these

- Serum Indices Programmes, questionnaires sent out as part of Programme repertoire re: pre analytical sample handling.
- Analytical interference Studies e.g. Bilirubin effect on Salicylate & Paracetamol, serum indices, hook effects in immunoassays, Biotin in immunoassays
- Post analytical cases provided with Programmes e.g. Interpretation cases, EQA for calculated parameters.

Preanalytical quality improvement. In pursuit of harmony, on behalf of European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working group for Preanalytical Phase (WG-PRE)
Lippi G, Banfi G, Church S, Cornes M, De Carli G, Grankvist K, Kristensen GB, Ibarz M, Panteghini M, Plebani M, Nybo M, Smellie S, Zaninotto M, Simundic AM.
Clin Chem Lab Med 2015;53:357-70

Kristensen, GBB, Aakre, KM, Kristoffersen, AH. **How to conduct external quality assessment schemes for the pre-analytical phase?** Biochem Med (Zagreb) 2014; 24: 114–122.

Clin Chim Acta. 2018 Dec;487:293-298. doi: 10.1016/j.cca.2018.10.013. Epub 2018 Oct 5.

Comprehensive assessment of biotin interference in immunoassays.

Li J[1], Wagar EA[1], Meng QH[2].

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Expectations of EQA Provider

Clinically relevant performance criteria

- Based on clinical outcomes
- Based on biological variation

Reporting to Professional body / Regulatory body.

- Mechanism for identification and reporting of Persistent Poor performance issues

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DE GRUYTER Clin Chem Lab Med 2015; 53(6): 833–835

Consensus Statement

Sverre Sandberg*, Callum G. Fraser, Andrea Rita Horvath, Rob Jansen, Graham Jones, Wytze Oosterhuis, Per Hyltoft Petersen, Heinz Schimmel, Ken Sikaris and Mauro Panteghini

Defining analytical performance specifications: Consensus Statement from the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine

DOI 10.1515/cclm-2015-0067

The Organisers and the Scientific Programme Committee (SPC) of the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) on 'Defining analytical performance goals 15 years after the Stockholm Conference on Quality Specifications in Laboratory Medicine', held in Milan (IT) on November 24–25, 2014, are pleased to report on the success of the Conference.

The primary aim was to revisit the 'Consensus Agreement' from the Stockholm Conference investigating to what extent the advocated hierarchy is still valid or if it should be changed. A revision of the original hierarchy established by the Stockholm Conference was presented to the meeting with opportunity for discussion and feedback by conference participants. This revision further underwent modification and explanatory additions by the SPC in an attempt to simplify the hierarchy and improve its application by various stakeholders.

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

DOI 10.1515/cclm-2017-0151
Received February 21, 2017; accepted April 18, 2017; previously published online May 23, 2017

Abstract: External Quality Assurance (EQA) is vital to ensure acceptable analytical quality in medical laboratories. A key component of an EQA scheme is an analytical performance specification (APS) for each measurand that a laboratory can use to assess the extent of deviation of the obtained results from the target value. A consensus conference held in Milan in 2014 has proposed three models to set APS and these can be applied to setting APS for EQA. A goal arising from this conference is the harmonisation of EQA APS between different schemes to deliver consistent quality messages to laboratories irrespective

Laboratory Medicine (EFLM) Task and Finish Group on Performance Specifications for External Quality Assurance Schemes (TFG-APSEQA) and on clear terminology for EQA APS. The recommended terminology covers six elements required to understand APS: 1) a statement on the EQA material matrix and its commutability; 2) the method used to assign the target value; 3) the data set to which APS are applied; 4) the applicable analytical property being assessed (i.e. total error, bias, imprecision, uncertainty); 5) the rationale for the selection of the APS; and 6) the type of the Milan model(s) used to set the APS. The terminology is required for EQA participants and other interested parties to understand the meaning of meeting or not meeting APS.

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Clinically Relevant Performance Specification

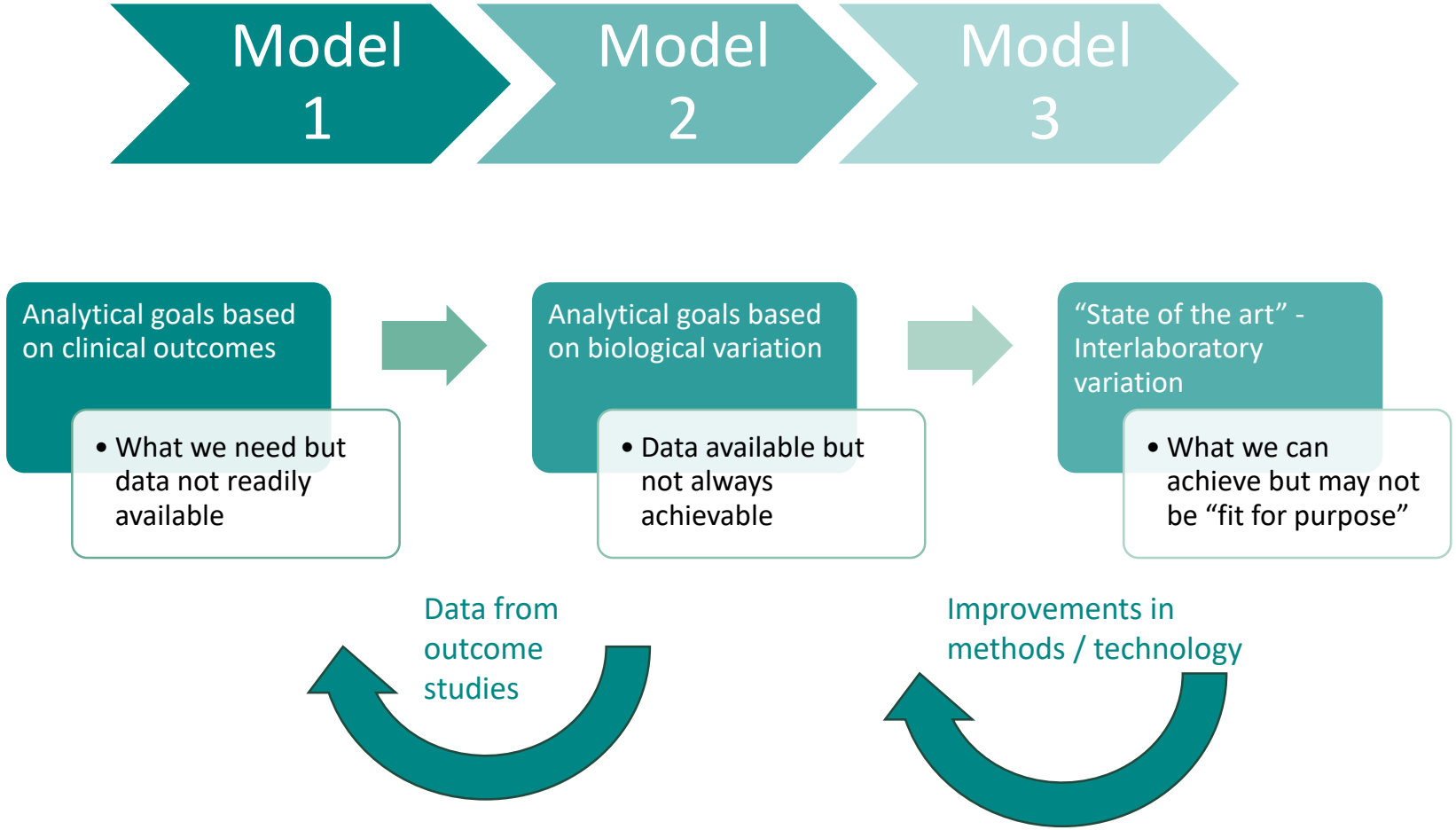


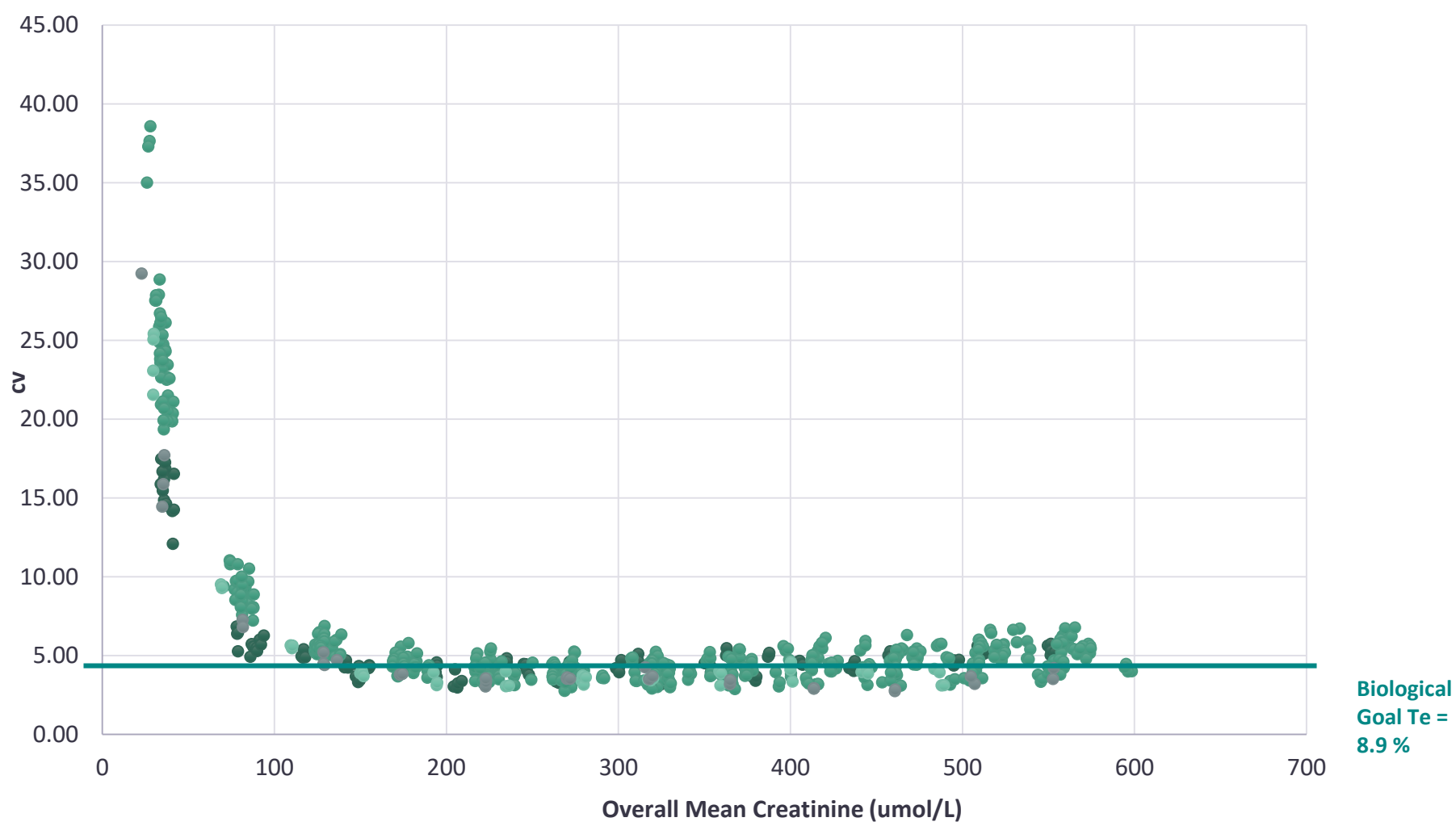
Table 1: Examples of current variation in models used to assign analytical performance specifications (APS) to External Quality Assurance (EQA) schemes.

EQA Program	Models
CSCQ Switzerland	Governmental regulations (combination of BV and state of the art) and Combination of limits given by scientific societies and Z-score
CTCB France	Z-score/state of the art/limits given by scientific societies or other/limits based on clinical impact
DEKS Denmark	Combination of BV, state of the art and expert opinion
NOKLUS Norway	Fixed percentage limits and based on a combination of BV, state of the art and expert opinion
RCPAQAP Australia	Combination of BV and state of the art
SEHH Spain	Statistical/state of the art/BV
SEQC Spain	Combination of BV and statistical results
SKML The Netherlands	Combination of BV and state of the art
WEQAS UK	Combination of BV and state of the art
CMCEQAS	Combination of state of the art and statistical considerations

		Biological goals			Weqas TE criteria		
Analyte	**Conc.**	**I (%)**	**B (%)**	**TE (0.01)**	**SD**	**2 SD**	**TE**
Albumin	40	1.6	1.3	**4.9**	1.3	2.6	**6.5**
Bicarb	20	2.4	1.6	**7.2**	1.3	2.6	**13.0**
Ca	2.3	1	0.8	**3.1**	0.05	0.1	**4.3**
Cl	100	0.6	0.5	**1.9**	1.4	2.8	**2.8**
Creat	80	2.2	3.4	**8.4**	8	16	**20.0**
Glucose	4.2	2.2	1.9	**7.0**	0.16	0.32	**7.6**
Mg	0.8	1.8	1.8	**6.0**	0.03	0.06	**7.5**
Osmo	245	0.7	0.4	**2.0**	3.4	6.8	**2.8**
Phos	0.8	4.3	3.2	**13.1**	0.03	0.06	**7.5**
K	4	2.4	1.8	**7.4**	0.08	0.16	**4.0**
Na	135	0.4	0.3	**1.2**	1.5	3	**2.2**
T P	70	1.4	1.2	**4.4**	1.6	3.2	**4.6**
Urate	0.34	4.3	4.8	**14.8**	0.02	0.04	**11.8**
Urea	8	6.2	5.5	**19.8**	0.35	0.7	**8.8**

Highlighted TE are those where Biological goals not achievable

“State of the art” v Biology



Biological goal is only achievable down to 150umol/l Creatinine

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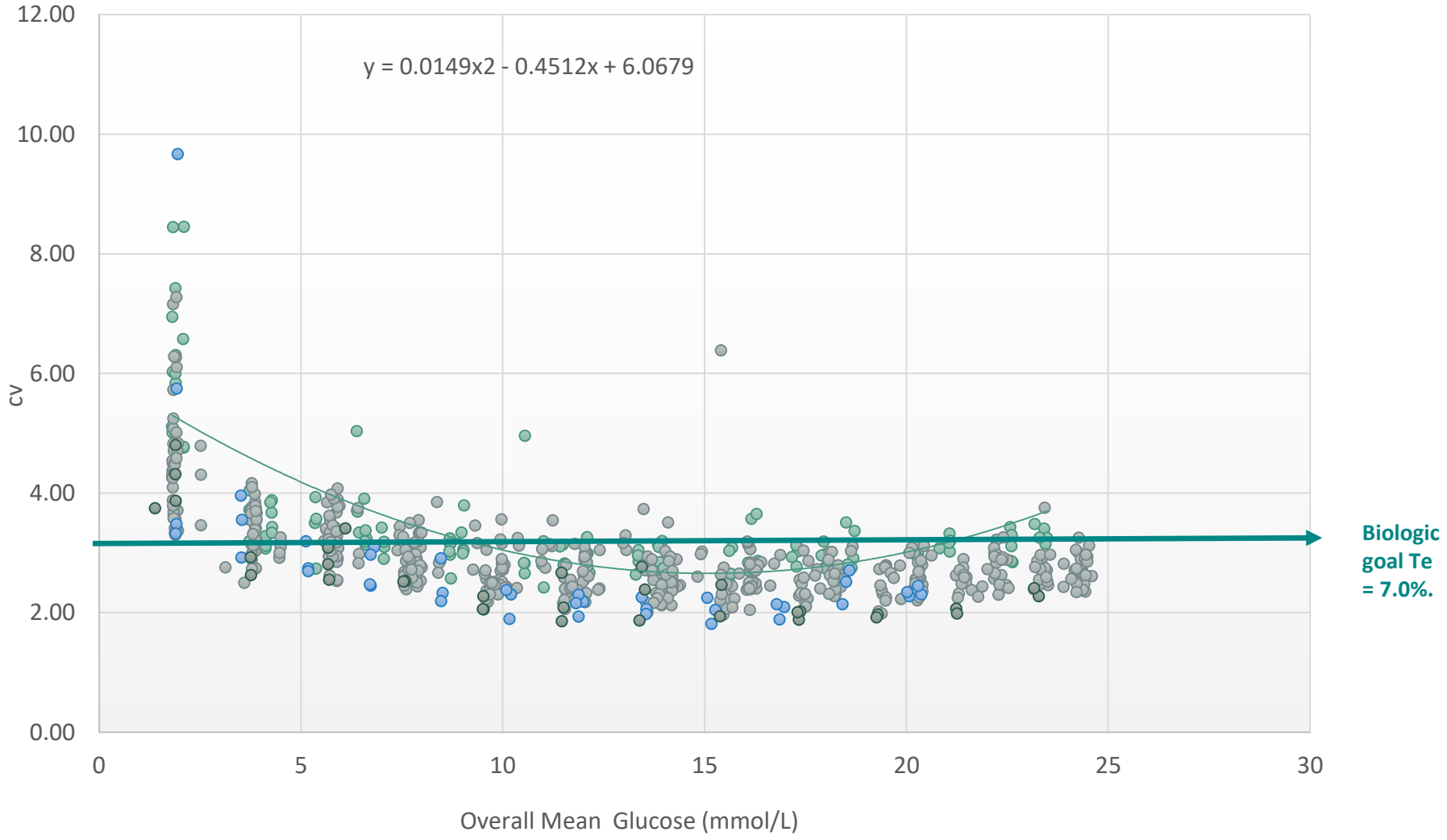
Glucose Precision Profile (CV%)



Biological goal is only achievable down to 4 mmol/l Glucose

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Expectations of EQA Provider

Education

- Training
- Helpline
- Pre analytical
- Post Analytical

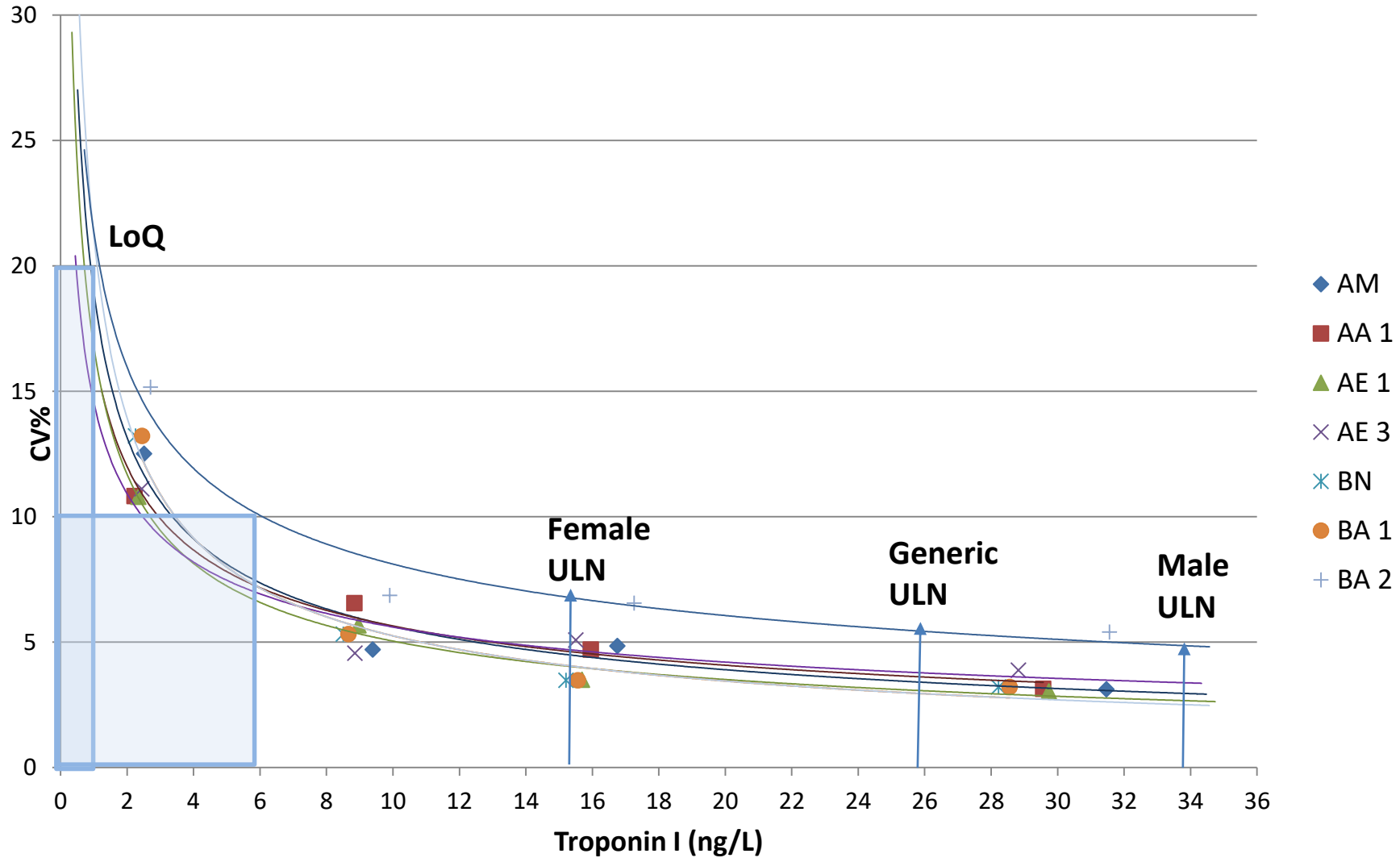
Post-marketing surveillance

- Alerts manufacturers
- Alerts competent authority
- Alerts laboratories
- Alerts professional bodies

Educational role (quality improvement)

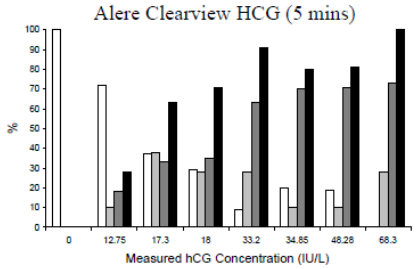
- Pre-analytical effects
- Performance of methods – state of the art
    - accuracy
    - precision
    - limits of detection
    - linearity
- Susceptibility of methods to interference
    - including other analytes and matrix
- Interpretation of results – standard units, global cut off
- Undertaking audit of clinical services – identify good practice
- Understanding how to use Quality tools – IQC, EQA, audit

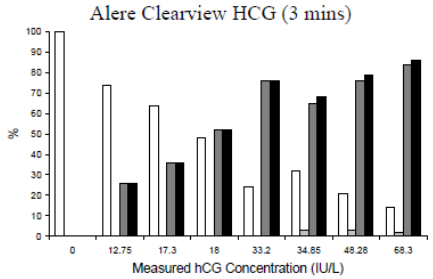
Method performance – hs TnI

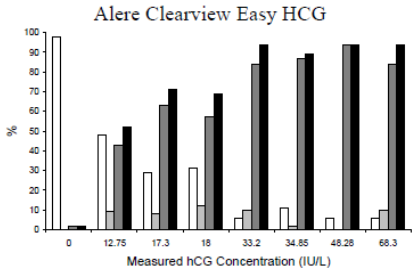


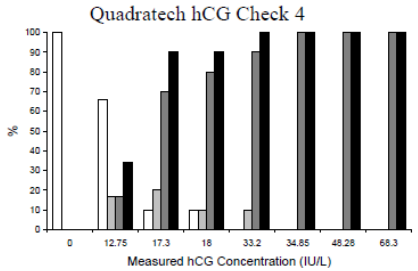
Specificity and Sensitivity Studies

Pregnancy testing









Bile Acids

Results

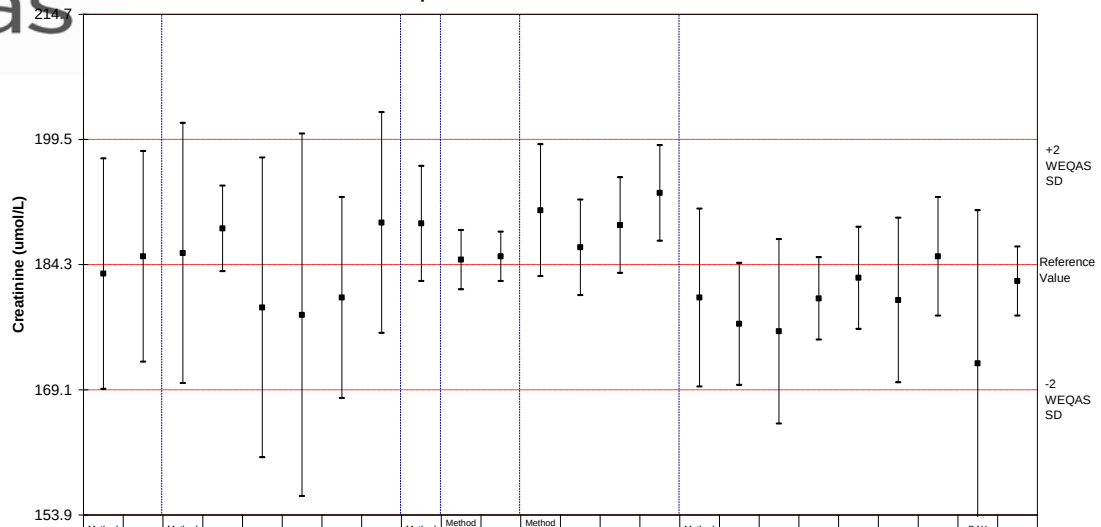
Table 3 shows the summary data from the distributed recovery samples. The predominant group is represented by the Enz-Thio-NADH method (86% of scheme participants), with the Enz-Formazan group representing 5% of scheme participants and the Sentinel Enz-Formazan group 9% of scheme participants.

Table 3 Bile Acid Recovery Experiment: comparison with ID-GCMS Targets

POOL ID	CHOLIC ACID				DEOXYCHOLIC			
	µmol/L				µmol/L			
	ID-GCMS Target				ID-GCMS Target			
POOL A (sample 4)	103.18							
POOL B (sample 5)					108.78			
POOL C (sample 6)								
POOL D (sample 7)								
Returned results	mean	SD	n	% recovery	mean	SD	n	% recovery
overall	101.18	7.54	111	98.06	137.80	15.87	110	126.68
Enz-Thio-NADH	99.89	6.59	95	96.81	141.27	15.64	94	129.87
Enz-Formazan	89.5	1.50	5	86.74	137.00	15.00	2	125.94
Enz-Formazan (Sentinel)	112.41	4.90	15	108.95	119.42	5.08	15	109.78
POOL ID	**URSODEOXYCHOLIC**				**CHENODEOXYCHOLIC**			
	µmol/L				µmol/L			
	Spiked Target				ID-GCMS Target			
POOL A (sample 4)								
POOL B (sample 5)								
POOL C (sample 6)					77.14			
POOL D (sample 7)	100							
Returned results	mean	SD	n	% recovery	mean	SD	n	% recovery
overall	57.81	8.44	107	57.81	56.05	7.30	107	72.66
Enz-Thio-NADH	56.00	4.44	98	56.00	54.25	4.61	95	70.32
Enz-Formazan	51.50	0.5	2	51.50	51.00	2.00	2	66.11
Enz-Formazan (Sentinel)	90.47	3.33	15	90.47	77.05	2.88	12	99.88

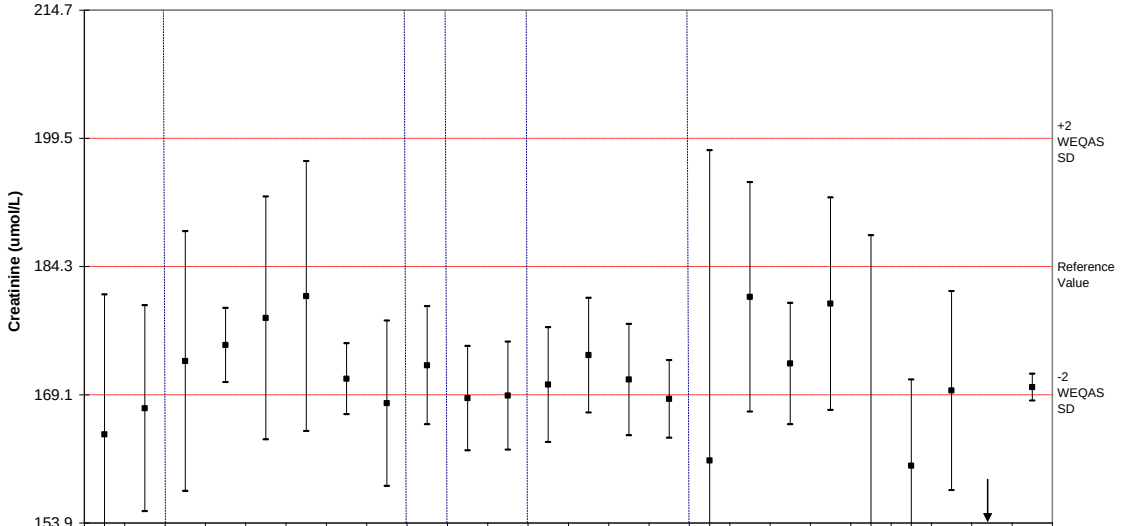
Interference Reports – bilirubin effect on creatinine

Sample 2 - Creatinine - Non Icteric Pool



	Method JR n=4	C n=4	Method KJ n=53	AD n=3	OL n=10	AU n=10	A n=7	C n=25	Method Vit n=4	Method VIDMS n=9	VI n=8	Method Enz n=53	AD n=12	M n=7	C n=32	Method JI n=120	AD n=18	OL n=5	AU n=7	DX n=26	C n=34	M n=14	DAY n=13	A n=3
Mean	183.2	185.3	185.7	188.7	179.1	178.2	180.3	189.4	189.3	184.9	185.3	190.9	186.4	189.1	193.0	180.3	177.1	176.2	180.2	182.7	180	185.3	172.3	182.3
+2SD	197.2	198.1	201.5	193.9	197.3	200.2	192.5	202.8	196.3	188.5	188.3	198.9	192.2	194.9	198.8	191.1	184.5	187.4	185.2	188.9	190	192.5	190.9	186.5
-2SD	169.2	172.5	169.9	183.5	160.9	156.2	168.1	176	182.3	181.3	182.3	182.9	180.6	183.3	187.2	169.5	169.7	165	175.2	176.5	170	178.1	153.7	178.1

Sample 3 - Creatinine - Icteric Pool

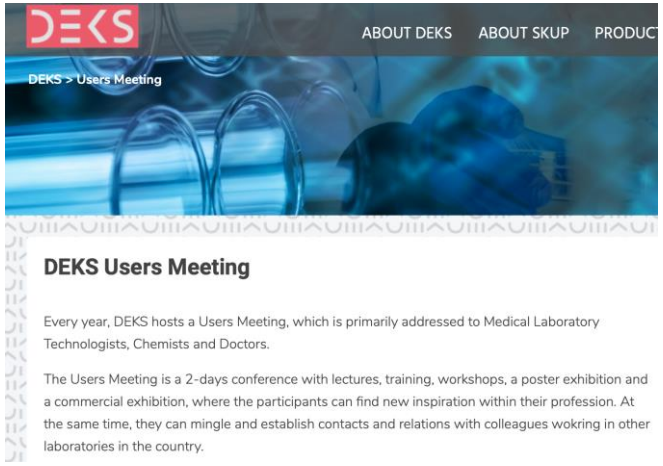


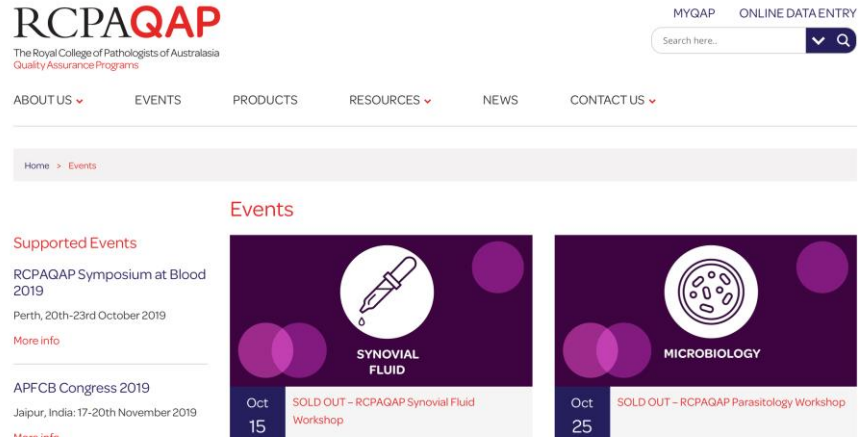
	Method JR n=4	C n=4	Method KJ n=53	AD n=3	OL n=10	AU n=10	A n=7	C n=25	Method Vit n=4	Method VIDMS n=9	VI n=8	Method Enz n=53	AD n=12	M n=7	C n=32	Method JI n=120	AD n=18	OL n=5	AU n=7	DX n=26	C n=34	M n=14	DAY n=13	A n=3
Mean	164.4	167.5	173.1	175.0	178.2	180.8	171.0	168.1	172.6	168.7	169.0	170.3	173.8	170.9	168.6	161.3	180.7	172.8	179.9	153.0	160.7	169.6	128.7	170
+2SD	181	179.7	188.5	179.4	192.6	196.8	175.2	177.9	179.6	174.9	175.4	177.1	180.6	177.5	173.2	198.1	194.3	180	192.5	188	170.9	181.4	142.1	171.6
-2SD	147.8	155.3	157.7	170.6	163.8	164.8	166.8	158.3	165.6	162.5	162.6	163.5	167	164.3	164	124.5	167.1	165.6	167.3	118	150.5	157.8	115.3	168.4

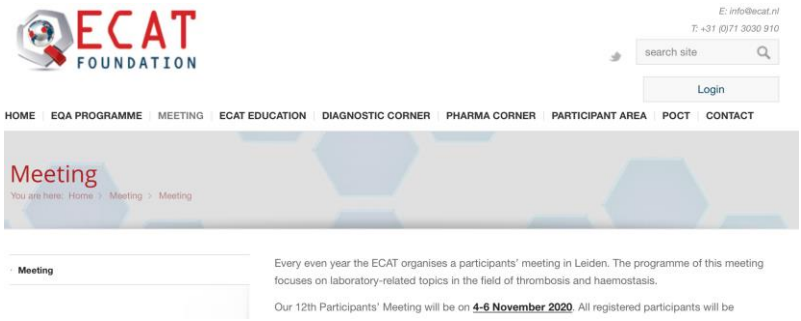
The reference value (ID-GCMS) was 184.3 µmol/L for sample 2 and 184.4 µmol/L for sample 3

Educational days

- More & more EQA providers now organize annual conferences / regional workshops in Laboratory Diagnostics.







UK NEQAS Cellular Pathology Technique BMT workshop October 2019

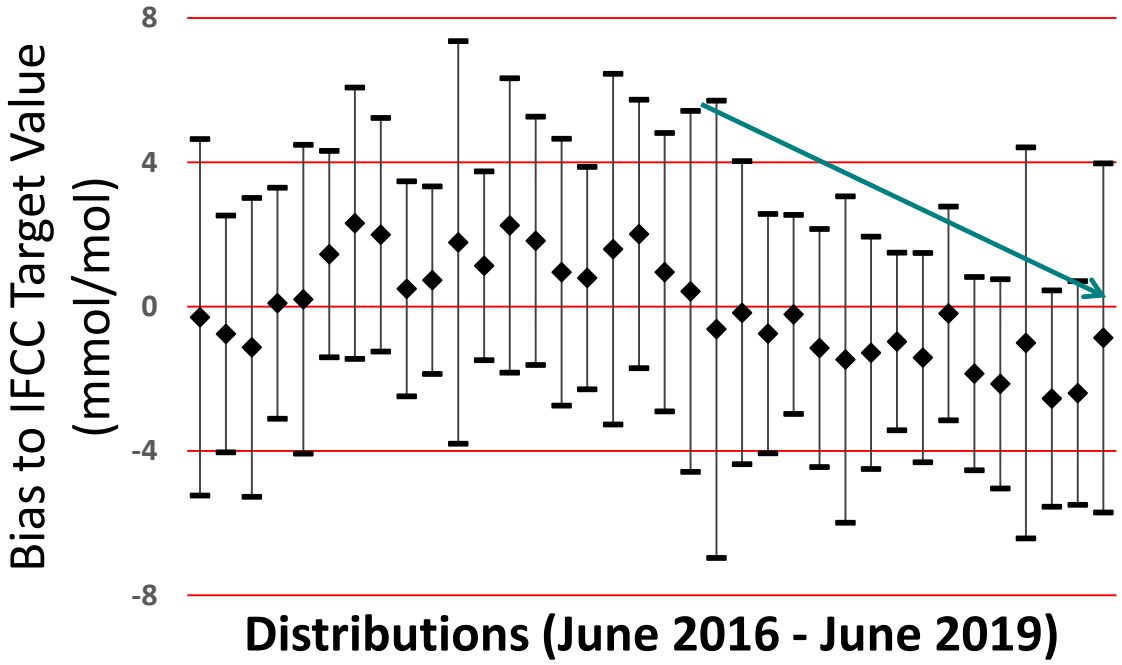
This introductory workshop provides an introduction to the theory and application of specialist BMT techniques.

Troubleshooting Support & post market vigilance

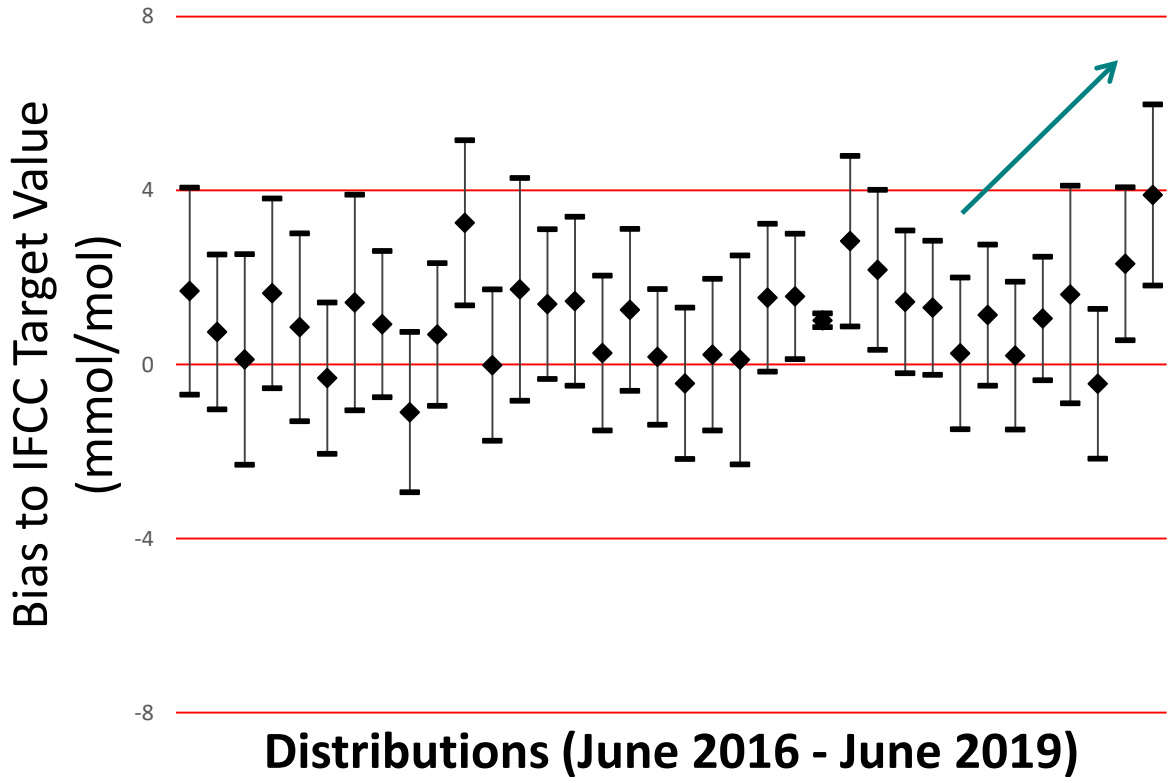
- Now part of the EQA providers role
- To provide **help** with
  - Participant Performance queries
  - report interpretation
  - Provide additional material for problem solving
- To alert manufacturers of potential issue
  - To assist in issue resolution
- To alert regulatory authority

Weqas

DCA 2000/ Vantage HbA1c Bias Plot

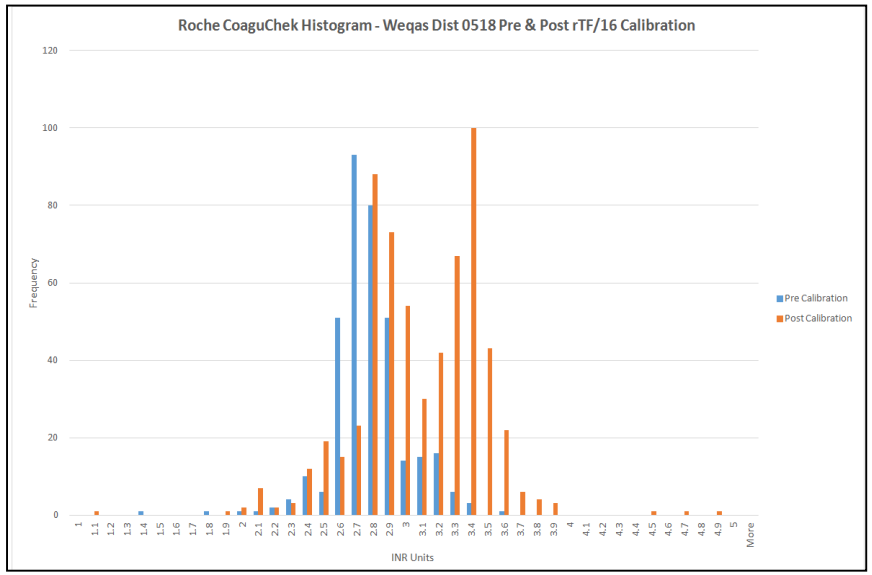


G8 HbA1c Bias Plot

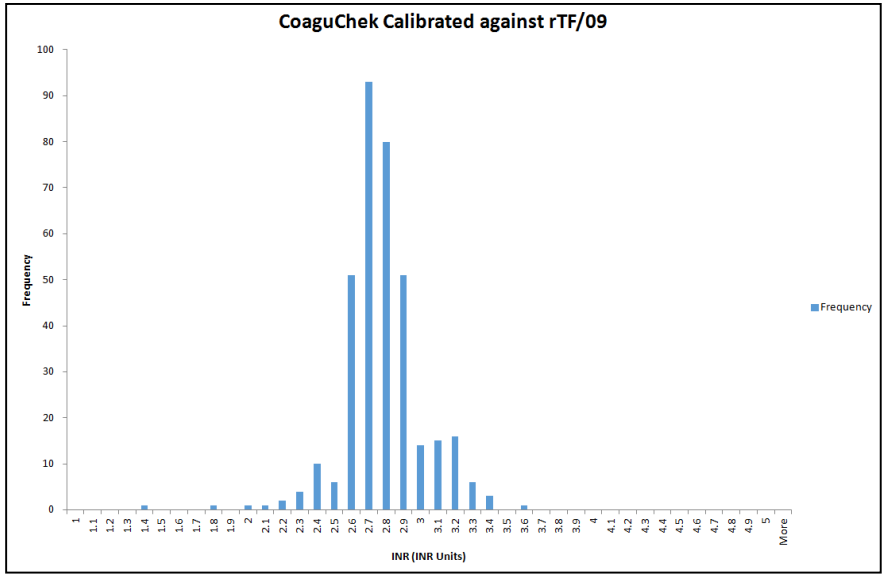


Post Market vigilance – INR thromboplastin

INR results classified into pre and post recalibration.



participants using strips calibrated to WHO reference thromboplastin rTF/09



The pre calibration strips compared well with the results from Distribution 0517 (Median 2.8) however much higher results and a wider distribution of results was observed for the post calibration strips. Weqas immediately contacted the manufacturer and sent them the data.

Aug 2018 – Urgent field safety notice issued to inform users that the manufacturer was reverting back to previous WHO reference standard.

Weqas

Web portals

- EQA data assessment can now be undertaken in a timely manner with data uploaded via web portals and the use of electronic EQA reports. A wealth of additional information can be provided to participants with direct links to the EQA databases providing useful troubleshooting tools.

- EQA providers are also providing tools for laboratories to achieve ISO 15189 accreditation

ISO 15189 tools from EQA reports

Scheme: Serum Chemistry. Distribution Code: RH.
Distribution Date: 2/01/18. Final. Report Issued: 24/01/18

Glucose (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		11.4	8.1	20.7	1.8	
Method Corrected Result		11.40	8.10	20.70	1.80	
Hexokinase	Mean	11.42	8.21	21.11	1.85	
	SD	0.20	0.15	0.41	0.05	
	Number	170	172	169	168	
	Uncert.	0.015	0.012	0.032	0.004	
Cobas C Module	Mean	11.45	8.26	21.13	1.88	
	SD	0.17	0.13	0.31	0.04	
	Number	91	95	92	91	
	Uncert.	0.018	0.013	0.033	0.004	
Overall	Mean	11.39	8.21	21.05	1.86	
	SD	0.22	0.15	0.46	0.06	
	Number	191	188	188	186	
	Uncert.	0.016	0.011	0.033	0.004	
Reference Values ID-GCMS		11.40	8.15	20.95	1.76	
Ref. Value Uncertainty		0.100	0.070	0.190	0.020	
Non-scoring Reference Values						
WeQas SD		0.34	0.25	0.65	0.12	
SDI		**0.00**	**-0.20**	**-0.38**	**0.34**	**0.23**

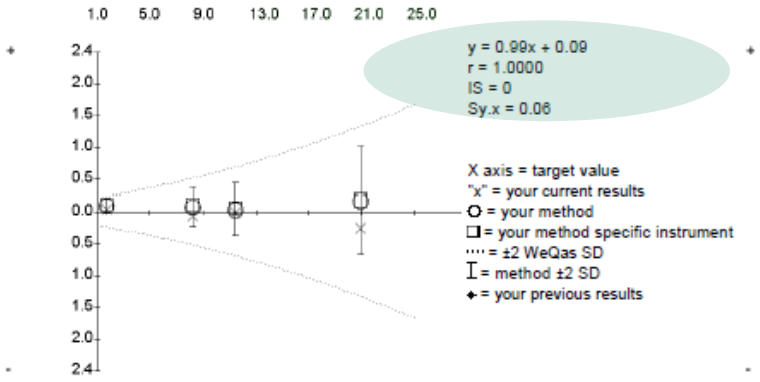
Sigma Metrics

Critical Level 1: 7 mmol/l

Minimum Acceptable score	1.62	Critical Level 1 Sigma score	7.4
MAPS Allowable TE	6.9%		
MAPS Allowable bias %	2.20%	Lab |bias| %	0.2%
MAPS Allowable CV %	2.90%	Lab CV %	0.9%

Please note: Linear regression uses CF corrected data.

This Distribution *RH* Prev



- traceability to higher order method
- Linearity assessment

Weqa

Scheme: Serum Chemistry. Distribution Code: RH.
Distribution Date: 2/01/18. Final. Report Issued: 24/01/18

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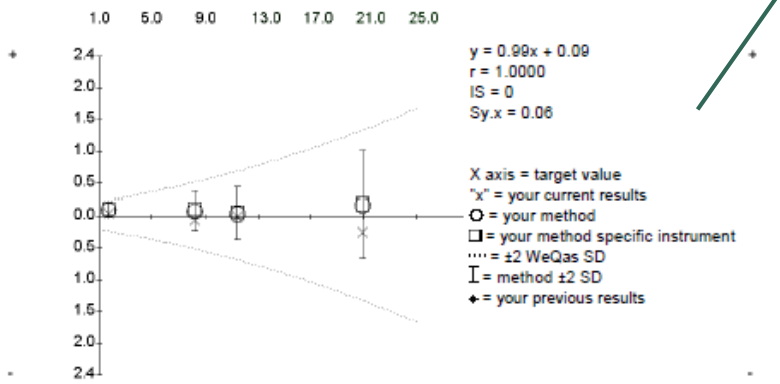
Please note: Linear regression uses CF corrected data.

This Distribution *RH* Prev



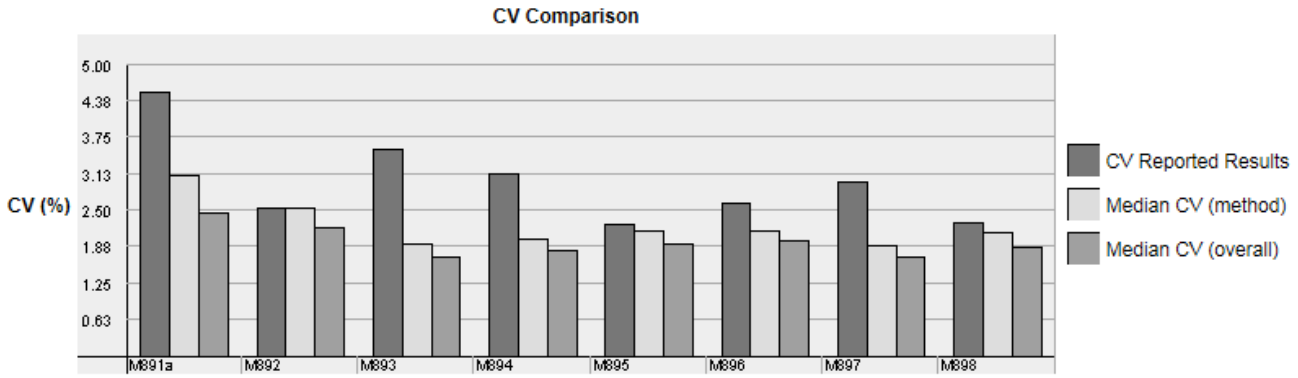
Uncertainty

- Laboratory within run Imprecision:
- Sy.x = 0.06 mmol/L
- CV% = (Sy.x/ x)*100 = 0.06/7*100 = 0.86%

Uncertainty – long term

Analyte: Creatinine (µmol/L)

Method: **Jaffe - IDMS**	M891a	M892	M893	M894	M895	M896	M897	M898
Section Stats								
Mean reported results	64.5	133.6	206.8	276.7	346.9	420.1	490.6	558.4
SD reported results	2.9	3.4	7.3	8.6	7.8	11.0	14.7	12.7
CV(%) reported results	4.51	2.52	3.52	3.10	2.25	2.61	2.99	2.27
Number of results	5	5	4	3	5	5	5	6
Method Result Stats								
Mean method mean	67.7	139.3	213.3	286.6	357.4	428.9	498.4	570.0
Median CV	3.08	2.52	1.91	2.00	2.14	2.14	1.88	2.11
Overall Result Stats								
Median CV	2.44	2.19	1.69	1.81	1.92	1.97	1.70	1.85



- Between batch CV% provided on End of Batch reports (12 month review)
- E.g Pool M891a - CV% of reported results: 4.51%

Weqas

EQA and User in partnership

Part of Quality Improvement

- Should not be viewed as a pass/fail exercise
- Educational – troubleshooting, recommendations of best practice
- Identify poor methods
- Provide training and help

Weqas

Healthcare and the Digital revolution - the next decade

What's next for EQA

NHS

The NHS Long Term Plan

In ten years' time, we expect the existing model of care to look markedly different. The NHS will offer a 'digital first' option for most, allowing for longer and richer face-to-face consultations with clinicians where patients want or need it. Primary care and outpatient services will have changed to a model of tiered escalation depending on need. Senior clinicians will be supported by digital tools, freeing trainees' time to learn. When ill, people will be increasingly cared for in their own home, with the option for their physiology to be effortlessly monitored by wearable devices. People will be helped to stay well, to recognise important symptoms early, and to manage their own health, guided by digital tools.

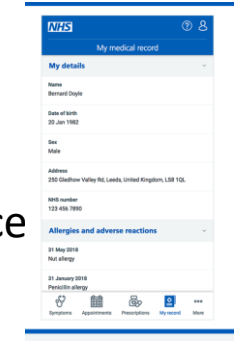
Digitally-enabled care will go mainstream across the NHS

Practical priorities will drive NHS digital transformation

- Create straightforward digital access to NHS services, and help patients and their carers manage their health.
- Ensure that clinicians can access and interact with patient records and care plans wherever they are.
- Use decision support and artificial intelligence (AI) to help clinicians in applying best practice, eliminate unwarranted variation across the whole pathway of care, and support patients in managing their health and condition.
- Use predictive techniques to support local health systems to plan care for populations.
- Use intuitive tools to capture data as a by-product of care in ways that empower clinicians and reduce the administrative burden.
- Protect patients' privacy and give them control over their medical record.
- Link clinical, genomic and other data to support the development of new treatments to improve the NHS, making data captured for care available for clinical research, and publish, as open data, aggregate metrics about NHS performance and services.
- Ensure NHS systems and NHS data are secure through implementation of security, monitoring systems and staff education.
- Mandate and rigorously enforce technology standards (as described in The Future of Healthcare) to ensure data is interoperable and accessible.
- Encourage a world leading health IT industry in England with a supportive environment for software developers and innovators.

Document first published:
7 January 2019

Health Apps



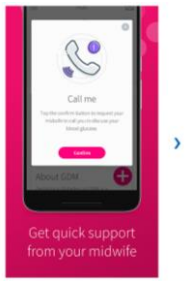
- 1.6 m searches for Health information on the NHS Choices website each day.
- 60% of the people who use the internet to check a medical condition do not then go on to access a frontline service
- 170,000 mHealth Apps available in Apple and Google stores.
- 10% of mHealth apps can connect to a device or sensor that provides physical function data.
- NHS Apps library recommended apps contains over 70 apps and offers a trusted source of health apps for patients and the workforce.
- new NHS App rolled out 2019. By 2021, it will allow people to upload data from their wearables and lifestyle apps,
- safely and securely, and consent for those data to be linked with their health records

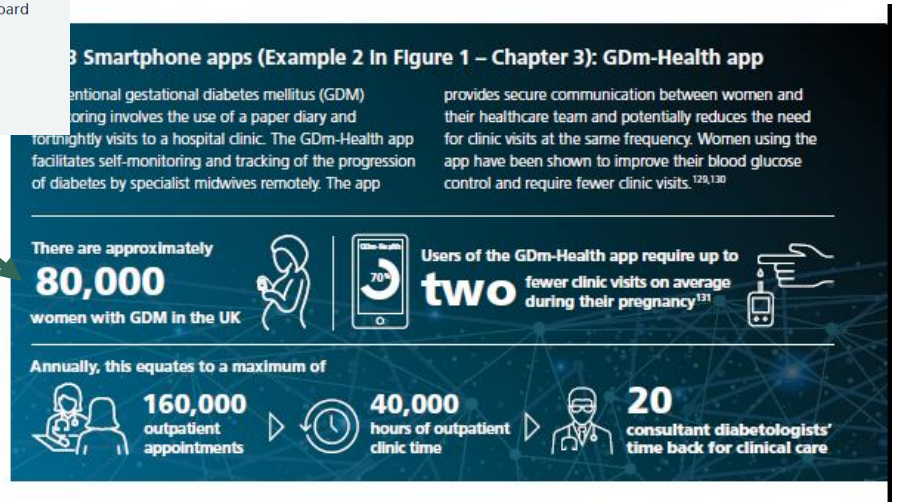
GDm-Health
Categories: Diabetes, Pregnancy and baby
Free

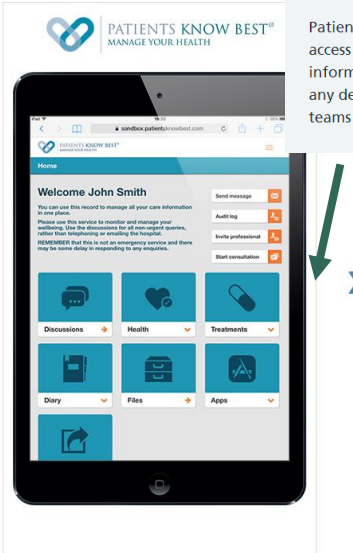
The GDm-Health app is part of a system that helps clinicians manage diabetes in pregnancy.

The system comprises a patient app that can receive readings wirelessly from a blood glucose monitor, and a web-app dashboard for use by medical professionals.

Using the web-app dashboard, clinicians can view your blood glucose readings in real-time and proactively manage your condition.



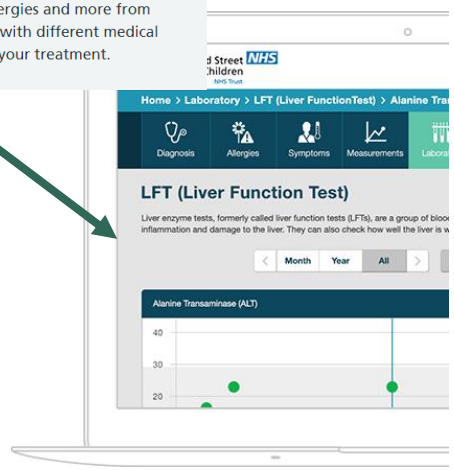




NHS
Health A-Z | Live Well | Care and support | Health
Home > NHS Apps Library

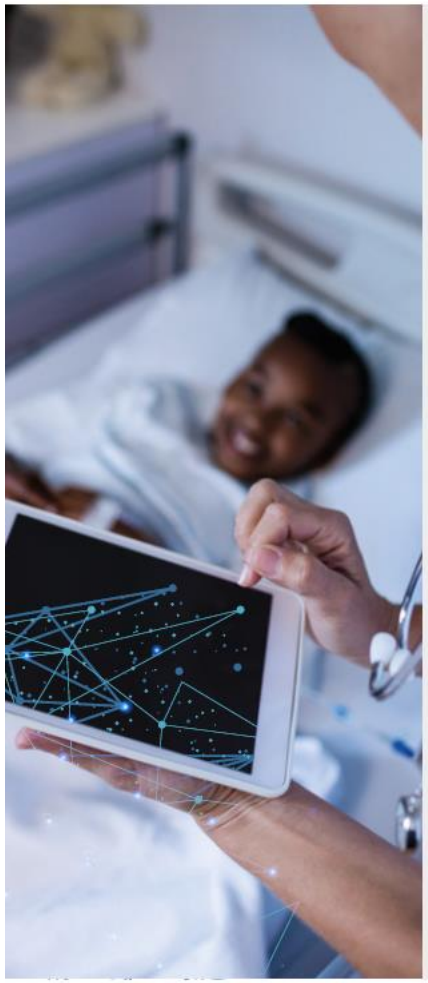
Patients Know Best
Category: NHS services
Free where available

Patients Know Best works with the NHS to give patients instant access to their medical records. You can access up-to-date information on treatments, medication, allergies and more from any device. This information can be shared with different medical teams and carers to speed up and improve your treatment.



The top digital healthcare technologies impacting the workforce

Topol Review 2019



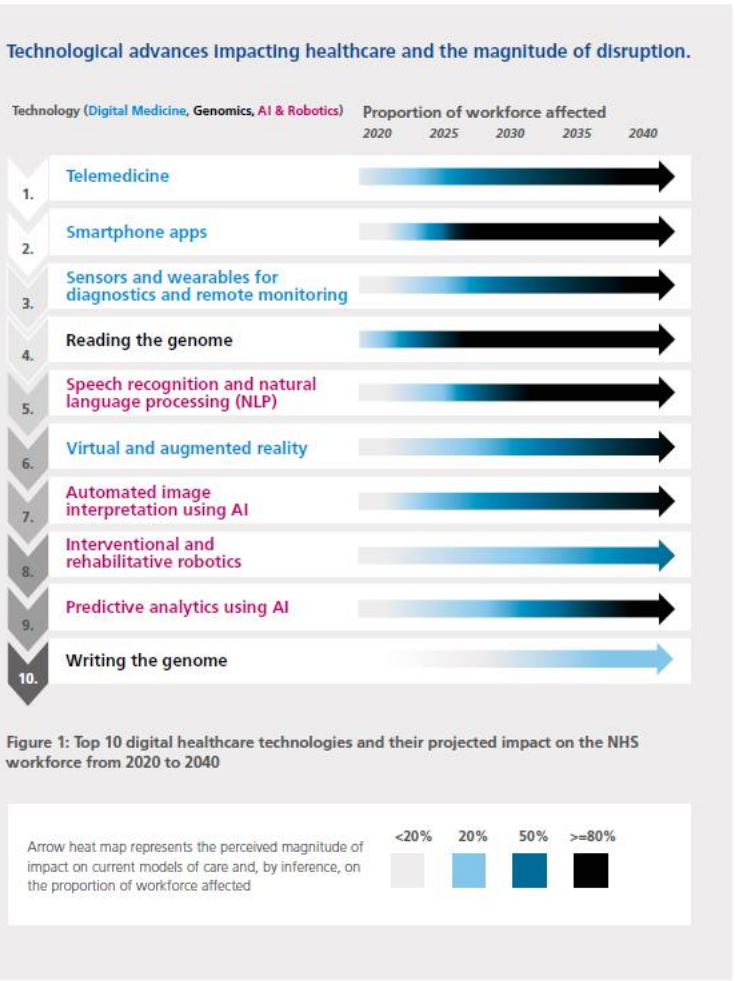


Figure 1: Top 10 digital healthcare technologies and their projected impact on the NHS workforce from 2020 to 2040

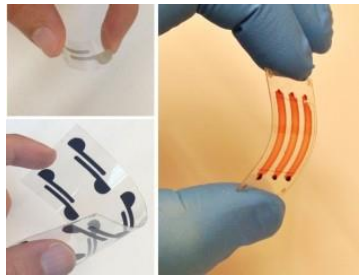
Weqas

The Drivers…digital health for wearable sensor

- Decreasing costs of sensors
- Miniaturization of physiological sensors
- Integration of sensors into consumer-end devices and accessories
- Rising share of ageing population
- Increasing incidences of chronic and lifestyle diseases
- Increased health and fitness awareness
- Rise in home and remote patient monitoring
- Reduced digital health costs
- Increasing mobile and smartphone penetration
- Increasing patient/physician acceptance
- Entry of big players such as Apple, Google, Microsoft and Amazon

Rapid advances in biosensor technology - the smartphone

Stanford University School of Medicine (Bio-Acoustic MEMS in Medicine Labs) developed assays for the simple and rapid detection of HIV-1, various bacteria, and CD4+ T lymphocytes



sensors

MDPI

Article

A Smartphone-Based Automatic Measurement Method for Colorimetric pH Detection Using a Color Adaptation Algorithm

Sung Deuk Kim [1], Youngmi Koo [2] and Yeoheung Yun [2,*]

[1] Department of Electronic Engineering Education, Andong National University, 1375 Gyeongdong-ro, Andong, Gyeongsangbuk-do 36729, Korea; sdkim@andong.ac.kr
[2] FIT BEST Laboratory, Department of Chemical, Biological, and Bioengineering, North Carolina A&T State University, 1601 E. Market St., Greensboro, NC 27411, USA; kooym20120503@gmail.com
* Correspondence: yyun@ncat.edu; Tel.: +1-336-285-3226

RESEARCH ARTICLE

A lab-on-phone instrument with varifocal microscope via a liquid-actuated aspheric lens (LAL)

Yiin-Kuen Fuh[1,2]*, Zheng-Hong Lai[1], Li-Han Kau[1], Hung-Jui Huang[1]

1 Institute of Opto-mechatronics Engineering, National Central University, Jhongli City, Taoyuan County, Taiwan, 2 Department of Mechanical Engineering, National Central University, Jhongli City, Taoyuan County, Taiwan

* mikefuh@ee.ncu.edu.tw

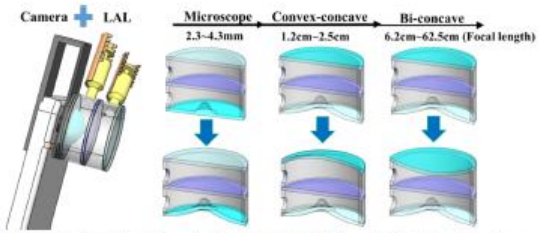


Fig 3. The structure and working mechanism of proposed LAL. Three distinctively different modes can be operated as microscope, convex-concave and bi-concave modes, respectively. The proposed LAL can be easily mounted on a smart phone via a 3d printed fixture as indicated. In the microscope mode, the tunable shapes of APLMC vary with injected volume at the bottom chamber (tunable range is experimentally measured 2.3~4.3 mm). For the operations of convex-concave mode and bi-concave mode, the tunable range can be achieved as 1.2~2.5cm (macro mode) and 6.2~62.5cm (macro mode) respectively.

https://doi.org/10.1371/journal.pone.0179388.g003

www.nature.com/scientificreports

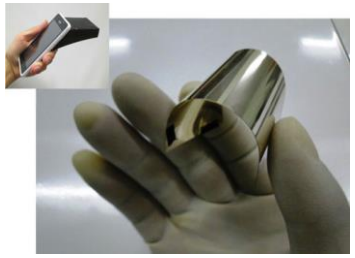
SCIENTIFIC REPORTS

OPEN

All-printed highly sensitive 2D MoS_2 based multi-reagent immunosensor for smartphone based point-of-care diagnosis

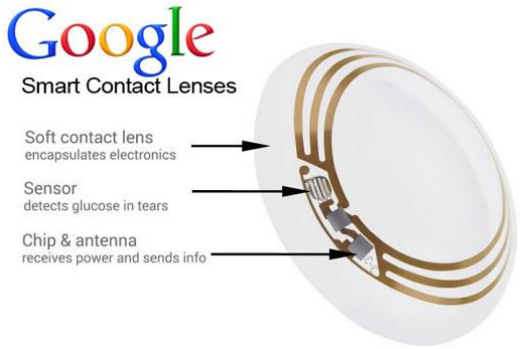
Received: 3 March 2017
Accepted: 30 May 2017
Published online: 19 July 2017

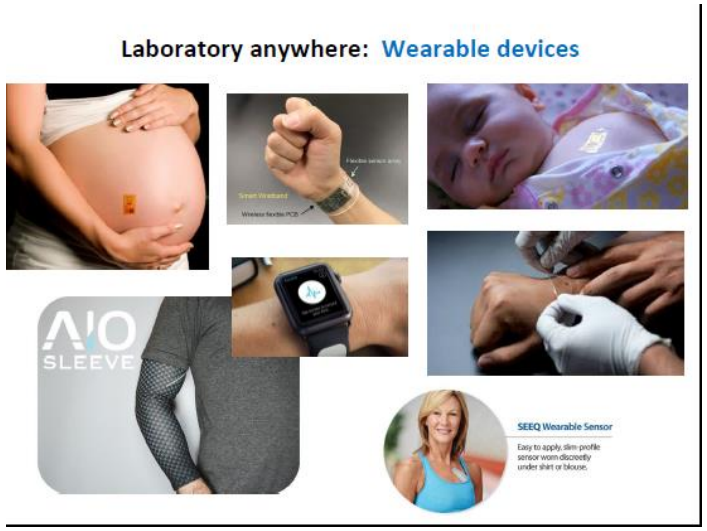
Memoon Sajid[1], Ahmed Osman[2,3], Ghayas Uddin Siddiqui[1], Hyun Bum Kim[1], Soo Wan Kim[1], Jeong Bum Ko[1], Yoon Kyu Lim[4] & Kyung Hyun Choi[1]



Large number of applications on infectious disease

Diagnostics Anywhere – passive measurement

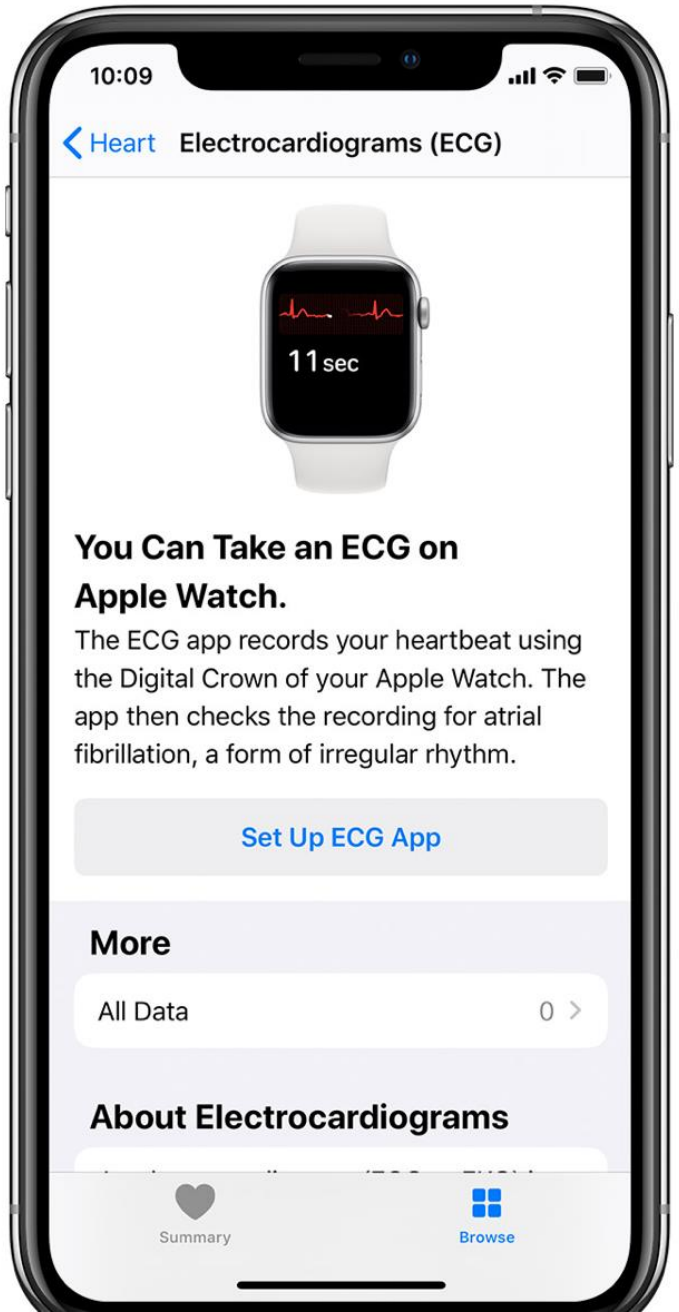




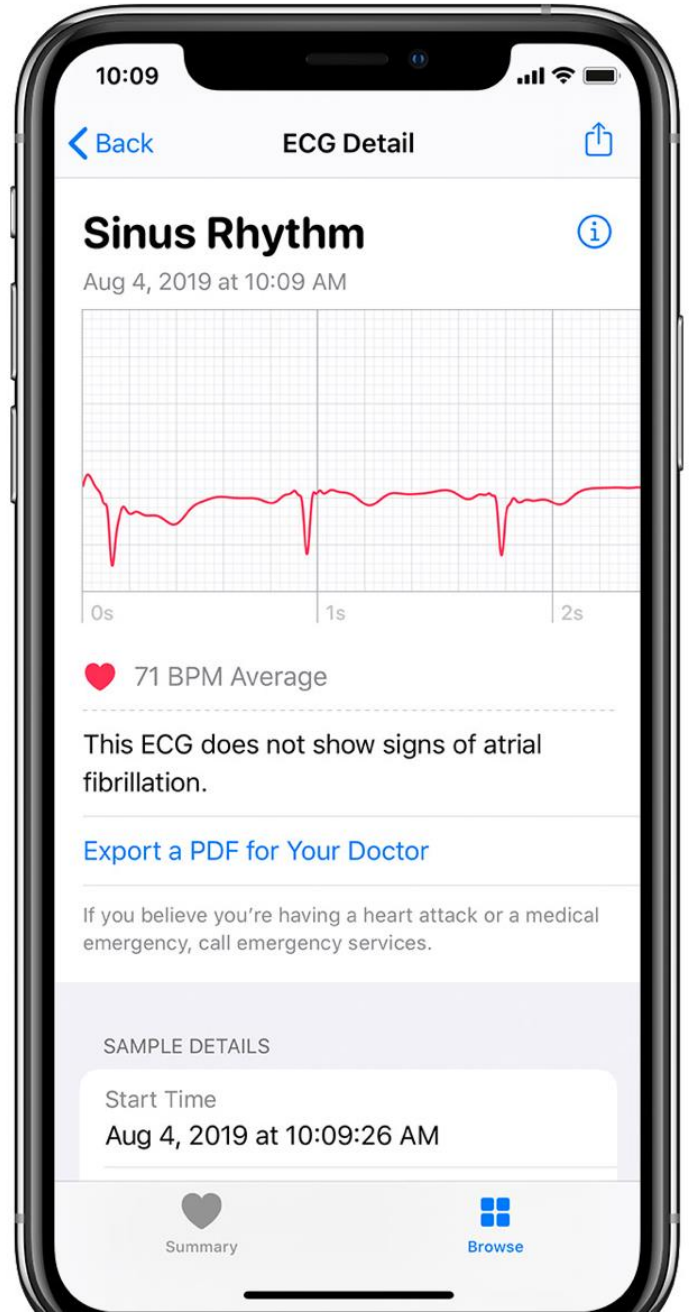
CGM funding available on the NHS UK

Flash glucose meter

Weqas


10:09
Heart
Electrocardiograms (ECG)
11 sec
You Can Take an ECG on Apple Watch.
The ECG app records your heartbeat using the Digital Crown of your Apple Watch. The app then checks the recording for atrial fibrillation, a form of irregular rhythm.
Set Up ECG App
More
All Data
0
About Electrocardiograms
Summary
Browse


10:09
Skip
26 sec
Take Your First
Recording an ECG typically
30 seconds.
First, open the ECG
Apple Watch.
Rest your arms on
lap, and hold your
Digital Crown.
Note: To take an accurate ECG
Watch needs to be snug on the
selected in Settings.
ECG
10:09
Hold your finger on the crown.


10:09
Back
ECG Detail
Sinus Rhythm
Aug 4, 2019 at 10:09 AM
0s
1s
2s
71 BPM Average
This ECG does not show signs of atrial fibrillation.
Export a PDF for Your Doctor
If you believe you're having a heart attack or a medical emergency, call emergency services.
SAMPLE DETAILS
Start Time
Aug 4, 2019 at 10:09:26 AM
Summary
Browse

The Royal College of Pathologists
Pathology: the science behind the cure

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HOMEPAGE > DISCOVER PATHOLOGY > PUBLIC AFFAIRS > DIGITAL PATHOLOGY

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DIGITAL PATHOLOGY

What is digital pathology? Digital pathology includes the acquisition, management, sharing and interpretation of pathology information — including slides and data — in a digital environment. Digital slides are created when glass slides are captured with a scanning device, to provide a high-resolution image that can be viewed on a computer screen or mobile device.

Digital pathology has the potential to improve patient care, and support the pathology workforce by making the diagnosis and monitoring of disease much more efficient. However, in order to transform pathology services, we need investment to support IT infrastructure, staffing and training.

THE IMPACT OF DIGITAL PATHOLOGY

Digital pathology:

- **Benefits patients** by enabling the rapid referral of cases between organisations or across pathology networks, enhancing access to expert advice and opinion on diagnoses
- **Improves laboratory workflow** and connectivity and increases flexibility and efficiency of the workforce, helping create digital training resources that support the development of specialists in training
- **Increases our power to share** slides and more, making it easier for others to benefit from the fantastic expertise in our profession
- **Sets the scene** for the use of artificial intelligence which will help bring advances to pathology services.

Scottish Pathology Network
National Managed Diagnostic Network

NHS SCOTLAND

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Digital Pathology

By 2021 there will be a network of Pathologists who are trained to report digitally.

The rapid progress of whole slide imaging technology, along with advances in software applications, LIMS interfacing, high speed networking has made it possible to fully integrate digital pathology into pathology workflows

How We Are Going Digital

NHS Wales Health Collaborative shares the story of Wales' ongoing transition to digital pathology, the verification program used to inform the move – and the positive results seen so far

Melanie Barker and Jane Fitzpatrick | 07/21/2017

At a Glance

- Six Welsh health boards collaborated on a verification program for digital pathology equipment to be rolled out across the country
- Verification involved comparing digital reporting against traditional glass slide methodology
- Results were favorable, with 95 percent concordance between digital and glass slide reports
- Based on those results, the program is now entering its second phase: a nationwide implementation of digital technology

1 Million Reasons

In a quiet, yet purposeful way, the world of pathology changed with little fanfare on February 22, 2019 – a change that will allow pathologists to positively impact the lives of people all over the world.

03/19/2019

SPONSORED BY Inspirata

This change was put in motion at the Ohio State University (OSU) James Cancer Center, when Inspirata and the OSU pathology team scanned the 1,000,000th tissue image to form the largest library of whole slide images (WSI) in the world. Forming the most extensive tissue image resource for cancer research and laying the foundations of accelerated clinical care, this monumental achievement established the new era of digital pathology as real. Every patient's battle with cancer begins with their diagnosis. With the advent of slide scanning devices, pathologists are using whole slide images (WSI) for primary diagnosis and treatment effectiveness assessment, as well as conferences, tumor boards, and

https://thepathologist.com/inside-the-lab/digital-and-computational-pathology

SURGICAL ROBOTS, NEW MEDICINES AND BETTER CARE: 32 EXAMPLES OF AI IN HEALTHCARE

July 4, 2019 · **Updated:** September 23, 2019 Written by **Sam Daley**

Freenome

FREENOME
EARLIER CANCER DETECTION WITH AI

Location: San Francisco, California

BETH ISRAEL DEACONESS MEDICAL CENTER
DIAGNOSING DEADLY BLOOD DISEASES FASTER

Location: Boston, Massachusetts

How it's using AI in healthcare: Harvard University's teaching hospital, Beth Israel Deaconess Medical Center, is using artificial intelligence to diagnose potentially deadly blood diseases at a very early stage.

ENLITIC
AI DEEP LEARNING FOR ACTIONABLE INSIGHTS

Location: San Francisco, California

How it's using AI in healthcare: Enlitic develops deep learning medical tools to streamline radiology diagnoses. The company's deep learning platform analyzes unstructured medical data (radiology images, blood tests, EKGs, genomics, patient medical history) to give doctors better insight into a patient's real-time needs.

MIT named Enlitic the 5th smartest artificial intelligence company in the world, ranking above Facebook and Microsoft.

H2O.AI
AI FOR DATA THROUGHOUT THE HEALTH SYSTEM

Location: Mountain View, California

How it's using AI in healthcare: H2O.ai's AI analyzes data throughout a healthcare system to mine, automate and predict processes. It has been used to predict ICU transfers, improve clinical workflows and even pinpoint a patient's risk of hospital-acquired infections.

Using the company's artificial intelligence to mine health data, hospitals can predict and detect sepsis, which ultimately reduces death rates.

KenSci

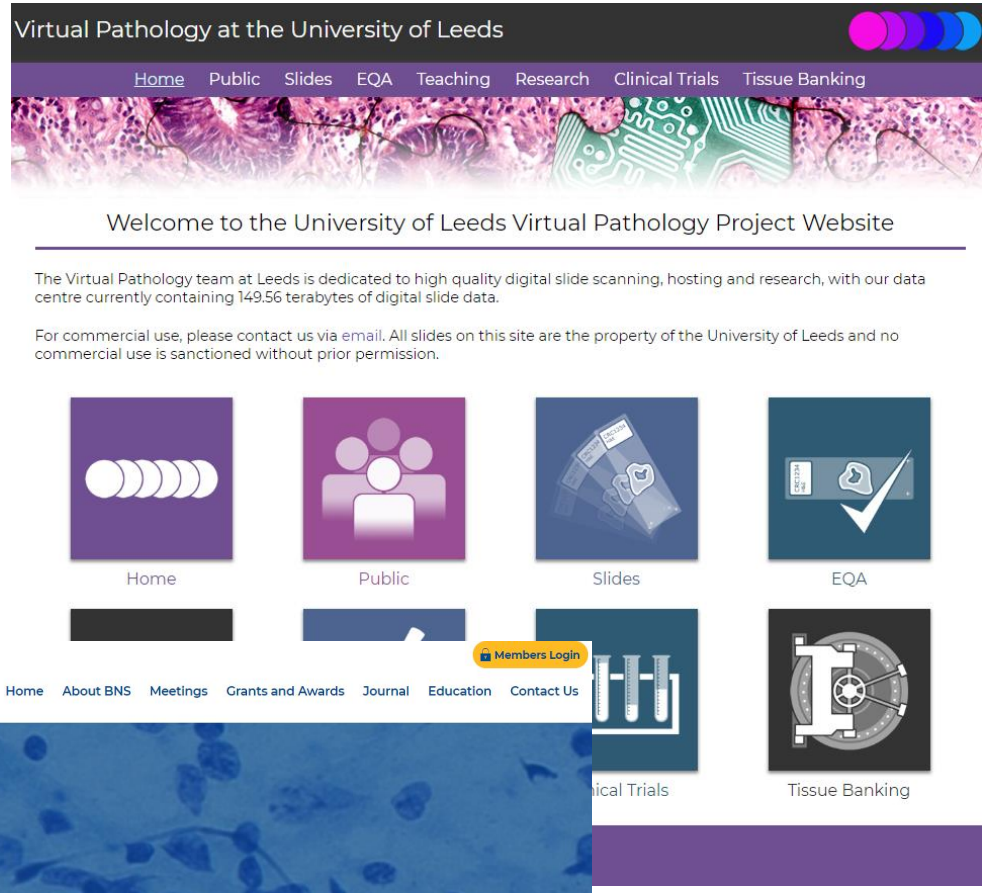
KENSCI
AI FOR HOSPITAL RISK PREDICTION

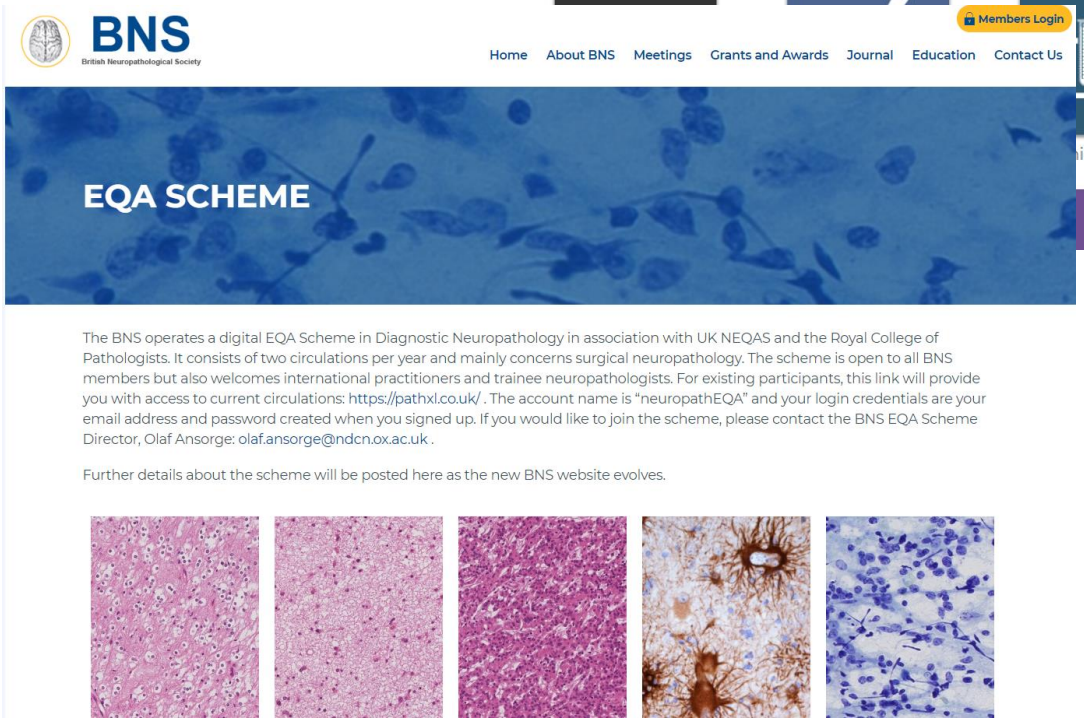
Location: Seattle, Washington

Weqas

Healthcare delivery is changing so where does that leave EQA?

Digital Pathology EQA





Weqas

EQA Challenges – the patient test workflow

- How do we assess the full patient testing pathway ?
- How can we mimic the laboratory and POCT test workflow with greater use of automation?
- How can we assess the integrity of the data?

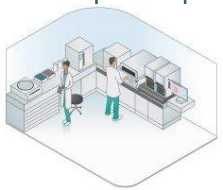
Laboratory test workflow

- e-test request by clinician
- Patient demographics/ order/ clinical details sent to lab LIMS
- Patient demographic barcode label printed
- Sample taken
- Sample barcoded and transported to laboratory

Pre-analytical
Outside lab

Pre-analytical
Inside lab

- Sample scanned / matched in LIMS
- Sample prepared – robotics module
- Intelligent workflow sends to 1 of n analytical modules



- Indices check
- Sample Analysed on 1 of n modules
- Quality control checks

Analytical

Post analytical

- Authorisation / Interpretation
- e-Reporting

EQA workflow

- EQA Sample labelled with instructions and shipped to laboratory

Pre-analytical
Outside lab – EQA provider

Pre-analytical
Inside lab

- EQA Sample information manually entered in LIMS
- Bar code generated
- Sample scanned
- Analyser selected

- Indices check
- Sample Analysed on selected or all modules
- Quality Control checks

Analytical

Post analytical

- Results released (may include Interpretation)
- Results transcribed onto EQA return form and/or
- Entered into EQA portal

POCT test workflow

- Test requested by clinician
- User bar code scanned – details checked in POCT middleware
- Patient ID scanned - details checked in POCT middleware
- Sample taken (cap/ven)

Pre-analytical
Outside lab

Analytical

- Sample Analysed
- Quality control checks

- Results available immediately
- Auto Validation
- Connectivity to LIMS
- e-Reporting

Post analytical

EQA workflow

- EQA Sample labelled (may not have unique bar code)
- Sample and instructions shipped to laboratory

Pre-analytical
Outside lab – EQA provider

Pre-analytical
Inside lab

- EQA details manually entered in POCT middleware
  - EQA barcode generated
  - EQA Sample and instructions transported to POCT site

- User bar code scanned
- EQA sample ID scanned

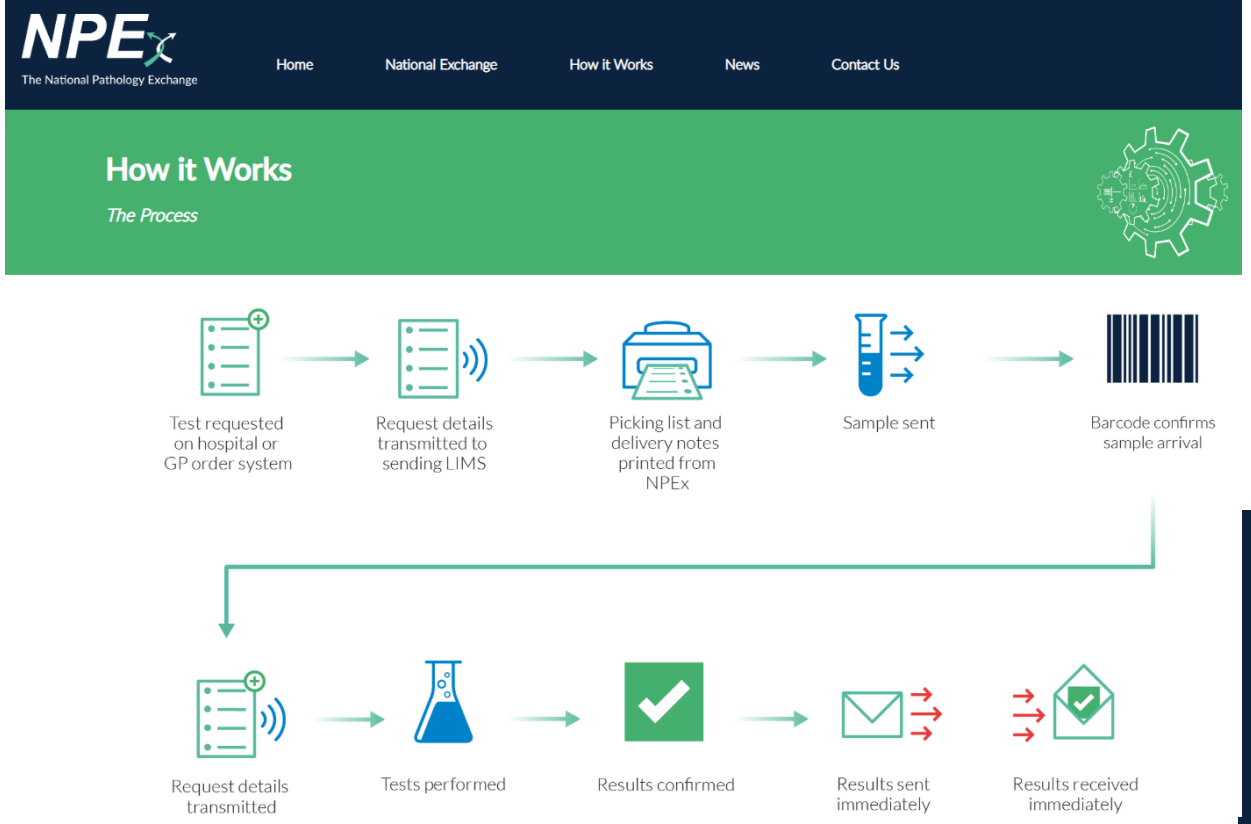
Pre-analytical
Outside lab

Analytical

- Sample Analysed
- Quality Control checks

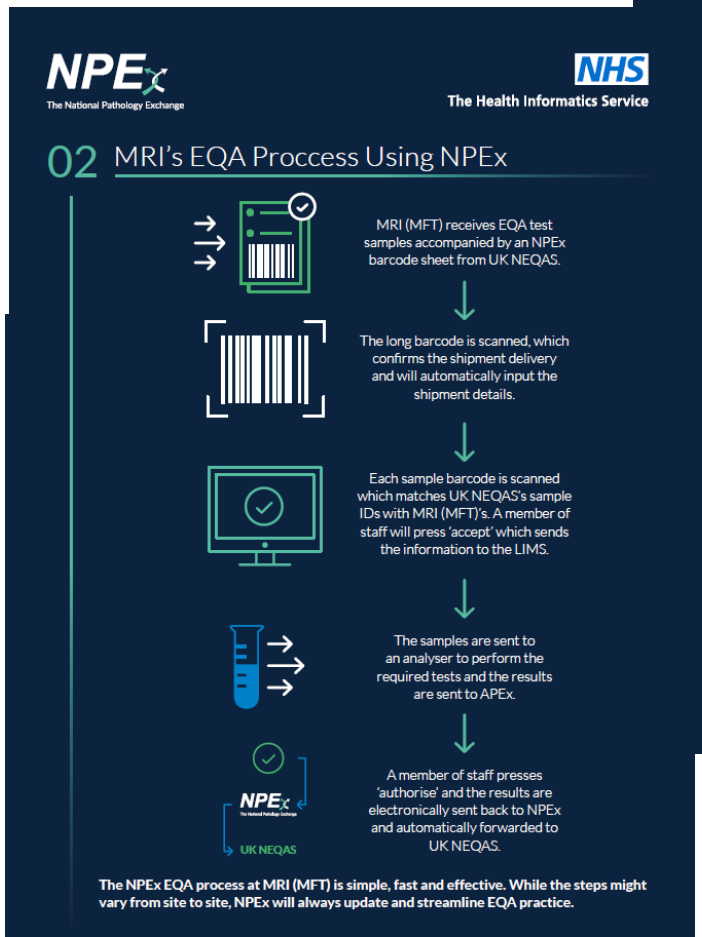
- Results released (may include Interpretation)
- Results transcribed onto EQA return form and/or
- Entered into EQA portal

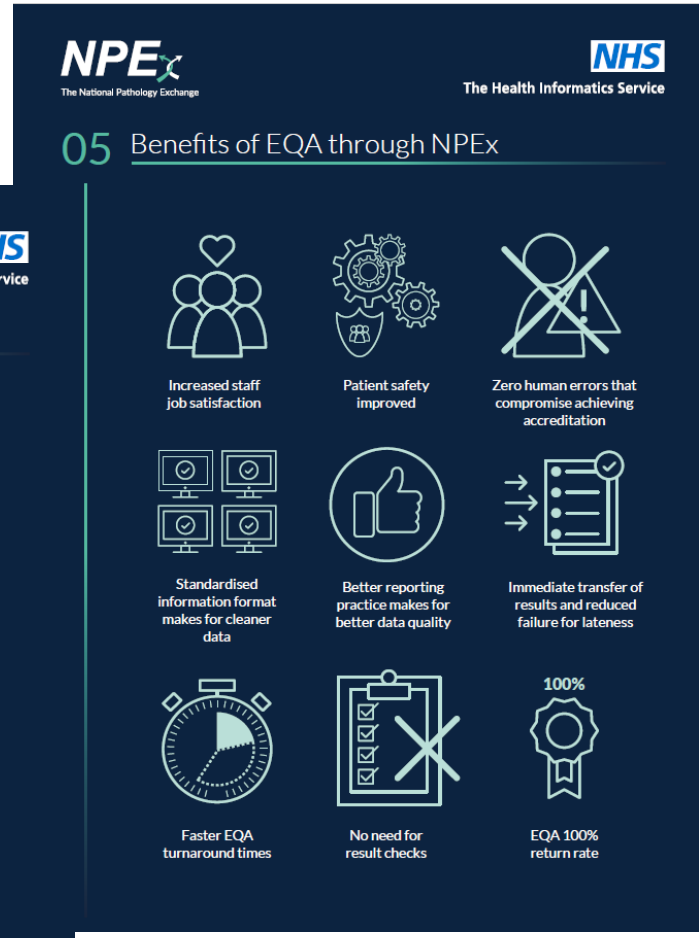
Post analytical



The National Pathology Exchange (NPEx) is a national service for NHS pathology managers to connect all UK labs together through a single exchange hub so that test requests and pathology results are sent digitally from any lab to any lab in a matter of seconds.

NPEx has worked with UK NEQAS to enable the transfer of EQA requests and referrals through the solution. EQA testing through NPEx is now live 11 sites. Due to start pilot with Weqas shortly to accommodate both laboratory and POCT workflows.





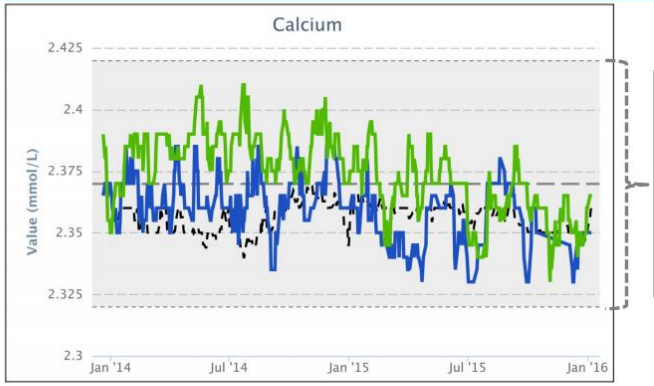
Data transfer and data mining - Some good examples

IQC - Using moving averages of laboratory data as an IQC tool.

EQA – STT Consulting Empower Percentile and Flagger project (now run by NOKLUS)

- aims at documentation of stability and comparability of in-vitro-diagnostic tests in medical laboratories across laboratories and manufacturers.
- instrument-specific, daily outpatient medians, number of results, and daily outpatient flagging frequencies (%-hypo, %-hyper) are calculated and transmitted by a laboratory from their middleware or laboratory Information system (LIS).
- The data are transmitted by e-mail, which is automatically uploaded into a MySQL database.

User interface – Percentiler



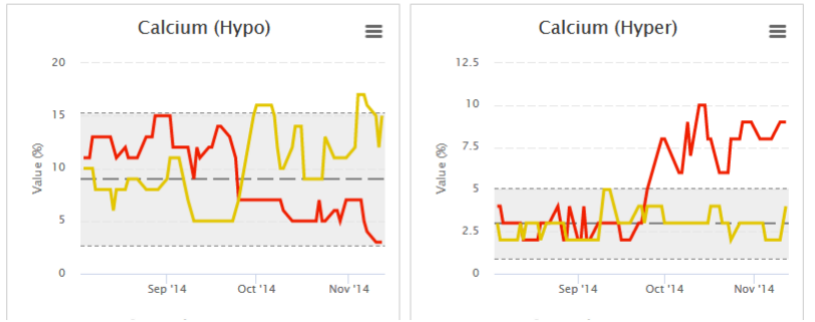
The shaded zone reflects stable performance; the limits ----- around the long-term median are the bias limits; in the calcium example they are at the median ± 0.05 mmol/L or 2.1%

Legend:

Moving median from Jan 2014 til Jan '16 for two instruments in a laboratory.
Grey dotted line: the laboratory's long-term median.
Black dotted line: the peer group moving median.

NOTE: plots can be downloaded by users.

User interface – Flagger



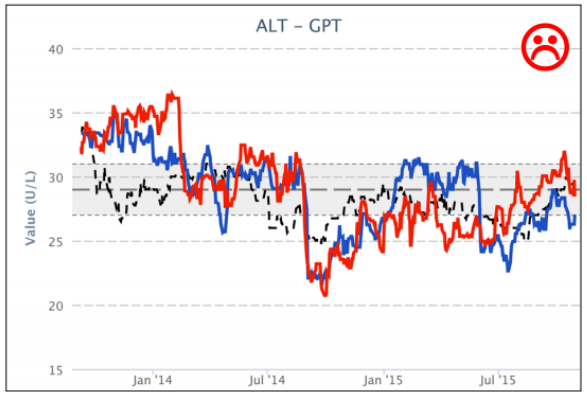
Legend:

Moving median of % hypo and hyper flagging rate from July 2014 to Nov '14 for two instruments in a laboratory.
Grey dotted line: the median of the laboratory's long-term flagging rate.

The shaded zone reflects stable flagging rate; for the calcium example the limits ----- of the zone are at ± 70% of the median for the long-term flagging rate.

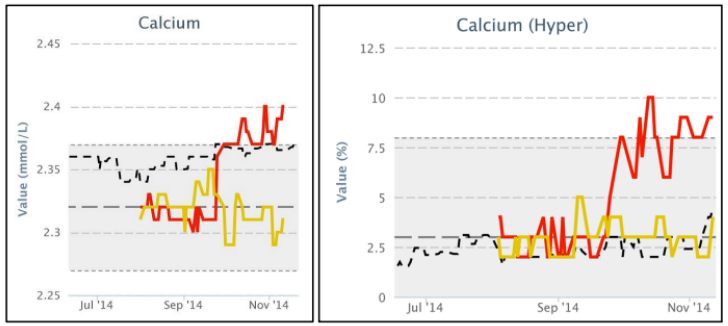
Percentiler – selected examples

Identifies unstable performance for ALT–GPT in the selected laboratory and peer group due to the effect of lot-to-lot changes (see the shifts of the moving medians outside the limits of the stability zone)



Percentiler & Flagger synergy

Demonstrates the effect of analytical instability on the flagging rate as surrogate of medical decision



Explanation:
-Left hand plot in the Percentiler; the yellow instrument has stable performance for calcium; in contrast, the red one shows a shift of ~0.06 mmol/L.
-Right hand plot in the Flagger: the hyper flagging rate for the yellow instrument is stable, while for the red one it is triplicated (median from 2.5% to 7.5%).

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Weqas

EQA Challenges – defining Quality for new technology

- Define what is adequate? – Quality compromise
- Specification should be designed to provide performance that best meets the needs of the service.
- It will depends on clinical utility of test - what it is being used for.
- And how the service is being provided – how it is being used
- TAT can be more important e.g. HIV results / high risk population.
- Greater patient engagement– remote areas / at risk population.
- Greater patient compliance e.g. ownership of chronic disease management

Weqas

EQA Challenges – Matrix

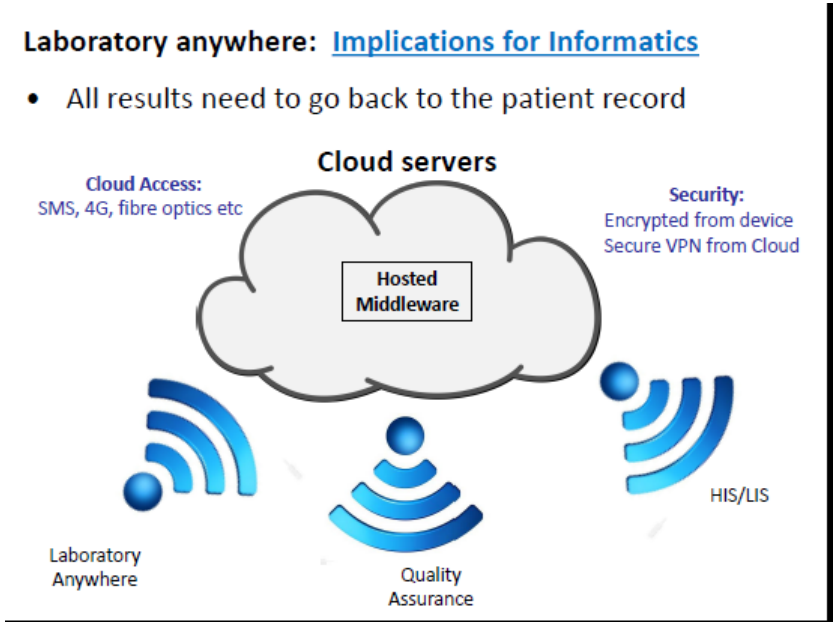
- How do we design EQA for implanted devices?
- Matrix effects - measurand in whole blood may not be stable so how do we undertake EQA?
- How do we assess the complete process? – for pre term markers the procedure involves obtaining a swab of cervical secretion and eluting in buffer – EQA of analytical process but not pre-analytical stage?

Weqas

EQA Challenges – Data Governance

- IG – Patient data entering the wrong hands or being lost in error. Need robust data security. Privacy and security concerns
- Lack of clarity in health communication protocols and standards
- Interoperability issues with TECS
- How do we assess the quality of data transfer?
- Is there a role for EQA informatics?

(good examples in genomic EQA Schemes)



Data governance

Many new and emerging digital healthcare technologies rely critically on the ability to collect, store, access and share medical and other health-related data.

The *quality* of the data used to inform these tools, including data gathered through continuous monitoring and tracking that many could consider intrusive, must be assured in order to facilitate their safe and effective use.

For **genomic data**, the challenges of data governance are particularly complex due to the biological link with Relatives.

A major new dialogue has found the public are enthusiastic and optimistic about the potential for genomic medicine but have clear red lines on use of data

"This report highlights the crucial role that ethics and participant engagement play in establishing and maintaining public trust in genomics. It is essential reading for everyone with an interest in genomic and data-driven medicine. It presents the results of an inclusive and thorough process of public dialogue and makes a vital contribution to ongoing discussions about genomic medicine. It reveal that the relationship between the NHS, patients, and the public is currently understood in terms of three core values: reciprocity, altruism, and solidarity. These values are likely to continue to inform the understanding of the appropriate relationship between medicine, research, and society as genomic medicine plays a more central role in healthcare." Professor Michael Parker, Wellcome Centre for Ethics and Humanities, University of Oxford,

Weqas

Conclusion

- Rapid advancement in biosensor technology combined with the “digital revolution” within healthcare is driving the increase in the development and use of POCT, digital imaging and use of AI.
- Our challenges are to ensure that the performance meets the clinical utility of the test, that governance processes are robust and that information governance is not compromised.
- EQA design must “keep up” with the times - more use of data mining.