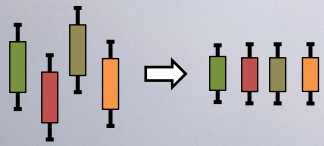
Harmonisation and traceability: a global effort

- A joint project between ICHCLR and EQALM



EQALM

European Organisation For External Quality Assurance Providers in Laboratory Medicine

Sverre Sandberg
Eline van der Hagen

Missions of EQA

- EQA is used to evaluate measurement procedure performance by comparing a laboratory´s results with those of other laboratories.
- Ideally, an EQA program should inform the participants if their measurement procedure has a bias from a true value.
- This requires the use of commutable material

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When commutable EQA material is used, we get information about performance of

- Participants compared to a true value
- Participants compared with others using the same measurement method
- Measurement methods compared to a true value and to each other

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We know

- ✓ There are systematic differences between measurements methods.
- ✓ Information about bias needs to be communicated to the IVD industry and to the users so they can take actions to harmonise results
- ✓ **We need evidence**

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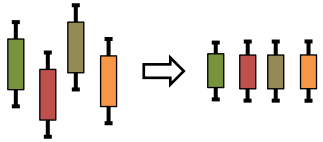
Collaboration between

- International Consortium for Harmonization of Clinical Laboratory Results, ICHCLR



- EQALM

EQALM
European Organisation For External Quality Assurance Providers in Laboratory Medicine

- Others?

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Mission

Aggregate results from EQA providers that use commutable materials for the same measurand to

1) Get more results

2) See if the results are similar from different schemes and different regions

3) Provide the data to the IVD industry

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Pilot project: creatinine

Pilot group:

- Greg Miller
- Finlay MacKenzy
- Cas Weykamp
- Sverre Sandberg
- Eline van der Hagen
- Anne Stavelin

Results from

- SKML
- Noklus/Labquality
- UK-NEQAS
- CAP

Pilot – aggregation of creatinine results

- 4 EQA organizations, 1011 results.
- Creatinine concentrations ~ 70 µmol/L (0.8 mg/dL).

- Requirements:
  - Target values and uncertainty using a Reference Method Procedure/Reference Material.
  - Samples must not contain known potential interfering substances, e.g. Glucose or total protein.

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Pilot – aggregation of creatinine results

- Important aspects for aggregating results:
  - Definition of methods: e.g. compensated vs kinetic Jaffe
  - Definition of instruments:
    - Differences in naming: e.g. Ortho Clinical Diagnostics vs. Vitros
    - Differences on details of instruments: e.g. Cobas/Modular vs. c501

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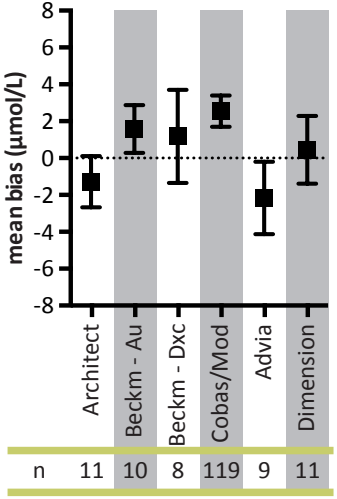
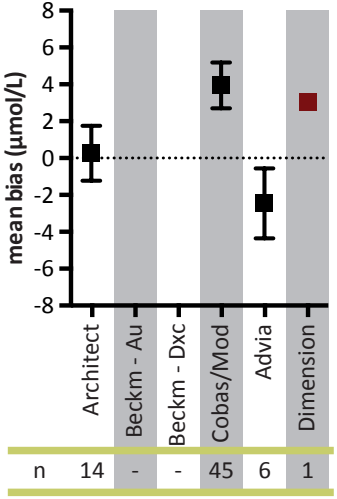
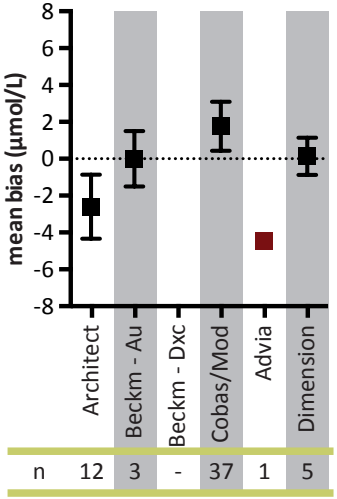
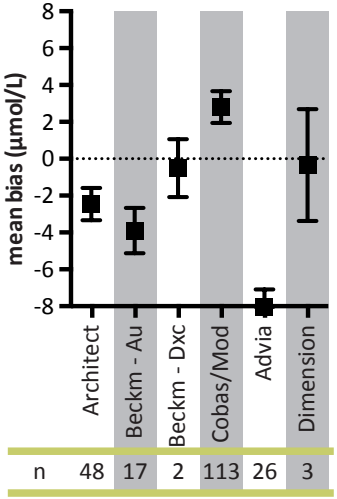


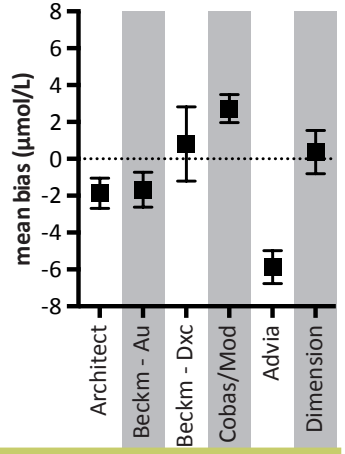






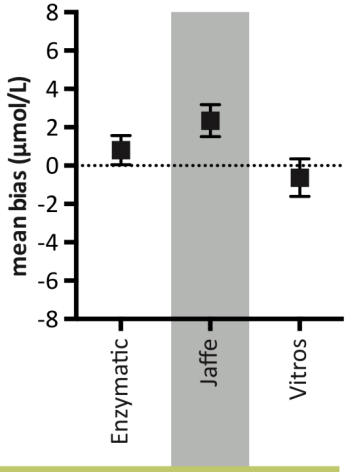
Results are quite similar between EQAS.

Combined



	Architect	Beckm - Au	Beckm - Dxc	Cobas/Mod	Advia	Dimension
Bias	-1.9	-1.7	0.8	2.7	-5.9	0.4
ExpU	0.8	1.0	2.0	0.8	0.9	1.2
n	85	30	10	314	42	20
% Outlier	1.2	-	-	0.6	-	-

Pilot – challenges in aggregation of creatinine results



	Enzymatic	Jaffe	Vitros
Bias	0.8	2.3	-0.6
ExpU	0.8	0.8	1.0
n	519	435	48
% Outlier	0.8	0.5	-

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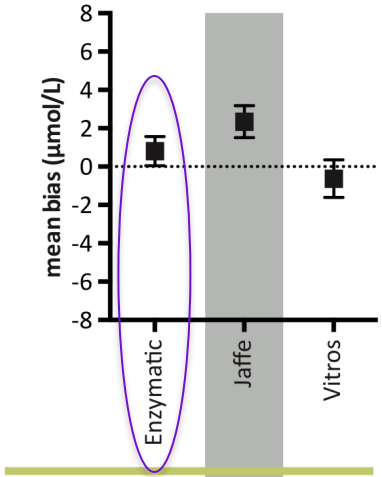
	1.2	-	-	0.6	-	-

	6000	8000	c500s	c700s	c111	c311	Integra	Modular	not spec
	2.3	3.6	2.5	4.8	-2.2	0.9	0.1	-3.4	2.8
	0.9	1.0	1.1	1.6	1.2	-	4.3	1.6	0.9
	78	39	50	23	5	1	3	2	113
	-	5.1	-	-	-	-	-	-	-

** ExpU = combined Uncertainty of the target and Interlab SD.*

Pilot – challenges in aggregation of creatinine results



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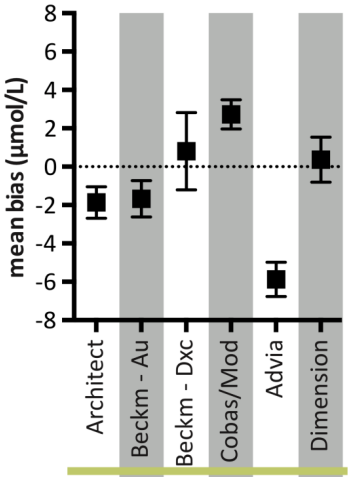

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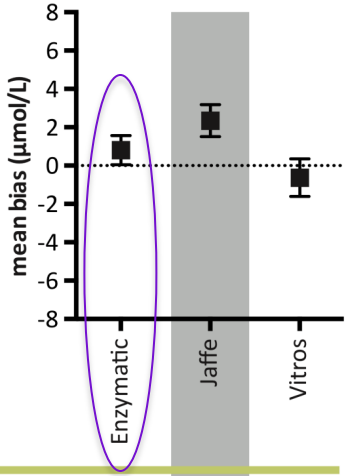
Pilot – challenges in aggregation of creatinine results

A significant part is not specified.



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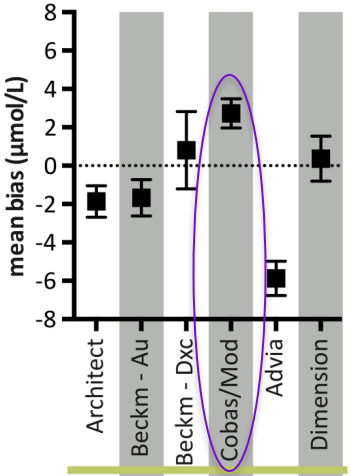

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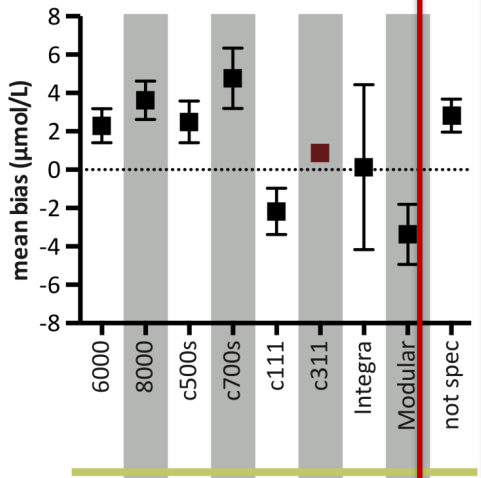

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Pilot – aggregation of creatinine results

- Aggregation of results is feasible with currently available data.
- Results strengthen conclusions regarding specific IVDs/Methods.
  - **Jaffe vs Enzymatic**, mean bias 2.3 vs 0.8 µmol/L.
  - **Clear biases can be observed** e.g. Siemens Advia all EQA demonstrate similar negative biases, ***mean bias -5.9 µmol/L*** with 42 instruments, ExpU 0.9 µmol/L.
  - **Large amounts of data** e.g. Roche Cobas/Modular mean bias is 2.7 µmol/L with ***314 instruments,*** ExpU 0.8 µmol/L.

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Pilot – aggregation of creatinine results

Possible improvements:

- Harmonization of Method/Instrument definitions, especially on instrument details.
- This can be taken even further by including calibrator/reagent types/lot numbers.

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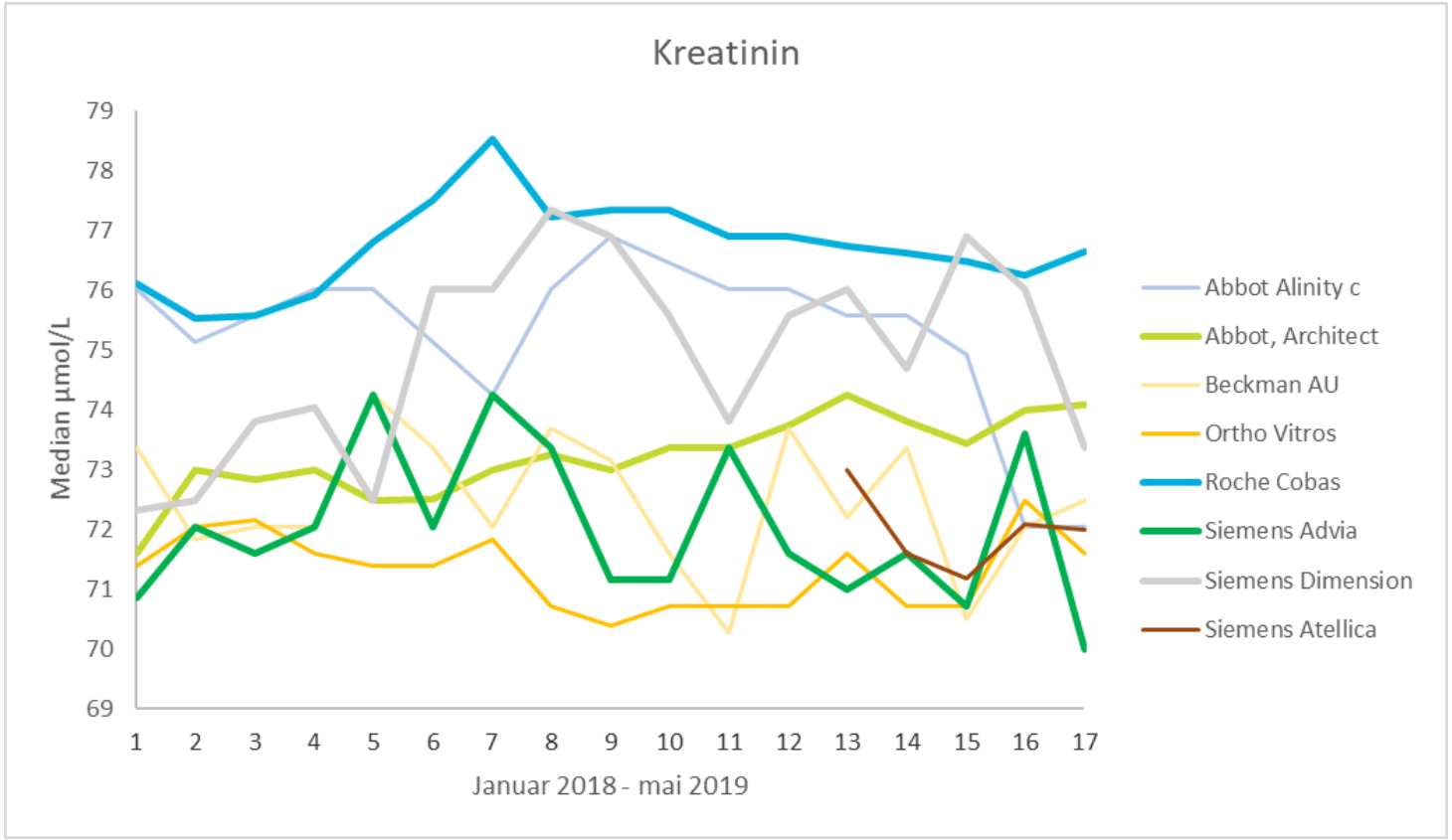
Creatinine Percentiler (daily patient medians)



The way forward

- Contact with scheme organisers in Europe, Australia, Japan and S.Korea to expand pilot.
- Are European scheme organisers interested in participation?
- Go on with a joint working group from ICHCLR and EQALM
- Write a paper to increase visibility of the project

Challenges to be discussed

- How to prove commutability for the scheme
- Document how the target value is established with its uncertainty
- Harmonise the descriptions of the measurement methods in the schemes to be able to aggregate the results
- How to communicate results to IVD manufacturers

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- Are EQA providers interested in participating in this project?
- For what measurands do we have commutable material and established reference target values?


Thank you