

Overview Of QA/QC Issues in Chemistry AND Lessons Learned

Read Hakantu/Esnart Nunkwe

Background

- CIDRZ has 2 Chemistry analyzers- 2 Olympus AU400 since December 2008.
- Switched from Roche COBAS 400+.
- We test over 800 samples a day.
- We have 31 analytes on our test platform, duplicated on each analyzer

Background

- CIDRZ enrolled with CAP EQA program from 2007 to 2010.
- From 2010 to present day CIDRZ has been on the Accutest EQA program for all Chemistry, Hematology and Immunochemistry.

Total Bilirubin

- Total Bilirubin is one of our network study analytes.
- We receive only 2 or 3 T. Bilirubin samples per month from network studies.
- The assay was performing well with EQA until 2009 after the switchover to Olympus AU400.

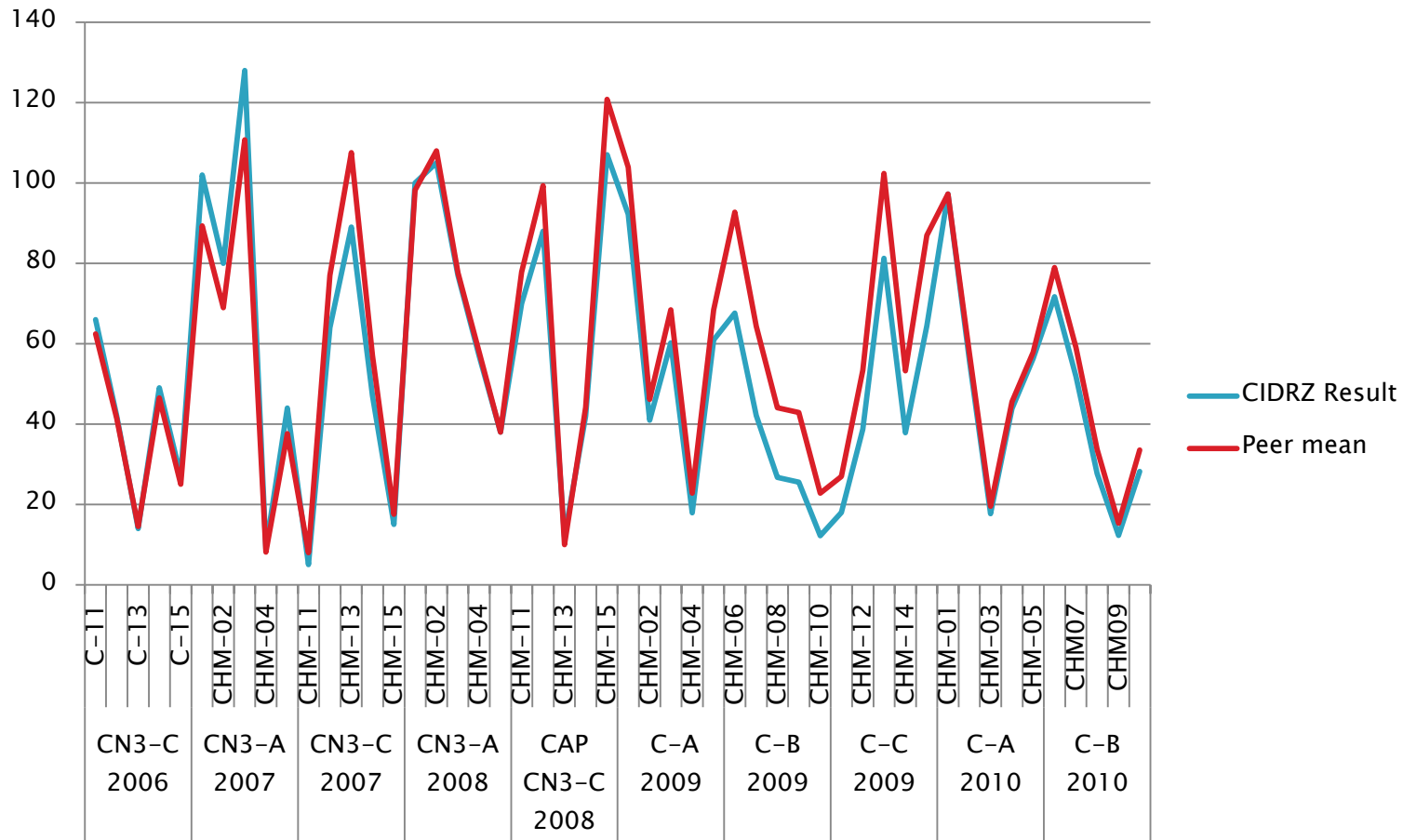
Total Bilirubin

- 2 CAP EQA surveys were tested in 2009; one during the validation process and the other one after approval of validation.
- We failed on both.
- Investigations went well into 2010.

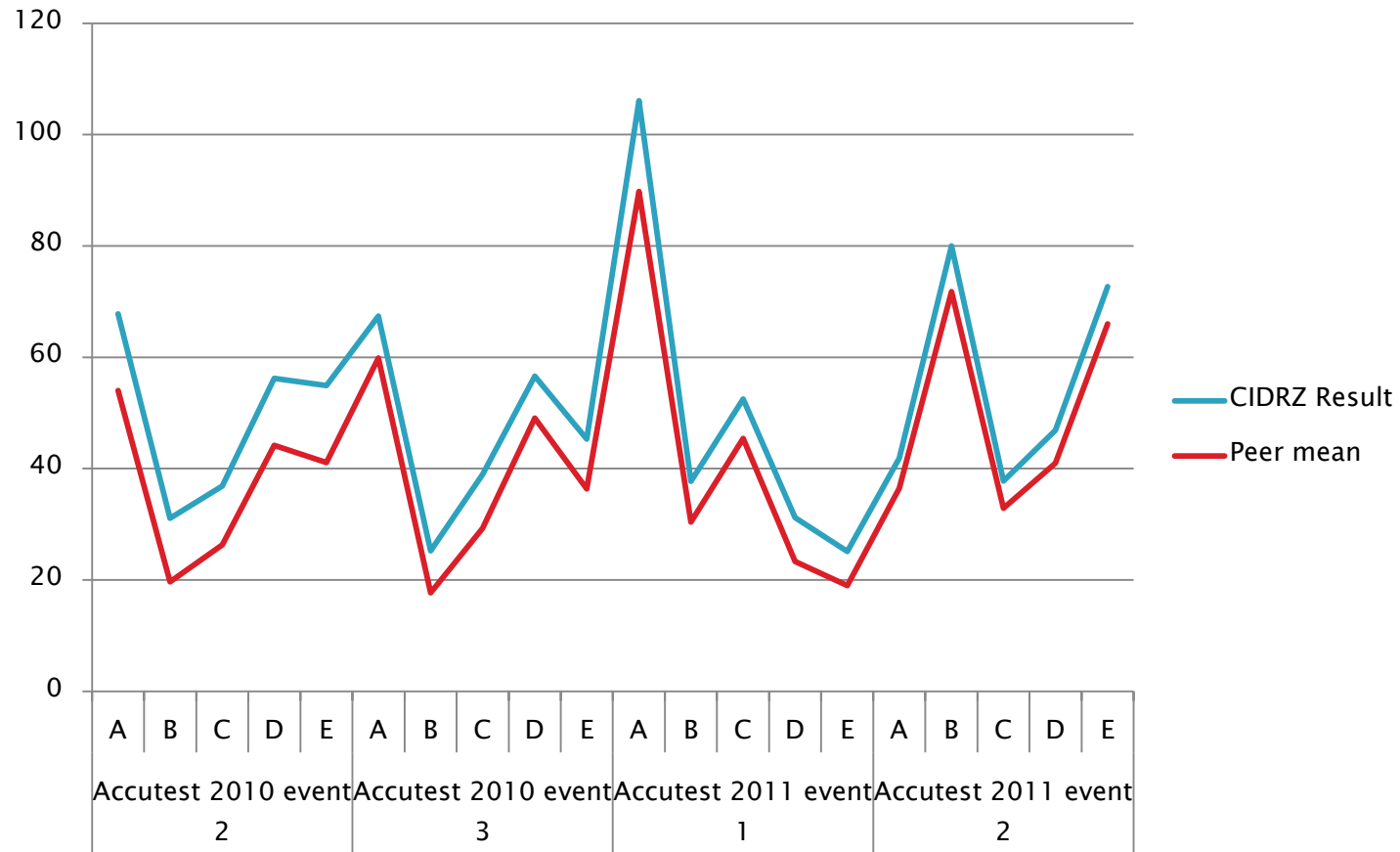
Reasons for delayed Investigations

- All control data were verified so difficult to pin-point the cause of the biases.
- Alternative controls were purchased from Europe (six week delivery time).
- Water analysis had to be done at another lab (it took weeks to get results back.
- Alternate samples had to be ordered from South Africa through the procurement system

CIDRZ vs Peer group mean on CAP



CIDRZ vs Peer group on Accutest



Investigations

- Calibration data checked – OK
- Daily QC verified
- Two sets of controls used (BIO-RAD (better stability and longer shelf life) and Olympus (good results but shorter stability time)).

Investigations (cont.)

- Reagents checked- expiry ok but our source was Europe when most of the peers had US sources.
- Water quality was suspect- tests were done and filters changed.
- Survey samples checked- no quality problems.
- Calibrator ran as patient sample – on target.

Possible causes of failures investigated

- Poor water quality
- Sample handling in transit (cold chain)
- Wrong peer group in EQA programs
- Different reagent manufacturers from our peers.
- EQA Sample matrix problems

Possible causes of failures investigated

- Instrument problems: substances from patient samples due to inadequate cleaning cycles.
- Irregular preventive maintenance of instruments by both lab staff and support technical service.

2010

- February 2010: Thistle EQA samples acquired- passed all.
- 1st CAP EQA passed at same time as the Thistle samples but negative bias was observed.
- Decision made to switch to Accutest for mid-year EQA surveys after discussion with PNL and pSMILE.

2010

- Both CAP and Accutest ran in June 2010.
- Passed CAP with 100%: negative bias observed.
- Failed all 5 Accutest samples : Strong positive bias.
- Failure attributed to poor handling.

2010

- Samples in transit for 7 days and received warm.
- Tested late due to instrument breakdown.
- October 2010- 3RD Accutest event: failed (40%).
- Instrument manufacturer called in.

2010-11

- Beckman Coulter took over Olympus analyzers and set up Preventive maintenance plan starting January 2011.
- Engineer came and worked on analyzers, installed new water logic system, improved cleaning system.
- Accutest Event 1- March 2011: **80%!**

SMILE and networks Intervention

- Throughout 2010 and 2011 conference calls between CIDRZ, PNL and pSMILE were going on to:
 - 1. troubleshoot
 - 2. exchange ideas
 - 3. set targets and timelines

pSMILE and networks Intervention

- pSMILE continued to discuss with Accutest
- Finally pSMILE sent good news: We were in wrong peer group
- Results were re-evaluated and we passed all Accutest Total bilirubin!!!
- Event 2 2011: **100%!!!!** 😊 😊 😊 😊

Lessons learned

- Always work closely with pSMILE and your PNL with investigations
- Ensure enrolment into correct peer group: pSMILE assists.
- Monitor water quality
- Regular and Thorough instrument Maintenance

Lessons learned

- Persevere, don't get discouraged by failures, even multiple ones.
- 100% is great but getting a few failures keeps one alert to shifts and biases.

Acknowledgements

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THANK YOU!!!!