Australian National University

Integrated Predictive Modelling to Improve Pathology Laboratory Quality

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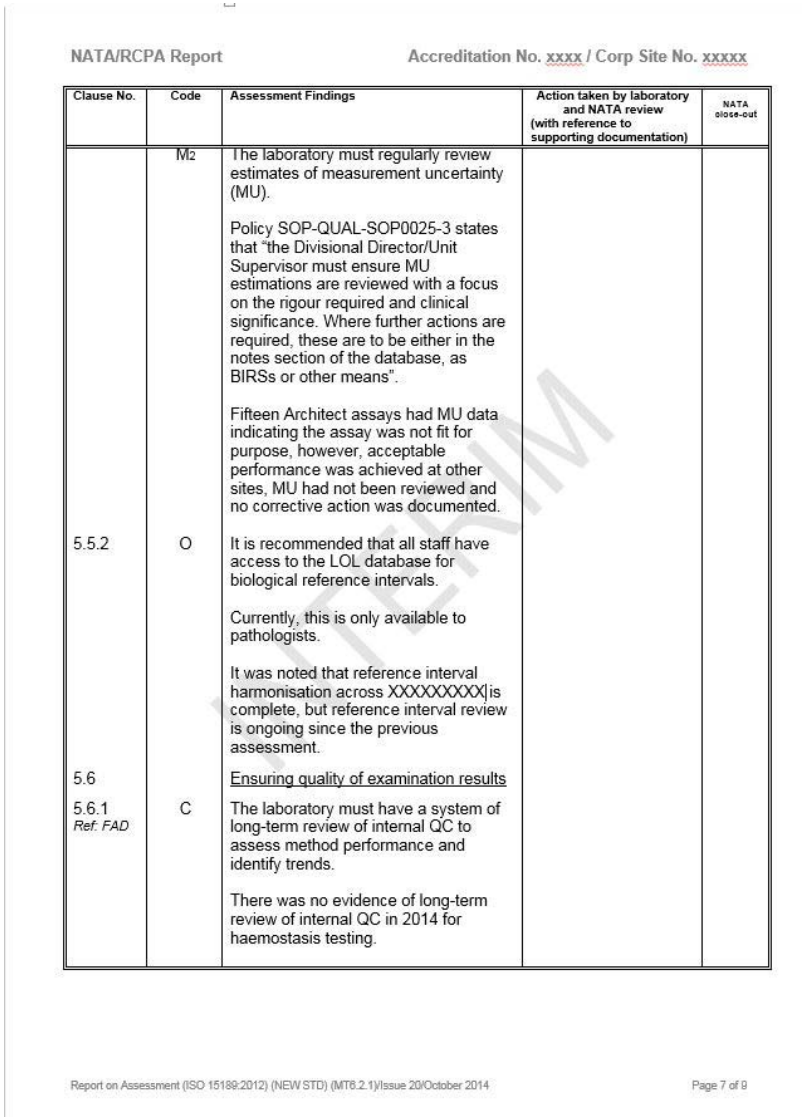
Overview

- NATA and QAP
- Our study
- Data
- Results
- Conclusions
- The future

NATA

- Audit report
- Involves site visit and physical inspection
- Up to 30 assessments against ISO 15189 clauses
- Technical and Management



NATA/RCPA Report — Accreditation No. xxxx / Corp Site No. xxxxx

Clause No.	Code	Assessment Findings	Action taken by laboratory and NATA review (with reference to supporting documentation)	NATA close-out
	M2	The laboratory must regularly review estimates of measurement uncertainty (MU). Policy SOP-QUAL-SOP0025-3 states that "the Divisional Director/Unit Supervisor must ensure MU estimations are reviewed with a focus on the rigour required and clinical significance. Where further actions are required, these are to be either in the notes section of the database, as BIRSs or other means". Fifteen Architect assays had MU data indicating the assay was not fit for purpose, however, acceptable performance was achieved at other sites, MU had not been reviewed and no corrective action was documented.		
5.5.2	O	It is recommended that all staff have access to the LOL database for biological reference intervals. Currently, this is only available to pathologists. It was noted that reference interval harmonisation across XXXXXXXXX is complete, but reference interval review is ongoing since the previous assessment.		
5.6		Ensuring quality of examination results		
5.6.1 *Ref: FAD*	C	The laboratory must have a system of long-term review of internal QC to assess method performance and identify trends. There was no evidence of long-term review of internal QC in 2014 for haemostasis testing.		

Report on Assessment (ISO 15189:2012) (NEW STD) (MT6.2.1)/Issue 20/October 2014 — Page 7 of 9

- O = observation
- M1 = minor
- M2 = major
- C = condition

- Must be addressed to maintain accreditation, but not urgent
- could lose accreditation!

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RCPAQAP External Quality Assurance

- Mock samples sent by the RCPA
- Arms length process unlike NATA
- 16 cycles annually
- Individual assay accuracy is the aim

Our study

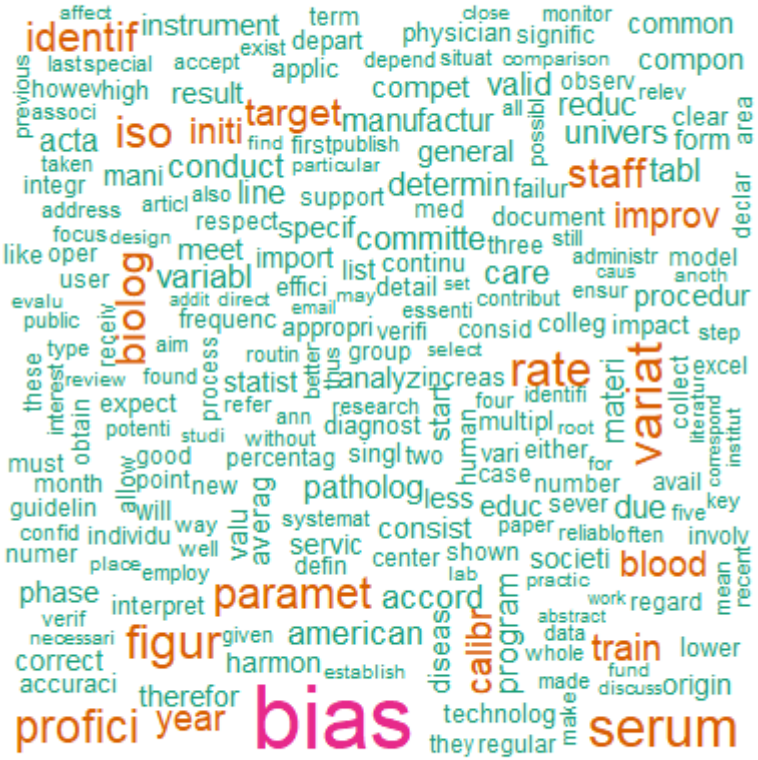
- 21 laboratories
  - 10 B: larger, full-time pathologist present
  - 11 G: smaller, supervised by B
  - Selected by linked data availability
- 16 cycles of EQA data on 20 analytes
- True value of analyte NOT given, use cycle sample mean for now

Research questions

- What does a systematic review of literature reveal about the relationship between analytes and laboratory quality?
- What is the distribution of O/M_1/M_2/C amongst laboratories of different types?
- Can analyte data be used to predict quality (operationalised by the number or proportion of M_1/M_2/C)?

Text mining

- MeSH terms: EQA, external quality assurance, ISO 15189, 15189, proficiency testing, pathology laboratory performance
- 144 articles (1992 – 2016)
- 37 out of scope, 6 no full text
- Analyse 101 articles
- R libraries `tm`, `libsnowballC`, `wordcloud`, `cluster`

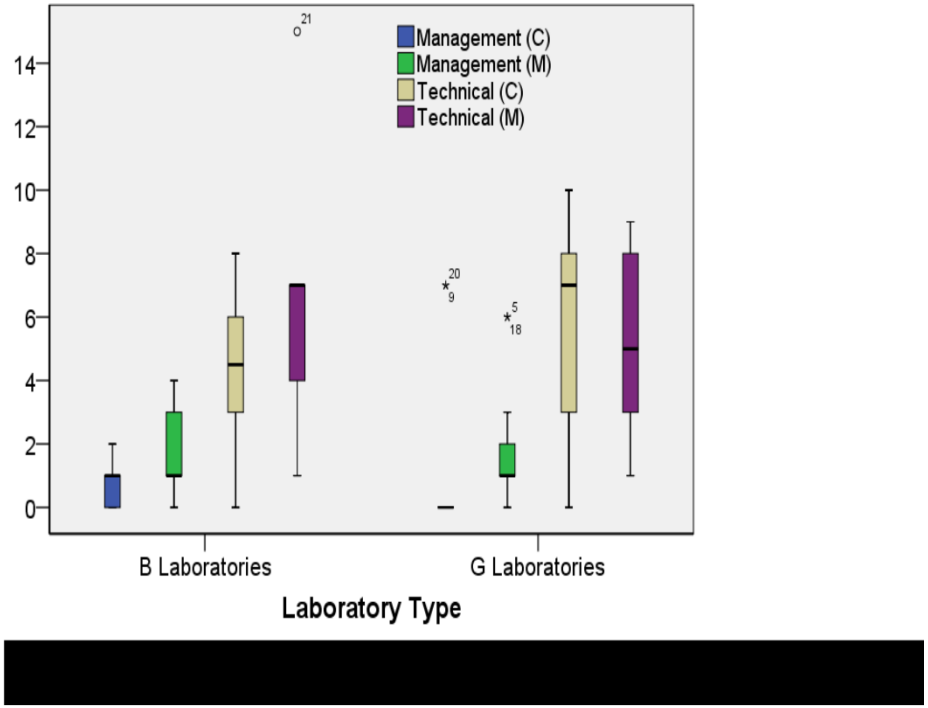


- Interpretation in progress …

Distribution of M and C

- Linear model
  - Outcome:
  - sum of $M_1 + M_2 + C$
  - Predictors:
  - type of clause (management or technical)
  - Type of lab (B or G)

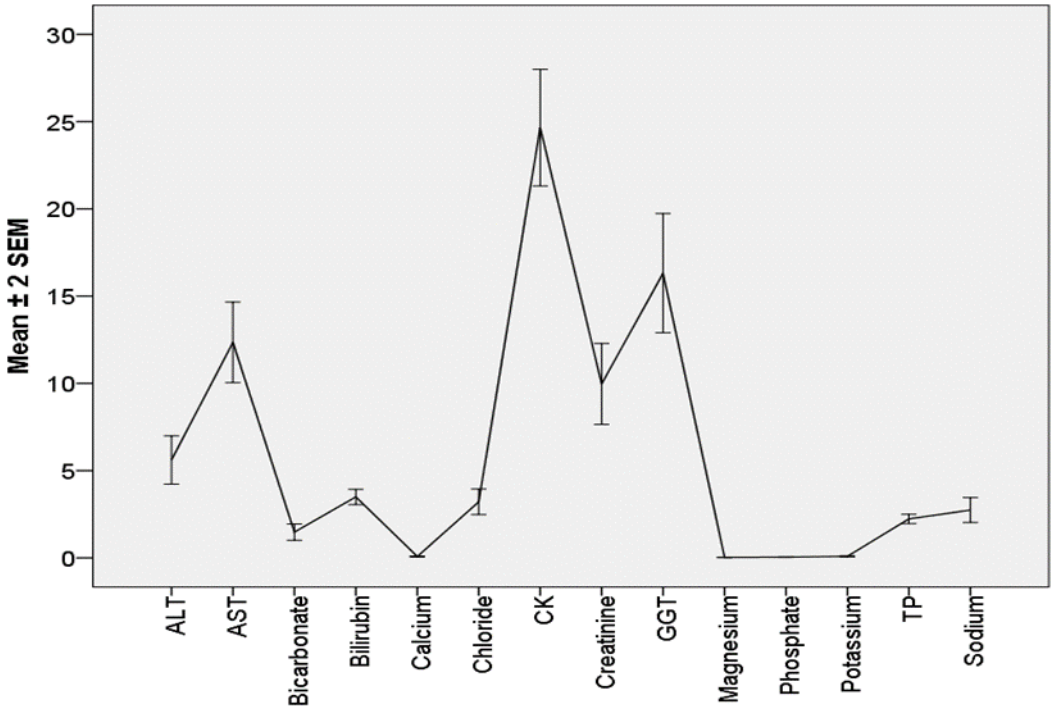
- Significant differences between Technical and Management but not between B and G or Minor/Major and Condition



Predictive modelling

- Random forest
- Outcomes from NATA: (1) above or below median M count (2) above or below median C count
- Predictors: from QAP, % Bias for 20 analytes
- $Bias(\%) = 100\,\frac{x_{ij} - \bar{x_i}}{\bar{x_i}}$
- x_i = assay value at time point i, lab j
- $\bar{x_i}$ = EQA assay value at time point i

- Absolute % Bias
- Mean ±2 SEM
- 21 labs and 16 time points combined
- liver function tests, serum electrolytes and creatinine, and creatinine kinase (CK)



- Absolute % Bias
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- 10 B labs
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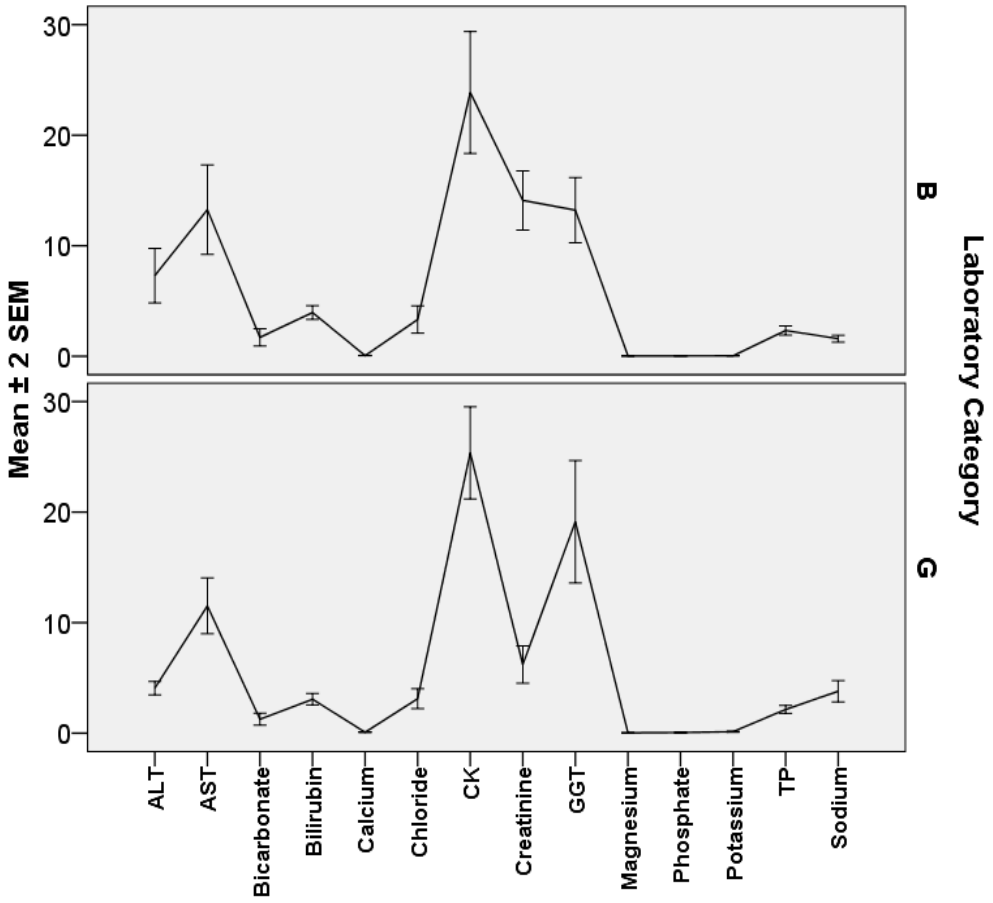
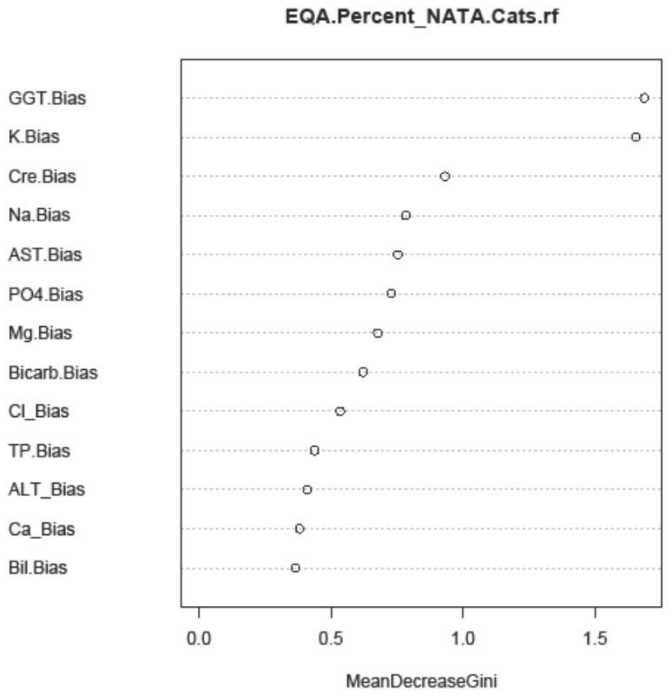
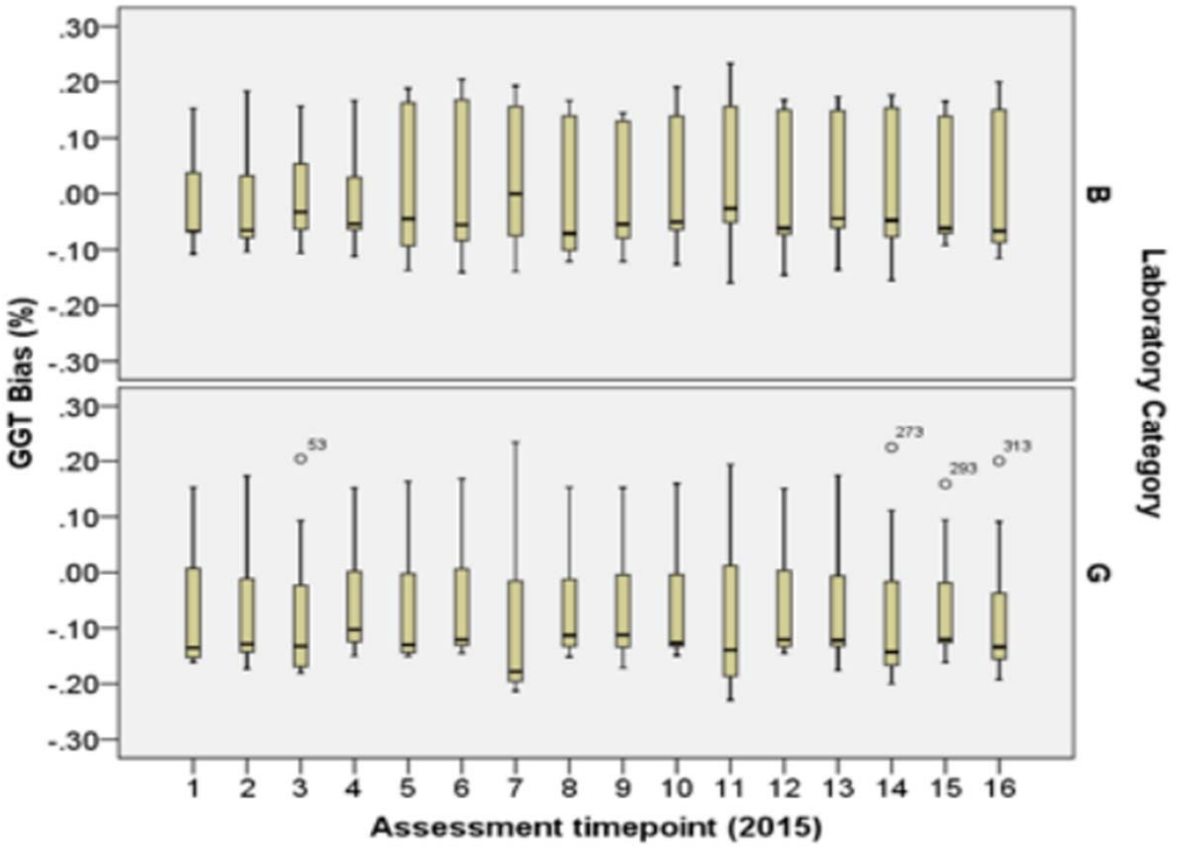


- QAP results predict minor lab infractions from NATA inspections
- OOB estimate of error rate: 14.29%



	L	H	error
L	9	1	0.1
H	2	9	0.18

Investigating GGT variation



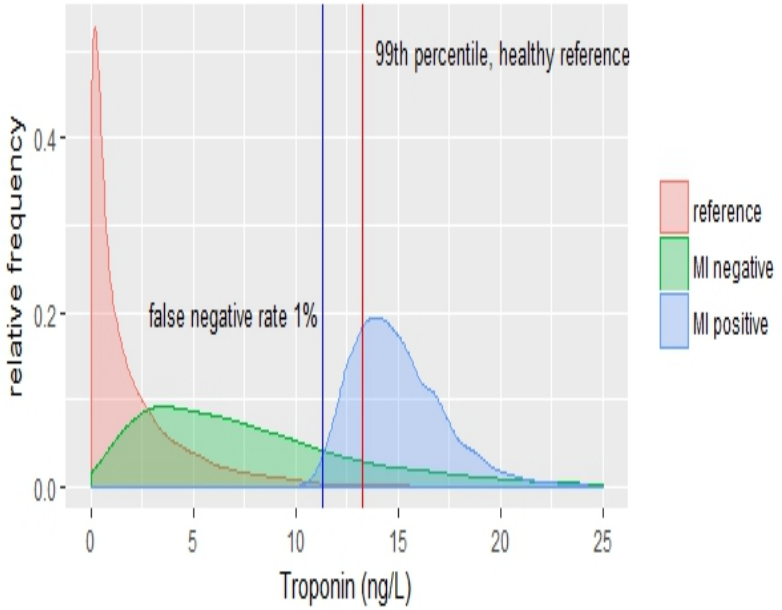
Explaining GGT variation

- Serum K+ bias a strong predictor
- Total M score significant
- Lab category (B or G) not significant

Source	Df	F	P-value
Lab category	1	2.5	0.134
Bicarbonate Bias	1	1.1	0.310
K+ Bias	1	27.27	< 0.001
Total M count	1	8.23	0.011
Error	16		

Future work

- Troponin turnaround time
- 99th percentile of troponin in multiple populations



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Acknowledgements

- QUPP of the DoH
- NATA
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NATA
WORLD RECOGNISED ACCREDITATION

RCPAQAP
RCPA Quality Assurance Programs