Adverse event reports of hip prostheses and prediction of prostheses with higher than anticipated rates of revision

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- Prostheses that are performing poorly or to a level less than expected ➡ take prompt and proper regulatory action (which could range from monitoring/observation to withdrawal from the market).

- The earlier and the more precise this identification takes place, then the possibility of further harm decreases.

- Our "gold standard": Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) identifies prostheses as having higher than anticipated rates of revision.

- Additional tool for the investigation of this issue and possibly enhance the early identification of the problem?

NATIONAL JOINT REPLACEMENT REGISTRY

Hip, Knee & Shoulder Arthroplasty

AOA
AUSTRALIAN ORTHOPAEDIC ASSOCIATION

ANNUAL REPORT 2018
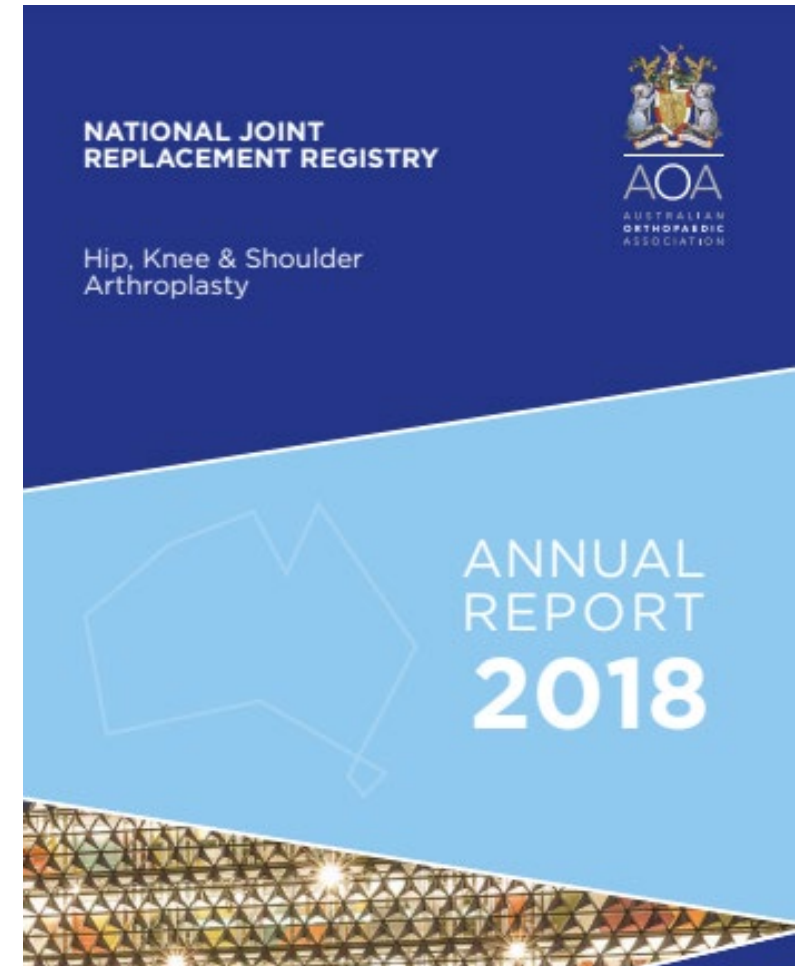
Research question

Is there a direct correlation between prostheses identified as suspicious of being problematic by the AOANJRR and potential signals available in the TGA post-market databases?


PROSTHESES WITH HIGHER THAN ANTICIPATED RATES OF REVISION	379
Introduction	379
Identified Prostheses	380
Primary Partial Hip Replacement	381
Primary Total Hip Replacement	384
Total Resurfacing	395

Protocol

Comparison between two public health datasets:

– Registry (owned by the Australian Orthopaedic Association - AOA)

   • Hip prostheses identified in the report as "problematic" (which is basically dependant on revision rates)

– Adverse event reports (IRIS) – TGA internal

   • Such as number of incidents reported yearly or type of adverse events

2

- 1512 adverse events 2008-2020 (according to final report)

* Per 1000 implants

Demographics
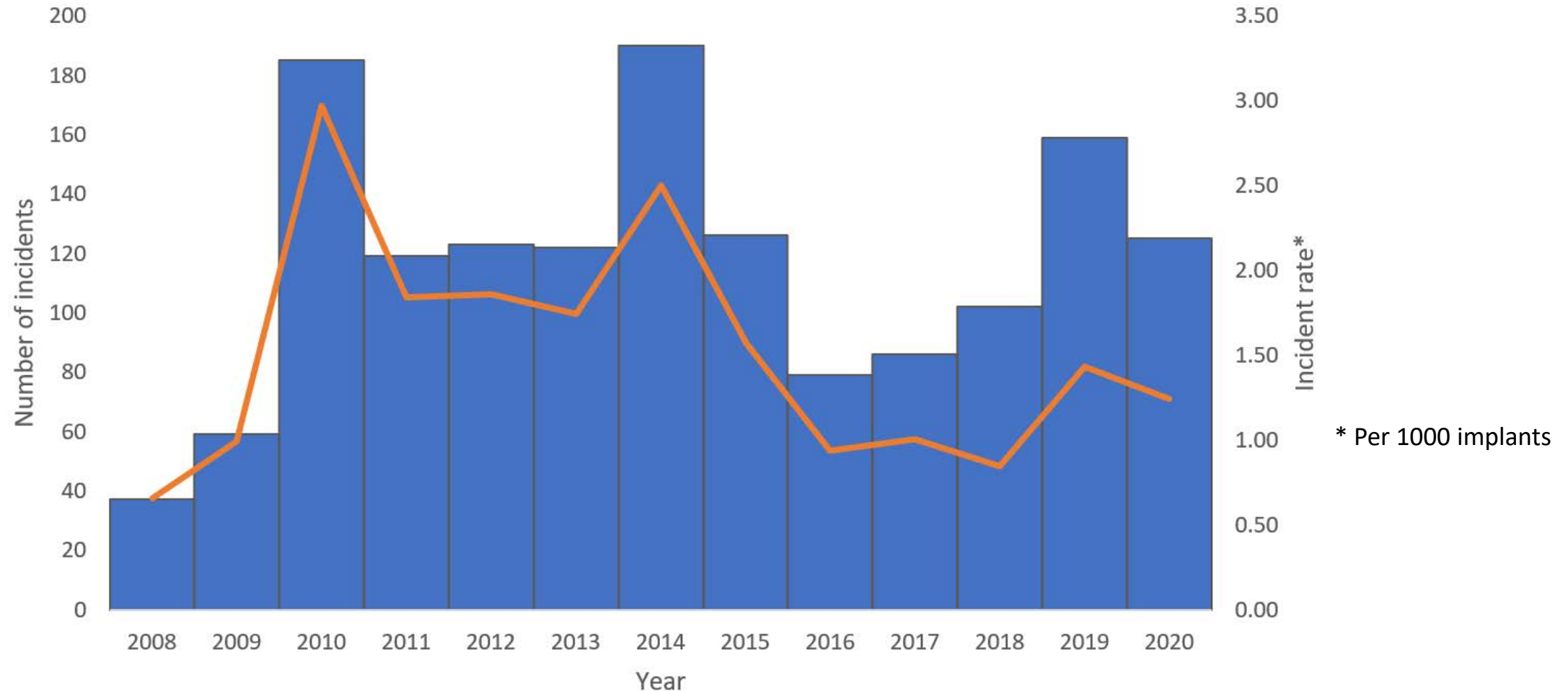
- Male: 494 - Female: 413

- Weight: 1220 not reported

  Mean: 92.14kg

- Age: Mean: 65.11years (range 28-96)

- State:

Gender distribution

ACT	23
NSW	331
QLD	200
SA	51
TAS	4
VIC	121
WA	108

Demographics

- Male: 494 - Female: 413
  Not reported: 605

- Weight: 1220 not reported
              Mean: 92.14kg
  Height: ?

- Age: Mean: 65.11years (range 13-96)
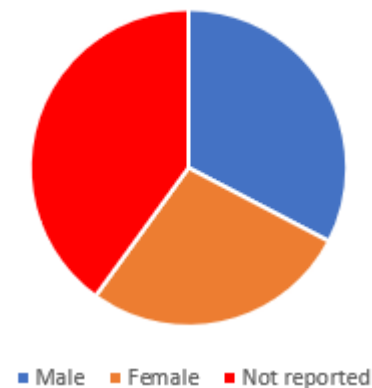 Not reported: 803

- State:

ACT	23
NSW	331
QLD	200
SA	51
TAS	4
VIC	121
WA	108

Not reported: 674

Gender distribution

■ Male ■ Female

Gender distribution

■ Male ■ Female ■ Not reported

WHAT IS THE GLASS?
- HALF EMPTY
- HALF FULL
- 50% FILLED WITH LIQUID

Severity

- Actual harm: death, serious injury (n=1301), temporary injury
- Problem causes:

  design deficiency (n=4), materials and chemistry (n=9), "known complication"
- Problem types:

  device failure, incompatibility, mechanical/mechanical problem, "other" (n=327)

Not ortho-designed

Keyword categories

- Revision
- Pain
- Fracture
- Loosening

- Dislocation
- Corrosion
- Infection
- Metallosis

Correlation (according to products)	p value
Adverse events rates vs registry revision rates	< 0.0001
Adverse events rates vs prostheses identified by the registry	0.072

Correlation per keyword analysed (according to products)	p value
Revision	0.735
Pain	0.044
Fracture	0.274
Loosening	0.245
Dislocation	0.001
Corrosion	0.072
Infection	0.687
Metallosis	0.025
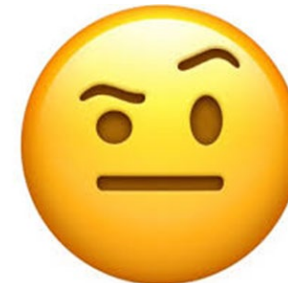
Correlations calculated by logistic regression in STATA

Results & Analysis

Sensitivity, specificity, PPV and NPV for keywords

	Revision	Pain	Fracture	Loosening	Dislocation	Corrosion	Infection	Metallosis
Sensitivity	47.06%	41.18%	26.47%	32.35%	11.76%	17.65%	17.65%	32.35%
Specificity	65.03%	80.37%	78.53%	79.14%	87.73%	96.32%	92.64%	96.32%
PPV	21.92%	30.43%	20.45%	24.44%	16.67%	50.00%	33.33%	64.71%
NPV	85.48%	86.75%	83.66%	84.87%	82.66%	84.86%	84.36%	87.22%

Conclusions

- Quality of post-market reporting

- Under-reporting of adverse events

- No strong direct correlation found

- Pain, for example, as possible keyword

- Continuous collaboration with the AOANJRR is critical