# The Body Speaks in Patterns

## Intuition, Data and the Future of Practice


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SPEAKER

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PhD Blood biomarkers in Alzheimer's disease

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SPEAKER

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BDes Design Futures




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SECTION 01

# The Why


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# The Problem

**60%**

of the Australian population had a pathology test in FY25

+ The problem isn't lack of testing. The problem is extracting meaningful clinical insight from the testing that is already occurring

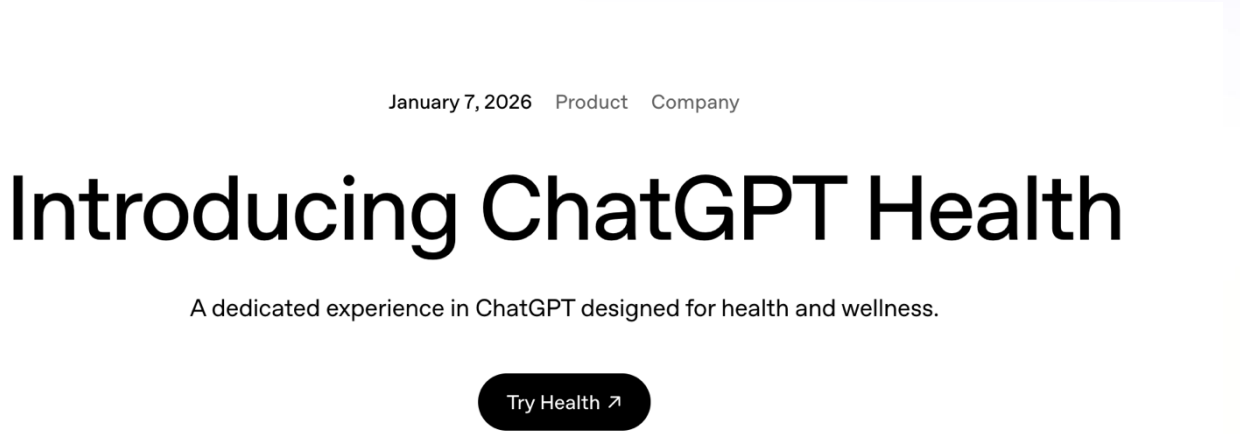
+ Patients often arrive with pathology results that can support clinical decision-making

+ Practitioners report a need for further education and support to help them recognise and interpret patterns in pathology results.

+ Pathology interpretation is complex, time-consuming and requires connecting patterns across multiple data points


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https://www.aihw.gov.au/reports/diagnostic-services/pathology-imaging-and-other-diagnostic-services

# AI in Healthcare




**230M+ people** ask **ChatGPT** health and wellness questions every week


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# Not all uses of AI carry the same risk

The closer AI gets to the clinical decision, the higher the stakes

LOWER RISK

HIGHER RISK



### Documentation

Notes, summaries

### Operations

Administrative workflows

### Clinical decisions

Evidence, screening, diagnosis, treatment

### Patient self-care

Self-triage, self-diagnosis, self-management


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Adapted from Scott et al. Med J Aust. 2025;223(11). doi:10.5694/mja2.70057

# Digital scribes and clinical advice

Many digital scribes now include generative AI-enabled features. Some of these features may require regulation as a **medical device.**

LOWER RISK

HIGHER RISK



## DOCUMENTING THE CONSULTATION

Captures and organises what was said, without adding clinical interpretation.

## CONTRIBUTING CLINICAL ADVICE

Analyses information or generates outputs that may impact clinical decision making.

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Source: TGA, Digital scribe review outcomes, 16 October 2026

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| Date | 17/08/24 | | |
|---|---|---|---|
| Fasted | 0830 | Units | Reference |
| Prolactin | 546 | mUI/L | 150-500 |
| Cortisol | 520 | nmol/L | 150-535 |
| DHEAS | 4.3 | µmol/L | 1-17.4 |
| Testosterone | 6.0 | nmol/L | 6.7-26 |

- **Cortisol:** 546 nmol/L (Elevated, ref 150–535)
- **Testosterone:** 520 nmol/L (Normal)
- **DHEAS:** 6.0 µmol/L (Low-normal, ref 6.0–17.4)
- **Prolactin:** 4.3 mIU/L (Normal)

HPA Activation-Stress

Priority Markers

No Priority Markers associated with this test

Additional Markers

H L

DHEAS - Suboptimal

**Testosterone: 520 nmol/L (Normal)**

**Interpretation:** High cortisol with borderline-low DHEAS could suggest chronic stress or HPA axis dysregulation.

**Testosterone is holding fine.**

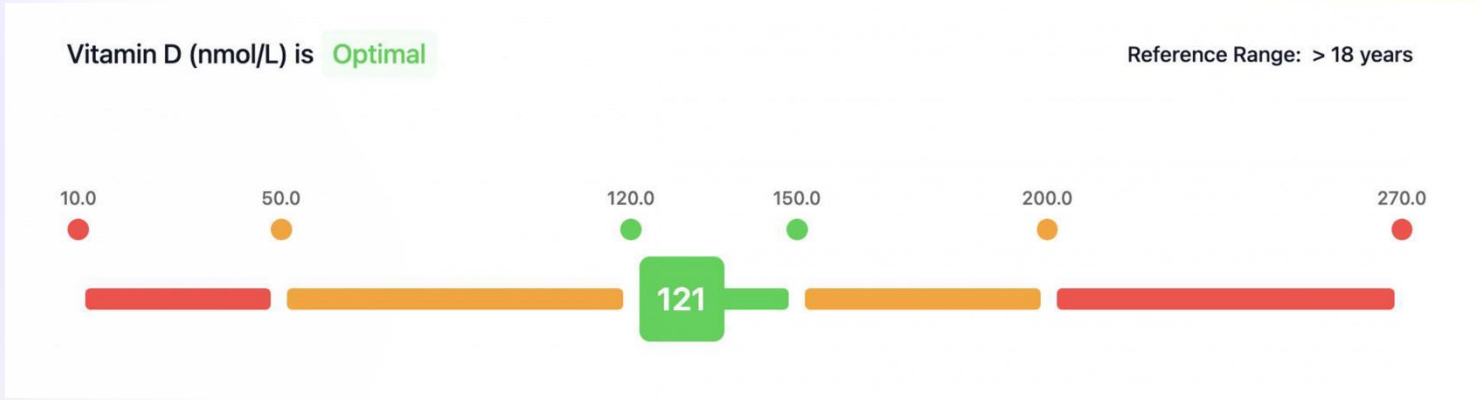



A value of 520 nmol/L for testosterone is extremely **high** (RR – 6.7-26.0 nmol/L)
If it was FREE testosterone the units would be pmol/L (RR: 260-750)


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| Date | 17/08/24 | | |
|---|---|---|---|
| Fasted | 0830 | Units | Reference |
| Vitamin D | 121 | nmol/L | 50-200 |
| Vitamin B12 | 569 | pmol/L | 120-680 |
| Folate | 16.7 | µg/L | >3.8 |






**Vitamin D: 16.7 nmol/L (Severely deficient, ref 50–150)**

**Interpretation:** This vitamin D level is bad—severely deficient, and potentially contributing to inflammation, insulin resistance, mood issues, or low energy.

Prescribe high-dose cholecalciferol (e.g. 5000 – 10000 IU/day short-term, then maintenance

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| | Correct | Incorrect |
|---|---|---|
| 1st Run | Lipid Panel<br>Liver function<br>Glucose and insulin<br>Inflammatory markers | All hormone values are wrong -TT completely wrong<br>Doesn't report UA and HCy<br>Say's normal but doesn't state value rad by OCR for many analytes<br>Vitamin D value is folate and says severely deficient |
| 2nd Run | Lipid Panel<br>Glucose and insulin<br>Inflammatory markers | Liver function – misreads GGT and gives no ALP value<br>Vit D value is folate- says severe deficiency<br>Vitamin B12 – 221 should be 569<br>Says hormones are normal but PRL above the RR, F above the OR, TT below the RR<br>Says micronutrients are normal but Mg below the OR<br>Says iron studies are normal but ferritin is above the RR<br>Recommends HCy testing for vitamin B12 deficiency.<br>HCy was on the report |
| 3rd Run | Glucose and insulin | Lipids -read LDL as 6.6 which is value for non-HDL. Should be 3.9. No Non-HDL was read.<br>LFTs -GGT read as ALP value. Should be 32.<br>No HCy read.<br>Vit D value is folate- says severe deficiency.<br>Selenium value is Mg value. No Mg or Cu read.<br>Says endocrine function normal - no values given and Test is 6.0 on report which is below the RR. DHEAS also below OR. Cortisol is above RR and PRL above RR.<br>Says iron studies normal but ferritin is above RR.<br>Says haematology normal – but ESR above OR and CRP above RR. No values given |

# Different uploads, different results

- In three uploads, only glucose and insulin were correct
- Different formats/fonts presented – pattern recognition difficult
- Regular, inconsistent, incorrect OCR reading of reports
- Says 'normal' without reporting what the value is
- Read GGT value as ALP value multiple times
- Multiple analytes incorrectly and consistently misread


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HIGHER RISK



**Clinical decisions**

Evidence, screening, diagnosis, treatment

**Patient self-care**

Self-triage, self-diagnosis, self-management


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# Tacit Knowledge

- Clinical reasoning often relies on **tacit knowledge**: expertise gained through experience that is difficult to fully articulate or document.
- “We know more than we can tell.”
- Intuition is not guesswork. It is rapid pattern recognition built from repeated exposure to real-world cases.
- If interpretation becomes fully automated, practitioners may have fewer opportunities to build or maintain those capabilities.
- Software and tools that amplifies rather than replaces clinical judgement
- AI can automate analysis, but judgement, intuition and tacit knowledge remain **fundamentally human capabilities.**


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# Keeping the Practitioner in the Loop

- **Start with clinical needs:** Understanding the problem through direct conversation
- **Building with practitioners:** involving end users from initial design through ongoing development.
- **Letting feedback shape the software:** ensuring practitioner input guides features and how they work


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HIGHER RISK



**Clinical decisions**

Evidence, screening, diagnosis, treatment

**Patient self-care**

Self-triage, self-diagnosis, self-management


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SECTION 02

# Software as a Medical Device (SaMD)


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# What is a Medical Device?

- Built for a medical purpose
- Demonstrating that the software performs as intended
- Generating Clinical Evidence
- Identifying and managing risk
- Validating performance
- Meeting regulatory requirements

## Familiar examples

Blood pressure monitors

Heart monitors

X-ray equipment

Ultrasound machines

Pacemakers

Medical software


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# General software and medical devices

## General software

**Broad purpose**

Everyday software and general-purpose chatbots, such as ChatGPT or Claude.

**Clinical use needs checking**

A fluent answer alone does not establish safety or performance for a medical task.

## SaMD

**Defined medical purpose**

Software intended to screen, diagnose, monitor or guide treatment may be a medical device.

**Evidence and oversight**

Applicable requirements cover safety, performance and controls throughout its lifecycle.


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# Why Medical Device Regulation Matters

## Patient Safety

Patient safety sits at the core of medical device development.

## Evidence, Not Assumptions

Medical devices must demonstrate that they perform as intended

## Quality Built In

Quality is embedded throughout the design and development processes

## Ongoing accountability

Medical devices operate within structured quality and monitoring systems.


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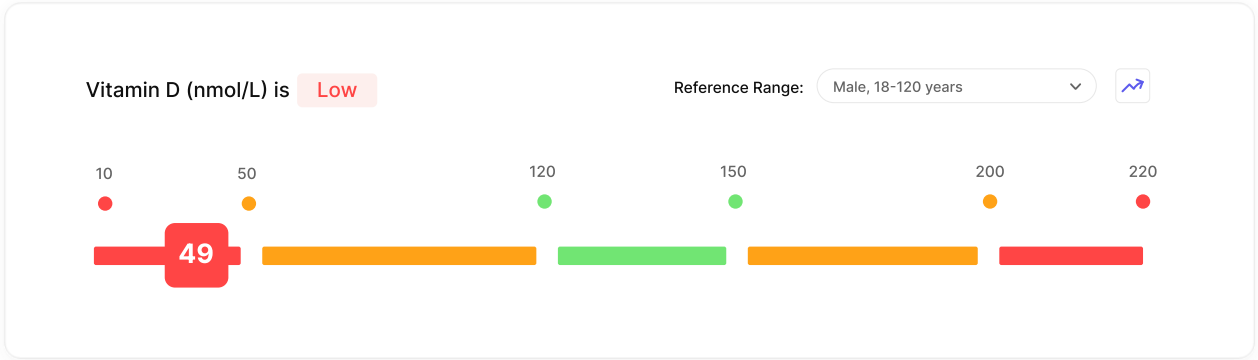
SECTION 03

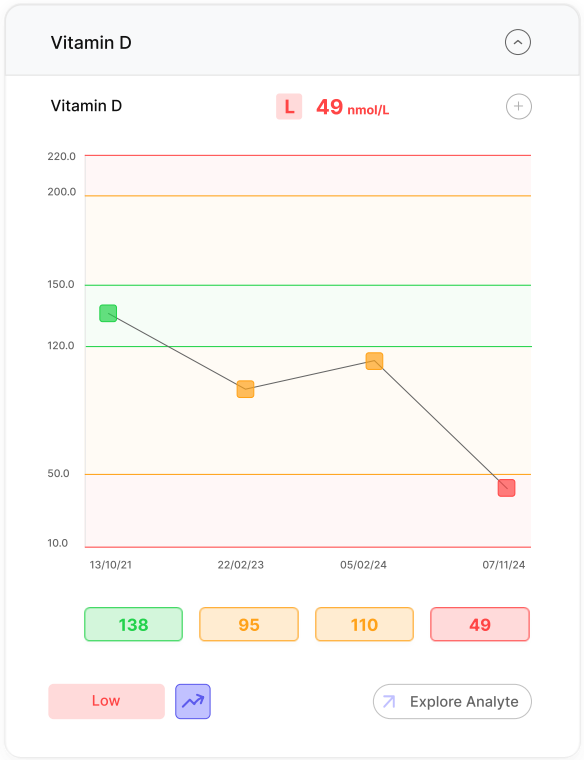
# Our Answer

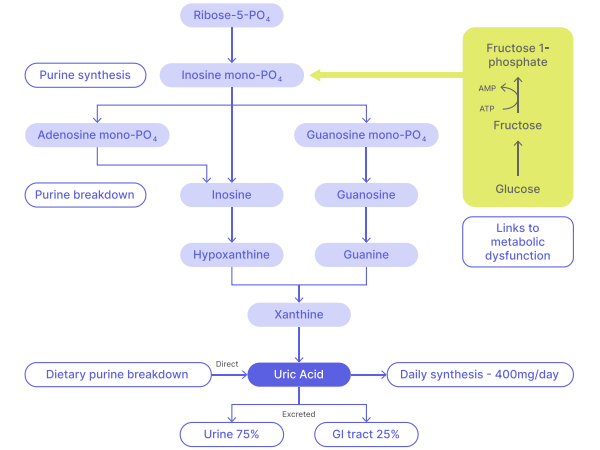

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# Meet **PIA**

- Assists practitioners with pathology interpretation using laboratory results and patient parameters
- Monitors analyte and biomarker trends over time
- Screens for potential health conditions requiring further investigation
- Flags patients who may require referral to a primary healthcare practitioner
- Provides detailed and referenced educational content




Cardiovascular/Kidney/Metabolic

Prediabetes

Hyperlipidaemia Referral Required


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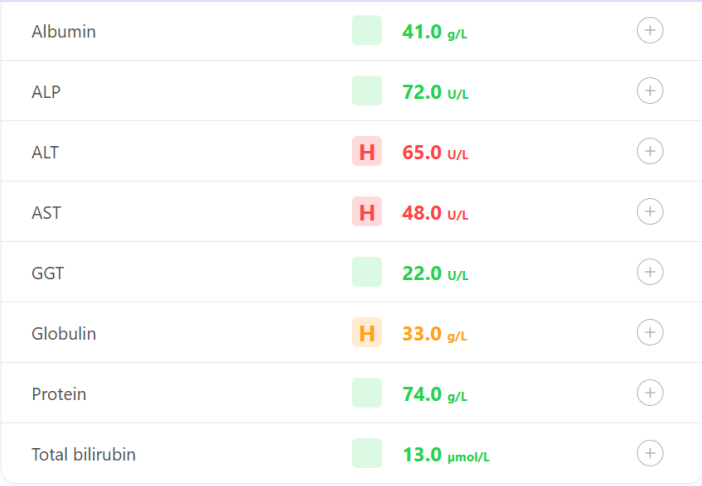
# Research



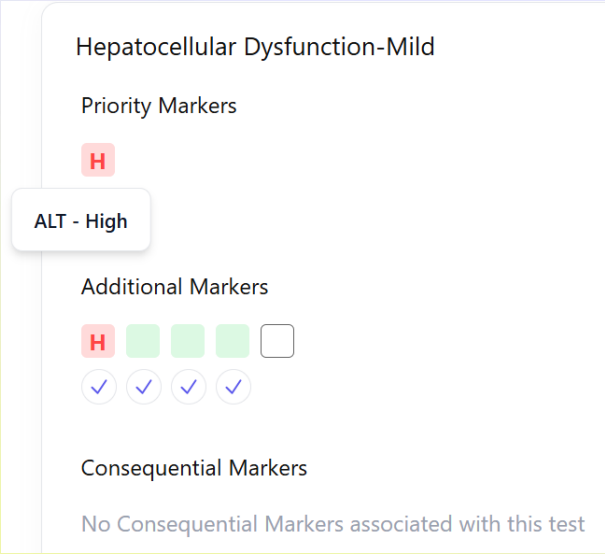
- Content has been written according to the latest guidelines and research
- All content is fully referenced according to NHMRC guidelines –no blogs or influencers
- Regular content reviews to reflect the most up to date evidence
- Built and written with assistance of an experienced Senior Medical Laboratory Scientist, Researcher and Nutrition Medicine Practitioner
- The content is not AI generated
- Information is focused on testing and provides a powerful educational platform


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# PIA



| | | |
|---|---|---|
| Albumin | | 41.0 g/L |
| ALP | | 72.0 U/L |
| ALT | H | 65.0 U/L |
| AST | H | 48.0 U/L |
| GGT | | 22.0 U/L |
| Globulin | H | 33.0 g/L |
| Protein | | 74.0 g/L |
| Total bilirubin | | 13.0 µmol/L |




# AI

Data

**2. Liver Function – Abnormal**

- **ALT**: 65 U/L (High; Ref: 5–40)
- **AST**: 48 U/L (High; Ref: 5–35)
- **GGT**: 72 U/L (High; Ref: 5–50) On report GGT = 22 (normal)
- **ALP**: 122 U/L (High; Ref: 30–110) On report ALP= 72 (normal) – read this as 22 (GGT value) and added 100
- **Total bilirubin**, **albumin**, **protein**, **globulin**: Normal (doesn't say what value is)

📌 **Interpretation**:

- **Mixed hepatocellular and cholestatic pattern**. – no elevation in ALP or GGT on original, both normal
- Elevated ALT/AST suggest **liver inflammation**.
- Elevated GGT/ALP could indicate **fatty liver (NAFLD)** or **alcohol use**.
- Possibly related to metabolic syndrome.


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# PIA can help systematically guide

- Condition matching is not AI generated – PIA shows you which markers match
- Reference and optimal ranges for analytes are fully referenced according to NHMRC guidelines
- Use of calculated and derived values to add weight to condition matching - e.g.microcytic anaemia
- Appropriate questions to ask the patient to help determine cause of condition e.g.medication use

Prioritise the most likely

Identify the primary condition

Recommend referral

Suggest further testing


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SECTION 04

# Roadmap


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# Why this product takes time

- ✓ Generating clinical evidence
- ✓ Establishing quality management systems
- ✓ Identifying and managing risk
- ✓ Validating performance
- ✓ Meeting regulatory requirements
- ✓ Demonstrating that the software performs as intended

It is a longer pathway, but one that is essential when technology influences and impacts patient care.


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# TGA Pre-Submission Meeting

- Formal TGA Meeting to discuss intended users and clinical trial strategy and expectations
- In-person, in Canberra. Multiple TGA staff in the room and online.
- A lot of questions around it due to novel nature of the software
- Even suggesting that PIA may fall into a higher risk category than originally thought.

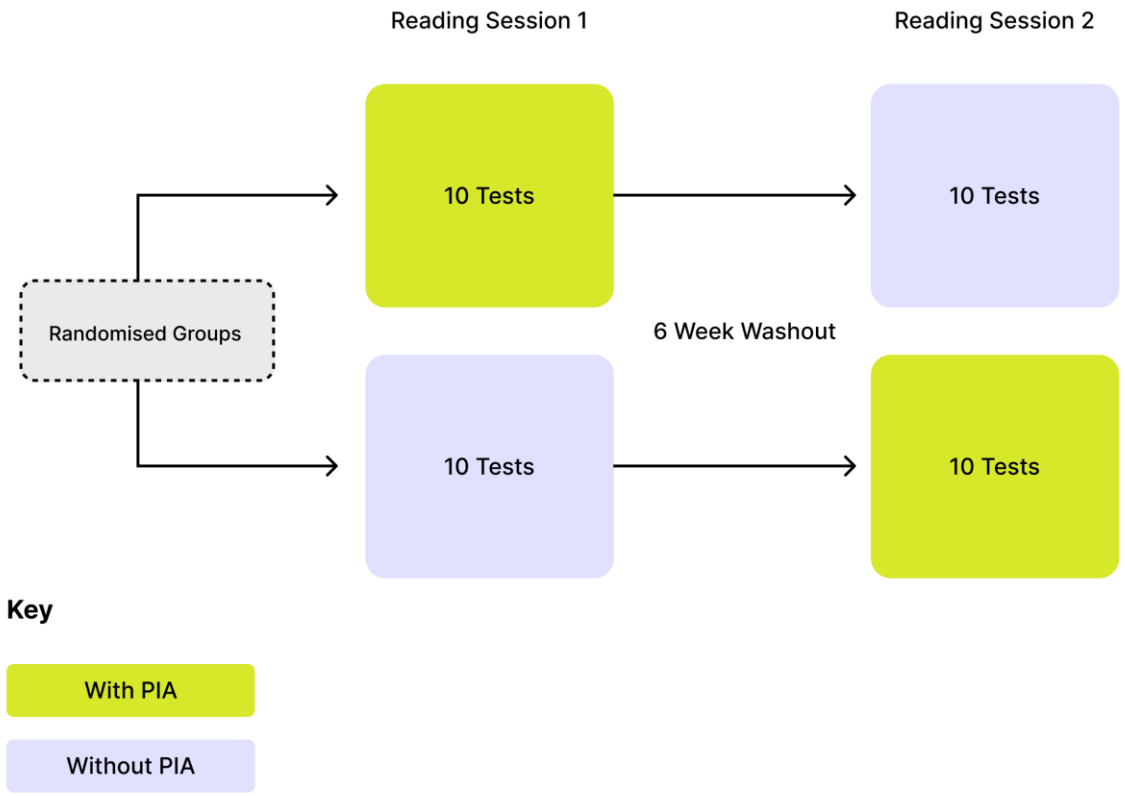

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SECTION 05

# Proven Effectiveness through Clinical Trials


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# How we **Tested PIA**

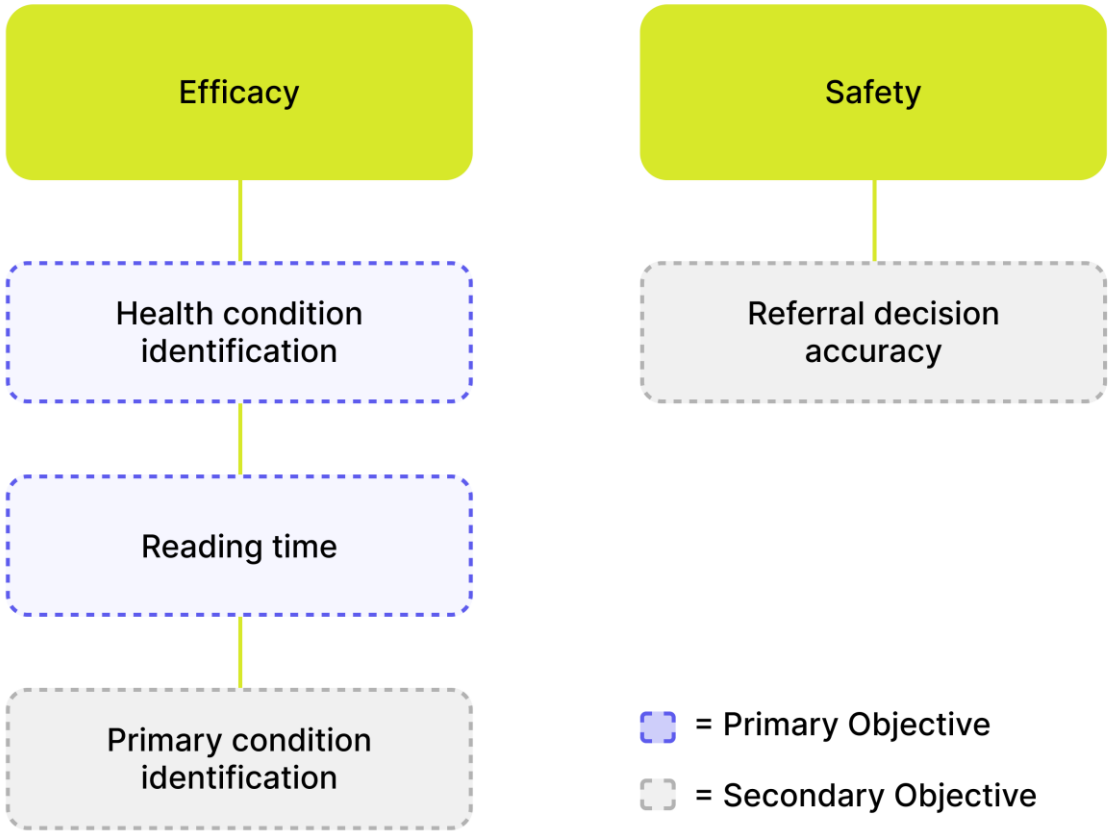



- Remote randomised crossover study
- Conducted in practitioners usual clinical settings
- 10 pre-defined pathology cases per reading session
- Ethics approved
- ACTRN12625000288426p

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# How we **Tested PIA**





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| Characteristic | Treatment sequence | | Total (n=145) |
|---|---|---|---|
| | PIA-SP (n=72) | SP-PIA (n=73) | |
| **Sex** | | | |
| Male, n(%) | 5 (6.9) | 5 (6.8) | 10 (6.9) |
| Female, n(%) | 67 (93.1) | 68 (93.2) | 135 (93.1) |
| **Profession** | | | |
| Naturopaths, n(%) | 53 (73.6) | 62 (84.9) | 115 (79.3) |
| Nutritionist, n(%) | 18 (25.0) | 10 (13.7) | 28 (19.3) |
| GP, n(%) | 1 (1.4) | 1 (1.4) | 2 (1.4) |
| **Years of Experience** | | | |
| < 3 years, n(%) | 14 (19.4) | 14 (19.2) | 28 (19.3) |
| 3-10 years, n(%) | 27 (37.5) | 27 (37.0) | 54 (37.2) |
| > 10 years, n(%) | 31 (43.1) | 32 (43.8) | 63 (43.4) |
| **Number of pathology tests per week** | | | |
| 1-10 tests, n(%) | 63 (87.5) | 57 (78.1) | 120 (82.8) |
| 11-20 tests, n(%) | 3 (4.2) | 9 (12.3) | 12 (8.3) |
| > 20 tests, n(%) | 6 (8.3) | 7 (9.6) | 13 (9.0) |


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| Characteristic | Completed (n = 75) | Drop-outs (n = 70) | P-value^ |
|---|---|---|---|
| **Sex** | | | 0.52 |
| Male, n(%) | 4 (5.3) | 6 (8.6) | |
| Female, n(%) | 71 (94.7) | 64 (91.4) | |
| **Profession** | | | >0.99 |
| Naturopaths, n(%) | 60 (80.0) | 55 (78.6) | |
| Nutritionist, n(%) | 14 (18.7) | 14 (20.0) | |
| GP, n(%) | 1 (1.3) | 1 (1.4) | |
| **Years of Experience** | | | **0.01** |
| < 3 years, n(%) | 12 (16.0) | 16 (22.9) | |
| 3-10 years, n(%) | 37 (49.3) | 17 (24.3) | |
| > 10 years, n(%) | 26 (34.7) | 37 (52.9) | |
| **Number of pathology tests per week** | | | 0.13 |
| 1-10 tests, n(%) | 66 (88.0) | 54 (77.1) | |
| 11-20 tests, n(%) | 3 (4.1) | 9 (12.7) | |
| > 20 tests, n(%) | 6 (8.0) | 7 (10.0) | |

^Fisher's exact test or Pearson's Chi-squared test


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# Analysis of Data

## Intention-To-Treat

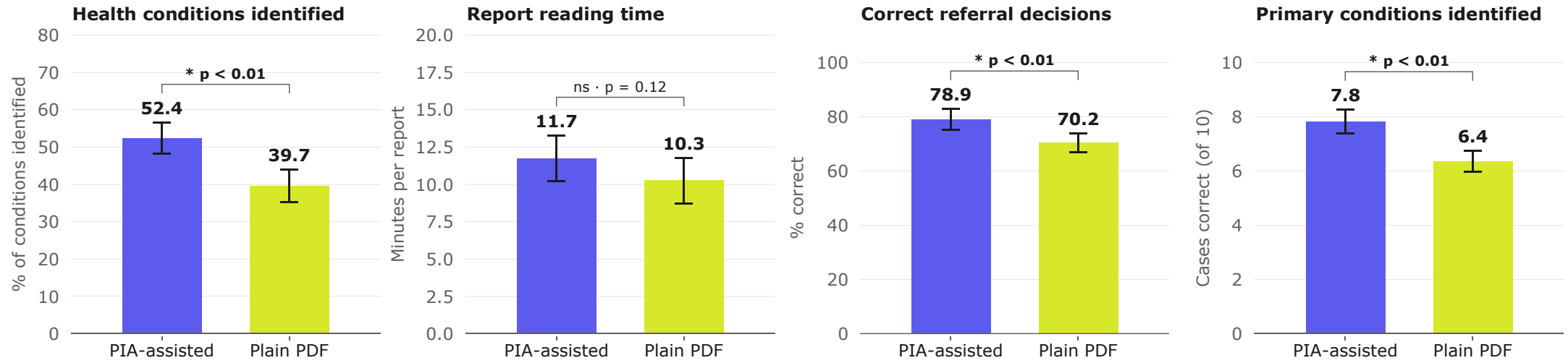
- Primary analysis method
- Included all participants who were randomised into the trial (n=145).
- Participants were analysed according to their allocated treatment arm, regardless of whether they completed both reading sessions.
- Missing data were addressed using multiple imputation methods.

## Per-Protocol

- Included only participants who completed both reading sessions according to the study protocol.
- Used as a sensitivity analysis to support the primary ITT findings.
- Results were consistent with the ITT analysis and generally demonstrated larger effect sizes.


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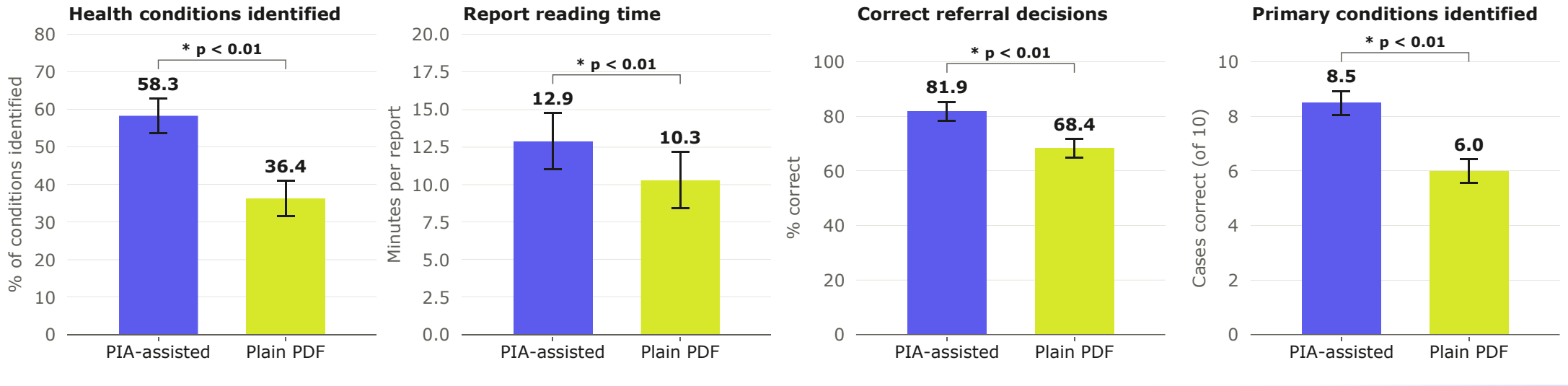
**Figure 1. Intention-to-treat analysis (n = 145) — PIA-assisted vs plain PDF reading**





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**Figure 3. Per-protocol sensitivity analysis — participants who completed both sessions (n = 75)**

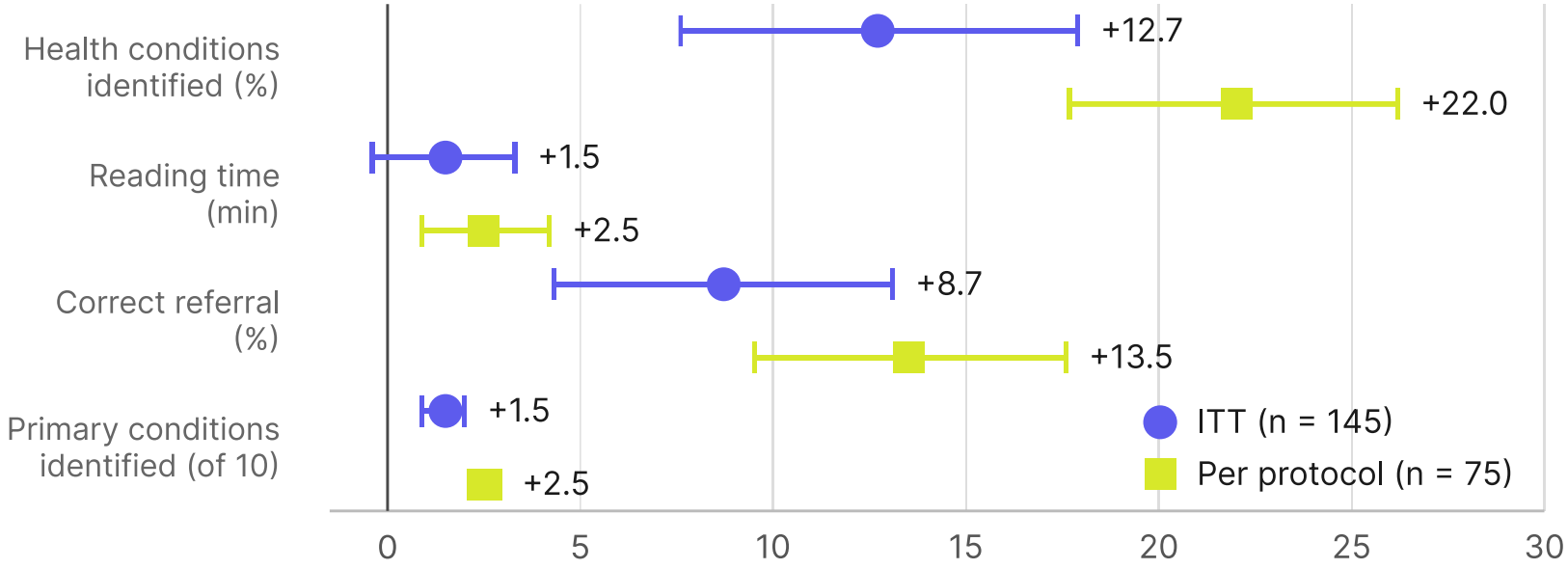




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## Figure 5. Effect estimates: ITT vs per-protocol

Estimated mean difference, PIA-assisted minus plain PDF (95% CI).






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# Key Trial **Learnings**

**Overall, our study found improved efficacy and safety, supporting our P1, S1, S2 objectives. However, we did not find improvement in time to analyse the pathology report, disproving objective P2.**

- **P1 -** PIA improved identification of health conditions
- **S1 -** PIA improved identification of primary conditions
- **S2 -** PIA improved referral decision accuracy
- **P2 -** PIA did not reduce interpretation time during first-time use
- Cross-over designs resulted in high participant attrition


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# Building on Learnings from **PIA001**

- Parallel study design instead of cross-over
- Larger and statistically representative practitioner population
- **Confirmation of efficacy outcomes**
  - Health condition identification
  - Primary condition identification
- **Confirmation of safety outcomes**
  - Referral decision accuracy
- **Expanded evaluation of:**
  - Identifying clinically relevant optimal ranges and correctly identifying out-of-range analytes


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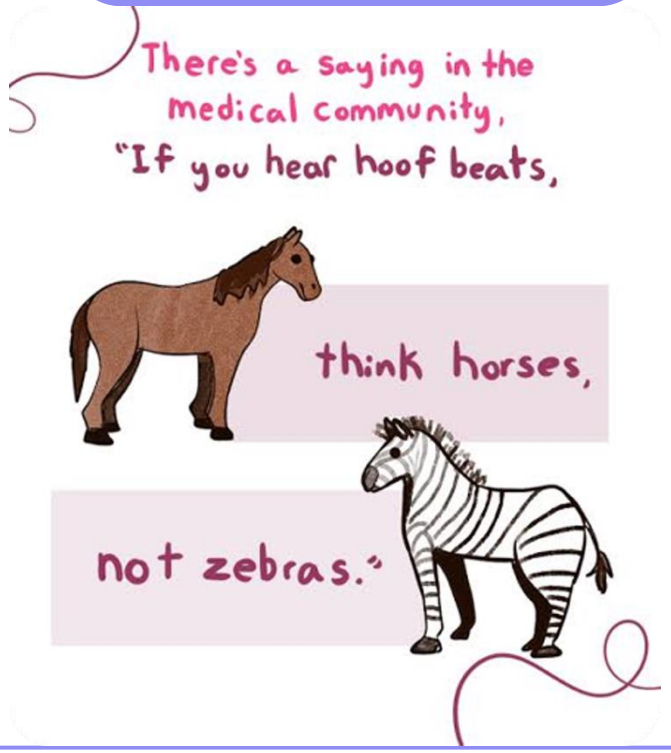
# Clinical Learnings

## Prioritise

A phrase coined by Dr. Theodore Woodward in the 1940s to remind medical students that common conditions are far more likely than rare ones, helping reduce misdiagnosis and unnecessary testing

PIA logically prioritises common conditions over rare ones – better clinical reasoning

## Common vs Exotic



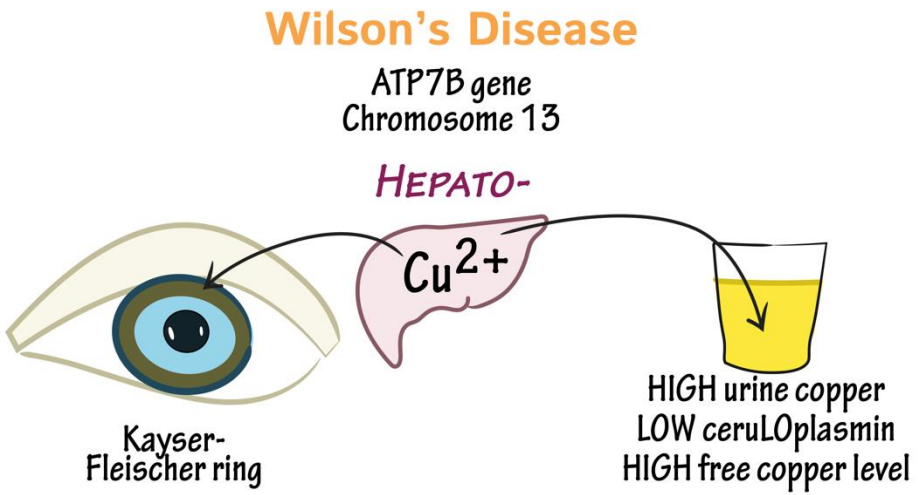


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# Clinical Learnings

**10 reports in the PIA trial – 2 out of 10 were identified as Wilson's disease based on high/normal serum copper**

- Incidence of Wilson's disease in Australia is essentially the same as global estimates: about 1 in 30,000–50,000 people
- With ~26 million people, Australia would have ~520–870 individuals living with Wilson's disease – our clinical trial had 10 reports with 2 being matched to Wilson's - 20%!
- Autosomal recessive mutations in **ATP7B,** a copper transport protein




- High/normal serum copper is not a reliable test for Wilson's disease
- PIA prioritised the copper value as part of a chronic inflammatory response where copper and zinc are re-distributed as caeruloplasmin is an acute phase reactant


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Roberts, E *et al.* N Engl J Med 2023;389:922-38. DOI: 10.1056/NEJMra1903585

# Clinical Learnings

## Incorrect

The incorrect condition was identified multiple times:

- Haemochromatosis – based on elevated ferritin
- Hypothalamic amenorrhoea in a 62-yr old male
- Hypothyroidism with low normal TSH

## Why?

- Haemochromatosis – a hereditary iron overload with elevated ferritin, but also a % saturation within the reference range. No HFE gene studies done
- Hypothalamic amenorrhoea – inappropriate for patient parameters
- Hypothyroidism with TSH and fT3 appropriate for non-thyroidal illness syndrome as the case was severe uncontrolled diabetes


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# Clinical Learnings

## Primary Condition

Included in the cases were primary conditions that should have been identified:

- Low eGFR for age
- Megaloblastic anaemia
- Biliary stasis/obstruction
- Uncontrolled diabetes
- Iron deficiency anaemia
- Metabolic syndrome with CVD risk factors

## Referral?

Referral required to identify cause and recommend further testing:

- Cause of reduced renal function
- Cause of vitamin B12/folate deficiency
- Cause and extent of biliary dysfunction
- Extent of CVD risk and renal function
- Investigate blood loss in a male
- Assessment of CVD risk


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# Clinical Learnings

## Calculated Values

Microcytic anaemia – IDA vs **β-thalassaemia** (incl trait)

- use MCV/RCC (Mentzer)
- >13 likely IDA, <13 β-thalassaemia
- MCV is usually lower in β-thalassaemia, but a RCC can be normal or high
- Use RDW – in IDA there is a mixed population of cell sizes (trial results high RDW ~ 22), whereas in β-thalassaemia, the RCC are uniformly small

## Appropriate Use

- Knowing when calculations are relevant - e.g. APRI, FIB4, R-value not triggered unless obvious liver damage (elevated liver enzymes)
- LH:FSH in females for PMOS
- Markers of insulin resistance – TyG
- MCV/RCC in microcytic anaemia


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SECTION 06

# Designed by Laboratory-Medicine Expertise


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# Interferences with test results

**Hidden interferences**

Things that skew results, often unseen:

- **collection conditions** - fasted, exercise, time of day, stress, hydration, recent supplementation, appropriate handling (collection tube /anticoagulant, light exposure, centrifugation/separation)
- **assay interference** – medications, biotin, haemolysis

**Invisible without lab experience**

You may not know what to look for

**PIA flags them**

So, you know what to be mindful of


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# Reference ranges - why they differ?

## Same analyte — Different result - Method dependent

LAB A

**Albumin 39–45**

**Method - BCP**

More specific for albumin as  less affected by globulins and acute phase proteins - more accurate in inflammatory conditions

More difficult to calibrate

Underestimates in hypoalbuminaemia

LAB B

**Albumin 40–50**

**Method - BCG**

Method commonly used due to speed and simplicity, but tends to **overestimate albumin** and A:G, especially at low levels



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# The detail behind the calculations

## PIA records method, units (with conversions) & study population

RESEARCH TOOL

### HOMA-IR / HOMA2-IR

Different measures, often confused

Research tools, not used clinically

Based on a linear relationship between glucose and insulin –does not account for glucose use by liver and peripheral tissues or proinsulin (immunoassays)

MORE RELEVANT

### Triglyceride-glucose (TyG)

A more relevant insulin-resistance marker

Addresses the dyslipidaemia and dysglycaemia of early insulin resistance

Avoids the use of insulin in the calculation – not always available



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SECTION 07

# Shaping the Future


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# What's Next **for PIA**

2027 & Beyond | The Journey Continues

- Continued product development
- Ongoing clinical research including PIA002 Pivotal Trial
- Usability research and practitioner involvement
- Continued regulatory activities including (hopefully) submitting for regulatory audits
- Working towards building PIA for health professionals

Built for Practitioners | Clinical Tools to Simplify Complexities in Practice


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# Practitioners shape PIA's future

### Clinical judgement stays central

PIA supports practitioners' expertise and decision-making.

### Your feedback guides development

Practitioner input shapes features and how they work in practice


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# Stay Connected with the **PIA Journey**

- Participate in future studies and research
- Be among the first to hear about key milestones
- Clinical research updates
- Launch announcements



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ANY QUESTIONS?

# Thank you for joining us today


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