

# Cost consequence analysis of using the Elecsys Anti-Müllerian Hormone Plus immunoassay as part of polycystic ovary syndrome assessment in the United Kingdom

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## Introduction

- Polycystic ovary syndrome (PCOS) is a prevalent endocrine and metabolic disorder amongst women.<sup>1</sup> In addition to the common PCOS symptoms, the risk of developing comorbidities such as type 2 diabetes (T2D) and stroke increases in women with PCOS.<sup>2</sup>
- Diagnosis of PCOS is based on the Rotterdam criteria, which require at least two of the following conditions to be met:<sup>3–5</sup>
  - Oligo-anovulation,
  - Clinical/biochemical hyperandrogenism,
  - Polycystic ovarian morphology (PCOM).
- PCOM detection has previously relied on transvaginal ultrasound (TVUS), which is limited by diagnostic performance, accessibility and inter- and intra-operator variability.<sup>4,6</sup>
- Testing serum anti-Müllerian hormone (AMH) levels is a new recommended alternative to TVUS.<sup>5</sup>

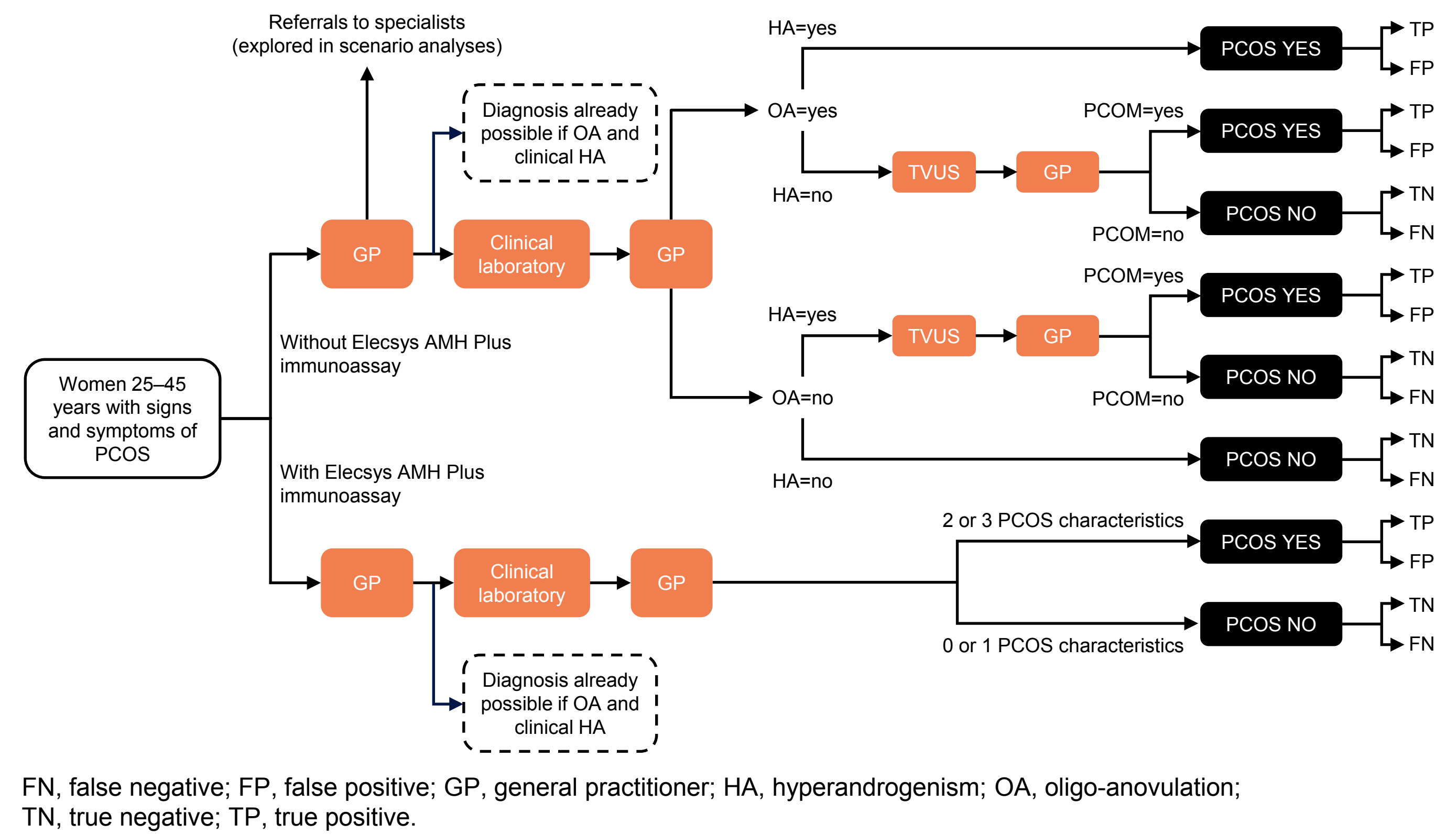
## Objective

- This study assessed the economic impact of using the Elecsys® AMH Plus immunoassay (Roche Diagnostics International Ltd, Rotkreuz, Switzerland) to detect PCOM for the diagnosis of PCOS in the United Kingdom (UK) compared with TVUS.

## Methods

- A decision tree model (**Figure 1**) was developed to estimate health and cost outcomes when replacing TVUS with the Elecsys AMH Plus immunoassay to assess women aged 25–45 years with signs and symptoms of PCOS in different diagnostic pathways.
- The model focused on the UK National Health Service (NHS), assuming in the base-case case that the 2023 International Evidence-Based Guidelines were followed.<sup>5</sup>
- Model parameters were obtained from published literature, unit cost registries and expert opinions. Several scenario and sensitivity analyses were performed to assess the impact of uncertainty on results and identify its drivers.

**Figure 1.** Model representing the typical pathway for patients with signs and symptoms of PCOS.



FN, false negative; FP, false positive; GP, general practitioner; HA, hyperandrogenism; OA, oligo-anovulation; TN, true negative; TP, true positive.

## Results

- In the base-case analysis, the Elecsys AMH Plus immunoassay was associated with an additional 136 true positive diagnoses of PCOS per result type per year, compared with TVUS (6,720.66 versus 6,584.25, respectively; **Table 1**).
- Total cost per year for diagnosing PCOS were £19,941,733.80 with TVUS and £19,657,704.66 with the Elecsys AMH Plus immunoassay; a saving of £284,029.15 per year (£21.90 per diagnosis).
- In addition, savings could also be made with the cost of component, such as cost of performing a TVUS and consultation.

## Disclosures

- O.U.G., A-M.O. and J.S. are employees of Roche Diagnostics International Ltd, Rotkreuz, Switzerland. J.L. received unrestricted research grants from Ansh Labs, Ferring, Merck and Roche Diagnostics; received consultancy fees from Ferring, Gedeon Richter and Titus Healthcare. R.M. and S.F. declare no conflicts of interest. T.P. received a research grant and honoraria from Roche, and fees or honoraria from Exeltis, MSD, Ferring, Gedeon Richter and Organon.
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- ELECSYS is a trademark of Roche.

## Results (cont.)

**Table 1.** Number of diagnoses and costs per year from the UK NHS perspective, 2022.

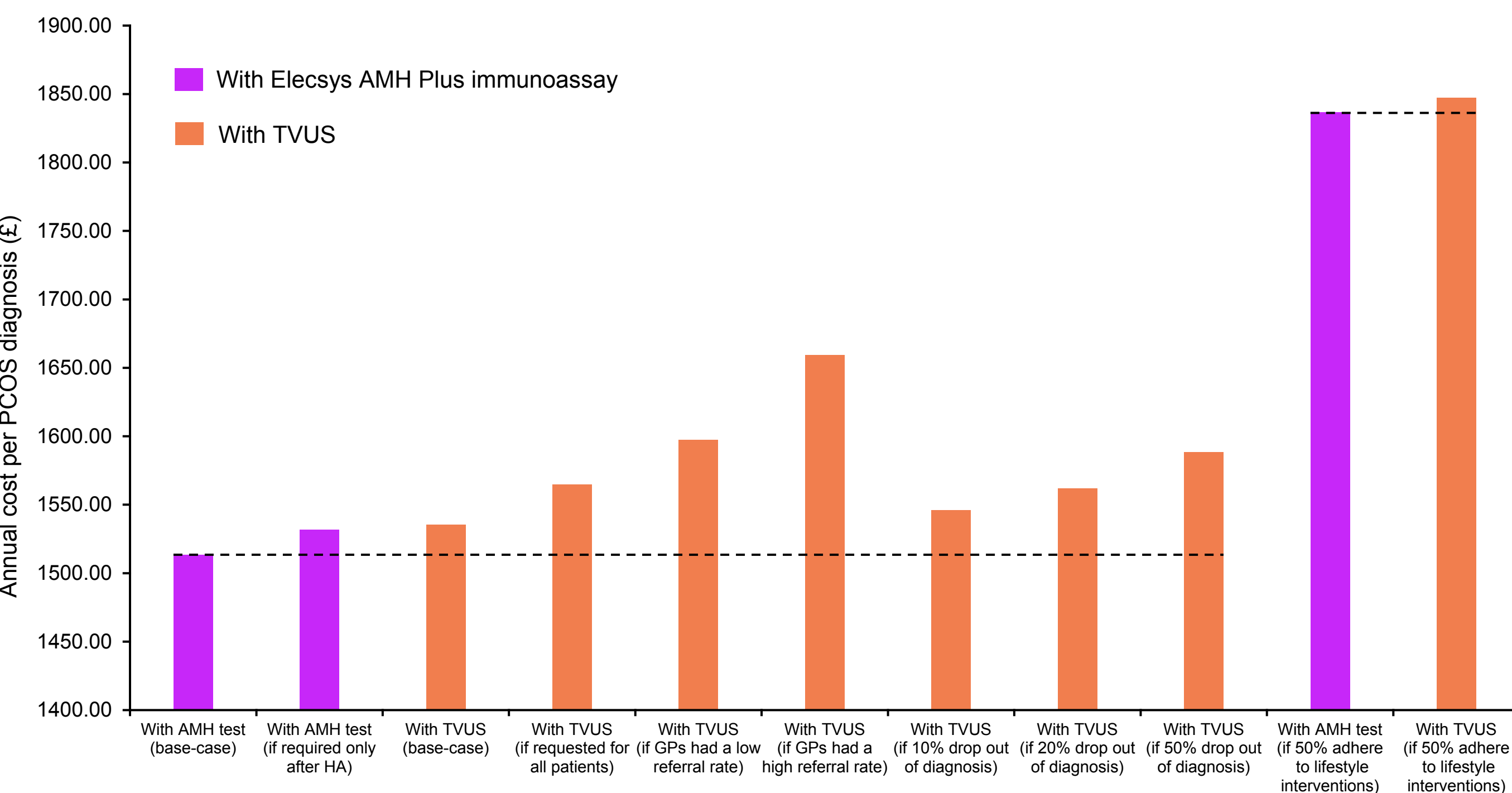
| Number of diagnoses and costs (per year) | With TVUS (base-case) | With AMH test* (base-case) | Difference  |
|------------------------------------------|-----------------------|----------------------------|-------------|
| PCOS diagnoses, n                        | 12,986.96             | 12,986.96                  | 0.00        |
| PCOS diagnoses per result type, n        |                       |                            |             |
| TP                                       | 6,584.25              | 6,720.66                   | 136.41      |
| FP                                       | 344.10                | 697.25                     | 353.15      |
| TN                                       | 5,477.89              | 5,124.74                   | –353.15     |
| FN                                       | 580.72                | 444.31                     | –136.41     |
| New cases of T2D and stroke, n           |                       |                            |             |
| T2D                                      | 187.14                | 185.18                     | –1.96       |
| Stroke                                   | 204.75                | 202.61                     | –2.14       |
| Cost of PCOS, £                          |                       |                            |             |
| Total                                    | 19,941,733.80         | 19,657,704.66              | –284,029.15 |
| Per diagnosis                            | 1,535.52              | 1,513.65                   | –21.87      |
| Diagnosis of PCOS costs components, £    |                       |                            |             |
| Consultations/consultation time          | 761,179.73            | 574,750.87                 | –186,428.86 |
| Laboratory costs                         | 269,222.32            | 269,222.32                 | 0.00        |
| AFC with TVUS                            | 512,938.18            | 0.00                       | –512,938.18 |
| Elecsys AMH Plus immunoassay             | 0.00                  | 403,934.47                 | 403,934.47  |
| Other cost components, £                 |                       |                            |             |
| Lifestyle interventions                  | 2,512,188.55          | 2,689,701.66               | 177,513.11  |
| T2D                                      | 6,459,542.82          | 6,392,000.41               | –67,542.41  |
| Stroke                                   | 9,426,662.19          | 9,328,094.92               | –98,567.27  |

\*The Elecsys AMH Plus immunoassay was used for the AMH test. AFC, antral follicle count.

## Scenario and sensitivity analyses

- Across all scenario analyses, the Elecsys AMH Plus immunoassay resulted in a lower cost for the UK NHS compared with the TVUS pathway (**Figure 2**).
- The deterministic sensitivity analysis showed that the most influential parameters were the sensitivity of TVUS, Elecsys AMH Plus immunoassay unit cost and percentage risk reduction (efficacy of lifestyle interventions).

**Figure 2.** Annual cost per PCOS diagnosis. Base-case and scenario analyses for Elecsys AMH Plus immunoassay (AMH test; illustrated in purple) and SoC including the use of TVUS (illustrated in orange) from the UK NHS perspective, 2022.



The horizontal black dotted line facilitates the comparison between the Elecsys AMH Plus immunoassay base-case annual cost per PCOS diagnosis and the cost calculated by the other base-case and scenario analyses. SoC, standard of care.

## Conclusion

- This analysis suggests that by utilising the Elecsys AMH Plus immunoassay for assessing women with signs and symptoms of PCOS, the UK NHS could benefit from substantial cost savings, increasing the number of women diagnosed with PCOS, reducing the cost associated with PCOS diagnosis and reducing the cost associated with common secondary comorbidities.

## References

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