COST-EFFECTIVENESS ANALYSIS OF THE PROSTATE HEALTH INDEX (*phi*) TEST AFTER A PROSTATE-SPECIFIC ANTIGEN (PSA) TEST IN THE U.K.

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#EE221

BACKGROUND

- Prostate cancer (PCa) accounted for 23.2% of all new cancer cases (excluding non-melanoma skin cancers) diagnosed in men and for 9.9% of all deaths due to cancer in men in EU-27 countries in 2020.[1]
- The total economic cost of PCa in the EU was estimated at €8.43 billion in 2009.[2]
- In 2006, 106–179 million euros (€) were dedicated to PCa management in the European countries exemplified by the UK, Germany, France, Italy, Spain and the Netherlands with increasing cost expected due to earlier diagnosis and increasing survival.[3]
- Research indicates that Prostate Health Index (*phi*) can be used alongside imaging technologies to increase diagnostic accuracy.[4]

STUDY OBJECTIVES

This analysis aimed to determine the clinical and economic consequences of introducing *phi* into the current diagnostic pathway for clinically significant PCa (csPCa, Gleason Grade ≥7) in the United Kingdom.

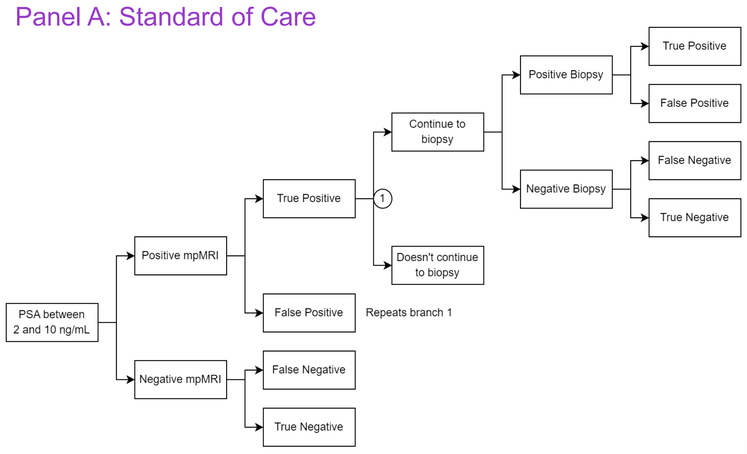
METHODS

A decision-tree-based cost-effectiveness model was developed. Model details:

- The population included men with PSA >2 and <10 and have not yet had a biopsy
- Prevalence of csPCa in the grey zone is 38%[5]
- Hypothetical cohort of 1,000, starting age of 63 years
- Two diagnostic strategies were considered:
  1. SoC + *phi* (*phi* cutoff 25)
  2. SoC
- Outcomes included:
  - Total and incremental costs and quality-adjusted life years (QALYs)
  - Incremental cost-effectiveness ratio (ICER)
  - Net monetary benefit (NMB)
  - Net health benefit (NHB)
  - Total biopsies conducted
  - Total negative biopsies avoided
  - Total csPCa cases missed
- The analysis was performed from the perspective of the UK NHS and personal social services (PSS)
- Time horizon was 1 month to reflect the time it takes to receive a PCa diagnosis in the U.K.
- Disease prevalence, adverse event, health-related quality of life, diagnostic test (*phi*, mpMRI, TRUS biopsy) accuracy, and associated resource use data were obtained from the published clinical literature.
- Cost information was obtained from National Cost Collection (NCC) and the Personal Social Services Research Unit (PSSRU), and *phi* test manufacturer
- Analysis was limited to the diagnostic phase; further diagnostics and treatment of PCa were not considered
- Probabilistic sensitivity analyses (PSA) included: PCa prevalence (beta), diagnostic accuracy (beta), unit costs (listed & literature-based, fixed), resource use proportions (beta), population utility norms (beta), and utility decrements (beta)

MODEL STRUCTURE AND INPUTS

Panel A: Standard of Care



Panel B: *phi* followed by mpMRI

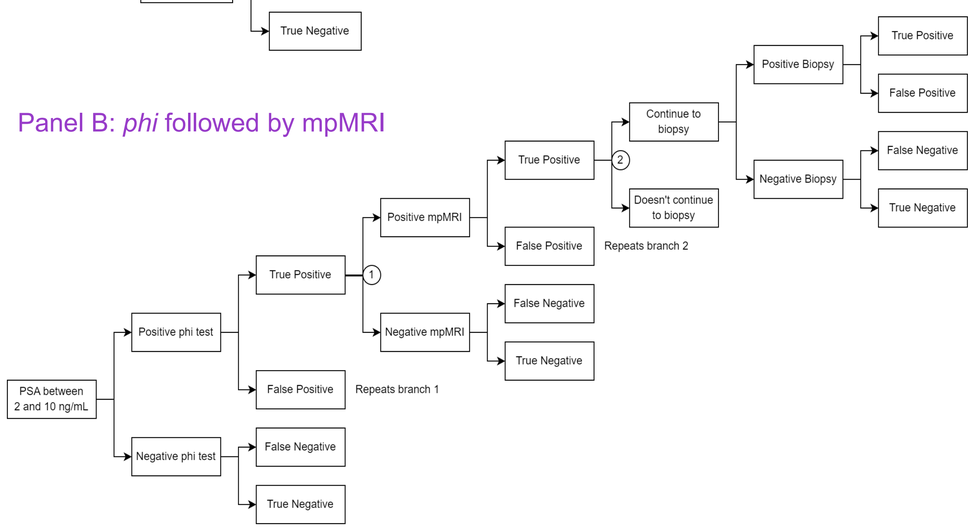


Figure 1. illustrates the decision tree with the current SoC for the UK (Panel A) and *phi* followed by mpMRI (Panel B)

Diagnostic Clinical Inputs

Input	Sensitivity	Specificity	Source
phi (cut off 25)	96%	25%	Kim et al. (2020)
mpMRI	87%	47%	Ahmed et al. (2017)

Biopsy-Related Adverse Event Inputs

Event	Probability	Source
Urinary infection	1.00%	Nam et al. (2010)
Urinary bleeding	0.27%	Nam et al. (2010)
Urinary obstruction	0.13%	Nam et al. (2010)
Rectal bleeding	0.09%	Rosario et al. (2012)
Monthly utility decrement	0.004	NICE NG131

Biopsy-Related Resource Utilization Inputs

Input	Probability	Source
GP Visit	8.02%	Rosario et al. (2012)
Urology nurse consultation	1.22%	Rosario et al. (2012)

Cost Inputs

Input	Unit Cost	Source
phi test	£30	Beckman Coulter
mp-MRI	£257	NCC 2022/23: RD03Z
TRUS-guided biopsy	£811	NCC 2022/23: LB76Z
Biopsy-related AE treatment		
GP consultation	£42	PSSRU
Urology nurse consultation	£146.23	NCC 2022/23: WF01A
Hospital Admission		
Urinary infection	£422	NCC 2022/23: LA04S
Urinary bleeding	£657	NCC 2022/23: LB18Z
Urinary obstruction	£2,303	NCC 2022/23: LB09D
Rectal bleeding	£173	NCC 2022/23: WF01B

RESULTS

Deterministic Base-Case Results (*phi* cut off 25)

	phi+mpMRI	SoC	Incremental
Total costs	£709	£801	£92
Total QALYs	0.07	0.07	0.00
ICER	Dominant		
Net Monetary Benefit	£100		
Total biopsies	564	659	-95
Total unnecessary biopsies	246	329	-82
# of csPCa missed	63	49	13
# of True positives	317	331	-13
# of False positives	246	329	-82
# of True negatives	374	291	82
# of False negatives	63	49	13

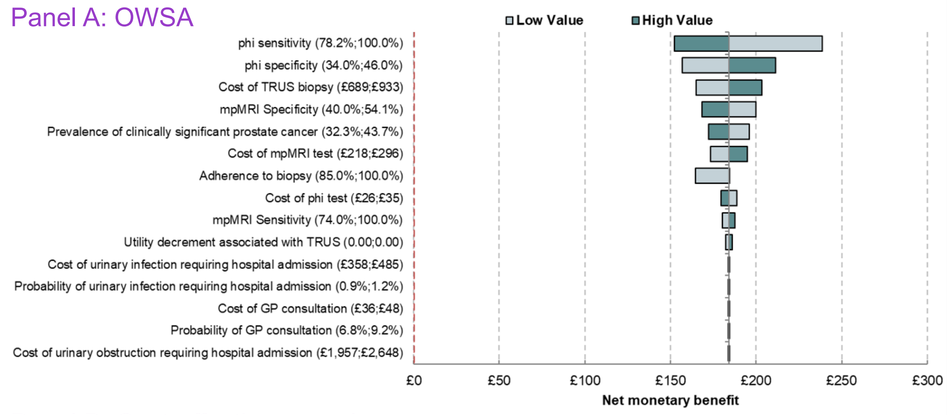
Base Case Cost Breakdown

	phi+mpMRI	SoC	Incremental
phi	£30	--	£30
mpMRI	£213.25	£257.00	-£43.74
TRUS biopsy	£457.26	£534.61	-£77.35
GP consultation	£1.90	£2.22	-£0.32
Nurse consultation	£1.05	£1.23	-£0.18
Urinary infection	£2.38	£2.78	-£0.40
Urinary bleed	£1.00	£1.17	-£0.17
Urinary obstruction	£1.69	£1.97	-£0.29
Rectal bleed	£0.09	£0.10	-£0.01
Total	£708.62	£801.08	-£92.46

- Both the deterministic and probabilistic per-person results showed that for a 30-day time horizon, *phi* + mpMRI was shown to be a cost-effective option, reducing costs and increasing QALY slightly in the csPCa diagnosis pathway in the UK due to fewer mpMRI and biopsies being conducted in the *phi*+mpMRI arm
- The *phi* + mpMRI arm was dominant 100% of iterations of the probabilistic analysis and was cost-effective 100% of iterations at £20,000 per QALY threshold
- There is a trade-off between the cost-effectiveness benefits of *phi* + mpMRI and the number of cases of csPCa that the arm misses compared with mpMRI

SENSITIVITY ANALYSIS

Panel A: OWSA



Panel B: Cost-effectiveness plane

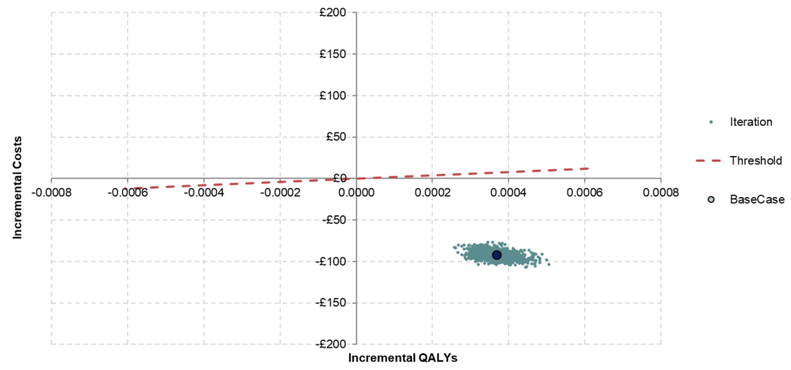


Figure 2. illustrates the one-way sensitivity analyses (Panel A) and the cost-effectiveness plane for *phi*+mpMRI (Panel B)

- The biggest univariate drivers of the results were the sensitivity and specificity of *phi*, followed by the cost of the TRUS biopsy and the concentrated cloud of iterations in the south-east quadrant indicates robustness of the results at the NICE threshold of £20,000 per QALY

STUDY LIMITATIONS

- Modeling study might not represent real-world clinical practice
- The effect of a missed csPCa is not captured by the model.
- The study assumed 100% diagnostic accuracy for biopsy, which might not be accurate in the real world
- Simulation does not include other potential comparators of *phi*.

CONCLUSION

- The use of *phi* before an mpMRI for men in the PSA 'grey zone' could result in fewer mpMRI and biopsies being conducted. This reduces NHS resource use and prevents unnecessary, risky, and invasive procedures
- The increase in missed csPCa cases can be mitigated if PSA/*phi* tests are conducted regularly; it is unlikely that a person will not be correctly diagnosed within 6 months of the original test
- Additional research is needed to confirm the benefits in a real-world setting

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MAPSS ID: 2025-14954
Presented at ISPOR EU, Nov 2025, Glasgow