Unity Insights

Real world evaluation of the WID-easy Test in secondary care

Triaging abnormal uterine bleeding referrals

October 2026

Working in collaboration with

Health Innovation Kent Surrey Sussex

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The Office for Life Sciences (OLS) is a government organisation promoting research, innovation, and the use of technology to improve health and care.

NHS University Hospitals Sussex NHS Foundation Trust

University Hospitals Sussex NHS Foundation Trust were the leading partner for this study and provided the clinical time and expertise for the project.

NHS Surrey and Sussex Cancer Alliance

SSCA are a collective of NHS organisations, local councils, charities, community and voluntary organisations, patient representatives and groups, and academic organisations, working together in partnership. They lead the transformation and improvement of cancer care and services across our local health and social care systems.

AGH AGHealth

Advanced Global Health Ltd is an obstetrics and gynaecology medical device company. They supply a range of products seeking to innovate women's health including the WID-easy test.

Advanced Global Health Ltd supplied the WID-easy testing service for this evaluation. The company remained blinded to individual patient results throughout the evaluation and had no role in data collection or analysis.

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1. Abstract

Background: Endometrial cancer is the most common gynaecological cancer in the United Kingdom and is commonly investigated through transvaginal ultrasound (TVUS) in women presenting with abnormal uterine bleeding. Increasing referral volumes, workforce constraints, and the limited specificity of ultrasound create pressure on diagnostic pathways and may lead to unnecessary invasive investigations. The WID-easy test is a cervicovaginal swab-based epigenetic assay designed to detect endometrial cancer and has the potential to improve diagnostic triage. This evaluation examined the real-world performance and economic implications of WID-easy within a secondary care urgent suspected cancer pathway.

Methods: A retrospective observational real-world evaluation was conducted at University Hospitals Sussex NHS Foundation Trust between August 2025 and February 2026. Women aged ≥45 years presenting with abnormal uterine bleeding and attending urgent suspected cancer clinics underwent both a WID-easy test and standard diagnostic assessment. Clinicians and patients were blinded to the WID-easy result and patients progressed on the standard of care pathway. Diagnostic accuracy was assessed against final clinical diagnosis and histology where available. Sensitivity, specificity, predictive values and inconclusive rates were compared between WID-easy and TVUS using standard screening metrics and McNemar's test. Positive cases were assumed to re-present within 3 months if they had been missed by TVUS screening. A counterfactual decision-tree model was developed to estimate the costs of a WID-easy-led diagnostic strategy compared with existing TVUS-led care. The final dataset comprised 487 patients.

Results: Endometrial cancer prevalence was 5.3% (26/487). For diagnosing cancer, WID-easy demonstrated sensitivity of 96.2% (95% CI 81.1%-99.3%) and specificity of 97.4% (95% CI 95.5%-98.5%), compared with TVUS sensitivity of 100.0% (95% CI 87.1%-100.0%) and specificity of 27.3% (95% CI 23.4%-31.6%) using the standard ≥4 mm endometrial thickness threshold. Specificity was significantly higher for WID-easy ($p<0.001$), while sensitivity was not significantly different between tests. WID-easy produced substantially fewer false-positive results (12 versus 327), a higher positive predictive value (67.6% versus 7.4%), and fewer inconclusive or incomplete tests (0.6% versus 5.4%). Diagnosis of benign and pre-cancerous conditions (such as hyperplasias) were reliant on wider diagnostic pathway design. Economic modelling estimated savings of £233 per patient using national reference costs and £287 per patient using Sussex-specific costs. Adoption of a WID-easy-led pathway was associated with 138 fewer acute diagnostic procedures, including marked reductions in ultrasounds, biopsies and hysteroscopies.

Conclusions: In routine clinical practice, WID-easy demonstrated sensitivity comparable to TVUS while achieving greater specificity and reducing the number of false-positive investigations. A WID-easy-led diagnostic strategy has the potential to reduce invasive procedures, improve pathway efficiency, and generate meaningful cost savings. Further interventional studies with longer-term follow-up are required to evaluate the management of negative-test patients, assess long-term outcomes, and confirm the economic benefits observed in this evaluation.

2. Introduction

2.1. Context

Endometrial carcinoma (EC), the second most prevalent women specific malignancy after breast cancer (Williams et al., 2019), represents a significant and increasingly pressing health concern. Endometrial cancer is among the few cancer sites in the UK where both incidence (+1.9% per annum, 1993–2018) and mortality (+1.1% per annum) rose over the past 25-year study period (Shelton et al, 2024). Uterine cancer also is the fourth most common cancer amongst females in the UK, and the most common gynaecological cancer, with EC being its most frequent type (Morrison et al., 2022).

The most common symptom of EC is abnormal uterine bleeding, particularly postmenopausal bleeding (PMB). The number of cases involving more severe and fast-growing forms of EC (known as non-endometrioid subtypes) is increasing quickly (Clarke et al., 2019). These specific types of cancer are more challenging to identify using ultrasound, making early detection and diagnosis more difficult (Kiff et al., 2023). Approximately 8,000 new ECs are diagnosed in the UK each year (NICE, 2021), yet no standardised screening procedure exists for this cancer. Given that delayed diagnosis has a profoundly negative impact on survival rates (Sud et al., 2020), early and accurate detection is crucial.

In the UK in 2021/22, 1.9 million women were prescribed HRT (Manley & Hillard, 2026) and prescriptions increased annually by 13.6% in the decade prior (Alsugeir et al., 2022). Similarly, there has been an increase in unscheduled bleeding on HRT and a 43% increase in referrals, over a 3-year period, to Urgent Suspicion of Cancer Pathways, but with no corresponding increase in cancer diagnoses, which increased by 2% in the same period (Manley & Hillard, 2026). These trends have created operational pressures for cancer diagnostic pathways, with increased referrals from lower risk patients.

Transvaginal ultrasounds (TVUS) are most often used in the NHS as the first line of diagnostics, but are particularly limited in specificity, resulting in many cases leading to unnecessary diagnostic interventions (Evans et al., 2023; Friar-Gomez et al., 2021).

In the NHS, less than 75% of women receive a gynaecological cancer diagnosis within 28 days, which is the Faster Diagnosis Standard target set by NHS England (NHS England, 2023). The current pathway poses significant challenges:

- Completing ultrasounds to assess endometrial thickness is insufficient in terms of specificity (Tabor et al., 2002), meaning that high numbers of women undergo further unnecessary diagnostic interventions.
- National shortage of sonographers (Lakhani, 2026) and recognised impact on opportunities to train (BMUS, 2024).

- Advanced imaging and blind biopsies (such as pipelle) are often inconclusive (> 40%), and women must return for a hysteroscopy and biopsy, which are often painful and add diagnostic pathway delays.

2.2. Intervention

The WID-easy test (epigenetic test using quantitative PCR) is a diagnostic method designed to detect endometrial cancer through a simple cervicovaginal swab. It has previously demonstrated a sensitivity of between 90.9% and 100% and a specificity of between 96% and 100% (Evans et al. 2023; Ken-Amoah et al. 2025). For women over 45 with abnormal uterine bleeding, the test has the potential to minimise unnecessary interventions and facilitates timely, effective diagnosis and treatment of endometrial cancer. The test was studied across University Hospitals Sussex NHS Foundation Trust (UHSx) secondary care local cancer referral clinics in late 2025, wherein women presenting with abnormal uterine bleeding, and referred to “one-stop” Urgent Suspicion of Cancer clinics (USC), were examined using WID-easy alongside the existing diagnostic pathway upon which diagnostic decisions were made.

3. Methodology

3.1. Evaluation protocol

Aims and objectives

The primary objective of this real-world evaluation was to generate data comparing the specificity of transvaginal ultrasound to the WID-easy test.

Secondary objectives were to generate:

1) Data on the WID-easy test false positive rate.
2) Rates of inconclusive results for both the WID-easy test and transvaginal ultrasound.
3) Numbers of interventions per patient and cost estimate data for the current clinical pathway and a future pathway including the WID-easy test.
4) Time to diagnosis data for the current clinical pathway.
5) Estimate the cost savings from moving from a TVUS-led diagnostic strategy to a proposed WID-easy pathway.

Participants and setting

Referrals considered for inclusion in the evaluation covered the period of August 2025 – February 2026. The inclusion criteria for the evaluation were all women aged 45 years or older with abnormal uterine bleeding attending the “one-stop” urgent suspected cancer clinics in UHSx and who had consented to both a WID-easy test and to participate in the evaluation. This included women who had been referred on the Bleeding on HRT pathway (Manley & Hillard, 2026) who mostly would have undergone an ultrasound prior in the community in Sussex. Only patients who received a WID-easy test were included in the sample to enable direct comparison. The follow-up

period was up to 3 months for each patient. In total, data was available for 487 patients in the final evaluation dataset.

Pathway

The WID-easy test was examined in secondary care, where previous peer-reviewed data has demonstrated the test's efficacy to triage women with bleeding symptoms over the age of 45. The standard of care post-referral and triage for women not on HRT involves an initial transvaginal ultrasound to assess endometrial thickness. If endometrial thickness is 4mm or greater, or the test is inconclusive, then patients are escalated to pipelle biopsy (usually within the same assessment in a "one-stop" diagnostic clinic), and/or to hysteroscopy. For women who entered the pathway because of bleeding on HRT, most would have had a community ultrasound scan demonstrating a thickened endometrium (>4mm on CC-HRT and >7mm on sequential HRT) and will therefore progress straight to test by pipelle or hysteroscopy. Once diagnosis has been made, different courses of treatment are available depending on malignancy following MDT discussion. Malignant cases, and some pre-cancerous cases, usually require surgeries that may include hysterectomy and salpingo-oophorectomy. Benign cases will see a range of follow-up treatment, ranging from removal of benign lesions (such as polyps or fibroids) or prescription-based therapies outside of hospital (e.g. vaginal oestrogens for vaginal atrophy).

In this evaluation, consenting patients were also administered a WID-easy test in addition to ultrasound. Patients were asked for their consent to provide a cervico-vaginal sample for the WID-easy test prior to ultrasound, and during the initial speculum examination as part of the clinical examination at their appointment. No action was taken based on the WID-easy test result, with both participants and clinicians blinded to the results and patients receiving follow-up according to the standard of care. Nonetheless, a counterfactual intervention pathway was designed via a workshop with clinicians from UHSx.

The TVUS pathway is displayed in Figure 1, and the counterfactual WID-easy pathway is displayed in Figure 2.

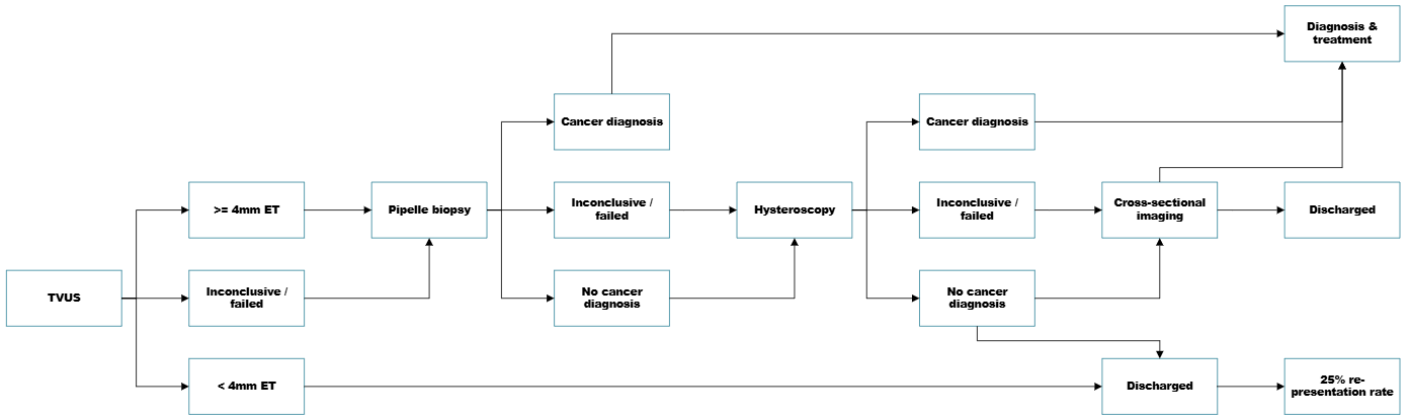


Figure 1: Pathway maps of TVUS-led diagnostic strategy in Sussex. Note that the pathway map is representative but does not cover every patient case in the pathway for legibility purposes.

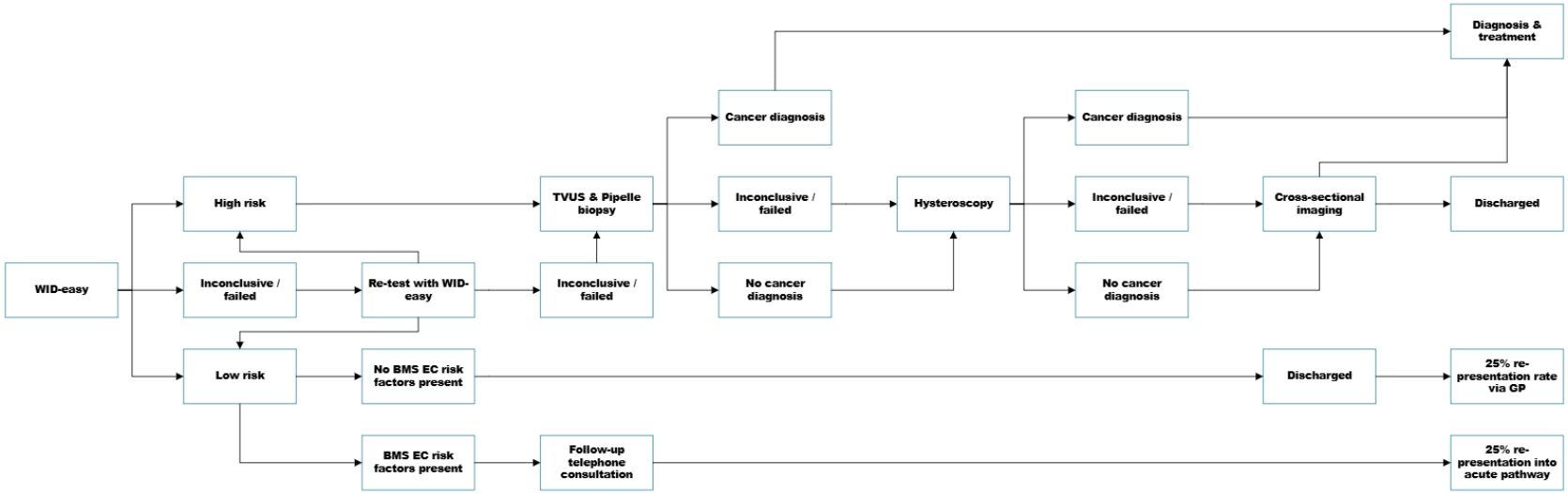


Figure 2: Pathway map of the counter-factual WID-easy led diagnostic strategy proposed for Sussex. Note that the pathway map is representative but does not cover every patient case in the pathway for legibility purposes.

3.2. Methods

Quantitative analysis

Data collection

Data was transcribed into a dataset from patient clinical notes by the clinical team at the Trust. All evaluation participants were pseudonymised with a unique participant ID. The dataset contained patient-level information regarding:

- Demographics
- Diagnoses
- Procedures conducted
- Histology

Data was assessed, cleansed, and restructured to facilitate analyses on patient journeys through the endometrial cancer diagnostic pathway. A retrospective decision tree was constructed in order to visualise the volumes of patients undergoing the given procedures in the existing endometrial cancer diagnostic pathway, what the results of the procedures were, and what actions were subsequently taken. This patient journey mapping served as a counterfactual to an intervention patient flow diagram: a second decision tree was constructed using a combination of pilot data and theoretical modelling to establish likely intervention-case patient flows where the WID-easy test is utilised as the primary initial diagnostic.

Screening accuracy

The WID-easy and TVUS procedures are compared for screening accuracy using standard metrics, including reporting of inconclusive or incomplete procedure rates. The TVUS procedure was assessed at a threshold of 4mm endometrial thickness or greater, with sensitivity analyses for 3mm and 5mm thresholds. A greater endometrial thickness threshold of 7mm or greater is used for patients on sequential HRT, but insufficient data was available to separate sequential HRT patients so a 7mm threshold was not assessed.

For the purposes of the primary analysis, an inconclusive or incomplete TVUS procedure was considered as a positive result, due to the necessity of follow-up in the diagnostic pathway. For WID-easy, the inconclusive or incomplete procedures are excluded from the analysis on the basis that a repeat WID-easy test would be the standard follow-up, but this did not occur due to the non-interventional nature of the evaluation and the WID-easy repeat test result could not be inferred through other methods.

Statistical analysis

The diagnostic endpoints of the evaluation (sensitivity, specificity, and inconclusive test outcomes) were subject to statistical hypothesis testing. The statistics were calculated based on a comparison of clinician-recorded diagnostic outcome from the standard of care pathway against the recorded

result of each test. Uncertainties for screening accuracy statistics were expressed using Wilson 95% confidence intervals.

The primary objective of the evaluation, to compare the specificity and sensitivity of WID-easy and TVUS, was assessed using McNemar's non-parametric test with continuity correction. The test was chosen as the screening procedures being assessed were performed on the same patients. The test was one-tailed, with the null hypothesis that the procedures have equivalent specificity, with the alternate hypothesis that WID-easy had a greater specificity than TVUS.

Cost minimisation analysis

A cost minimisation analysis has been conducted. Cost minimisation analysis assumes equivalent effectiveness between the two diagnostic strategies being studied. The strength of this assumption will rely upon whether changes to time-to-diagnosis at the scale involved with these two interventions materially affects quality of life and survival, and whether strategies to mitigate false negatives are sufficient to ensure patient safety and avoid adverse events and disease progression. Measurement of effectiveness in the endometrial cancer diagnostic pathway requires linked evidence from literature, usually collected via systematic review, and studies with long term follow-up with patients.

Due to the assumed equivalence in effectiveness, longer-term healthcare costs (such as cancer treatment adjusted for remission and relapse) are, by extension, also assumed to be equivalent.

Diagnostic pathway analysis

The cost minimisation analysis was conducted based on a comparison of the full wrap-around diagnostic strategies that each of WID-easy and TVUS were embedded within, incorporating analysis and costing of follow-up procedures based on test outcomes.

For TVUS, follow-up procedures and diagnostic outcomes for positive results were determined using actual activity as recorded within the clinical dataset. The following assumptions applied to each arm of the respective diagnostic strategies:

Diagnostic strategy	Screening test result	Key assumptions
WID-easy	High Risk	• WID-easy consultation costs were assumed to be 100% non-consultant led, in agreement with the UHSx clinical team. • All patients with a high-risk WID-easy result would progress to a TVUS scan and pipelle biopsy. • The number of follow-up procedures, and their expected costs per patient, were all assumed to be equivalent to the standard of care TVUS-led pathway.

Diagnostic strategy	Screening test result	Key assumptions
WID-easy	Low Risk	• WID-easy consultation costs were assumed to be 100% non-consultant led, in agreement with the UHSx clinical team. • Patients with risk factors highlighted in the BMS guidelines (Manley & Hillard, 2026) are expected to receive a telephone follow-up consultation at 6 weeks, at which 25% (Maldegem et al., 2024) are assumed to re-present to the acute pathway. • Patients who do not have BMS EC risk factors, and therefore are discharged and do not receive a follow-up telephone consultation, are expected to re-present in primary care with a 25% probability (Maldegem et al., 2024).
TVUS	Positive	• Pathway progression, procedures, and costs are as observed through clinically recorded data in the evaluation.
TVUS	Negative	• Patients are assumed to have a 25% probability of re-presentation (Maldegem et al., 2024), which is assumed to be a single GP practice appointment.

Model parameters

A discount rate of 3.5%, in line with the NICE reference case, was applied to all future costs. Costs were inflated to 2025 (2025/26 financial year) prices using the NHS pay and prices cost inflation index (Jones et al., 2026). Unit costs were sourced from the national NHS cost collection (NHS England, 2024), with relevant HRGs for the analysis listed in Appendix B.

Sensitivity analysis

Wherever appropriate, 95% confidence intervals are displayed alongside key estimates. A selection of additional scenarios to test the sensitivity of key assumptions are included in the report.

Scenario analysis

The primary analysis presented in the report is a national analysis using generic national NHS reference costs. A supplementary scenario specific to the Sussex region is also provided, with

local Sussex-provider variations to HRG tariffs applied. Sussex unit costs are not published in this report for reasons of confidentiality.

4. Results

4.1. Evaluation outcomes

Sample demographics

The demographics for the sample are provided in Table 1. Most women participating in the evaluation were post-menopausal, with half of the sample being on hormone replacement therapy (HRT). Almost all participants presented with symptoms of bleeding. Almost a third of patients had a higher BMI (greater than 30) associated with increased risk of endometrial cancer (NHS GatewayC, 2026). Presenting symptom data is grouped based on how it was recorded by the clinicians reviewing patient notes, which accounts for discrepancies in postmenopausal bleeding and the number of women who were postmenopausal, for example.

Table 1: Evaluation sample demographics

Demographic	Count	%
Total	**487**	**100.0%**
Age		
<45	0	0.0%
45-49	46	9.5%
50-59	258	53.1%
60-69	112	23.0%
70-79	49	10.1%
80+	21	4.3%
Mean age (SD)		59.2 (9.1)
Median age (range)		57 (45-93)
Ethnic group		
White	284	65.1%
British or mixed British	51	11.7%
Mixed	2	0.5%
Asian or Asian British	3	0.7%
Black or Black British	0	0.0%
Other Ethnic Groups	11	2.5%
Not stated	3	0.7%
Unknown	82	18.8%
Presenting symptom		
Bleeding symptoms	487	100.0%
No symptoms	0	0.0%
Current menopausal status		
Pre-menopausal	10	2.1%
Peri-menopausal	61	12.5%

	Post-menopausal	400	82.1%
	Unknown or not recorded	16	3.3%
Current HRT status			
	HRT	256	52.6%
	IUS	2	0.4%
	None	226	46.4%
	Unknown	3	0.6%
Parity			
	0	72	14.8%
	1	90	18.5%
	2	211	43.3%
	3 or more	105	21.6%
	Unknown	9	1.8%
BMI			
	<20	26	5.3%
	>=20 & <30	301	61.8%
	>=30 & <40	120	24.6%
	>=40	38	7.8%
	Unknown	2	0.4%

All conditions diagnosed

Table 13, Appendix A captures the full range of diagnoses captured through the standard of care pathway within the evaluation. For the analysis, these were clustered into endometrial cancers, non-endometrial cancers, hyperplasias, and benign conditions. A single patient could have multiple conditions diagnosed through the pathway. The proportion of cases captured incidentally through the two diagnostic tests (WID-easy and TVUS) is provided. Although WID-easy is not intended to detect non-cancerous conditions, it is useful information for understanding the diagnostic strategy to be set up around the test to ensure other conditions are appropriately diagnosed. Negative cases still require follow-up to treat benign conditions but is also a factor which will lead to additional follow-up (and, therefore, cost) and which is particularly important for hyperplasias that may be pre-cancerous.

Procedures conducted

Table 2 contains the procedures conducted during the evaluation.

Table 2: Procedures conducted during the evaluation

Procedure type	Procedure	Count of procedures	% of patients
Diagnostic	Transvaginal ultrasound	480	98.6%
	WID-easy swab tests	487	100.0%
	Pipelle biopsies	267	54.8%
	Imaging scans (including MRI, CT, PET, X-ray)	58	11.9%
	Ambulatory hysteroscopy	180	36.6%
	General anaesthetic hysteroscopy	40	8.2%

Surgery	Hysterectomy	26	5.1%
	Salpingo-oophorectomy	25	5.1%
	Colposcopy	4	0.8%
	Cervical polypectomy	7	1.4%

4.2. Screening accuracy

Comparison of WID-easy test with transvaginal ultrasound

Endometrial cancers

Comparing the standard TVUS threshold (4mm or greater endometrial thickness) with the results of the WID-easy swab test (Table 3), demonstrated similar performance in sensitivity, but a statistically significantly greater specificity ($p<0.001$) of 70.4 percentage points for WID-easy over TVUS. No significant difference was found in the sensitivity rates of the two tests ($p>0.999$). Two-thirds (67.6%) of WID-easy high-risk results were true positives for cancer, compared with less than a tenth (7.4%) of positive TVUS results.

Table 3: Comparison of screening accuracy for endometrial cancer between WID-easy and TVUS (>=4mm endometrial thickness (ET))

Metric	WID-easy	Transvaginal Ultrasound (>= 4mm ET)
Procedures	487	480
Prevalence (%)	26 (5.3%)	
Sensitivity (95% CI)	96.2% (81.1%-99.3%)	100.0% (87.1%-100.0%)
Specificity (95% CI)	97.4% (95.5%-98.5%)	27.3% (23.4%-31.6%)
PPV (95% CI)	67.6% (51.5%-80.4%)	7.4% (5.1%-10.6%)
NPV (95% CI)	99.8% (98.7%-100.0%)	100.0% (97.0%-100.0%)
Completed tests (%)	484 (99.4%)	454 (94.6%)
Inconclusive or incomplete tests (%)	3 (0.6%)	26 (5.4%)

Table 4 provides the 2x2 confusion matrices, comparing the performance of WID-easy and TVUS at the standard >=4mm endometrial cancer threshold. The improved specificity of the WID-easy test is demonstrated by 315 fewer false positive cases. WID-easy observed one false negative result where the patient had precancerous atypical hyperplasia from the hysteroscopy histology,

which was later diagnosed as FIGO stage 1A endometrial cancer on hysterectomy. The TVUS test had zero false negatives, under the assumption that discharged patients with ongoing symptoms would re-present within 3 months through benign follow-up care, but one cancer case had an inconclusive or incomplete test but still received follow-up escalation (and is treated as a positive TVUS for the purposes of the analysis).

Table 4: 2x2 screening accuracy matrix, compared with eventual reference histology result, showing results for WID-easy and for TVUS (>= 4mm endometrial thickness)

Procedure	Test result	Endometrial cancer (histology result) Positive	Negative	Total
WID-easy	Positive	25	12	37
	Negative	1	446	447
	Total	26	458	484
TVUS (>= 4mm ET)	Positive	26	327	353
	Negative	0	123	123
	Total	26	461	476

Four cases did not have sufficient TVUS outcome data and were excluded from the results. The results for atypical endometrial hyperplasias can often be included with endometrial cancer cases (for example, see Jacobs et al. (2011)), but are presented separately later in this section.

Non-endometrial cancers

A full confusion matrix is not provided for all cancer diagnoses, on account of low prevalence, diagnosis being incidental to the evaluation, and non-endometrial cancers not being within the primary purpose of the respective diagnostic strategies being examined. The same three cases were detected by both diagnostic strategies. Only one of the four cases was a non-uterine gynaecological cancer.

Table 5: Statistics on incidental detection of non-endometrial cancer cases

Cluster	Diagnosis	Prevalence Count	%	WID-easy test Count	Cases incidentally captured (%)*	TVUS Count	Cases incidentally captured (%)
Non-endometrial cancers	Early-stage	0	0.0%	0	-	0	-
	Late-stage	0	0.0%	0	-	0	-
	Unknown stage	4	0.8%	3	75.0% (30.1%-95.4%)	3	75.0% (30.1%-95.4%)

Any stage	***4***	***0.8%***	***3***	***75.0% (30.1%-95.4%)***	***3***	***75.0% (30.1%-95.4%)***
*The purpose of WID-easy is to detect the presence of cancer, and not the other conditions listed. This is not to be interpreted as a sensitivity value. Brackets denote Wilson 95% confidence intervals.						

Hyperplasias

Prevalence of hyperplasias was low (14, 2.9%). The TVUS screening strategy, however, performed better at detecting these cases, with a substantial effect size and sample size the main constraint on statistical significance.

Table 6: Statistics on incidental detection of hyperplasias

Cluster	Diagnosis	Prevalence		WID-easy test		TVUS	
		Count	%	Count	Cases incidentally captured (%)*	Count	Cases incidentally captured (%)
Hyperplasias	Hyperplasia without atypia	4	0.8%	1	25.0% (4.6%-69.9%)	4	100.0% (51.0%-100.0%)
	Atypical hyperplasia	10	2.1%	6	60.0% (31.3%-83.2%)	9	90.0% (59.6%-98.2%)
	Any hyperplasia	***14***	***2.9%***	***7***	***50.0% (26.8%-73.2%)***	***13***	***92.9% (68.5%-98.7%)***
*The purpose of WID-easy is to detect the presence of cancer, and not the other conditions listed. This is not to be interpreted as a sensitivity value. Brackets denote Wilson 95% confidence intervals.							

Benign conditions

Statistics for benign conditions are included within Appendix A. The TVUS procedure is superior at detecting all listed conditions at the 95% confidence level. Results for the two strategies, however, incorporating benign follow-up into the WID-easy strategy, are assumed to result in equivalent diagnosis rates, as the second line of the WID-easy strategy is assumed to be the TVUS strategy for patients with a high risk WID-easy result but low-risk patients who remain or become symptomatic are assumed to re-present with a probability of 25%, with other cases resolving spontaneously.

Sensitivity analysis for different endometrial thickness thresholds

The comparator case through the analysis has been TVUS with an endometrial thickness of 4mm or greater. A sensitivity analysis has been provided below for endometrial cancer screening accuracy, providing results for additional endometrial thickness thresholds of 3mm or greater and 5mm or greater.

Based on the evaluation sample, the results do not vary too much between different endometrial thickness thresholds. The standout results are the improvements in specificity (statistically significant) and positive predictive value as the thickness threshold increases, but even the 5mm or greater threshold still performs significantly worse than WID-easy in these two metrics.

Table 7: Comparison of screening accuracy for endometrial cancer between WID-easy and TVUS (multiple endometrial thickness (ET) thresholds)

	WID-easy	Transvaginal Ultrasound (>= 3mm ET)	Transvaginal Ultrasound (>= 4mm ET)	Transvaginal Ultrasound (>= 5mm ET)
Procedures	487	480	480	480
Prevalence (%)		26 (5.3%)		
Sensitivity (95% CI)	96.2% *(81.1%-99.3%)*	100.0% *(87.1%-100.0%)*	100.0% *(87.1%-100.0%)*	96.2% *(81.1%-99.3%)*
Specificity (95% CI)	97.4% *(95.5%-98.5%)*	14.9% *(11.9%-18.5%)*	27.3% *(23.4%-31.6%)*	39.1% *(34.7%-43.7%)*
PPV (95% CI)	67.6% *(51.5%-80.4%)*	6.4% *(4.4%-9.2%)*	7.4% *(5.1%-10.6%)*	8.4% *(5.7%-12.1%)*
NPV (95% CI)	99.8% *(98.7%-100.0%)*	100.0% *(94.6%-100.0%)*	100.0% *(97.0%-100.0%)*	99.4% *(96.9%-99.9%)*
Completed tests (%)	484 (99.4%)	454 (94.6%)	454 (94.6%)	454 (94.6%)
Inconclusive / incomplete tests (%)	3 (0.6%)	26 (5.4%)	26 (5.4%)	26 (5.4%)

4.3. Time to diagnosis and treatment

Table 8 contains the data on key waiting time metrics, as measured using the standard of care pathway. WID-easy presents the opportunity to reduce the time from referral to diagnosis, and therefore from referral to surgery, for cancer patients. Patients who tested positive with WID-easy had a hysteroscopy on average 20 days (median of 16 days) after their initial assessment (where TVUS and WID-easy tests were conducted), while the average wait for a hysteroscopy from the preceding pathway milestone (procedure or histology result) was 16 days (median of 12 days), leaving the potential for WID-easy to reduce the pathway length by 4 days for the highest risk patients with suspected cancer, without considering other unassessed pathway optimisations. There is high uncertainty, however, on these estimates, and a broader reallocation of resources will produce a greater unpredictable effect.

Patients that re-present following a negative test result, assumed to be 25% of the negative-result cohort, are likely to face a longer time-to-diagnosis, however. A patient with a benign condition or hyperplasia whose symptoms do not resolve and later re-present in primary care, will either be managed in primary care or follow a similar community TVUS-led diagnostic pathway that is similar

in length to the standard of care pathway assessed in this evaluation. Assessing the extent of these longer waits will require an interventional study.

Table 8: Waiting time statistics for all patients

Waiting time	Waiting time (days)	
	Mean (95% CI)	Median
Referral to assessment	18.2 (15.8-20.6)	12
Referral to diagnosis	31.2 (27.5-34.9)	16
Referral to surgery	65.4 (61.3-69.6)	55
Assessment to diagnosis	12.9 (6.1-19.8)	19
Diagnosis to surgery	44.1 (41.0-47.3)	33

4.4. Cost minimisation analysis

National (England) analysis

Diagnostic strategy cost comparison and procedures avoided

The results of the cost minimisation analysis (Table 9) show net savings of £233 per patient from the WID-easy strategy compared with TVUS-led standard of care. There are 138 fewer acute and outpatient procedures, which is offset by 180 additional discharge and primary care follow-up contacts. This represents a redistribution of healthcare activity from invasive, uncomfortable and painful procedures (TVUS, biopsies, hysteroscopies) towards WID-easy swab tests and less-invasive phone consultations and GP follow-ups, which are expected to be much easier and less painful for patients.

The initial consultation cost is also cheaper, with a WID-easy consultation cost agreed with the UHSx clinical team to be equivalent to a non-consultant led gynaecological oncology consultation (£100.67 from NHS national cost collection, when adjusted for inflation, plus the WID-easy list cost of £150, for a total of £250.67) compared with a weighted average first consultation cost of £307.68 for the TVUS strategy.

Differences in unit costs between strategies are related to case mix factors, with marginally higher unit costs being observed by WID-easy patients for some procedures due to the effect of more effective triage leading to procedures being concentrated on higher-risk patients who are more likely to require more complex procedures.

Table 9: Diagnostic strategy procedures avoided and cost minimisation analysis

Diagnostic procedure	WID-easy		TVUS (>=4mm ET)		Net WID-easy savings	
	Count	Cost	Count	Cost	Count	Cost
Transvaginal ultrasound (including pipelle biopsies)	71	£26k	480	£148k	409	£122k
WID-easy swab test (including consultation cost)	487	£122k	0	£0k	-487	-£122k

Hysteroscopies (including under general anaesthetic)	15	£10k	220	£140k	205	£130k
Imaging (CT, MRI, PET, X-ray etc.)	47	£12k	58	£14k	11	£2k
Post-discharge benign follow-up (telephone consultation)	137	£16k	0	£0k	-137	-£16k
Post-discharge benign re-presentation (GP appointments)	77	£4k	34	£2k	-43	-£2k
Acute procedures	620	£169k	758	£302k	138	£132k
Per patient	1.3	£348	1.6	£619	0.3	£271
Benign follow-up / re-presentation	214	£20k	34	£2k	-180	-£18k
Per patient	0.4	£41	0.1	£3	-0.4	-£38
Total	**834**	**£189k**	**792**	**£303k**	**-42**	**£114k**
Per patient	**1.7**	**£389**	**1.6**	**£623**	**-0.1**	**£233**

Costs per procedure

The mean average cost per procedure, considering case mix and variations in procedure, are presented in Table 10.

Table 10: Costs per procedure (national costs)

Mean cost per procedure	WID-easy strategy	TVUS strategy
TVUS (inc. pipelle biopsy)	£362.02	£307.68
WID-easy swab test (inc. consultation)	£250.67	-
Hysteroscopies (including under general anaesthetic)	£657.72	£636.88
Imaging (CT, MRI, PET, X-ray etc.)	£252.09	£236.73
Post-discharge benign follow-up (telephone consultation)	£119.00	-
Post-discharge benign re-presentation (GP appointments)	£48.00	£48.00

Sensitivity analysis for benign re-presentation

BMS risk factors for follow-up in a suspected endometrial cancer pathway include higher BMI (greater than or equal to 30), diabetes, polycystic ovary syndrome, and hereditary conditions. The analysis was only able to use the BMI risk factor as a proxy for the triaging approach for the primary analysis presented in Table 9. A global re-presentation rate of 25% was also applied using

the upper-bound from a literature source (Maldegem et al., 2024). Given the uncertainty of this element of the pathway, a sensitivity analysis based on volume of patients (and assuming in that these are representative of the average cost of patients from the evaluation) has been provided to demonstrate the effect on the economic results in Table 11 below. All other patients are assumed to be discharged without a representation related to this episode of care for at least 12 months.

Table 11: Sensitivity analysis for patient volumes into benign follow-up

Benign re-presentation rate	Net cost saving	Net cost saving per patient
30%	£111k	£227
25%*	£114k	£233
20%	£117k	£240
15%	£120k	£246
10%	£123k	£252
5%	£126k	£258
*Parameter used for primary analysis in Table 9 derived from literature.		

Sussex analysis

For UHSx, the modelling assumptions for procedures and pathways are identical. The only change is the use of local HRG tariffs in place of national reference costs where these varied. The results are presented in Table 12. The net benefit per patient is more than 23% greater than for the analysis with national reference costs, mostly due to greater local unit costs for hysteroscopies.

Similar to the national analysis, differences in procedure unit costs between strategies represent case mix effects from triage, with procedures being concentrated on higher risk patients for the WID-easy strategy.

Table 12: Diagnostic strategy procedures avoided and cost minimisation analysis

Diagnostic procedure	WID-easy		TVUS (>=4mm ET)		Net WID-easy savings	
	Count	Cost	Count	Cost	Count	Cost
Transvaginal ultrasound (including pipelle biopsies)	71	£26k	480	£145k	409	£120k
WID-easy swab test (including consultation cost)	487	£122k	0	£0k	-487	-£122k

Hysteroscopies (including under general anaesthetic)	15	£12k	220	£171k	205	£159k
Imaging (CT, MRI, PET, X-ray etc.)	47	£12k	58	£14k	11	£2k
Post-discharge benign follow-up (telephone consultation)	137	£16k	0	£0k	-137	-£16k
Post-discharge benign re-presentation (GP appointments)	77	£4k	34	£2k	-43	-£2k
Acute procedures	620	£171k	758	£329k	138	£158k
Per patient	1.3	£352	1.6	£676	0.3	£324
Benign follow-up and re-presentation	214	£20k	34	£2k	-180	-£18k
Per patient	0.4	£41	0.1	£3	-0.4	-£38
Total	**834**	**£191k**	**792**	**£331k**	**-42**	**£140k**
Per patient	**1.7**	**£393**	**1.6**	**£680**	**-0.1**	**£287**

5. Discussion

5.1. Screening accuracy

The results on screening accuracy for endometrial cancer are positive for WID-easy. Sensitivity for WID-easy is in line with TVUS, although future research would benefit from long-term follow-up with negative cases, but with the benefit of a statistically significantly improved specificity ($p<0.001$) to avoid a substantial number of false positive cases. The improved positive predictive value will, therefore, reduce healthcare resource usage, reduce anxiety or distress for patients unnecessarily waiting for further results on the pathway, and improve time to diagnosis (as discussed in section 4.3).

One of the hypothesised additional benefits of WID-easy was the ability to detect other types of cancer. The low prevalence of non-endometrial cancers (four cases) prevented a meaningful analysis, but three out of the four cases were positively flagged for follow-up by both WID-easy and TVUS.

For hyperplasias, particularly those with atypia, the design of the follow-up strategy to a negative WID-easy result is critical for patient safety, efficacy, and efficiency. It was out of scope for this evaluation to measure and test optimal strategies for negative WID-easy scenarios, but this remains an opportunity for future research.

Benign conditions for patients with a negative WID-easy result are expected to be diagnosed or treated through follow-up, either with their GP or via the standard of care pathway (TVUS-led).

5.2. Health economics

The results demonstrate cost savings from the WID-easy diagnostic strategy, including the benign follow-up second line, compared to the TVUS-led strategy equating to £233 per patient in the national analysis and, due to higher procedure unit costs, £287 per patient in UHSx. On average, the initial consultation was also cheaper by £57. Treatment costs were not included on the assumption that the same set of conditions would be diagnosed in each strategy, leading to the same courses of lifetime treatment. The strength of this assumption, and the cost minimisation analysis, is highly sensitive to the follow-up strategy pursued in the second line of diagnostics after WID-easy has returned a negative result.

The negative result arm of the evaluation was examined using an assumption-based approach combined with a sensitivity analysis. The results can be strengthened by collecting follow-up data from primary care and from systematic review in future studies. The sensitivity analysis does indicate that WID-easy is more likely than not to generate cost savings compared to the standard of care on the negative result arm, but the follow-up strategy remains a key area for future research and decision making.

The reduction in acute and outpatient diagnostic procedures caused by the proposed WID-easy diagnostic strategy should also generate benefits for non-cancer pathways, with additional capacity being freed up to support other pathways. Measuring this benefit was beyond the scope of this evaluation but a potential area for future research.

It was out of scope for the evaluation to consider the long-term healthcare costs and effectiveness of the cancer treatment pathway, and for the re-presentation of patients that tested negative more than three months after their assessment. A longer-term evaluation with 12-month follow-up or longer (including primary care data) and a systematic review, in a linked-evidence approach, are recommended to be able to accurately estimate the long-term effects of the implementation of WID-easy. Given the hypothesised improvement in time-to-diagnosis, some literature does indicate an association between earlier diagnosis and improved outcomes at a timescale of multiple weeks (for example, see Shalowitz et al. (2017)). It is also important to note the significant reduction in unnecessary procedures associated with the WID-easy diagnostic strategy, of which 138 acute and outpatient procedures were substituted for 180 primary care contacts and telephone consultations, most of which are painful and/or anxiety-inducing for patients. The results of this evaluation indicate that WID-easy is likely to improve effectiveness of the pathway, in addition to reducing cost, but further evaluations will be required to quantify and test this hypothesis.

6. Conclusion

WID-easy observes strong performance in sensitivity (96.2%) and specificity (97.4%). Specificity was found to be significantly improved ($p<0.001$) over TVUS for endometrial cancers, for similar levels of sensitivity ($p>0.999$). Inconclusive test rate performance was also better for WID-easy over TVUS, with rates of 0.6% and 5.4% for WID-easy and TVUS respectively.

WID-easy is found to be cost saving, under the assumption of equivalent effectiveness. It is estimated to save an approximate £233 per patient when priced at the list price (£150 per test), with a cheaper initial consultation cost by £57 on average. Adjusting the analysis for the Sussex region, local unit costs cause the net cost saving per patient to increase to £287. The result is driven by greatly improved specificity and positive predictive value, while maintaining a similar sensitivity to the TVUS strategy, enabling 138 fewer invasive and uncomfortable procedures (TVUS, biopsies, and hysteroscopies). The sensitivity of the result is based upon the triaging approach to negative WID-easy tests, however, and this should be a key area for future real world evaluations.

There is a trade-off in the WID-easy strategy for waiting times. Patients, in most cases, should be informed whether they do or do not have cancer more quickly, reducing anxiety, and cancer patients have the opportunity to enter treatment more quickly if resources and pathway management allow, but benign patients and some patients with hyperplasias may see longer waits for a final diagnosis, depending on how the pathway is able to reallocate resources once WID-easy is implemented.

WID-easy is a highly promising intervention in the endometrial cancer pathway, but further real world evaluation opportunities remain to optimise the diagnostic strategy around the test and to confirm the estimate of £233 in savings per patient. The underlying assumption of equivalent effectiveness should also be examined with longer-term evaluations and systematic review supported approaches.

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8. Appendix

8.1. Appendix A: Full dataset on conditions diagnosed through the standard of care pathway

Table 13: All conditions diagnosed through the evaluation

Cluster	Diagnosis	Prevalence		WID-easy test		TVUS	
		Count	%	Count	Cases incidentally captured (%)*	Count	Cases incidentally captured (%)
Endometrial cancer	Early-stage	20	4.1%	19	95.0% (76.4%-99.1%)	20	100.0% (83.9%-100.0%)
	Late-stage	4	0.8%	4	100.0% (51.0%-100.0%)	4	100.0% (51.0%-100.0%)
	Unknown stage	2	0.4%	2	100.0% (34.2%-100.0%)	2	100.0% (34.2%-100.0%)
	Any stage	***26***	***5.3%***	***25***	***96.2% (81.1%-99.3%)***	***26***	***100.0% (87.1%-100.0%)***
Non-endometrial cancers	Early-stage	0	0.0%	0	-	0	-
	Late-stage	0	0.0%	0	-	0	-
	Unknown stage	4	0.8%	3	75.0% (30.1%-95.4%)	3	75.0% (30.1%-95.4%)
	Any stage	***4***	***0.8%***	***3***	***75.0% (30.1%-95.4%)***	***3***	***75.0% (30.1%-95.4%)***
Hyperplasias	Hyperplasia without atypia	4	0.8%	1	25.0% (4.6%-69.9%)	4	100.0% (51.0%-100.0%)
	Atypical hyperplasia	10	2.1%	6	60.0% (31.3%-83.2%)	9	90.0% (59.6%-98.2%)
	Any hyperplasia	***14***	***2.9%***	***7***	***50.0% (26.8%-73.2%)***	***13***	***92.9% (68.5%-98.7%)***
Benign	Benign polyp(s)	143	29.4%	14	9.8% (5.9%-15.8%)	120	83.9% (77.0%-89.0%)
	Fibroids	94	19.3%	3	3.2% (1.1%-9.0%)	63	67.0% (57.0%-75.7%)
	Atrophic endometrium	65	13.3%	1	1.5% (0.3%-8.2%)	59	90.8% (81.3%-95.7%)
	Other benign	189	38.8%	3	1.6% (0.5%-4.6%)	111	58.7% (51.6%-65.5%)
	Any benign	***444***	***91.2%***	***19***	***4.3% (2.8%-6.6%)***	***316***	***71.2% (66.8%-75.2%)***
No diagnosis	Discharged with no diagnosis	17	3.5%	-	-	-	-

*The purpose of WID-easy is to detect the presence of cancer, and not the other conditions listed. This is not to be interpreted as a sensitivity value.
Brackets denote Wilson 95% confidence intervals.

8.2. Appendix B: HRGs and unit costs included in the analysis

Table 14: HRG unit costs included in the analysis

Source currency description	HRG code	Year	National average unit cost (£)	Number of procedures
Transvaginal Ultrasound	MA36Z	2024/25	£220.17	515,655
Transvaginal Ultrasound with Biopsy	MA37Z	2024/25	£370.14	10,208
Diagnostic Hysteroscopy (OP)	MA31Z	2024/25	£313.61	27,810
Diagnostic Hysteroscopy with Biopsy (OP)	MA32Z	2024/25	£394.30	82,980
Diagnostic Hysteroscopy with Transvaginal Ultrasound (OP)	MA45Z	2024/25	£321.14	1,604
Diagnostic Hysteroscopy with Transvaginal Ultrasound, with Biopsy (OP)	MA46Z	2024/25	£362.55	5,998
Diagnostic Hysteroscopy (Daycase)	MA31Z	2024/25	£1,596.00	3,730
Diagnostic Hysteroscopy with Biopsy (Daycase)	MA32Z	2024/25	£1,692.00	22,052
Computerised Tomography Scan of One Area, without Contrast, 19 years and over	RD20A	2024/25	£121.31	804,523
Computerised Tomography Scan of One Area, with Post-Contrast Only, 19 years and over	RD21A	2024/25	£140.38	247,160
Computerised Tomography Scan of One Area, with Pre- and Post-Contrast	RD22Z	2024/25	£153.77	14,177
Magnetic Resonance Imaging Scan of One Area, without Contrast, 19 years and over	RD01A	2024/25	£183.53	1,113,347
Magnetic Resonance Imaging Scan of One Area, with Post-Contrast Only, 19 years and over	RD02A	2024/25	£241.34	287,906
Magnetic Resonance Imaging Scan of One Area, with Pre- and Post-Contrast	RD03Z	2024/25	£248.98	41,094
Positron Emission Tomography with Computed Tomography (PET-CT) of One Area, 19 years and over	RN01A	2024/25	£851.40	56,308

Therapeutic Colposcopy	MA40Z	2024/25	£400.83	36,496
Diagnostic Colposcopy with Biopsy	MA39Z	2024/25	£369.55	88,459
Diagnostic Colposcopy	MA38Z	2024/25	£267.50	176,196
Major, Open or Laparoscopic, Upper or Lower Genital Tract Procedures for Malignancy, with CC Score 4+	MA06A	2024/25	£8,418.38	623
Major, Open or Laparoscopic, Upper or Lower Genital Tract Procedures for Malignancy, with CC Score 2-3	MA06B	2024/25	£7,214.02	1,002
Major, Open or Laparoscopic, Upper or Lower Genital Tract Procedures for Malignancy, with CC Score 0-1	MA06C	2024/25	£6,875.44	1,632
Histopathology and histology	PATH02	2024/25	£85.27	4,420
Histopathology and histology	PATH02	2024/25	£51.04	50,900
Histopathology and histology	PATH02	2024/25	£60.81	460,760
Plain Film	PF	2024/25	£80.58	155,727
Minimal Lower Genital Tract Procedures	MA23Z	2024/25	£271.58	229,884

8.3. Appendix C: Supplementary national economic results with phase-in to fully non-consultant led service

The primary analysis in this report models a 100% non-consultant led service for WID-easy consultations. Table 15 displays the main economic results in the case that the service starts at a 70% non-consultant to 30% consultant-led strategy before transitioning to 100% non-consultant led over the period of the study (approximately 6 months). In effect, this equates to an average 85% non-consultant led service if patient throughput is consistent throughout the period.

Table 15: Diagnostic strategy procedures avoided and cost minimisation analysis

Diagnostic procedure	**WID-easy**		**TVUS (>=4mm ET)**		**Net WID-easy savings**	
	Count	Cost	Count	Cost	Count	Cost
Transvaginal ultrasound (including pipelle biopsies)	71	£26k	480	£148k	409	£122k
WID-easy swab test (including consultation cost)	487	£132k	0	£0k	-487	-£132k
Hysteroscopies (including under general anaesthetic)	15	£10k	220	£140k	205	£130k
Imaging (CT, MRI, PET, X-ray etc.)	47	£12k	58	£14k	11	£2k
Post-discharge benign follow-up (telephone consultation)	137	£16k	0	£0k	-137	-£16k
Post-discharge benign re-presentation (GP appointments)	77	£4k	34	£2k	-43	-£2k
Acute procedures	620	£179k	758	£302k	138	£123k
Per patient	1.3	£368	1.6	£619	0.3	£252
Benign follow-up / re-presentation	214	£20k	34	£2k	-180	-£18k
Per patient	0.4	£41	0.1	£3	-0.4	-£38
Total	**834**	**£199k**	**792**	**£303k**	**-42**	**£104k**
Per patient	**1.7**	**£409**	**1.6**	**£623**	**-0.1**	**£214**

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Analytics and evaluation for positive change

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