Unscheduled bleeding on HRT pathway pilot evaluation

Produced in partnership by:

Wessex Cancer Alliance
NHS Dorset Integrated Care Board
University Hospitals Dorset NHS Foundation Trust

UNIVERSITY HOSPITALS DORSET UNSCHEDULED BLEEDING ON HRT GP DIRECT ACCESS PATHWAY PILOT EVALUATION: NOVEMBER 2023 TO NOVEMBER 2024	
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Objective	To evaluate and review the outcomes from the Unscheduled Bleeding on HRT GP direct access pilot, which commenced in November 2023 at University Hospitals Dorset NHS Foundation Trust. The evaluation will provide information and insight to inform proposals for the sustainability of this GP direct access pathway so it can be embedded as business as usual. This evaluation outlines the national strategic context, current pilot service delivery, benefits, risks, and issues, as well as outcomes including patient experience feedback.

SUMMARY

There is a national directive for all trusts to have a GP direct access unscheduled bleeding on Hormone Replacement Therapy pathway live by the end of March 2025.

The GP direct access unscheduled bleeding on HRT pathway at UHD has been well received by the patients using the service and the Primary Care clinicians. The pathway has been found to be reassuring and to provide a good patient experience with clear information about what to expect on the pathway.

There is evidence from the audit that shows having this pathway in place has improved UHD's Faster Diagnosis Standards target and caused a reduction in Post-Menopausal Bleeding referrals across the year it was being piloted. The pathway has reduced the anxiety of patient's as they now have an alternative, more appropriate pathway outside of attending an urgent suspected cancer pathway clinic.

The pathway has also been demonstrated to be safe, with a 0.4% conversion rate for cancer which is well below the 3% NICE risk threshold for USC referral.

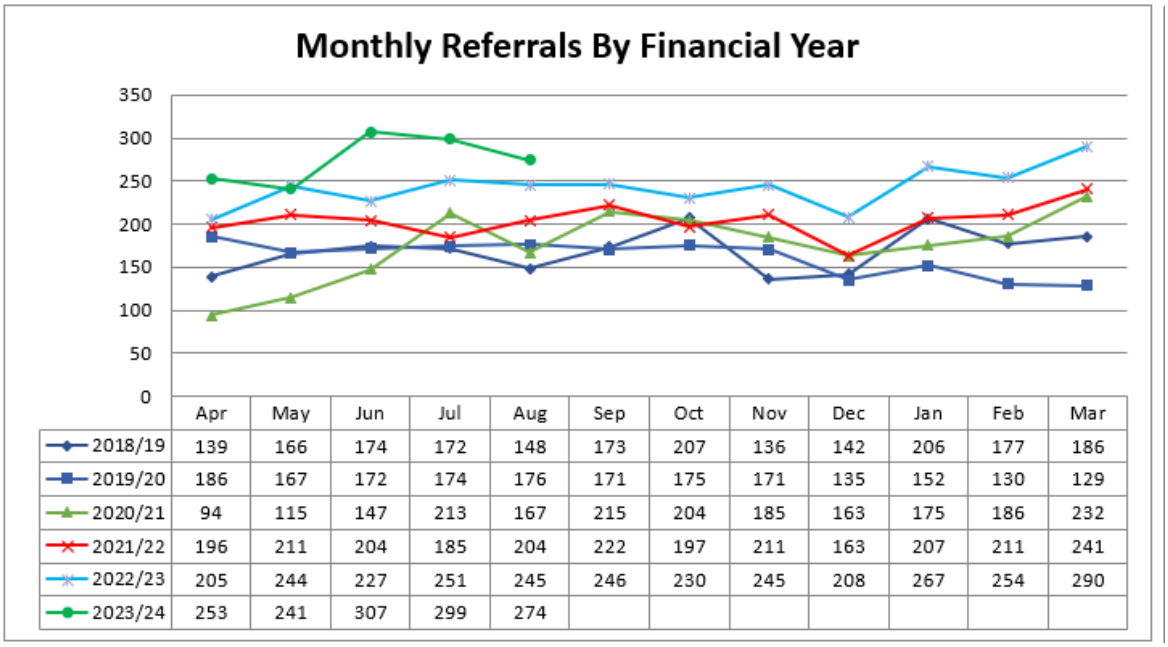
Although we had limited patient feedback, it was predominantly positive, with an overall pathway rating of 8-10 out of 10. GP feedback was also positive overall.

The pathway has saved 72 expensive one stop clinics preventing 433 patients the anxiety of attending cancer pathway clinics, which has meant the one stop clinics can be utilised for the patients who need them (patients who are at higher risk of cancer). This has led to a significant reduction in PMB referrals and has been the main factor in the improvement of UHD gynaecology FDS targets.

UNIVERSITY HOSPITALS DORSET BACKGROUND TO UNSCHEDULED BLEEDING ON HRT PATHWAYS

Prior to launching of the pilot in November 2023, University Hospitals Dorset (UHD) were experiencing a significant increase in gynaecology urgent suspected cancer (USC) referrals compared to pre-covid levels and were expecting this to continue to increase. For Y21/22 there was a 39% increase in referrals for postmenopausal bleeding (PMB) into the UHD gynaecology department, compared to the previous financial year. PMB one stop capacity was not able to meet this demand and there was a deficit of 2.6 one stop PMB clinics per week based on a local fast-track demand and capacity audit completed in April 2021. This patient deficit was being put into costly ad hoc sessions that were run on weekends. These ad hoc clinics were not one stop and therefore did not have access to ultrasound or hysteroscopy capability. The combination of lack of fast-track clinic availability and inefficient ad hoc clinics meant that UHD were not meeting the cancer waiting times targets. The April 2021 audit also showed that 58.5% of patients were being seen after the 14-day target for their first appointment. Furthermore, the average time from referral to the patient having a definitive diagnosis was 40 days. The target for referral to diagnosis introduced as part of the Faster Diagnosis Standard (FDS) in April 2020 was 28 days, and the challenges posed by the increasing gynaecology demand contributed to NHS Dorset Integrated Care Board (ICB) being ranked 35th out of 42 in Q2 21/22 for 28-day FDS performance.

Figure 1: Overview of Gynaecology Urgent Suspected Cancer Referrals



	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
2018/19	139	166	174	172	148	173	207	136	142	206	177	186
2019/20	186	167	172	174	176	171	175	171	135	152	130	129
2020/21	94	115	147	213	167	215	204	185	163	175	186	232
2021/22	196	211	204	185	204	222	197	211	163	207	211	241
2022/23	205	244	227	251	245	246	230	245	208	267	254	290
2023/24	253	241	307	299	274							

- There was an average of 168 gynaecology Urgent Suspected Cancer referrals per month in 2018/19
- There was an average of 275 gynaecology Urgent Suspected Cancer referrals in 2023/24, a 63.7% increase.

Over the past decade Hormone Replacement Therapy (HRT) prescriptions have increased annually by 13.6% in women aged 50 or older. Unscheduled bleeding on HRT is a common problem, affecting 38% of people using sequential HRT and 41% using continuous combined HRT. Nationally referrals to fast-track services for unscheduled bleeding on HRT have increased from 15% to 44%. NHS Dorset has the third highest ICB in England for prescription of

least 1 HRT item per 1000 residents, with 59 per 1000. The risk of endometrial cancer in women with bleeding on HRT is 1-2%, therefore not meeting the 3% threshold recommended by NICE for suspected cancer referrals.

It was recognized that patients and GPs often felt uncomfortable engaging in the British Gynaecological Cancer Society (BGCS) recommendation in stopping HRT for six weeks and for those with persistent bleeding to be referred to a rapid access gynaecology clinic without re-starting HRT. It was also identified in NICE recommendations that continuous combined HRT commonly produced irregular breakthrough bleeding or spotting in the first 4 to 6 months of treatment. If bleeding persists beyond 6 months, becomes heavier, or occurs after a spell of amenorrhoea, endometrial pathology should be excluded. This was often misinterpreted and all women even with explainable bleeding, for example missing doses of HRT, were referred on a fast-track basis. A local audit conducted in January 2023 showed that 46.3% of patients referred on the UHD PMB pathway were on systemic HRT.

The menopause is a major life event affecting all women in a variety of ways, both short and long term. It is important that we empower health care professionals to support women through this time by providing information and access to HRT. Therefore, UHD developed a separate pathway for women who have unscheduled bleeding on HRT, whereby primary care is provided with a direct access route to transvaginal scans (TVS) without the need to make an unnecessary and anxiety inducing referral via a suspected cancer pathway.

NATIONAL BACKGROUND TO UNSCHEDULED BLEEDING ON HRT PATHWAYS

There is a national directive to deliver performance improvements and high-quality care to minimise the number of low/ no risk of cancer referrals, allowing resources to be focused on those with a significant risk of cancer, and minimising unnecessary investigation and anxiety for those at extremely low risk of cancer or other significant pathology.

Since 2019, referrals for suspected gynaecological cancers have increased by 44.8% nationally, whilst the number of cancers diagnosed on a cancer pathway has only increased by 2.3% the percentage of these referrals diagnosed with cancer has been declining, with a decrease from around 4% in April 2019 to being consistently below 3% in 2024. Gynaecology was the third highest contributor for delayed diagnosis for September to November 2024. Overall, gynaecology represented 10% of all FDS referrals for the same period but amounted to 14% of breaches.

The rapid rise in USC gynaecology referrals has coincided with a significant increase in the prescribing of HRT. Data acquired from local USC pathway audits in England indicate that up to 42% of gynaecology USC referrals are from HRT users with unscheduled bleeding. As a result, there is a prospectively identifiable and rapidly growing cohort of women currently being referred on an USC pathway who are at an extremely low risk of being diagnosed not just with cancer but with any significant pathology.

The 2015 Suspected Cancer: Recognition and Referral Guidance (NG12) makes recommendations that clinicians make a USC referral, or consider a USC referral, for women aged over and under 55 years of age respectively if they have postmenopausal bleeding. This is defined as unexplained vaginal bleeding more than 12 months after menstruation has stopped because of the menopause. There is, however, no inclusion of or explicit guidance relating to unscheduled bleeding on HRT in NG12, which is different to postmenopausal bleeding and is defined as irregular bleeding which occurs after initiating, or changing, a HRT preparation which should be ‘bleed free’ – continuous combined hormone replacement therapy (ccHRT) or, which occurs, in addition to the scheduled monthly withdrawal bleed in persons taking sequential preparations (sHRT)Unscheduled vaginal bleeding is common and expected when beginning or altering a HRT regimen.

After the launch of the UHD pilot in November 2023, the British Menopause Society (BMS) published national guidance on the management of unscheduled bleeding on hormone replacement therapy in April 2024. In addition to this, in March 2025, the National Faster Diagnosis Team published their Implementation Guidance to provide guidance and principles for organisations in implementing pathways for unscheduled bleeding in patients on

hormone replacement therapy. This guidance was to be used in conjunction with the BMS guidance. The UHD pathway that has been implemented meets the recommended guidance that has been published, and the findings from the pilot period have demonstrated the desired impact predicated from the introduction of alternative management for this cohort of patients.

SAFETY

The safety of the pathway has been fully considered as part of the planning and evaluation, with the key components and considerations in terms of its safety outlined as follows:

- The Women's' Health Institution (WHI) HRT study reported a neutral effect on the risk of endometrial cancer with HRT compared to placebo
- The risk of endometrial cancer in women with unscheduled bleeding on HRT is significantly lower than that with postmenopausal bleeding in women not on HRT especially in women who had not been experiencing bleeding before commencing HRT
- A retrospective study of 469 patients identified atypical hyperplasia/endometrial cancer in 2% of women on sequential HRT versus 1% of women on continuous HRT
- The overall probability of endometrial cancer with post-menopausal bleeding is 5-10%
- BGCS recommends women on HRT with unscheduled bleeding should have their HRT discontinued for six weeks. Those with persistent bleeding should be referred to a rapid access gynaecology clinic without re-starting HRT
- NICE states 'Continuous combined HRT commonly produces irregular breakthrough bleeding or spotting in the first 4–6 months of treatment. If bleeding persists beyond 6 months, becomes heavier, or occurs after a spell of amenorrhoea, endometrial pathology should be excluded'
- Based on BMS, BGCS & NICE advice, we believe implementing a screening pathway for women with unscheduled bleeding on HRT will provide a safe means of addressing the current PMB capacity issues within the gynae service.
- This was further supported by the later publication of the updated BMS and NHSE guidelines as outlined above.

THE UNIVERSITY HOSPITALS DORSET GP DIRECT ACCESS APPROACH

The UHD unscheduled bleeding on HRT pathway operates using a General Practitioner (GP) direct access model. The pathway allows GPs to make a direct referral for the patient to have a Transvaginal Ultrasound Scan (USS) and then, if they meet the criteria, to be referred onto gynaecology for further examinations.

The pathway involves the referring clinician identifying the patient is on HRT and undertaking a speculum examination to rule out cervical, vulval and vaginal pathology. If this is the case, then the GP can send the patient for a direct access ultrasound scan. If the scan identifies an endometrial thickness of over 4mm or concerning ovarian pathology (as outlined in the Wessex Gynaecology Ultrasound Guidelines), the patient should be referred onto the Gynaecology fast-track service for further investigation. Gold standard practice would be for these patients to be booked directly into a 'see and treat' clinic, to enable effective and timely management and preserve the one stop clinics for those patients who have not yet been scanned. If the ultrasound result is normal (ET≤4mm) then the GP can continue to manage the patient in the community by adjusting their HRT regime in line with guidance provided by the UHD gynaecology service as part of the pathway and the BMS guidelines.

The service model designed and implemented by the WCA was developed using Community Diagnostic Centres (CDC) to make best use of the diagnostic capacity within the area. The pathway was developed in line with NHS England GP direct access guidance, which is targeted at identifying people at low risk, but not no risk, of cancer and therefore

with a risk of cancer being identified as 1-2%, this cohort of women would be suitable for a direct access approach, with a CDC based model being ideal for this.

OBJECTIVES AND ANTICIPATED OUTCOMES

The unscheduled bleeding on HRT pathway has been set up based on recommendations from the British Menopause Society so that patients with unscheduled bleeding on HRT can be safely removed from the fast-track service, in turn enabling more effective utilisation of capacity for patients at higher risk of cancer. The key purpose is to provide a pathway which allows patients experiencing unscheduled bleeding to be given an USS without being referred on an USC referral pathway.

According to the Abdullahai et al study, 43% of women on continuous HRT had normal pelvic ultrasound scans when referred with unscheduled bleeding. This is in the context of a subjective rate of a third to half of PMB referrals being for unscheduled bleeding on HRT. According to the UHD January 2023 audit findings, 46.3% of PMB referrals were for women on systemic HRT and 49.3% PMB patients on HRT had ET<4mm. Taking this information into account, based on an average monthly referral rate of 152.8 patients for PMB, we estimated that 50.9 to 76.5 patients would be referred to the unscheduled bleeding on HRT pathway per month. This would reduce one stop clinic patients by 23.4 to 32.9 per month (15.3% to 21.5%). The overall outcome would therefore be that those at higher risk of cancer should be seen and diagnosed more promptly.

Objectives for the pathway:

- To provide an efficient pathway to rule out endometrial pathology
- To provide an appropriate pathway to support patients and GPs with unscheduled bleeding on HRT
- To provide patients with appropriate information to understand the pathway and the diagnostic tests they may go through
- To receive patient and GP feedback in order to continuously improve the pathway
- To allow costly fast track clinics to be used for the most at-risk patients
- To improve cancer waiting times targets
- To empower patients and health care professionals to support women with information and access to HRT, with reassurance in primary care setting.

The service has delivered in response to the above:

- GP direct access referral to ultrasound scans with the ability to refer onwards directly to gynaecology on an urgent suspected cancer pathway
- Rapid turnaround time from the point of referral to gynaecology where required
- Patient information leaflet for patients to understand the pathway and diagnostic tests they may go through
- Clear advice for primary care on the management of HRT based on BMS guidelines
- Reduction in PMB referrals over 12 months
- Conversion rate well below the NICE 3% threshold for USC referral
- Improvement in cancer waiting times performance and turnaround times for investigations in secondary care

CONSIDERATIONS

During the development of the pathway, several considerations and limitations to rollout were discussed in detail amongst a variety of stakeholders across primary and secondary care:

- Sonography workforce/ capacity issues (noted to be a challenge nationally)
- CDC recruitment delays
- Actioning of abnormal scan results/ onwards referral- clinical oversight and scope of practice
- PCN cohort agreement- consideration of full or staggered rollout

- Scanning timescales
- Onward referral timescales
- National GP direct access guidance recommendations
- Inclusion and Exclusion Criteria- including risk factors
- Endometrial thickness cutoffs
- Communication/ interface between primary and secondary care

It is worth noting that at the time this pathway was being developed, the updated BMS guidance had not yet been published, however clinicians within the Trust (including the project clinical lead) were directly involved in the development and authorship of the national guidelines that were later published in April 2024 and were keen to ensure that the pathway with developed with this guidance in mind.

It was agreed that a full rollout across all PCNs in the East Dorset footprint was preferable to a staggered rollout, to ensure that there was not seen to be any disparity in access across the footprint, or lack of clarity in terms of who was able to be referred, and so that the full impact of the pathway could be realised and evaluated within reasonable pilot timescales.

It was determined by the project group that a more simplified pathway would achieve better buy in from both primary care and radiology, and therefore it was agreed that the pathway would not specify the requirement to consider minor risk factors within the inclusion criteria, and that a 4mm cutoff for endometrial thickness would be applied regardless of HRT type. Whilst the BMS guidance does refer to a 7mm cutoff for sequential HRT, it was noted that it is not always clear on referral what HRT the patient is taking (with the referrer themselves sometimes being unclear on this) and that referral of any patient on sequential HRT with an ET>4mm would provide good opportunity for gynaecology to review these patients given their additional risk of cancer when taking these medications for a prolonged period.

During the pilot phase of the pathway, a number of additional supportive tools and measures were discussed and developed to ensure that the pathway was as accessible and effective as possible, which included:

- Attendance by the lead consultant and GP at primary care education events and Q&A sessions across the locality
- Advice and training offered by the lead consultant to the sonography workforce, including the outsourcing company supporting delivery of scans at CDC sites, on the management of unscheduled bleeding HRT and the agreed pathway
- A clear definition agreed around the classification of ‘postmenopausal’, given acknowledgement that this can be difficult to determine if patients have been established on HRT prior to LMP
- A clear help section built into the ICE referral form clarifying the criteria, along with a link to the pathway map and SOP, with pop-ups embedded into ICE to support GPs to refer appropriately
- A one-page GP information sheet on HRT management and prescribing based on the BMS guidance, attached as an appendix to the pathway map
- A weekly report set up by the radiology service outlining the referrals received via the dedicated form to enable auditing of the pathway and its outcomes
- A dedicated email address set up for any GP queries- managed by the gynae pathway navigator with support from the lead consultant
- A letter template developed to signpost GPs on the pathway criteria and how to access it, if they referred a patient via the PMB pathway inappropriately
- An ICE user guide with screenshots showing step-by-step how GPs in the different localities could access the pathway
- A patient information leaflet to support with managing expectation of the pathway, which was also developed into video and easy read format with the support of the cancer alliance
- Support to the radiology service to develop template wording for ultrasound reports to ensure GPs were clear on any actions taken or required following the scans

- Discussions with the Society of Radiographers around scope of practice and ensuring there was support for sonography/ radiography staff in terms of onward referral and clarity on responsibility for the patient, with an aim to support development of a national statement
- Development of a local capacity tool which enabled the gynaecology service to easily track their demand and capacity and monitor the impact of this pathway and support with forward planning.

CURRENT SERVICE MODEL

The pilot service model required referring clinicians (GPs) to identify that their patient was post-menopausal and currently on systemic HRT.

For the purposes of this pathway, we defined post-menopausal as having cessation of periods for greater than 1 year, or >50 year of age and established on any HRT prior to cessation of periods.

Primary care clinicians were expected to perform a speculum examination to rule out cervical, vulval and vaginal pathology before making a referral.

Inclusion criteria for the direct access pilot - all of the criteria must be fulfilled:

- Currently taking systemic HRT
- Post-menopausal (cessation of periods for greater than 1 year, or >50 years of age and established on any HRT prior to cessation of periods)
- Experiencing unscheduled bleeding beyond 6 months of initiating systemic HRT
- Has had vaginal and speculum examination to rule out vaginal, vulval and cervical pathology
- No additional risk factors for endometrial cancer, such as BMI>40 or genetic predisposition to endometrial cancer (Lynch syndrome, Cowden syndrome, strong family history).
- Has not had ultrasound scan within the last 6 months
- Consider referral if heavy bleeding (flooding) or persistent (almost daily) bleeding arise within 6 months of initiation of HRT, or within 3 months of change in dose/ preparation. Adjustments to comorbidities and progestogen dose should be considered prior to referral to scan and whilst awaiting ultrasound scan.

Exclusion criteria for the pilot- refer via fast-track cancer (USC) pathway:

- Women with additional risk factors: BMI>40 or genetic predisposition to endometrial cancer (Lynch syndrome, Cowden syndrome, strong family history)
- Has stopped HRT for 6 weeks and bleeding persists
- Vaginal, vulval or cervical pathology noted on examination
- Any PMB with a TVS showing endometrial thickness of >4mm, or with an irregular endometrium, increased vascularity or a focal lesion
- Continued unscheduled bleeding 3 months on from ultrasound scan despite change in HRT preparation or dose. If GP uncertain on how to adapt HRT doses to prevent bleeding, please refer to pathway map or conduct advice and guidance route prior to fast-track referral.

Exclusion criteria- refer via routine gynaecology or advice and guidance route:

- Bleeding within 6 months of starting HRT or within 3 months of changing the progesterone dose or regime is common. Scanning is not recommended within the first 6 months of commencement of HRT. The advice and guidance route can be used for any concerns or queries during this time.
- It is recommended that progesterone dose/ regime should be adjusted before considering referral to prevent patients having unnecessary interventions. If GPs are uncertain regarding dose or regime change, please refer to pathway map or refer via advice and guidance.

- Women who are taking HRT for the peri-menopause should be referred via routine generic gynaecology pathways.
- Asymptomatic endometrial thickening without bleeding should be referred to routine generic gynaecology.

The ultrasound scan / trans vaginal scan was arranged within 4 weeks of the referral being received by the ultrasound department. The ultrasound scan is used to determine the endometrial thickness to assess the appropriate next steps:

- **ET ≤4mm:** GP to manage patient in primary care in line with guidance provided on management of HRT by British Menopause Society (see pathway map for advice).
- **ET >4mm, ill-defined or difficult to access:** Sonographer to refer patient to gynaecology fast track urgent suspected cancer pathway on the day of the scan by adding a flag on Soliton.
- **Ovarian pathology:** Sonographer to refer patient to gynaecology fast track pathway on the day of the scan by adding a flag on Soliton.
- **Other abnormal findings:** GP to manage/ make appropriate onward referrals in line with NICE guidance

For the first 6 months of the pilot (November 2023 to May 2024), the GP remained responsible for actioning any onward referrals to gynaecology based on the results of the ultrasound scan. The expectation was that referral be made as soon as possible, and within 3 working days, to prevent any delays in onward management. After the first six months, the project group worked together to agree a process whereby abnormal findings were referred directly to gynaecology via an internal process, in line with NHSE GP direct access guidelines and directive from the ICB that this be developed into the pathway within the first six months of launch.

From May 2024, for patients with abnormal ultrasound results, the sonographer triggered a gynaecology fast-track urgent suspected cancer referral by adding a flag on Soliton, with an administrator then passing the information from the flagged scans onto the gynaecology department via email twice per week. The sonographer would also then notify the GP of the referral in their scan report.

On receipt of the fast-track referral from the sonography department, the patient was then booked into the appropriate gynaecology clinic, triggering a 28-day pathway clock start from the date of the ultrasound scan, in line with CWT guidance which advises that:

“Where a pathway has been implemented and agreed locally where a patient is directly triaged from an abnormal direct access diagnostic scan with a suspicion of cancer then the decision to triage directly would act as the start of the pathway and counted as an urgent suspected cancer referral, and not an upgrade”. (V12, section 2.2.9).

SERVICE BENEFITS & ISSUES

Benefits

- The pathway provides a new access route for patients to receive an ultrasound scan without going through the urgent suspected cancer route.
- The pathway provides patients clear information around what to expect.
- The pathway appears to be safe with a cancer conversion rate below the NICE 3% target (0.4%).
- The pathway has saved one stop clinics preventing a number of patients the anxiety of attending cancer pathway clinics.
- The pathway has led to a significant reduction in PMB referrals (Nov 23 185 vs Nov 24 122).

- The pathway has been a main factor in the improvement of UHD's FDS performance.

Issues

- The service requires administrative to support for onward referrals, as there is currently no option for an automated system to send these referrals on. Development of a digital tool using Robotic Process Automation (RPA) is currently under discussion in another Trust within Wessex, with potential to explore economies of scale if this proves successful.
- Sonographers have not consistently copied in the report statement wording, leaving referring clinicians unsure of the next steps for their patients. The ultrasound leads are taking this forward to ensure compliance across the sonography cohort and further training is being arranged, which includes the outsourcing company who are supporting the CDC clinics.
- Initial reluctance for sonographers to action abnormal findings and concern around this being outside of scope of practice. This is being explored further by the Cancer Alliance with the Society of Radiographers, alongside the NHSE Faster Diagnosis and GP direct access leads, as part of wider discussions around GPDA pathways.

ACTIVITY AND OUTCOMES

810 referrals were received via the GPDA Unscheduled bleeding on HRT pathway between November 2023 to the end of November 2024. There was a steady increase in utilisation of the pathway over the pilot period, with referral numbers within the parameters expected from the pre-pilot audit.

19/810 cancelled or Did Not Attend, leaving 791 who had an USS.

Figure 2: Overview of referrals received via the GPDA Unscheduled bleeding on HRT pathway

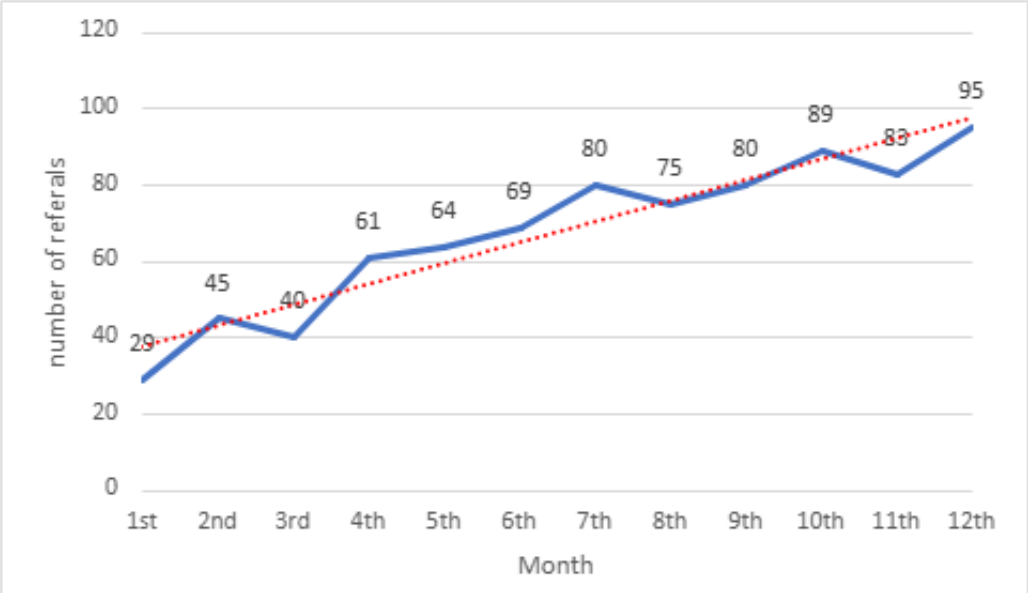


Figure 3 demonstrates the median time from GP referral to ultrasound scan taking place, which reduced significantly after the 8th month, reaching just 21 days by the last month (November 2024).

- The target was 28 days
- The average time was 29 days
- The median was 25 days

Figure 3: Median Time from referral to USS

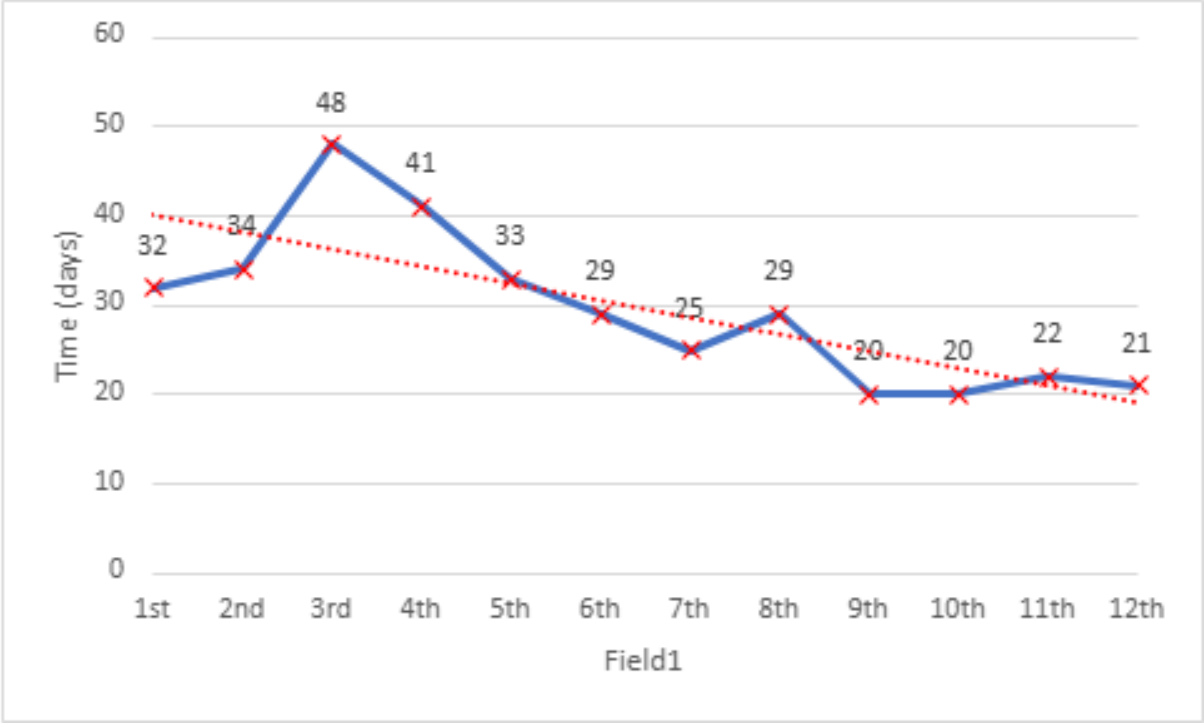
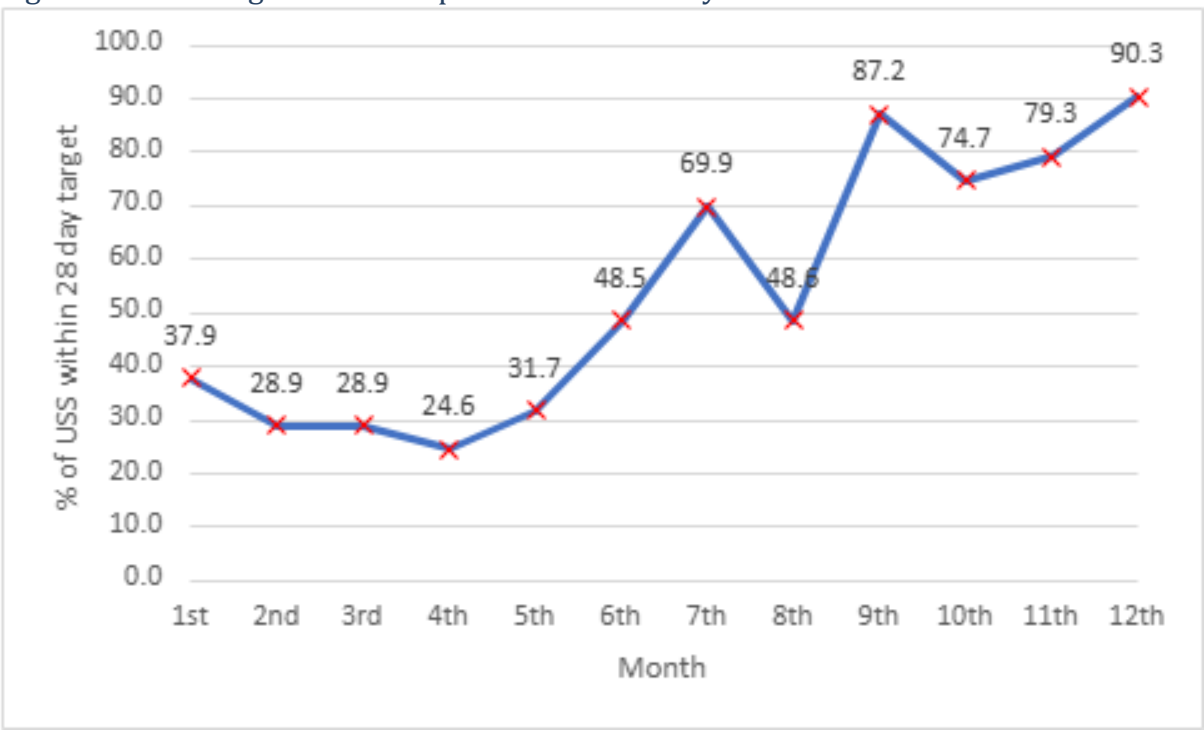


Figure 4 shows the percentage of ultrasound scans that were completed within 28 days. The percentage increased throughout the year, reaching the highest percentage in the final month (November 2024).

Figure 4: Percentage of USS completed within 28 days

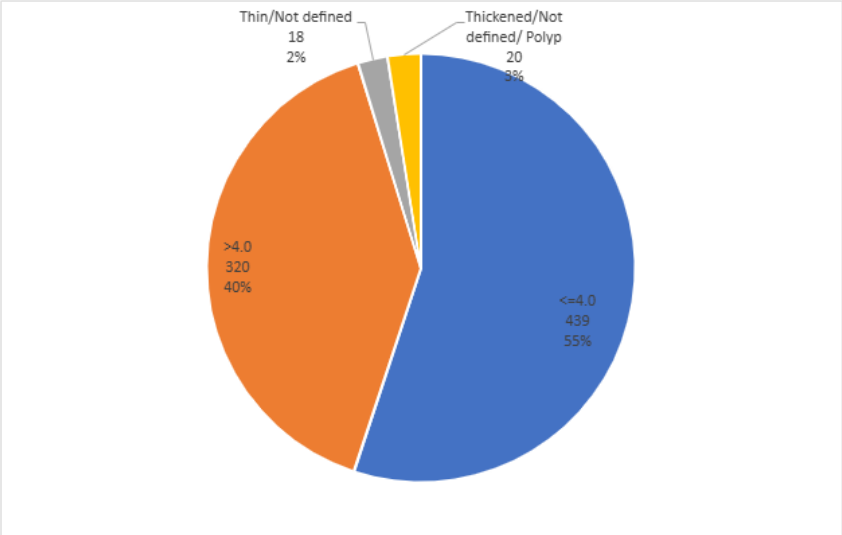


357 patients required Urgent Suspected Cancer referrals on to gynaecology due to their ultrasound findings.

- 320 patients had an endometrial thickness of over 4mm
- 20 patients had thickened / not defined / endometrial polyp

- 13 had ovarian pathology
- 4 had cervix pathology

Figure 5: Ultrasound Endometrial Findings



The pathway prevented 433 Urgent Suspected Cancer appointments being made, which resulted in saving 72 PMB fast track clinics.

Out of the 357 referrals required:

- 18 were not actioned
- 1 was already on the waiting list and had a final histology confirming simple hyperplasia
- 16 did not attend (DNA) their appointments
- 1 was seen prior to their ultrasound scan for suspicious cervix
- 321 had their appointments

Figure 6 demonstrates the median time from the GPDA ultrasound scan being undertaken to the patient being reviewed in the gynaecology clinic, for those patients who required onward USC referral following their scan. The median time reduced over the year, reaching 10 days.

- The target was 14 days
- The average was 33 days
- The median was 29 days

Figure 6: Median time from USS to Gynae Clinic

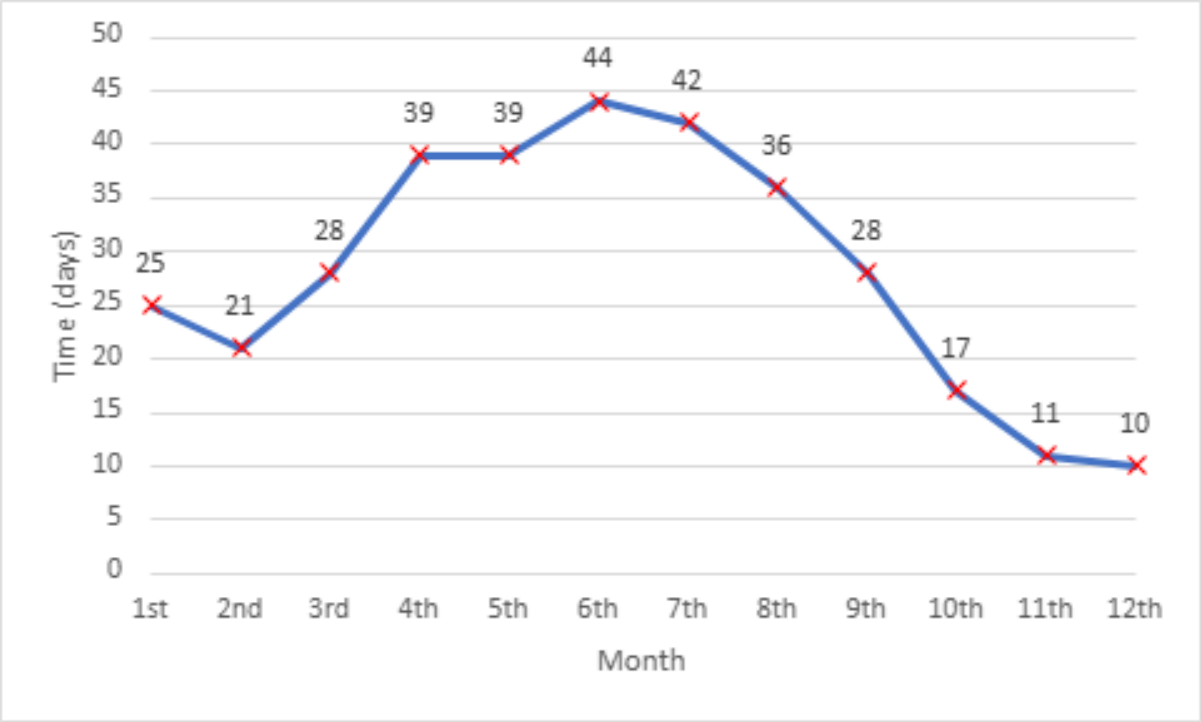


Figure 7 demonstrates the time from receipt of the fast-track referral into the Gynae clinic (post-USS) to the patient's first appointment for those patients who had abnormal scans on the GPDA pathway. The turnaround time for first appointment in gynaecology reduced significantly across the year.

- The target was 14 days
- The average was 27 days
- The median was 25 days

From month 10 onwards (September 2024) the time from fast-track referral to appointment for this cohort reduced significantly and was within the 14-day target.

Figure 7: Time from fast-track referral to Gynae Clinic

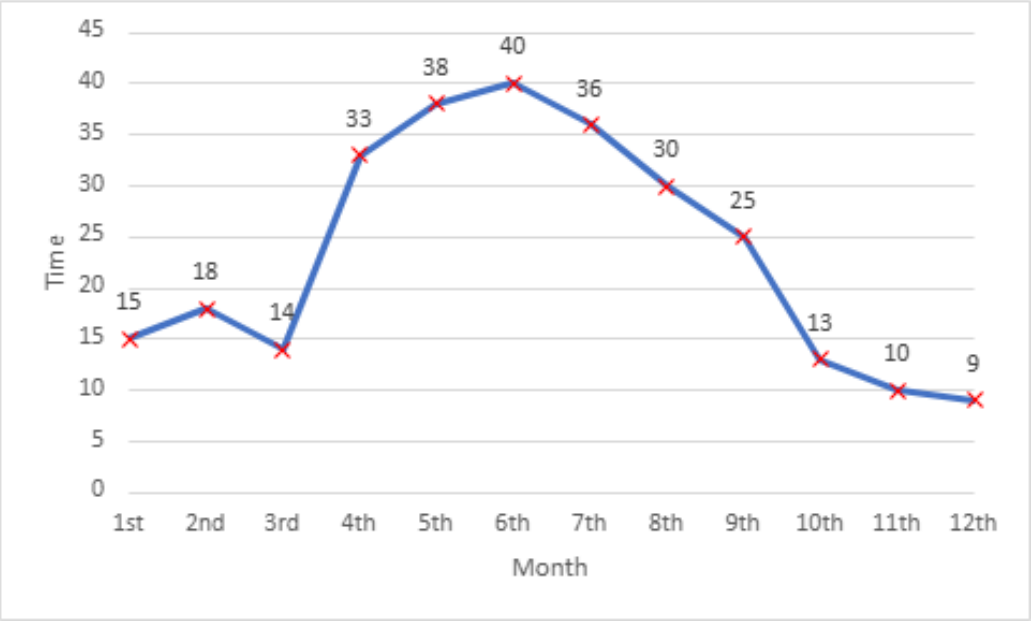
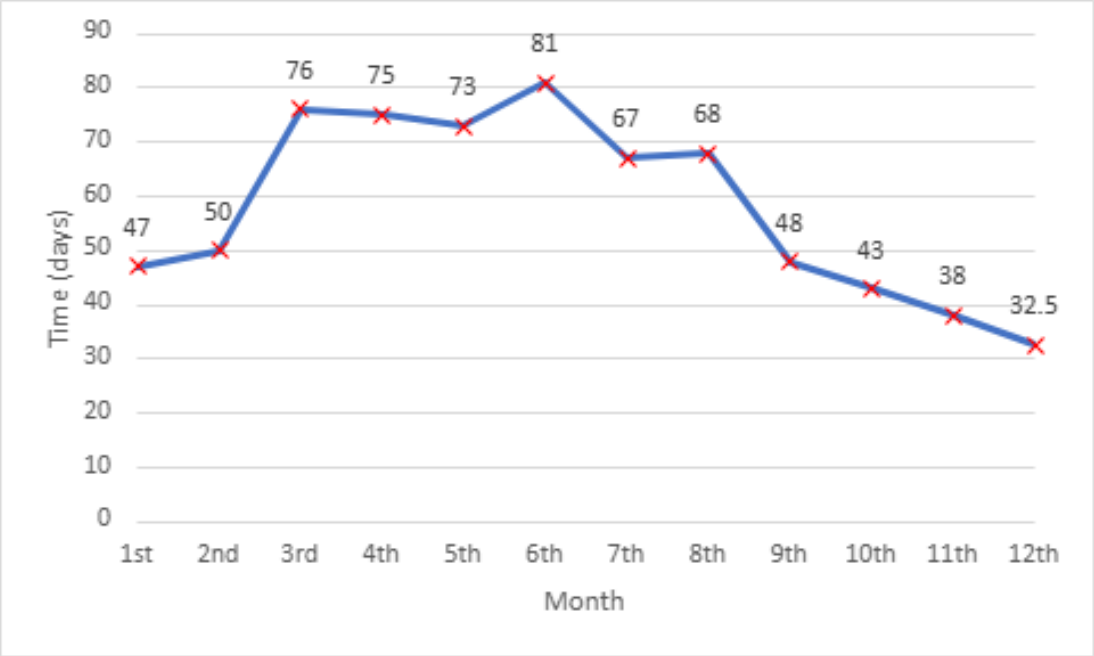


Figure 8 shows the time from GPDA referral for USS to the USC Gynae clinic appointment for those who required onward referral. By the end of the pathway, we had reduced the time to 32.5 days.

- The target was 42 days (28 days for USS + 14 days for clinic review)
- The average was 62 days
- The median was 56 days

Figure 8: Time from GPDA referral to clinic



Out of 321 patients who had an appointment, 295 were seen in a one-stop and 23 were not seen in a one-stop. 8 patients did not require one-stop appointments due to being referred on an urgent suspected cancer referral for ovarian pathology. 3 patients' documentation was not available for the audit.

CANCERS DIAGNOSED

There were 3 cancers diagnosed out of the 791 patients managed via this pathway giving a conversion rate of 0.4%, which is well below the NICE 3% target. The following cancers were diagnosed during the pilot:

- 1 endometrial cancer
- 1 G2 mucinous adenocarcinoma with omental deposits
- 1 G1 1c Endometroid Ovarian Cancer
- From the audit, we can also confirm that to date, not cancers have been subsequently diagnosed in the cohort of patients discharged back to their GP with a normal scan result.

Hyperplasia

4 out of 791 patients who had an USS were found to have simple hyperplasia:

- First: ET 6mm, A/W Mirena and having follow up, HRT – Estradiol 0.06% gel x 2, Utrogestan 100mg
- Second: ET 5mm, Unopposed oestrogen gel due to mirena being in for 7 years, has new mirena and under follow up
- Third: ET 10mm, stopped HRT and is under follow up, HRT – Estradiol 0.06% gel x 4, Utrogestan 100mg
- Fourth: ET 8mm, HRT - Zumenon 2mg utrogestan 100mg, now has mirena and reduced her oestrogen and under follow up

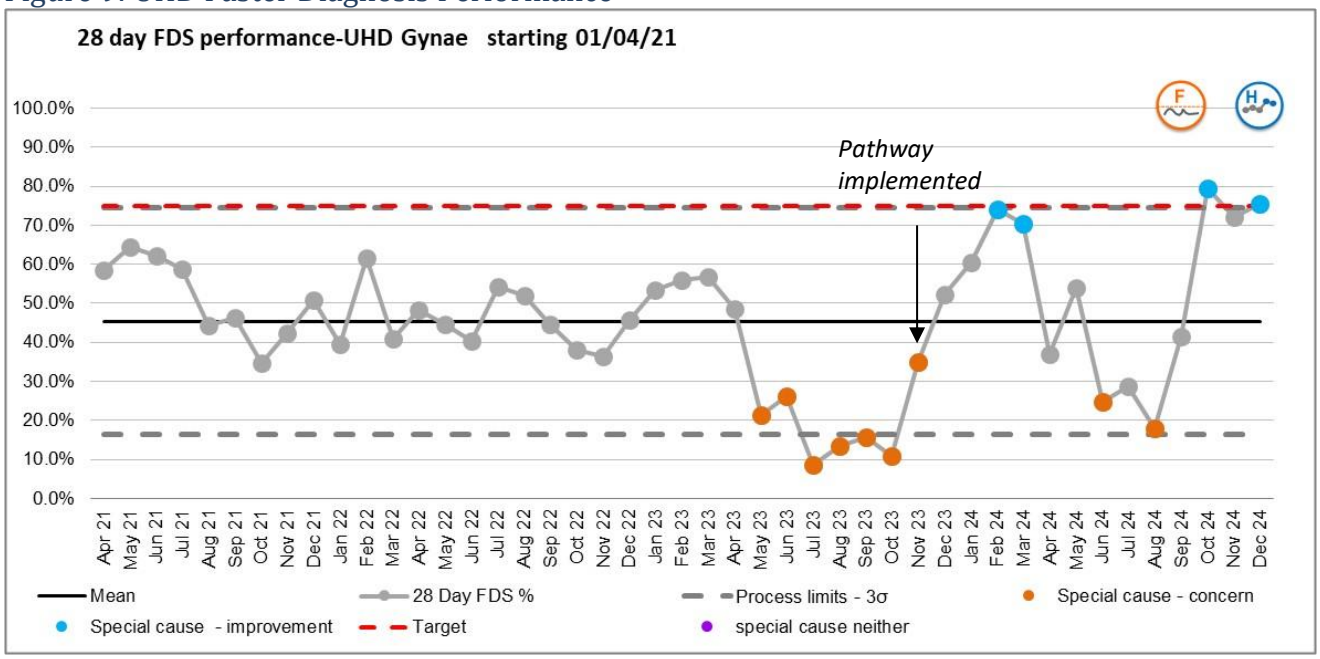
2 out of 791 patients who had an USS were found to have atypical hyperplasia:

- First: ET 10.7mm, HRT – estradiol 0.06% x1, utrogestan 100mg, A/W TLH BSO
- Second: ET 7.5mm, HRT – estradiol 0.06% x 2, utrogestan 100mg, down regulated to simple hyperplasia by MDT and has mirena with follow up

PATHWAY IMPACT

Prior to the implementation of the pathway, UHD were not meeting the FDS target of 75%, which will be rising to 80% in 2025/26. Since implementation of the pathway, the UHD FDS performance has increased significantly so that UHD are now meeting, if not exceeding the target. There were challenges with workforce and fast-track clinic capacity due to long-term absence of a consultant in early 2024, which had an impact on performance. The FDS target was first met in October 2024. Figure 9 shows the FDS performance for UHD.

Figure 9: UHD Faster Diagnosis Performance

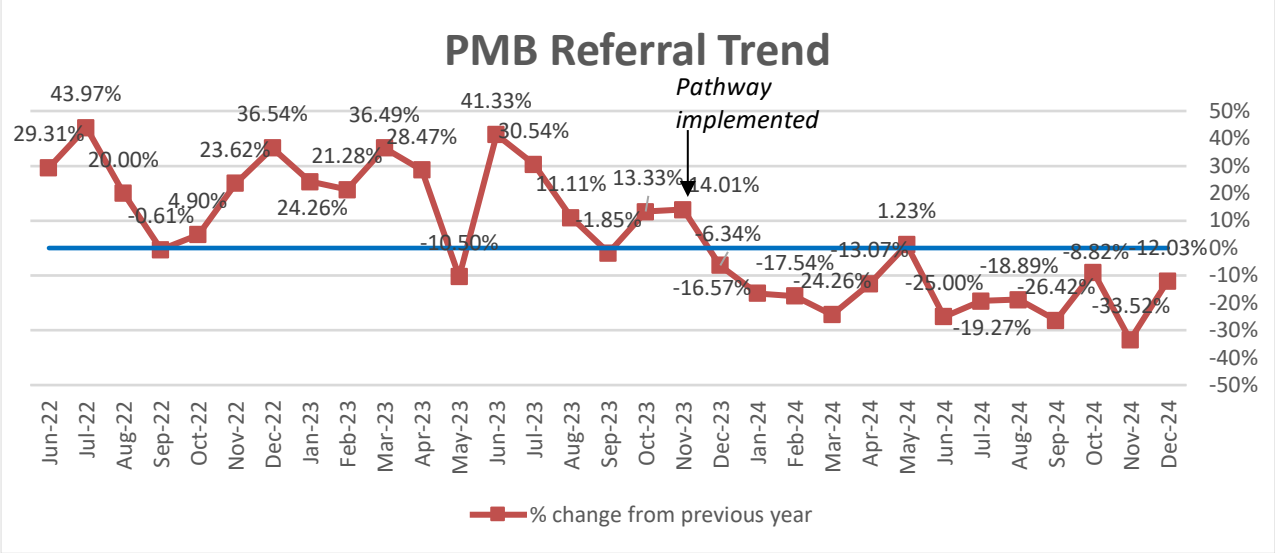


The number of referrals being made for PMB have reduced significantly since the pathway was implemented in November 2023.

Figure 10: PMB referral rates at UHD

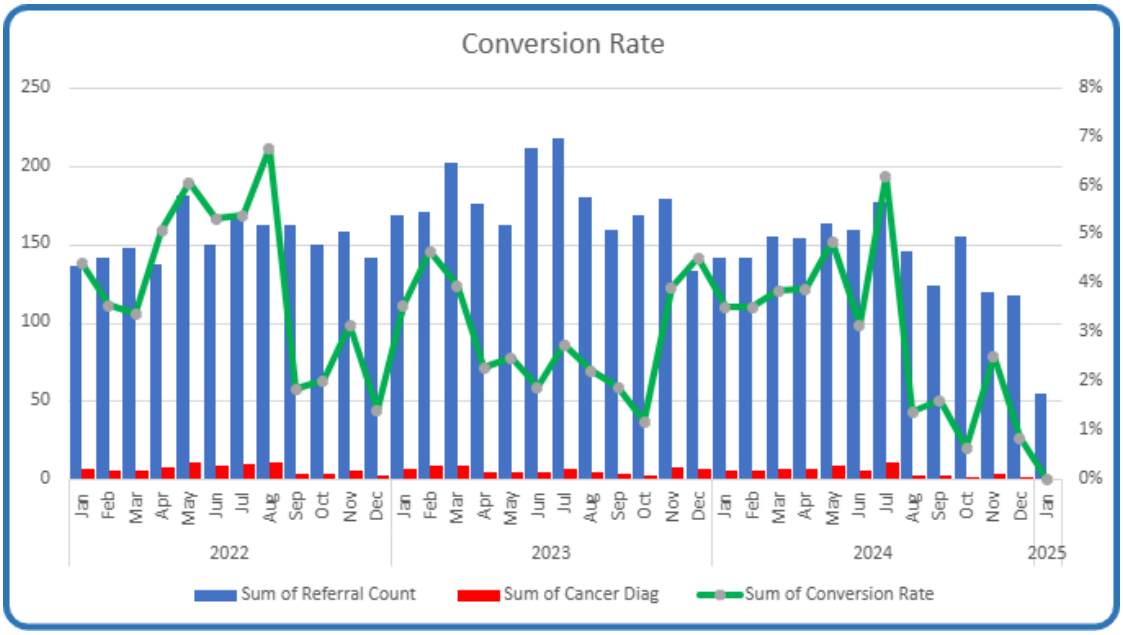
	April	May	June	July	August	September	October	November	December	January	February	March	average	rate of change	Cumulative change
21/22			116	116	135	162	143	127	103	134	141	148	133		
22/23	136	181	148	167	162	162	150	158	142	169	172	202	162	21%	21%
23/24	178	164	215	218	181	161	174	185	135	145	144	157	171	6%	29%
24/25	156	174	166	183	148	137	160	122	119				152		

Figure 11: PMB referral rates at UHD (% change)



Since the introduction of the pathway, the conversion rate on the USC pathway has increased, which mean that this pathway has reduced the number of inappropriate referrals coming in via the USC route. Figure 12 outlines the conversion rates for the PMB pathway for UHD from January 2022 onwards. Please note that the conversion data lags and therefore the data from August 2024 onwards will not yet be complete and validated.

Figure 12: PMB Conversion rates



TYPES OF HORMONE THERAPY
• 693 out of 810 (85.5%) patients referred onto the pathway were on continuous combined HRT • 82 out of 810 (10.1%) patients referred onto the pathway were on sequential HRT • 35 out of 810 patient's HRT regimen was unknown

Figure 13: HRT types

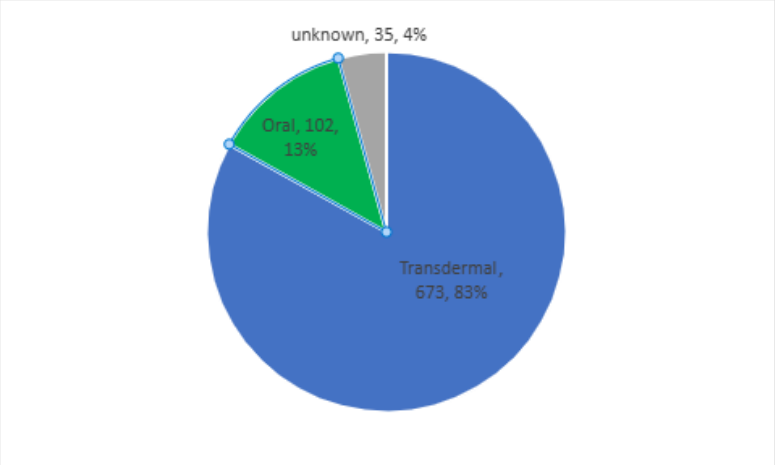
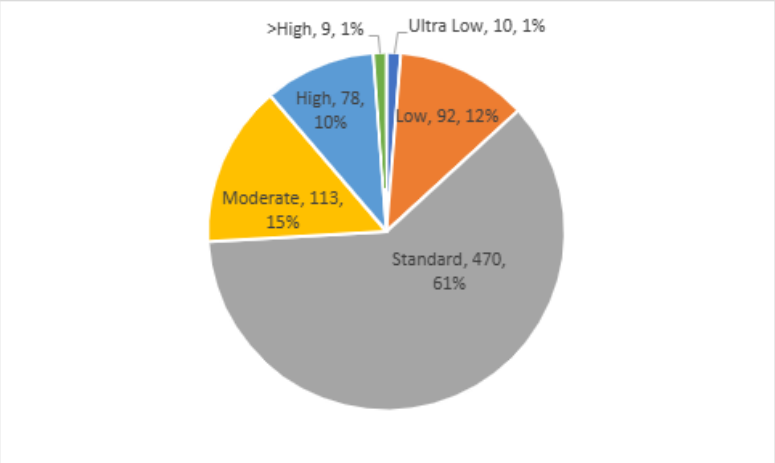


Figure 14: Oestrogen dose



	Ultra-low dose	Low Dose	Standard dose	Moderate dose	High dose
Oestrogel	½ pump	1 pump	2 pumps	3 pumps	4 pumps
Sandrena	0.25 mg	0.5 mg	1 mg	1.5-2 mg	3 mg*
Lenzetto spray	1 spray	2 sprays	3 sprays	4-5 sprays*	6 sprays*
Patch	12.5 µg	25 µg	50 µg	75 µg	100 µg
Oral estradiol	0.5 mg	1 mg	2 mg	3 mg^	4 mg^

Figure 15: Progesterone type

Progesterone Type	Number	%
Utrogestan	422	54.7
Norethisterone	237	30.7
Mirena	54	7
Dysrogesterone	36	4.7
Levnorgesterel	11	1.4
MPA	7	0.9

Tibolone	3	0.4	
Unopposed	2	0.3	

ROUTES TO DIAGNOSIS

The table below outlines how the diagnosis was made for the patients who attended the gynaecology clinic.

Figure 16: How the diagnosis was made

Method	Number	%
A/W	18	5.6
Endometrial biopsy only	24	7.5
Hysteroscopy only	79	24.6
Hysteroscopy and Endometrial biopsy	91	28.3
Polypectomy	62	19.3
Other	28	8.7
Review only	19	5.9

Of the 'Other' route, 5 declined an appointment, 3 had no documentation, 2 did not attend, 1 had total laparoscopic hysterectomy (TLH), 2 had an MRI and 15 were non endometrial. Of the 15 non endometrial, 2 came from cervix Urgent Suspected Cancer, 2 required surgery and the rest were decided to be benign ovarian cysts.

PRIMARY CARE STAFF FEEDBACK

GPs from the practices participating in the pilot pathway were asked to provide feedback through a short survey which was distributed to primary care in October 2024. 11 GPs responded to the survey, with responses received from 7/13 PCNs included in the pilot.

Figure 17: PCNs GPs were responding from

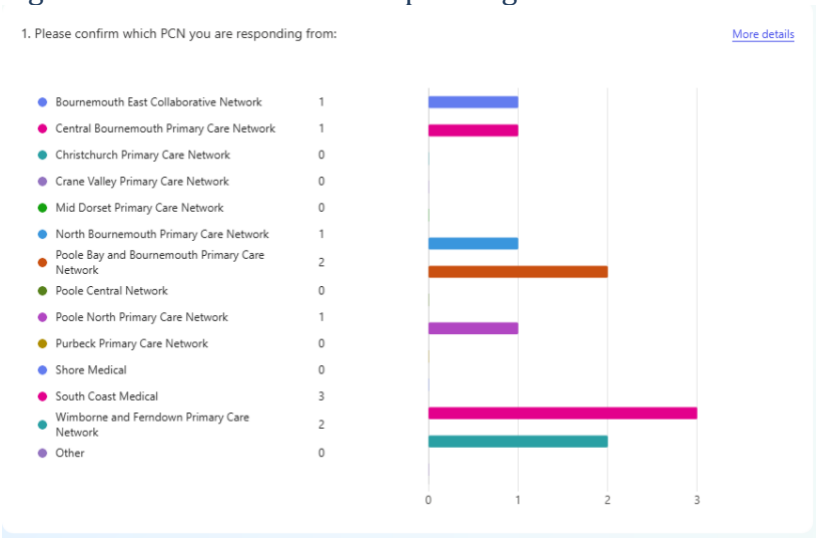
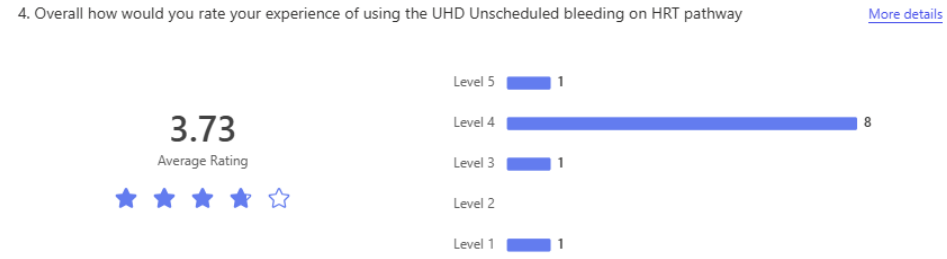


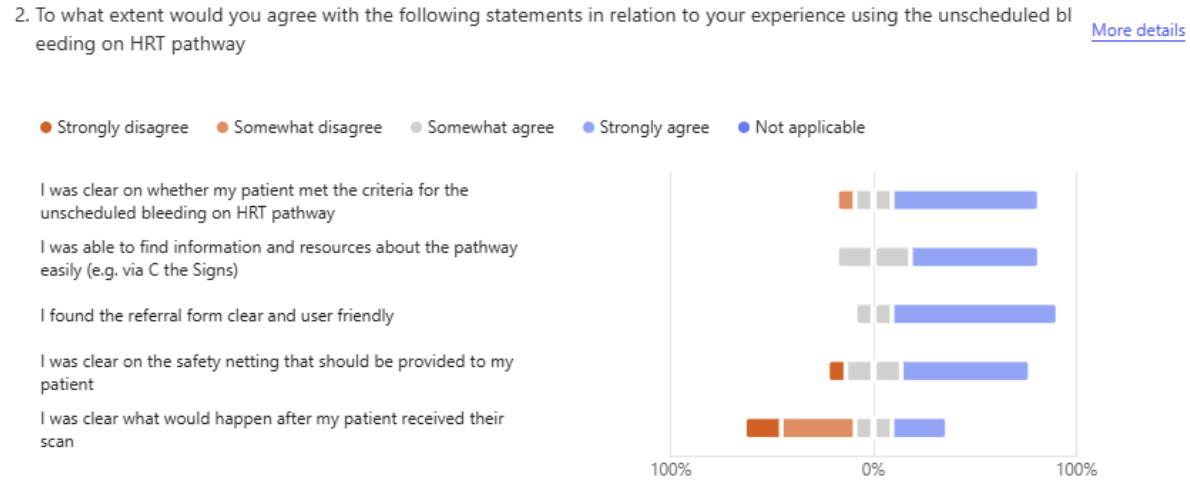
Figure 18: GP experience rating



A summary of the feedback was as follows:

- 80% of GPs said they would rate their experience of the pathway highly (4 or 5 out of 5)
- 90% of GPs said they were clear on whether their patient met the criteria for the unscheduled bleeding on HRT pathway
- 100% of GPs said they were able to find information and resources about the pathway easily
- 100% of GPs said they found the referral form clear and user friendly
- 90% of GPs said they were clear on the safety netting that should be provided to their patient
- 45% of GPs were clear what would happen after their patient received their scan. 55% were not clear what would happen after their patient received their scan

Figure 19: GP clarity around the pathway



Generally, the feedback from Primary Care was mostly positive. GPs advised that they found the one-page guide on HRT management useful, and as well as acknowledging the impact the pathway would have in reducing USC referrals. The main suggestions for improvement were around clarity on what would happen after the scan had taken place, and USS reports being unclear on whether patients have been referred on to gynaecology or whether the referring clinician would need to submit this referral. Throughout the pilot, we did also receive feedback and queries directly from referrers asking about the latter issue.

As a result of the feedback received, an action plan was developed by the project group to improve the communication back to GPs following the patient's scan, and template report wording was developed to make the next steps of the process clearer, i.e. whether a referral to gynaecology had already been actioned. A dedicated email

address was also set-up which could be used by GPs to direct any queries from GPs around actions required following receipt of their patient's scan report. An example of the report wording can be found in Appendix 6.

Additional training is also being arranged with sonographers, including those from the outsourcing company who are supporting with conducting these scans in the CDCs.

The SOP pathway map included a GP guidance section for managing HRT, which was received positively by primary care.

PATIENT FEEDBACK

A patient feedback survey was developed to receive comments about the pathway. Patients were given opportunity to complete the survey both whilst they were at the clinic and afterwards.

- 3 patients responded to the survey, but overall, response rate was low.
- 2 of the patients were scanned at Beales Community Diagnostic Centre. 1 was scanned at Bournemouth Hospital.
- 2 patients felt the information their GP provided before the scan was helpful
- 2 patients agreed they knew what to expect at their scan appointment
- All patients agreed they were given enough notice about the date and time of their scan appointment
- 2 patients were made aware they might need further investigations after their scan
- 2 patients were given a patient information leaflet prior to their ultrasound scan
- All patients agreed they found the department easily
- All patients were made to feel welcome on arrival
- All patients felt their privacy and dignity was well-maintained
- All patients agreed that the clinician explained what was going on in ways they understood
- All patients were treated with kindness and understanding
- 2 patients were updated on their scan results in a timely manner
- 2 patients were informed of what would happen next
- 2 patients were made aware of who to contact if they had questions or concerns
- 1 patient was referred on to the gynaecology department
- 1 patient did not answer the question about onward referral

The pathway was rated 8 – 10 by the patients, which is very positive.

There were challenges with obtaining patient feedback on the pathway, despite the patient feedback survey being live since April 2024. The project group worked with the CDC management team to promote the survey in the clinics using QR codes and a link to the survey was also provided on the back of the patient information leaflet, however this did not appear to increase response rates. Opportunity to promote completion of the survey by patient referred on to the gynaecology department was also explored, with the acquisition of an iPad meaning that this could be done electronically whilst patients were still onsite.

It was noted by the UHD patient surveys team that patients attending the CDC clinics were being asked to complete surveys on their CDC experience by volunteers whilst they were attending their appointments, and there is potential that this could have resulted in reluctance from patients to complete a further feedback survey for this pathway.

RECOMMENDATIONS

Based on the data we audited during the pilot and the feedback we have received, we recommend that we embed this pathway as business as usual within University Hospitals Dorset as per the national directive. We also recommend that this pathway be expanded across the Wessex footprint.

We should continue to monitor the progress of the automated onward referral process being explored at another local Trust as this could be a beneficial software for the unscheduled bleeding on HRT pathway and could reduce the administrative burden.

There is ongoing support from the project lead and project manager to address the outstanding actions around the onward referral process in terms of training, template wording and supporting the development of the Society of Radiographers statement.

ACKNOWLEDGEMENTS

We would like to acknowledge and thank the following staff for their support in the development of this pathway.

- Ms Rachana Dwivedi- Obstetrics & Gynaecology Consultant, University Hospitals Dorset
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- Lucy Seare- Deputy General Manager for Women's Health, University Hospitals Dorset
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- Joanne Halfpenny- Lead sonographer, Poole, University Hospitals Dorset
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- Dr David Broadley- Medical Director integrated Care (GP)- University Hospitals Dorset
- Kerry Terry- Cancer- Pathway Improvement & Performance Programme Lead, NHS Dorset ICB

Appendices

Appendix 1: BMS Flowchart (April 2024)

Appendix 2: UHD Pathway Map

Appendix 3: UHD GP HRT Guidance

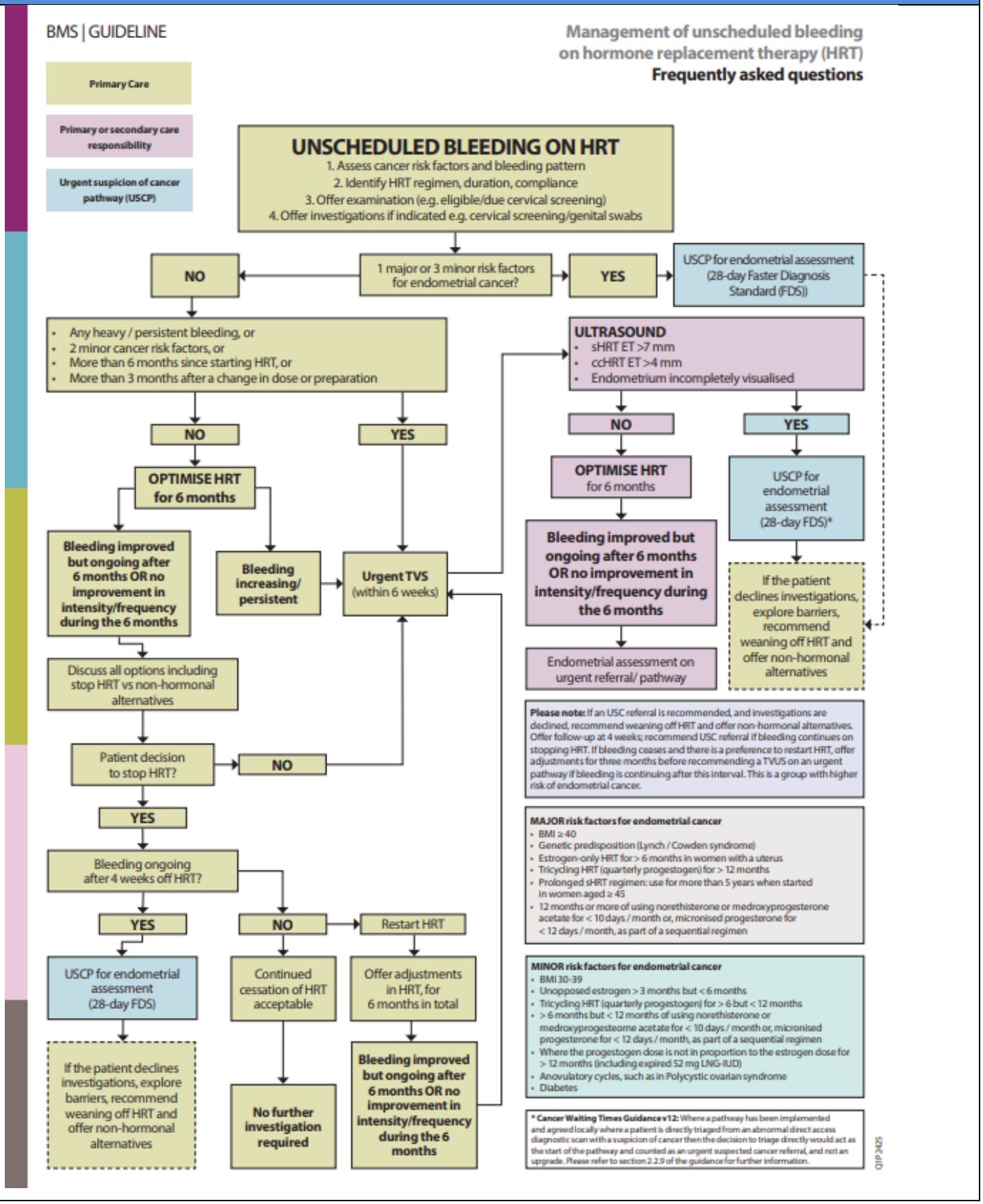
Appendix 4: ICE User Guide- How to access the pathway

Appendix 5: UHD Patient Information Leaflet

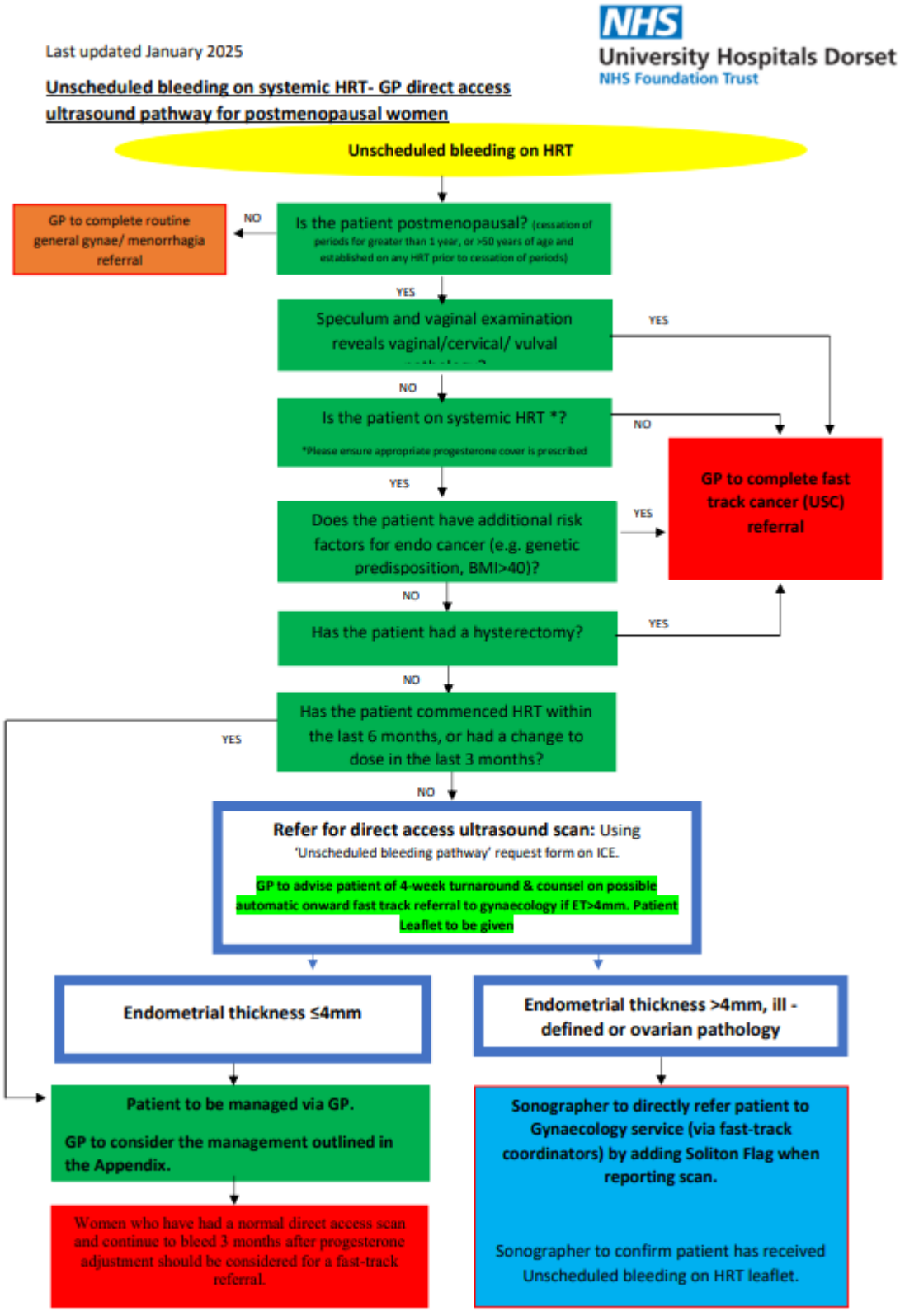
Appendix 6: Ultrasound report template wording

Appendix 7: Fast-track GP signposting letter

APPENDIX 1: BMS Flowchart



APPENDIX 2: UHD Pathway map



APPENDIX 3: GP HRT guidance

Last updated January 2025

NHS University Hospitals Dorset NHS Foundation Trust

Appendix: HRT guidance for GPs

For advice on HRT preparations and equivalent doses please see following link to the British Menopause Society:

www.Thebms.org.uk/publications/tools-for-clinicians

GP to consider the following management:

- If on sequential HRT regimens, consider increasing dose of progesterone to 300mg micronised progesterone (Utrogestan) for 12 days a month instead of 200mg, or switch to a different progesterone, or increase duration of progesterone intake (can take progestogen for 14 days a month or for 21 days out of a 28-day HRT intake cycle)
- If on continuous combined HRT regimens, consider increasing the dose of progestogen (e.g. increase micronised progesterone daily dose from 100mg to 200mg daily on a continuous basis), particular when combined with higher dose estrogenic regimens or raised BMI
- For continuous HRT regimens in a combined preparation or have the levonorgestrel intrauterine system consider adding micronised progesterone/ medroxyprogesterone acetate or norethisterone
- If breakthrough bleeding occurs after 3 to 6 months after switching from sequential to continuous HRT they can be switched back to sequential for at least one year
- Unscheduled bleeding is higher with transdermal preparations than oral preparations
- If evidence of urogenital atrophy (despite those on systemic HRT) consider vaginal oestrogens

Consider scan if heavy bleeding (flooding) or persistent (almost daily) bleeding arises within 6 months of initiation of HRT, or within 3 months of change in dose/ preparation. Adjustments to comorbidities and progestogen dose should be considered prior to referral to scan and whilst awaiting ultrasound scan.

Consider Advice & Guidance route if additional advice required.

Progestogen in HRT recommended doses

Micronised progesterone
200mg PO 12 days/cycle (cyclical)
100mg PO daily (continuous combined)
Preparations: Utrogestan 100mg PO

Dydrogesterone
10mg for 12-14 days a month (cyclical)
5mg a day (continuous combined)
2.5mg a day (low dose continuous combined)

Medroxyprogesterone acetate (MPA)
10mg for 12 days a month (cyclical)
2.5mg a day (continuous combined)

Norethisterone
5mg for 12 days a month (cyclical)
0.5-1mg a day (continuous combined)

Levonorgestrel IUS
Licensed for 4 years in the UK

Vaginal oestrogen preparations for vaginal atrophy

Intravaginal cream
Ovestin (1 mg estriol in 1 gram cream) - insert one applicatorful daily for a maximum of 4 weeks, reducing to one applicatorful twice a week)

Vaginal tablets
Vagifem vaginal tablets (estradiol 10 micrograms) - insert one vaginal tablet daily for 2 weeks then reduce to one vaginal tablet twice a week.

Vaginal gel
Blissel® (50 micrograms estriol in 1 gram vaginal gel) -insert one applicator dose daily for 3 weeks, reducing to one applicator dose twice a week. Reassess after 12 weeks.

APPENDIX 4: ICE user guide

Download: [ICE user guide – Accessing the Unscheduled bleeding on system HRT]

APPENDIX 5: Patient Information Leaflet

Download: [Unscheduled bleeding on HRT]

APPENDIX 6: Report statement wording

Normal scans (discharged to GP):

As per the unscheduled bleeding on HRT pathway no onward referral has been made. The final interpretation of the ultrasound scan result is with the GP. For any queries regarding the pathway a link can be found here: Updated-Pathway-Map-for-Unscheduled-bleeding-on-HRT-pathway-UHD-March-2024.pdf.

Abnormal scans (referred to gynaecology):

Following an abnormal ultrasound finding, an automatic gynaecology Urgent Suspected Cancer Referral has been made for this patient, as per the unscheduled bleeding on HRT pathway. No additional referral by the GP is required. The patient has confirmed receipt of the patient information leaflet. For any queries, please email: ubonhrt@uhd.nhs.uk

APPENDIX 7: Fast-track signposting letter to GPs

Download: [Draft sign-posting letter to GPs]