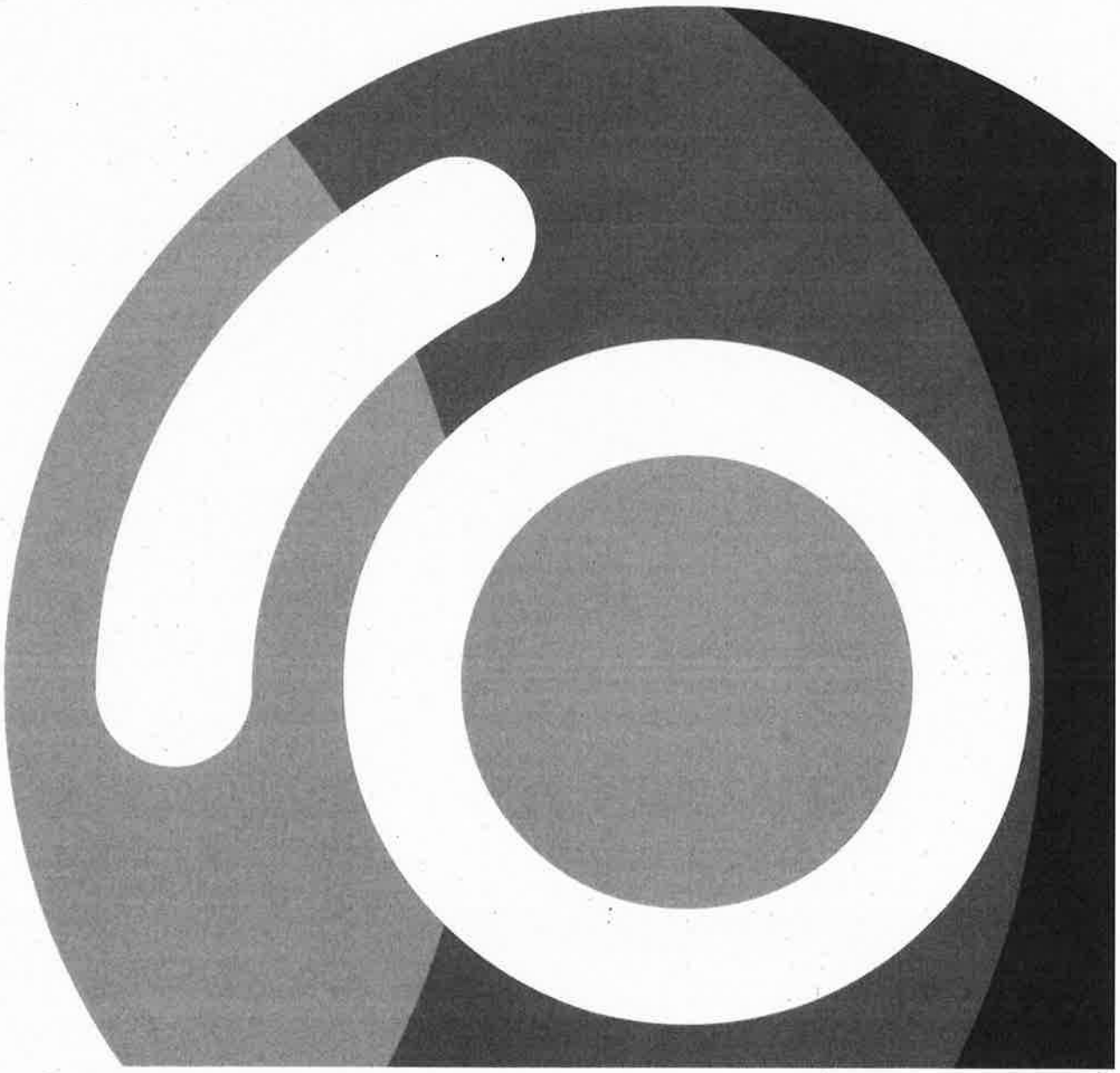
Royal College of Obstetricians & Gynaecologists

REPORT

Review of Gynaecological Services at the University Hospitals of North Midlands NHS Trust.

On 27–28 February 2019



Undertaken by:

Mr Paul L Wood MD FRCOG
Professor Linda Cardozo OBE MD FRCOG
Ms Linda Pepper

On behalf of
Royal College of Obstetricians and Gynaecologists
27 Sussex Place
Regent's Park
London NW1 4RG
Tel: +44 (0)20 7772 6200
Website: www.rcog.org.uk
Registered charity no. 213280

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1. EXECUTIVE SUMMARY

The Royal College of Obstetricians and Gynaecologists (RCOG) was commissioned to undertake an external review to investigate the care provided by the University Hospitals of North Midlands (UHNM) NHS Trust in gynaecology.

The Medical Director contacted the RCOG in 2018 to commission the review in response to the following:

- An anonymous letter from a worried employee in respect of the number of surgical complications relating to an individual consultant in the gynaecology department, herewith referred to as the 'named consultant'.
- Concerns raised by other specialties (colorectal and urology) about morbidity rates in gynaecology.
- RCOG benign gynaecology indicators report suggesting higher than average readmission rates after laparoscopic hysterectomy.
- Getting It Right First Time (GIRFT) data suggesting higher than average readmission rates after hysterectomy for benign disease.

The review took place on 27–28 February 2019 at the Royal Stoke University Hospital.

The assessors found that based on the information made available to them the basis for the anonymous letter was unfounded. The assessors were therefore able to reassure the Trust accordingly.

Morbidity rates were compounded by the manner in which postoperative reattendance and readmission rates were being managed and coded; often readmission was not required on clinical grounds. Surgeons with lower workloads appeared to have a disproportionate number of readmissions and concerns were raised over the undertaking of major gynaecological surgery at the County Hospital site, often by more junior consultants without the support of the facilities available at the Royal Stoke University Hospital.

The Trust is a national outlier for hysterectomy rates and this needs to be explored and addressed, thereby potentially freeing up resources to be able to streamline the gynaecology surgical service and provide safer surgery.

There was a lack of engagement by medical staff in gynaecology services with regards to adverse incident reporting and this needs to be addressed. Once adverse and serious incidents were logged these were managed efficiently and to a high standard with appropriate action plans and fulfilment of the duty of candour. Patient and public involvement was robust.

The assessors made recommendations relating to the high hysterectomy rate at the Trust, surgical workload, teambuilding, leadership, consolidation of the endometriosis service and adverse incident reporting.

2. INTRODUCTION

This review has been commissioned by the Medical Director at UHNM in order to assess the gynaecology services at the Trust. The report is based on information provided by the Trust and on interviews undertaken during the visit.

The Medical Director, at Royal Stoke University Hospital (UHNM NHS Trust) contacted the RCOG with concerns over patient safety including suspected higher than average readmission rates after laparoscopic hysterectomy, higher than average readmission rates after hysterectomy for benign disease, comments on morbidity rates in gynaecology made by consultants from other specialties, and by an anonymous letter referring to surgical complications. Gynaecology services were considered by the Trust to be high achieving and safe with a good reputation.

The assessors were asked to review gynaecological practice, with an emphasis on patient safety, leadership, incident reporting and management, provision of services, team behaviours, morbidity rates over a 12-month period, and risk management, identifying areas of good practice and make relevant recommendations.

The assessors visited the Trust on 27–28 February (see Appendix I for timetable) and were based solely at Royal Stoke University Hospital.

Interviews were conducted with members of staff as detailed in Appendix I. The assessors were unable to interview the Chief Nurse individually, for reasons out of the assessors' control, and the Chief Nurse was also unable to attend the feedback session at the end of the visit.

The assessors requested specific information and data from the Trust prior to the review (see Appendix II).

Additional information obtained on site included:

- Gynaecology clinical incidents between 1 January and 31 December 2018
- Audit of Datix completion for unexpected gynaecology readmissions after surgery
- PowerPoint presentation on GIRFT at the UHNM
- Readmissions for the surgeon with the highest readmission rate
- Safety alert for vaginal pack
- List of audits performed by the gynaecology department 2017–19
- Lessons learned from gynaecology clinical incidents
- Memo to staff – gynaecology readmissions – return to theatre – intraoperative injuries, dated 9 January 2018
- Minutes of a meeting to review laparoscopic injuries, 11 December 2017
- Exclusion criteria for County Hospital (undated)
- Obstetrics and gynaecology rota, February 2019

3. TERMS OF REFERENCE

1. To review gynaecology practice at UHNM in the context of patient safety and to identify any concerns that may prevent staff raising patient safety concerns within the Trust.

2. To assess if services are well led and the culture supports learning and improvement following incidents.

3. To review the current provision of gynaecology services in relation to national standards, published data and comparable indicators.

4. To establish facts and determine any evidence to substantiate or refute any criticisms or concerns raised by staff to the practice of individual consultants and as a department as a whole.

5. To assess professional relationships, behaviours, team interactions, communication, attitudes, conduct and their potential impact on patients' safety and outcomes.

6. To review morbidity rates over a 12-month period for:

   - Unplanned readmissions within 28 days of an operative procedure
   - Return to theatre – within 1 week following surgery
   - Unexpected injuries sustained at operative procedure: ureteric/bowel/vascular.

7. Review the risk management process in relation to adverse event reporting, including feedback from incidents, complaints and claims.

8. To identify areas of good practice.

9. To make recommendations to the Trust based on the Review Team's findings and anything else that comes to light.

4. CONTEXT

The Directorate of Obstetrics and Gynaecology at UHNM NHS Trust includes 22 consultants. Of these, 15 perform gynaecological surgical procedures. Following a merger between County Hospital and Royal Stoke University Hospital (18 miles apart) in 2014, gynaecological surgery takes place at both hospitals, with the majority of cases being undertaken at the latter. It would appear that the initial proposal to limit gynaecological surgery to day cases at County Hospital has been superseded by the introduction of inpatient cases at both sites, although this approach has not been adopted by other specialties such as urology, where major cases are restricted to Royal Stoke University Hospital. The assessors were advised that the decision as to where the gynaecological surgery for individual cases took place had been delegated to individual departments.

The Trust offers a wide range of surgical procedures with a high proportion of minimal access surgery (traditional laparoscopic and robotic using the Da Vinci system). The Directorate provides gynaecological oncology, urogynaecology and complex endometriosis services, being a recognised endometriosis centre. There are approximately 1100 elective surgical procedures each year of which approximately 60% are hysterectomies (this represents a high rate and is explored under ToR 3).

A Care Quality Commission (CQC) routine inspection in 2015 reported that there was no dedicated gynaecological ward, and that women were cared for on a surgical ward. There was capacity for six to nine gynaecology patients, but the management team said that at least 11 beds were needed. Women could not be cared for in one area, were spread across the ward, and plans for a women's hospital were in their infancy. A Trust Board action plan report responding to the CQC indicated that longer term the Trust planned to develop a dedicated women's hospital.

The assessors were asked to provide a sound unbiased review of the gynaecological services over a 12-month period (1 January–31 December 2018) in the context of patient safety and identify any relevant concerns.

Directorate of obstetrics and gynaecology

The Directorate has a budget of £27 million per annum and employs approximately 347 WTE staff.

The Maternity Centre at Royal Stoke University Hospital currently has approximately 6500 births per annum, with an adjacent regional tertiary referral centre Level 3 Neonatal Unit, Feto-maternal Unit and Early Pregnancy Unit. There is a Women's Health Centre located at County Hospital which houses a midwifery birthing centre, antenatal, postnatal and gynaecological clinics, as well as a diagnostic ambulatory unit.

The Directorate provides elective and emergency inpatient, outpatient and ambulatory care for women of North Staffordshire and the surrounding areas, who are referred with either gynaecological problems or are pregnant. Gynaecology inpatients at the Royal Stoke University Hospital are cared for on a female gynaecology and urology ward, with the majority of women seen as outpatients in the Surgical Clinic within the main hospital. Clinics and surgical lists are also provided at County Hospital.

The consultant medical workforce of 22 is supported by a team of trainee doctors, Advanced Nurse Practitioners (ANP) and Clinical Nurse Specialists (CNS).

Directorate structure

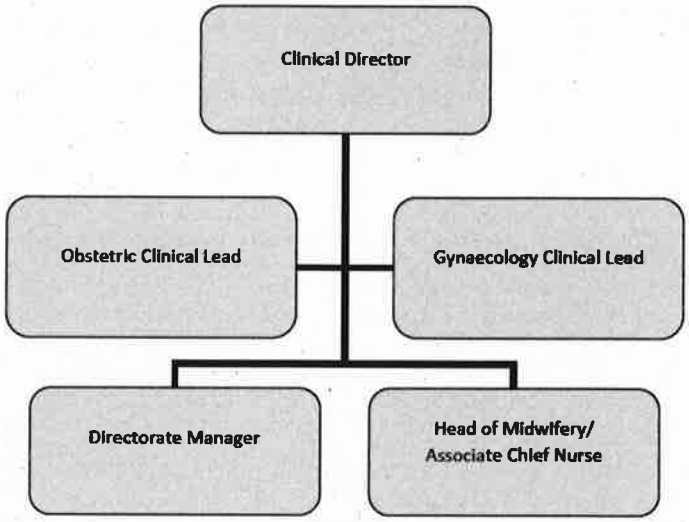


Figure 1: This Directorate structure was implemented in 2010 as part of the Trust-wide management restructure.

Gynaecology

General gynaecology

The Trust is able to offer all appropriate treatments and accept tertiary referrals for some conditions. They offer services in the community and are looking to expand this presence in the local community.

Early Pregnancy Unit

This is a nurse-led service for women experiencing problems in early pregnancy, e.g. threatened miscarriage at less than 16 weeks of gestation. Women may attend the department on a number of occasions over the period of a few days for repeat investigations/scans.

Colposcopy

Consultant and ANP-led service following abnormal smear results or ongoing follow-up which receives approximately 4500 referrals per annum.

Gynaecological oncology

The current team is comprised of five consultants who provide a specialist service for gynaecological cancers including outpatient, diagnostic and operative treatment. The team is further supported by three CNSs, who provide advice, counselling and support to women throughout their treatment. The

consultant body are able to offer a full portfolio of surgical options, including laparoscopic and robotic. The gynaecology oncology service receives over 2000 referrals per annum, with an average of 254 treatments completed, 181 of which are surgical.

Endometriosis

UHNM NHS Trust is a recognised, accredited centre for endometriosis. The centre manages deep infiltrating endometriosis cases and receives referrals from all over the region. The team encompasses two gynaecological surgeons, colorectal surgeons, urologists, pain specialists and endometriosis specialist nurses. There are no CNSs for endometriosis.

Urogynaecology

Specialist consultant and nurse-led service for the investigation and treatment of female continence problems. The team works closely with specialist physiotherapists in the hospital and the community, and colorectal and urology colleagues.

Ambulatory gynaecology

This service supports the Trust's objective of reducing length of stay and has converted traditionally inpatient and day case general anaesthetic procedures into ambulatory cases under local anaesthetic.

Paediatric gynaecology

The Trust offers an outpatient general gynaecology service for children under the age of 16, with input from a consultant paediatrician.

5. GENERAL FINDINGS

ToR 1: To review gynaecology practice at UHNM in the context of patient safety and to identify any concerns that may prevent staff raising patient safety concerns within the Trust.

The assessors did not identify any concerns over the surgical ability of those consultants reviewed. In fact, the overwhelming message from the staff interviewed was that they had implicit trust in the ability of the consultants' surgical skills and would have no hesitation in undergoing major surgery at the Trust under their care.

Consultants from other disciplines (colorectal surgery, anaesthetics, urology) explained how they had no concerns over the gynaecological surgical skills or judgement with respect to each other's responsibilities, being unaware why such concerns might have been raised in the first place.

The colorectal and urology surgeons and anaesthetists considered the consultant gynaecologists to be safe, and the surgeons added that they were called to help appropriately by the gynaecology consultants. The gynaecology team were described as 'really good' and not dysfunctional. The consultants from other disciplines felt that their views reflected those of the general staff and that conflict between the consultant gynaecologists was not evident. Nursing staff described the

gynaecology consultants as supportive and had no recognition of the criticism in the letter. The Clinical Director confirmed that there had been no concerns registered by junior or middle grade medical staff, nursing staff or theatre staff.

The Trust deals with the more complex challenging gynaecological major cases, not only as a consequence of its gynaecology oncology service, but also because it is an accredited endometriosis centre. Review of intraoperative injuries registered in 2018 reveal appropriate multidisciplinary involvement and a spread of surgeons, with no trend in injuries. The urology view was that there were not as many ureteric injuries as might otherwise have been expected for the size of the unit and the number of operations performed.

The major surgical complication rates as reviewed are considered to be acceptable, although they appear to be higher proportionately at the County Hospital where fewer major (and ostensibly lower risk) cases are performed. There are gynaecology surgical lists at the County Hospital on Tuesdays and Thursdays, with review by the visiting registrar or consultant the following day. There was some pooling of lists. The assessors noted that two of the most junior and least experienced consultants had been allocated surgical lists at County Hospital to include major cases, without the back-up facilities available at Royal Stoke University Hospital. The more junior consultants felt that they had been thrown in at the deep end at County Hospital when appointed. Theatre staff at County Hospital felt there was a lack of back-up at the unit both in terms of staff and facilities.

The documentation reviewed by the assessors included a document entitled 'Exclusion criteria for County Hospital', but this was undated with no authorship and seems to be limited to anaesthetic concerns which in the event do not appear to be upheld (e.g. obesity).

There is no middle grade resident cover for gynaecology at County Hospital, with overnight cover by a junior doctor, such as a Foundation Year doctor, Year 2 trainee or General Practice trainee. It was apparent to the assessors that senior clinical management in the Directorate were not particularly acquainted with the workload and events at County Hospital and were less than optimally involved, where it was admitted "there was not a huge handle on the County". There was a perception that staff were used to a culture of not having continuity of care.

The service might improve with greater managerial involvement at County Hospital and more senior level out-of-hours cover. However, this would not change the fact there is often no urologist or coloproctologist available when the gynaecology operating lists are being conducted. In addition, if there are complications encountered during or following surgery at County Hospital the patient has to be transferred by ambulance to Royal Stoke University Hospital, which can incur considerable delay.

The assessors have not identified any concerns that may prevent staff raising patient safety concerns within the Trust.

The policies adopted by the Trust including whistle-blowing are sound and the fact that an anonymous letter was sent to various individuals does not detract from the established pathway which should have been followed by the author(s) of that letter. It is noteworthy that not all were aware of the existence of support advisers provided by the Trust to help individuals.

ToR 2: To assess if services are well led and the culture supports learning and improvement following incidents.

The assessors perceived a lack of strong decisive leadership in the gynaecology department, influenced by a desire to pacify individuals and avoid confrontation; although the Clinical Director was held in high regard generally, potentially reflecting a general desire to please.

The dignity at work policy was of the required standard as were the policies on grievance and disputes, risk management, handling complaints and concerns, duty of candour and procedures for raising concerns at work.

There was a clear learning and improvement culture following adverse and serious incidents. The assessors reviewed examples of both at the time of the visit and were satisfied that the necessary responses are being effected.

Board meetings held in public have agendas and relevant papers available on the website; agendas include patient stories and opportunity for the public to ask questions.

Example of learning through feedback:

- Retained vaginal pack readmission with bleeding following routine surgery: two packs inserted only one pack removed
    - Verbal requirements for the investigation met, written being completed
    - Root cause analysis (RCA) leads identified
    - 72 hour brief completed and draft circulated for Directorate comments.

The assessors noted that this had not been logged as a Never Event. The Trust explained that this had not been logged since the pack had been left in the vagina intentionally and therefore did not constitute a Never Event[1] by definition. The assessors noted that the Trust policy for reporting and management of incidents was sound regardless of this, the responses to this incident were appropriate and adopted following provision of external advice.

The alert issued below by the Trust exemplifies the actions taken.

Issue:
Practitioners are not always reviewing the operative notes prior to removal of the pack. In one incident, two vaginal packs were inserted and only one was removed. In a similar case where two packs were inserted it was alleged by the patient that only one was removed.

Risk/implications to the patient:
While retained vaginal packs are not a Never Event they are serious incidents with the potential to cause sepsis and ongoing morbidity to the patient.

[1] https://improvement.nhs.uk/resources/never-events-policy-and-framework/

Action required:

- Operating surgeon to clearly detail in the notes the type of pack, i.e. gauze swab or ribbon gauze, and how many packs have been inserted.
- If two packs are inserted these must be tied together.
- Attach a yellow wristband to the patient to alert the practitioner and patient that a pack is in situ. If two packs have been inserted, two wristbands will be used. These will remain on until the pack/packs are removed. Please note that no patient identifiable data needs to be added to the wristband.
- The patient must be informed of the number of packs inserted and that these will need to be removed before discharge, this must be documented.
- Two practitioners must confirm and document the removal of the pack/packs, i.e. two person signature.
- If two packs have been removed the documentation must clearly state two packs removed. Please do not state 'packs removed' as this statement is ambiguous.
- UHNM NHS Trust to review and amend the relevant guidance: Policy C04 Ensuring the safety of Patient Undergoing Surgical Interventions and Policy C07 Policy and Procedure for Ensuring the Removal of Swabs, Needles and Instruments from Patients.
- UHNM NHS Trust to develop a Local Safety Standards for Invasive Procedures (LocSSIP) for the insertion and removal of vaginal packs.

The assessors were impressed with the extent of patient and public involvement. Information on the Trust website for 'Patients and Visitors' is friendly and comprehensive, including detailed information on making a formal complaint, the Patient Advice and Liaison Service (PALS), and the two independent complaints advocacy services. The information provided includes details of how to get involved in the Trust in different ways, e.g. as a volunteer. The PALS offices are open to the public on both hospital sites.

The Trust has a patient experience and involvement strategy (Proud to Care 2017–20) aimed at supporting all levels of staff to involve patients and recognise the benefits in doing so.

The patient information leaflets were generally to the required standard. Leaflets are written internally, with input from patients commenting on drafts via a Patient Information Ratification Group.

The leaflet for robotic surgery, which was due for review in February 2018, requires redrafting as it contains unnecessary bias, e.g. advising women that the alternative to robotic surgery was a midline abdominal incision when this is patently not the case. The same leaflet adds that "*Laparoscopic surgery is similar to robotic surgery in that it can be performed through small cuts in and around the area of your tummy however it does not have the additional benefit of the camera that would make it easier to see the operating site*" a statement that requires redrafting.

Other leaflets such as that on laparoscopic subtotal hysterectomy are comprehensive and responsive. "*You may have seen articles in the press about Laparoscopic Subtotal Hysterectomy and the risk that it may spread an undetected uterine cancer within the abdominal cavity. While in theory this may be possible and has been the subject of close scrutiny by many organisations such as the Royal College of Obstetricians and Gynaecologists and the European Society for Gynaecological Endoscopy. The*

conclusion is that Laparoscopic Subtotal Hysterectomy is a safe procedure". The leaflet however fails to mention or quote the risk of cyclical bleeding despite a subtotal hysterectomy.

ToR 3: To review the current provision of gynaecology in relation to national standards, published data and comparable indicators.

The consultant surgical workload varies considerably between individuals. Nine consultants operate exclusively at Royal Stoke University Hospital varying between 0.25–1 lists per week. Another consultant had 2.5 lists per week at both sites. Three other consultants operate at both sites (0.75–1.625 lists per week). Two consultants operate exclusively at County Hospital (0.5-1.25 lists per week). The Hospital Episode Statistics (HES) has identified UHNM as being an outlier for hysterectomy procedures, being ranked 132/137 Trusts. Staff generally were unaware of this finding.

The Trust's hysterectomy rates are not acceptable, especially total laparoscopic hysterectomy for benign disease, or in the absence of pathology (to be audited by the Trust).

Table 1: Number of hysterectomy procedures: HES Apr 2014–Mar 2016

Intervention	UHNM	England	
Total Number of hysterectomy procedures: HES Apr 2014–Mar 2016	**846**	**456**	**132/137**
Open abdominal: total HES Apr 2014–Mar 2016	252	174	112/137
Open abdominal: subtotal HES Apr 2014–Mar 2016	16	29	40/137
Open abdominal: conversion from laparoscopic HES Apr 2014–Mar 2016	0	0	1/137
Open abdominal: other HES Apr 2014–Mar 2016	0	2	1/137
Laparoscopic abdominal: total HES Apr 2014–Mar 2016	**297**	**73**	**134/137**
Laparoscopic abdominal: sub-total HES Apr 2014–Mar 2016	24	11	116/137
Laparoscopic abdominal: Other HES Apr 2014–Mar 2016	3	1	114/137
Laparoscopic-assisted vaginal: HES Apr 2014–Mar 2016:	103	36	133/137
Vaginal: HES Apr 2014–Mar 2016	151	128	92/137

This level of major intervention extends to hysterectomies performed for cases other than for malignancy, and the ranking does not reflect the gynaecology oncology workload.

Comments were made by members of staff that at hysterectomy the uterus often looked normal and queried why it was being removed.

The extent and impact of this high outlier rate of hysterectomy for benign disease does not appear to have been addressed by gynaecology services in any meaningful way, and should be seen in the context of the NICE Guidelines on heavy menstrual bleeding[2] and the alternative management options available. There was an inference from staff that women generally refused alternative options and the rates reflected patient demand, also that the legacy of work into premenstrual syndrome in the department might also be linked. Feedback from staff included a feeling that the use of a progestogen-releasing intrauterine system and outpatient endometrial ablation was not being given the support

[2] Heavy menstrual bleeding: assessment and management NICE guideline [NG88]

needed and indeed was being cut back. This might entail a change in culture at patient and clinician levels. The assessors believe that organisational change for safety should be the driver rather than perceived or real local attitudes in respect of more local access for provision of care as some patients refuse to be seen at an alternative site.

The total numbers of hysterectomies inevitably impacts on both risk management and bed occupancy, and a reasonable reduction in hysterectomy rates for benign conditions should open up opportunities to enable County Hospital to operate solely on planned day cases, thereby addressing a potential risk management issue with major surgery being undertaken away from Royal Stoke University Hospital.

Feedback from the nursing staff was that there was no proper postoperative advice, either verbal or written, given by the ward and that women's health appeared to be undervalued.

The assessors acknowledge the heavy workload relating to endometriosis (including referrals external to the Trust) and the relative lack of nursing expertise. The assessors were advised by other specialty consultants that the multidisciplinary team (MDT) worked well and was functioning (despite the interpersonal conflicts identified separately, see ToR 5). The MDT terms of reference were reviewed noting its establishment in 2014 and inclusion of an ANP. The terms of reference are appropriate and sufficient. The impression was that the department was getting busier with more cases of endometriosis and more complex cases. The Clinical Director has never attended an endometriosis MDT meeting and might benefit from doing so, in order to acquaint themselves with the way the MDT interacts between consultants and specialties, especially given the apparent significant personality issues that have been identified between the consultants running the endometriosis centre (see ToR 5). This needs to be addressed by the Clinical Director for the gynaecology services across both hospitals to be cohesive and successful.

ToR 4: To establish facts and determine any evidence to substantiate or refute any criticisms or concerns raised by staff to the practice of individual consultants and as a department as a whole.

The assessors explored the background to the letter and questioned individuals directly about its content. [redacted]. The letter is grammatically poor, yet two consultants described the letter as being well written with a good command of English, which was clearly not the case; whether written in this style was deliberate or not is a matter of conjecture. The author(s) referred to a log of concerns which would be raised when there was an enquiry – no such information proved to be forthcoming to the assessors during the visit despite the staff having been advised that a review was taking place. The assessors attempted to establish the facts and concluded there was significant conflicting evidence involving various consultants so as to question the reliability of the letter. There were significant direct contradictions between individuals as to who had seen the letter and who had not, with some nursing staff under pressure not to reveal the names of those who had admitted to seeing the letter. It was not possible to conflate or triangulate information sufficiently to establish the authorship of the letter, other than to state that the author(s) had previously raised concerns and those who had previously raised concerns numbered no more than two to three individuals. Upon receipt of a concern there was an immediate escalation by a consultant from another specialty about one of the cases. Those interviewed denied they had been complicit in the preparation or distribution of the letter. There was a view that the individual had been targeted deliberately. The assessors concluded that on balance the letter was nefarious and was unfounded based on the clinical allegations, and has proved to be disruptive, upsetting and costly to the Trust; it

could have been managed internally based on factual evaluation of data already available, although the assessors appreciated the Trust's desire for an objective external review of the gynaecology service based on this and other concerns.

Following an initial concern raised by a consultant gynaecologist and consultant surgeon about one case involving bowel injury, there had been a review of laparoscopic injuries with the 'named consultant' and a meeting in December 2017. The 'named consultant' produced theatre diary evidence which appears to have been accepted by the Clinical Director involving [redacted] from April 2016–December 2017. There had been five major complications which equated to a complication rate of less than 1.3% (adding that the Finnish database by Harkki-Siren quoted a major complication rate of 2.3% for laparoscopic procedures). Review of Datix (incident reporting system) had identified a range of surgical complications with all surgeons undertaking major surgery. Under-reporting was acknowledged, but with no trend indicating concerns over the 'named consultant'. [redacted] raised, [redacted]

As a result of the letter, the Trust Board minutes for December 2018 indicate it was agreed to set up a Taskforce with another Trust and the Clinical Commissioning Group to establish the actions required, but the Clinical Director was unaware of this and no further information was made available to the assessors.

The assessors have not identified evidence to substantiate concerns over the clinical practice of individual consultants.

ToR 5: To assess professional relationships, behaviours, team interactions, communication, attitudes, conduct and their potential impact on patients' safety and outcomes.

The assessors identified areas of concern with regards to the above. The Lead Assessor had previously been advised that there were some dysfunctional relationships between gynaecologists. This appears to have worsened with time, given the increase in numbers of doctors and the merger between the two hospitals.

Despite reassurances from some staff that the atmosphere in the operating theatre was satisfactory and the lists were popular, there were behaviours in theatres observed with individual consultants that was reported to the assessors. One example given was the extensive and intrusive use of mobile phones in theatre with one individual consultant de-scrubbing to take a call at County Hospital. One member of theatre staff did express some concerns about decision-making, conduct and distractions in theatre, but generally the atmosphere was described as good on the whole with good rapport with the consultants.

There appear to be strong personalities in the theatre staff and this has had an impact on rostering by avoidance of allocated shifts with some senior nursing staff and individual consultants. [redacted]

There are personality clashes at consultant level within the endometriosis team as evidenced by triangulation during interviews.

Crucially the assessors concluded that there was a lack of declared insight and obstacles to reconciliation.

[redacted]

At a wider level the assessors identified a general lack of engagement with the challenges facing the department by the wider gynaecological consultant staff.

The interpersonal strife within the department (described as "toxic") requires early intervention and resolution in order to allow the services to develop and provide the best care to patients. Teambuilding is advised at nursing and consultant levels but this will prove difficult if there is no shift in the fundamental attitudes of the relevant consultant staff to whom this applies. Engagement by and with the general gynaecology consultant staff is also required with due recognition of accountability to risk management and team working.

ToR 6: To review morbidity rates over a 12 month period

- **Unplanned readmissions within 28 days of an operative procedure**
- **Return to theatre – within 1 week following surgery**
- **Unexpected injuries sustained at operative procedure: ureteric/bowel/ vascular.**

Data from April 2015-March 2016 identified a 14% readmission rate for total laparoscopic hysterectomy. Between November 2017 and October 2018, 15 consultants performed 614 hysterectomies, with an additional 46 readmissions, producing a 7.5% mean rate of readmission. These high levels manifest in the GIRFT data (see below), but these need to be seen in the context of classification and coding of these readmissions as explored elsewhere within this report.

Review of the readmissions per consultant in the calendar year 2018 reveals a total unplanned readmission rate averaging approximately 6.4%. One consultant was recorded as having an unplanned readmission rate of 10.66%, yet this consultant was not the one referred to in the anonymous letter as having a worrying complication rate (the 'named consultant' in the letter had a readmission rate of 5.6%).

Table 2: Readmission count/unique patient by consultant 2018

*NB. This includes additional transient (locum) consultant staff.

2018	Grand total	Readmission rate (%)
Clinician		
A	18/232	7.75
B*	1/6	–
C	16/228	7
D	18/379	4.7
E	18/321	5.6
F	4/69	5.7
G	12/151	7.9
H	9/143	6.2
I*	1/1	–
J	7/210	3.3
K	29/272	10.66
E/K – Either unspecified	4/29	13.7
L	3/65	4.6
M	12/202	5.9
N	12/213	5.6
O	14/191	7.3
P	9/109	8.2
Q	12/257	4.6
R	3/35	8.5
Total	**202/3147**	**6.4**

Table 3: Admission rates to intensive care per consultant 2018

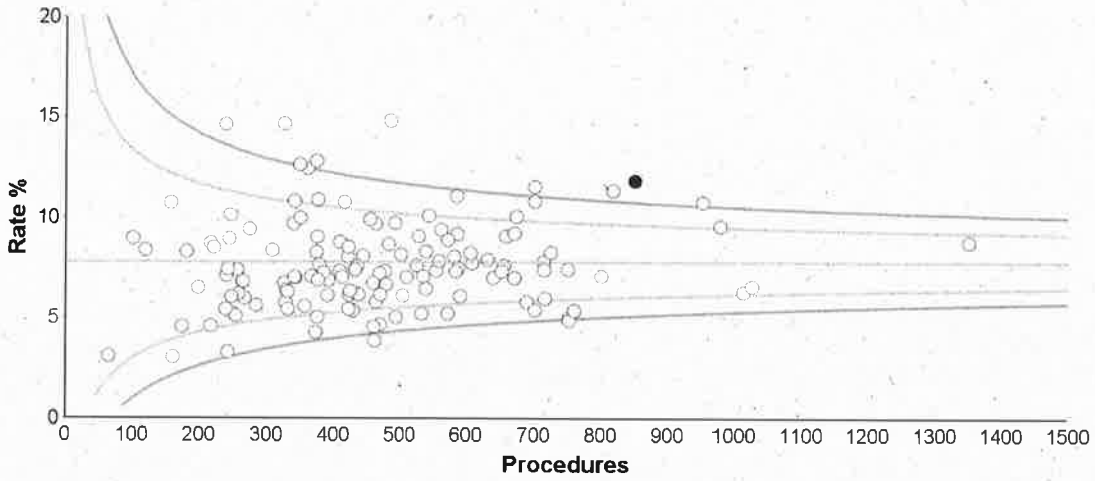
Clinician	Admissions to ITU 2018
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

No pattern was established for any particular consultant in respect of admissions to the Intensive Care Unit following gynaecological surgery.

GIRFT

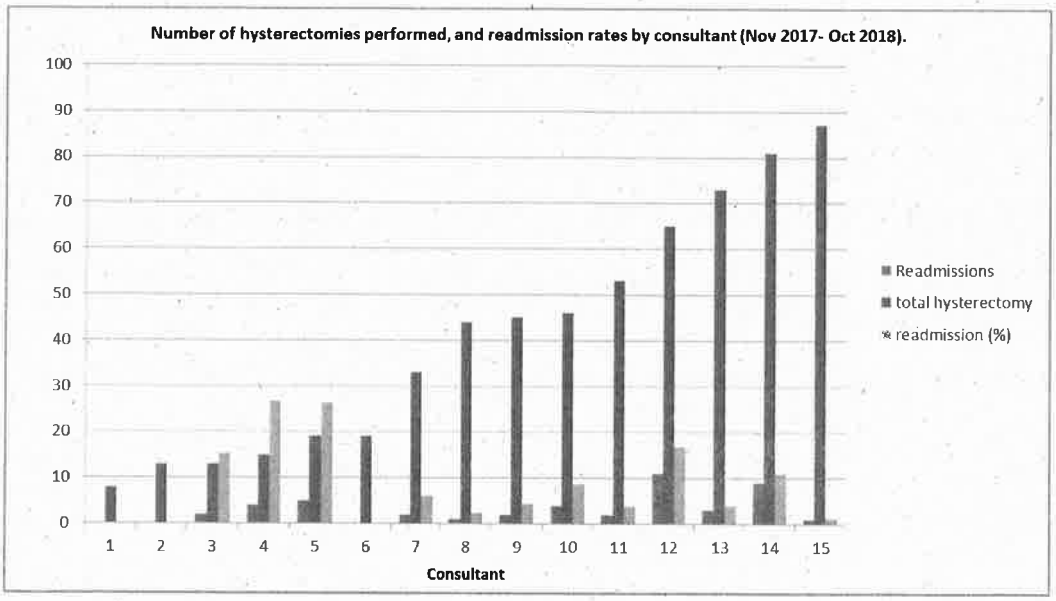
The GIRFT data highlight that the Trust is an outlier for emergency readmissions for hysterectomies, yet this is not manifested in the total number of cases for malignancy and reflects an increased readmission rate for benign hysterectomy.

Figure 2: All cause emergency readmission within 30 days of discharge date (all hysterectomies); HES Jan 2014–Dec 2015 (benign conditions)



The overall number of registered readmissions for hysterectomies per consultant regardless of severity has been tabulated below and reveals that those performing fewer hysterectomies generally had higher readmission rates over a 12-month period.

Figure 3: Number of hysterectomies performed and readmission rates by consultant (Nov 2017–Oct 2018)



Review of the readmissions proved valuable in establishing the extent and nature of this issue. It transpires that if a woman attends for a review it is classified as a readmission even if formal admission is not required. A majority of attendances were for minor issues which should not have resulted in the case being classified as warranting actual readmission. The extent of readmissions therefore needs to be seen in the context of the data accrued below.

An audit of readmissions involved 46 patients and 52 readmissions, many of whom no cause for the readmission was established or the patient's symptoms settled without additional treatment.

[redacted]

The Trust's own audit on readmission identified 14.3% cases relating to pain and 13.28% relating to bleeding, with other reasons including suspected thromboembolic disease, infection, constipation and seroma among others; 17.36% of readmissions required reassurance only, another 17.36% were given antibiotics.

Data from the department's audit on Datix completion identified that 80% of readmissions were within 15 days post-operatively. All of this needs to be analysed in the context of triage, management, classification and coding in order to ensure accurate data.

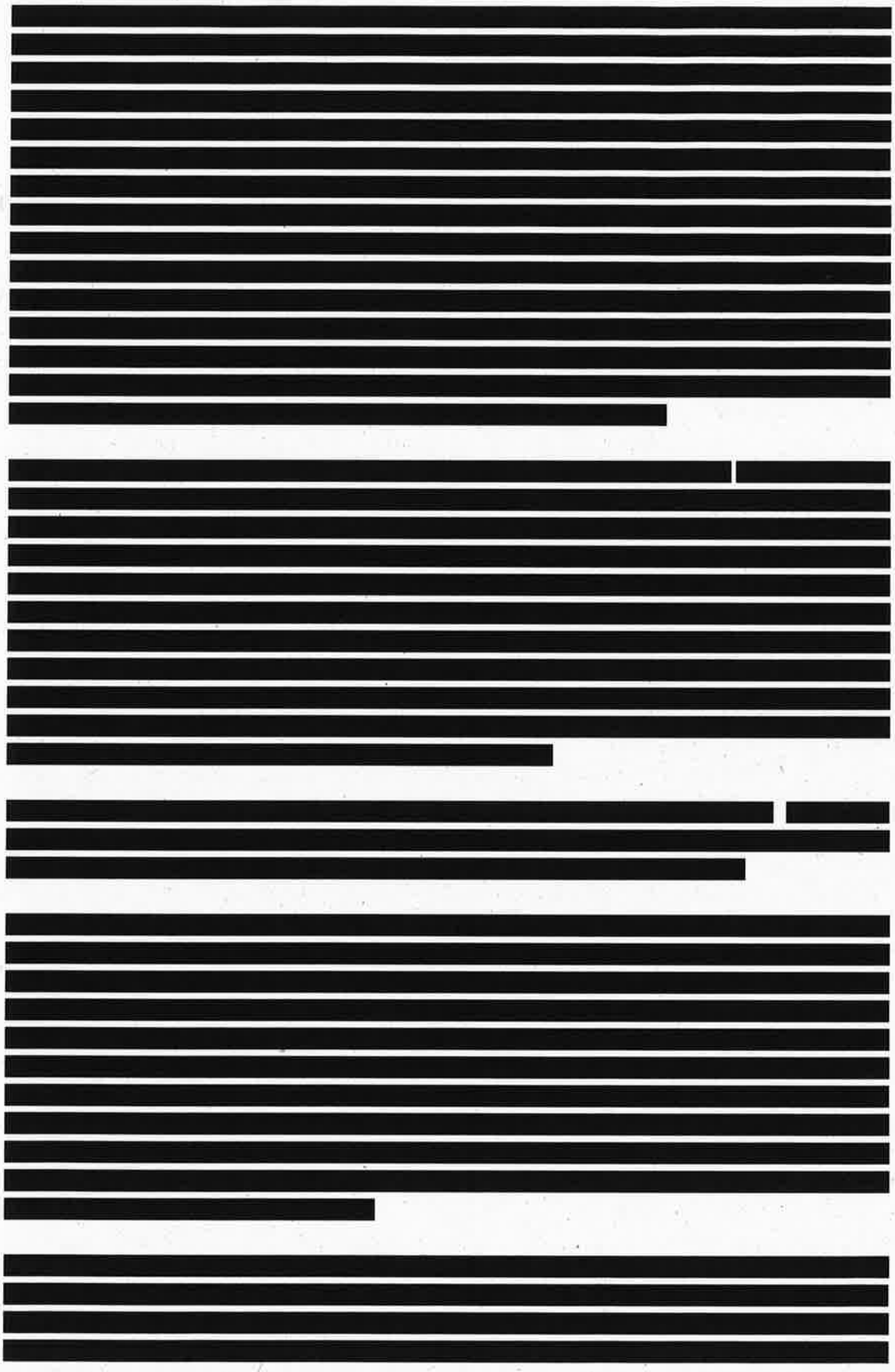
ToR 7: Review the risk management process in relation to adverse event reporting, including feedback from incidents complaints and claims.

The Directorate clinical governance reports, incident and complaints notifications and the quality and risk newsletters were of a high standard.

A total of 10 root cause analyses were reviewed by the assessors. Overall these were investigated to a good standard and reflected a sound risk management process once triggered.

1. A[redacted]

[redacted]



[redacted]

[redacted]

There were examples of positive patient experiences with references to a comprehensive postoperative care advice list and commendations on the skill of the surgeon.

Complaints Handling

Handling of complaints within the gynaecology department at the Trust appears to be of a high standard. The manner in which complaint letters were written meant that it was not possible to determine whether the complaints arose from either the County Hospital or Royal Stoke University Hospitals. The total number of complaints between February 2017 and the end of January 2018 was 76, with a maximum of ten complaints occurring in two of the 12 months.

Review of complaints from 2018 identified that these were actioned appropriately and responded to adequately in cases where the complaints were upheld or otherwise. Most related to clinical and administrative issues not linked to major intraoperative surgical complications.

When a subtotal hysterectomy was abandoned, the patient was advised that if the extent of the endometriosis had been known the case would have been discussed at the endometriosis MDT meeting and joint surgery planned. This example raises the question of major surgery being undertaken at the County Hospital site when unexpected complications arise. Other complaints included a case of ureteric injury at total laparoscopic hysterectomy requiring ureteric re-implantation.

The risk management processes in relation to adverse incident reporting are excellent once a case is investigated and scored highly in all respects including duty of candour and feedback to patients. The assessors had no concerns over the actual risk management process once triggered.

The gynaecology incidents tend to be presented alongside the obstetric risk management cases and analysed together as part of the wider departmental statistics.

There were complaints from some staff that the Datix system was cumbersome but this is part of the system which is widely used throughout the NHS in England. The assessors were advised that measures were being taken by the Trust to try and simplify the reporting system.

The documents reviewed by the assessors included a memorandum sent to all staff dated 9 January 2018 which requested that Datix forms be completed for all gynaecology readmissions following surgery, returns to theatre following an operative procedure and any injuries during operative procedures. Throughout 2017 there had been 23 unexpected readmissions, 6 returns to theatre and 11 injuries during the course of an operation. The memorandum adds that the audit data suggested that there was significant under-reporting.

However a clear pattern emerged during the visit that there continues to be under-reporting of clinical incidents within the gynaecology department; this was evident at all levels including higher levels of responsibility for risk management. The gynaecology risk lead appears to have been appointed in the absence of interest being shown by any other consultant. The assessors consider that the gynaecology

risk lead requires additional support and supervision to be able to fulfil this role to the required standard. Concern has been expressed over their degree of team working and self-reporting of incidents, being described as dismissive and defensive and not leading by example. The latter perhaps reflects a general lack of wider engagement by the consultant body. The assessors noted the due diligence of clinicians in registering lost ID badges on Datix but not significant clinical incidents.

An audit of Datix registrations relating to 47 unexpected readmissions after surgery identified that just one Datix form had been completed out of the 47 cases (98% non-reporting rate). Three patients had a second readmission and no Datix form was completed for any of these. Of these three cases, two related to total laparoscopic hysterectomies and one to an emergency laparoscopic salpingectomy none of which proved to have any significant complications but which should have been reported nonetheless.

ToR 8. To identify areas of good practice.

Clinical governance and patient and public involvement were scored highly by the assessors.

With regard to patient and public involvement, there is a hospital user group (HUG), chaired by the Head of Patient Experience with clear ToRs, which meets monthly on alternate hospital sites. HUG's membership includes patient representatives, local Healthwatch and the Chief Nurse and it reports to the Trust Quality and Safety Forum.

A complaints peer review workshop is held quarterly with patients, to look at redacted complaints and how the complaints process could be improved. It is planned to extend this to include neighbouring Trusts for the purpose of shared learning.

The Patient Experience Team intends to roll out the Patient Experience and Engagement Strategy to all staff through a series of workshops, and there are plans to train Trust volunteers to become patient leaders. These innovations would benefit from resources and support from the wider Trust.

6. RECOMMENDATIONS

The assessors were content that there was no need for the Trust take any immediate action as a result of the visit.

6.1 Review the decision to perform major gynaecological surgery at the County Hospital.

- in order to minimise risk to patients undergoing major surgery.

6.2 Ensure greater managerial involvement at the County Hospital and a more senior level of out of hours cover.

6.3 Review the surgical workload and hospital site of working for each consultant, to maintain competence and safety.

- concentrate on those surgeons with relatively less experience and reduced major operating exposure.
- options could include cessation of those duties (and in some cases on call gynaecology has already ceased with certain individuals) or relocation of their major cases to Royal Stoke University Hospital with or without a buddying system for more experienced consultants to carry out the bulk of the major surgery.

6.4 Undertake a detailed audit of cases with benign conditions leading to hysterectomy with a view to a reduction in the Trust's high hysterectomy rates.

6.5 Consider expansion of outpatient endometrial ablation for heavy menstrual bleeding and allow for high quality day case surgery to be developed at the County Hospital.

6.6 Encourage attendance at the endometriosis MDT meeting by the Clinical Director as this may support more cohesive working

6.7 Consider expanding the specialist nurse coverage to the endometriosis service, with appropriate recognition of the importance of this service to the Trust and the population as a whole.

6.8 Consider reintroducing a designated gynaecology ward or ward area at the Royal Stoke Hospital staffed by nurses with gynaecological experience.

6.9 There needs to be greater leadership in matters relating to staff and workload management within the gynaecology department.

6.10 Undertake teambuilding exercises with nursing and consultant staff as an early intervention and resolution in order to allow the department to develop and provide the best care to patients.

- engagement by and with the general gynaecology consultant staff is also required with due recognition of accountability.
- consider options such as mediation.
- the Clinical Director should attend the endometriosis MDT for an initial period of 12 months.

6.11 Ensure appropriate triage and coding is undertaken for re-attendance after surgery.

- treat as outpatients rather than classifying review of postoperative cases as admissions and not attendance (for triage)
- coding of postoperative reviews should be addressed and rectified.
- improve the quality of care by ensuring appropriate management of patients re-attending after surgery.
- address any access difficulties in primary care for simpler patient concerns.

6.12 Consider introducing morbidity and mortality meetings within gynaecology to highlight complications and their management and improve communication within the department. (Suggestion for it to be every two to three months with the gynaecology risk lead chairing. It should be multidisciplinary to include as many gynaecology consultants as possible, senior nursing staff, pathology/imaging staff and trainees in obstetrics and gynaecology when their timetables permit).

6.13 Improve the recording of clinical incidents and complaints by obstetricians and by gynaecologists and by hospital site.

6.14 Ensure support to enable staff to attend the planned workshops and resources are provided to roll out the Patient Experience and Engagement strategy to all staff.

7. SIGNATURES AND CONFLICTS OF INTERESTS

In formulating and signing this report the assessors confirm that the conclusions and recommendations are based solely on the information provided and on interviews that took place during the assessment visit described. The assessors also certify that they have no prior knowledge of the individuals concerned, and have not worked previously with them. The assessors have no relevant conflicts of interest to declare in respect of these matters.

[redacted]

Mr Paul Wood

Date 20 May 2019

[redacted]

Professor Linda Cardozo

Date 20 May 2019

[redacted]

Ms Linda Pepper

Date 20 May 2019

8. APPENDIX I: Timetable

Time	Description	Venue
08:00	Opening Meeting with Helen Ashley Deputy CEO, Dr John Oxtoby Medical Director and Liz Rix Chief Nurse	**SPRINGFIELD UNIT EXECUTIVE SUITE**
08:30-08:45	GiRFT presentation – Mr Richard Todd (Clinical Director)	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
08:45-09:15	Tour of the Gynaecology Service – Mr Richard Todd	
09:30-09:50	Interview with Mr Timothy Bullen – Consultant Colorectal Surgeon	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
10:00-10:20	Interview with Dr Neville Turner – Associate Specialist Anaesthetics	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
10:30-11:00	Interview with Mr Richard Todd – Clinical Director and Consultant Gynae Oncologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
11:00-11:30	Interview with Liz Rix Chief Nurse - Deferred and not reinstated	**SPRINGFIELD UNIT EXECUTIVE SUITE**
11:30-12:00	Interview with Rosie Smith – ODP, County Hospital Theatres	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
12:00-12:30	Interview with Mr Nitish Raut – Consultant Obstetrician and Gynaecologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
12:30-13:00	Interview with Mr Charles Redman, Consultant Gynaecologist	
13:00-13:30	Interview with Mr Zeiad El-Gizawy – Consultant Obstetrician and Gynaecologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
13:30-13:50	Interview with Miss Sa'ada Usman – Consultant Obstetrician and Gynaecologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
13:50-14:00	BREAK	
14:00-14:20	Interview with Mr Chris Luscombe – Consultant Urologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
14:30-15:00	Interview with Dr Will Parry-Smith – Registrar Obstetrics and Gynaecology	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
15:00-15:30	BREAK	
15:30-16:00	Interview with theatre staff from gynae theatre	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
16:00-16:30	Interview with Mr Anurag Golash – Consultant Urologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**

16:30-17:00	Interview with Sarah Bielby CNS, Lorna Roberts and Paula Hadden ANPs.	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
17:00-17:30	Interview with Miss Fidelma O'Mahony, Consultant Gynaecologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**

Day 2 – Thursday 28th February 2019

Time	Description	Venue
08:30-09:00	Interview with Mrs Sharon Wallis – Head of Midwifery and Lead Nurse for Gynaecology	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
09:00-09:30	Quality, Safety and Risk Team – Mr Jamie Maxwell and Dr Lynn Dudley	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
09:30-09:50	Interview with Mr Lyndon Gommersall – Consultant Urologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
10:00-10:30	Interview with Mr Jason Cooper – Consultant Gynaecologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
10:30-11:00	2nd Group of gynae theatre staff	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
10.30-11.00	Angela Grocott - Head of Patient Experience	
11:00-11:30	Interview with Dr Suman Kadian – Consultant Obstetrician and Gynaecologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
11:30-12:00	Interview with Dr John Oxtoby – Medical Director	**SPRINGFIELD UNIT EXECUTIVE SUITE**
12:00-12:30	Interview with Mr Neil Yeomans – Consultant Colorectal Surgery	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
12:30-13:00	LUNCH	
13:00-13:30	Interview with Mr Kirk Chin – Consultant Gynaecologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
13:30-14:00	Interview with Mr Gourab Misra – Consultant Obstetrician and Gynaecologist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
14:00-14:30	Interview with Dr Andrew Farrell – Consultant Anaesthetist	**RICHARD JOHANSEN ROOM 2, MATERNITY CENTRE**
15:30-16:00	Closing Meeting - with Helen Ashley Deputy CEO, Dr John Oxtoby Medical	**SPRINGFIELD UNIT EXECUTIVE SUITE**

	Director and Richard Todd, Clinical Director	

APPENDIX II: Documents Requested

- Job descriptions of gynaecology consultants
- Management structure and overview for Gynaecology
    - Trust senior management including divisional and board leadership post holders and areas of responsibility.
    - The O&G team structure including management roles,
    - The MDT Core and associate membership
    - The Trust's Governance structure and routes of escalation.
    - Trust Board Strategy paper.
- Information regarding gynaecology services within UHNM
- Relevant guidelines, standard operating procedures, policies
    - The MDT operational policy
    - Guidelines for Risk Management and Incident Reporting
    - Whistleblowing policy
    - Complaints policy
- Electronic access to relevant systems when on site
- Gynaecology related RCAs/Serious Investigations reported
- Incidents reported in Datix (to cover a 12 month period),
- GiRFT report - **Please present a 15 min presentation of the report** at the beginning of the first day
- Workload statistics by surgical gynaecology consultants
- Clinical governance information, e.g. audit reports, critical incident reports, etc. return to theatre within 24 hours, use of blood products, unexpected admission to ITU by individual consultant for the time period in question (January – December 2018). **These must be complete reports in the case of SI's (Sept 2017-Sept 2018 may be more appropriate)**
- Outcome data for surgical treated patients by individual consultants for the time period in question
- minutes of business meetings, for the period in question
    - Gynaecology governance
    - O&G Service meetings
- attendance registers (names and job titles) for MDT meetings for the period in question
- Complaints and all correspondence/litigation in last 5 years
- Any committees meeting minutes where feedback and complaints are discussed
- Service user feedback for the period in question
- Friends and Family feedback for Gynaecology
- Any gynaecology complaints through PALS
- Patient information leaflets for surgical procedures carried out by the O&G team
- Any previous reviews undertaken about the Gynaecology service
- Any other information felt to be appropriate by the Board
- CQC inspection report for UHNM 2015
- 151012 CQC Action Plan – Board summary v.8 7.10.15
- Patient Experience and Involvement Strategy http://www.uhnm.nhs.uk/patientexperience/Documents/181220 Patient Experience Strategy.pdf
- Compliments, Concerns and Complaints, and PALS Leaflets