Letterkenny University Hospital: Review of the Gynaecology Service

With a particular focus on Post-Menopausal Bleeding Pathways

Clinical Service Review Team

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Glossary

Term	Definition
DNA	Did Not Attend
HEB	Hospital Executive Board
HSE	Health Service Executive
LUH	Letterkenny University Hospital
MCAN	Managed Clinical and Academic Network
NCCP	National Cancer Control Programme
NTPF	National Treatment Purchase Fund
Gynaecologist	Obstetrics and Gynaecology is concerned with women's health – before, during and after the reproductive years. Gynaecologists focus on the health of the female reproductive system, including the diagnosis and treatment of disorders and diseases. Obstetricians focus on childbirth, providing prenatal care and pregnancy support along with postpartum care. Combined training in both Obstetrics and Gynaecology is crucial because of the overlap between these specialties.
PMB	Post-Menopausal Bleeding is vaginal bleeding that happens at least 12 months after a woman's period has stopped.
PPPG	Policies, Procedures, Protocols and Guidelines
QPSC	Quality and Patient Safety Committee
SIMT	Serious Incident Management Team
W&C	Women and Children
W&I	Women and Infants

Executive Summary

Introduction

This review of gynaecological services was initiated by the Saolta Chief Clinical Director following a series of incidents over a period of time which related to delays in diagnosing cancer of the endometrium.

Methodology

The purpose of this review was to assess the quality and safety of Letterkenny University Hospital (LUH) Gynaecology Service, with a particular focus on the pathway of care for women presenting with post-menopausal bleeding including subsequent diagnostic pathways for potential gynaecological cancers.

The scope of this review encompassed the Gynaecology Service, and particular focus was placed on the following areas:

- findings from reviews of reported incidents of women who suffered a suspected missed and/or delayed diagnosis of endometrial cancer.
- relevant pathways for women who present to LUH with post-menopausal bleeding, including but not limited to: assessment & triage; onward referral patterns and procedures; follow up of results; referral to gynaecological oncology services; and the management of inpatient and outpatient waiting lists.
- approach to how governance for quality and safety for the gynaecology service is delivered

The approach of this review was to identify areas of good practice, to identify areas for improvement, and to suggest what improvements should be considered by LUH. The Clinical Service Review Team conducted a site visit to LUH on 17th January 2020, and was provided with a wide range of evidence on request.

Findings & Discussion

It is clear that the experience for the women affected by these incidents, and the service provided to them, was unsatisfactory. All cases, in one form or another, are typified by delay. The reasons for which appear to be sub-optimal triage and administrative practices, sub-optimal follow-up practices, and limited fail-safes; underpinned by ineffective communication.

The Post-Menopausal Bleeding Clinic was established in on the 7th December 2018 to address the findings of a report relating to a missed diagnosis of endometrial cancer in the presence of post-menopausal bleeding. While the introduction of the Post-Menopausal Bleeding Clinic is commendable, the processes which support the functioning of the clinic are not sufficiently different than what existed before its introduction, and are heavily reliant on the newly appointed Oncology Liaison Nurse.

LUH is beset with large and worsening waiting lists for both inpatient, day case and outpatient services, and there is evidence that insufficient effort is being made to improve the situation. This is illustrated by high 'Did Not Attend' rates and failure to re-commission the Obstetric Theatre. This has the effect of reducing LUH general theatre access by 25% which significantly impacts on the ability of LUH to provide timely diagnostics and interventions to women in the care of the Gynaecology Service leading to long waiting lists.

While there is evidence of structures and processes in place in relation to the governance for quality and safety of the Gynaecology Service, significant effort is required to improve the robustness of the governance processes which support the governance structures so as to assure patients, and the Hospital Executive Board, that safe, effective and person-centred care is being delivered. LUH, together with Saolta, has put significant efforts into improving their management and response to incidents and serious incidents. This includes regular and ongoing training for frontline staff; and a monthly meeting of the senior medical and midwifery staff to review incidents from the prior month, and to agree and monitor improvement actions. Nevertheless, LUH Gynaecology Service do not have a clinical audit programme to determine their compliance against key policies, procedures and guidelines; do not use a standardised suite of benchmarked, quality indicators against which to monitor their performance; and do not have any formal or informal networking to support learning and sharing of information between the LUH Gynaecology Service and other gynaecology services within the Group.

Conclusion

The Clinical Service Review Team are of the opinion that the recommended actions contained in the body of this report are achievable and, if implemented, will improve clinical outcomes for patients and reduce the risk of delay causing harm to anyone referred to LUH with suspected endometrial cancer.

Recommendations

For each recommendation, there are a number of suggested improvements that the Clinical Service Review Team suggests, that if implemented, would satisfy the relevant recommendation. Please review the body of the report for more information.

1. Letterkenny University Hospital should build capacity in its Post-Menopausal Bleeding Clinic, and build the capability of staff working in the Post-Menopausal Clinic.
2. Letterkenny University Hospital should review their referral and triage system for gynaecology patients which should be robust, with built-in fail-safes and be monitored regularly.
3. Letterkenny University Hospital should build their capacity and capability for inpatient, day case and planned procedures; and should build their capacity and capability for outpatients, both of which should include a review as to how LUH manage their waiting lists.
4. Letterkenny University Hospital Gynaecology Service should review and improve upon their communication processes with service users and service referrers.
5. The Letterkenny University Hospital Women and Infant's Directorate should review its Governance for Quality & Safety structures, and improve the robustness of its Governance for Quality and Safety processes.
6. The LUH Gynaecology Service should undertake a robust and comprehensive self-assessment against the HIQA National Standards for Safer, Better Healthcare, 2012.

Introduction

Letterkenny University Hospital (LUH) is a general hospital which provides a broad range of acute services situated in the North West of Ireland. It provides healthcare services to the people of Donegal on an inpatient, day case, and outpatient basis serving a population of over 161,000. It is a constituent hospital of the Saolta University Health Care Group (Saolta).

This review of gynaecological services was initiated by the Saolta Chief Clinical Director following a series of incidents over a period of time which related to delays in diagnosing cancer of the endometrium. The review will determine how the Gynaecology Service functions with particular focus on pathways for the diagnosis of endometrial cancer.

Methodology

Purpose

The purpose of this review was to assess the quality and safety of Letterkenny University Hospital (LUH) Gynaecology Service, with a particular focus on the pathway of care for women presenting with post-menopausal bleeding including subsequent diagnostic pathways for potential gynaecological cancers.

The Clinical Service Review Team were required to make recommendations to improve the quality and safety of the Gynaecology Service in LUH, if applicable.

The Clinical Service Review Team were also required to comment on, or highlight for further review, any other areas which are outside of the Gynaecology Service in LUH but which impact the quality and safety of its gynaecology service, if applicable.

Governance

The Chief Clinical Director of Saolta University Health Care Group (Saolta) commissioned this review, and together with the Saolta CEO, will be responsible and accountable for its findings and the implementation of its recommendations.

Scope

While the scope of this review encompassed the Gynaecology Service, particular focus was placed on the following areas:

Findings from Incident Reviews

These are findings from reviews of reported incidents of women who suffered a suspected missed and/or delayed diagnosis of endometrial cancer. It is these incidents which triggered this review of the quality and safety of LUH Gynaecology Service, and as such, are a key source of information that guided the Clinical Service Review Team.

Pathways relating to Post-Menopausal Bleeding

The main focus of this review was to assess the relevant pathways of women who present to LUH with post-menopausal bleeding. Key areas included, but were not limited to:

- Assessment & triage of women referred to gynaecological services at LUH with symptoms of post-menopausal bleeding.
- Onward referral patterns and procedures, including timing of further diagnostic procedures such as ultrasound scans, hysteroscopy and endometrial biopsy; follow up of results; and referral to gynaecological oncology services.
- Overview of out-patient and in-patient waiting lists, including the governance of such lists.
- Administrative practices and challenges at interfaces of care relevant to the above points.

Governance for Quality & Safety of the Gynaecology Service

The Clinical Service Review Team sought evidence of the approach to how governance for quality and safety for the Gynaecology Service in LUH is delivered.

Approach

The approach of Clinical Service Review Team to this review was, within the scope described above, to identify areas of good practice, to identify areas for improvement, and to suggest what improvements should be considered by LUH, and Saolta, to improve the quality and safety of the Post-Menopausal Bleeding Pathway specifically, and the Gynaecology Service generally.

Site Visit & Evidence Request

The Clinical Service Review Team conducted a site visit to LUH on 17th January 2020. Prior to the visit, the Clinical Service Review Team requested that information be prepared for inspection and should contain, inter alia, the following:

- Overview of the Gynaecology Service, including an organisational chart of relevant governance groups; and process maps of the complete patient pathway for women who present with post-menopausal bleeding.
- Findings from reviews of reported incidents of suspected missed and/or delayed diagnoses of endometrial cancer.
- Evidence of implementation of recommendations from Incident Review Reference Number: 15142194.
- Relevant policies, procedures, protocols and guidelines (PPPGs) related to the Gynaecology Service, risk management, and governance, including relevant key performance indicators
- Previous self-assessments and audits against relevant gynaecology standards and relevant PPPGs.

The initial site visit comprised three main components: an initial discussion with senior clinical and senior managerial staff; a review of the relevant hospital facilities and an opportunity to speak with frontline staff; and a review meeting with the senior clinical and senior managerial staff to summarise the initial impressions of the Clinical Service Review Team.

A further request for evidence was sent on 2nd March 2020, and a response received on 15th April 2020.

Report

Draft Report: Both senior clinical and senior managerial staff of LUH were given an opportunity to review a draft report for factual accuracy to ensure due process and fair procedures.

Final Report: A final report was sent to the Chief Clinical Director of Saolta University Health Care Group on 8th May, 2020.

Findings

Overview of the Gynaecology Service

Governance

The Letterkenny University Hospital (LUH) Women and Infants (W&I) Directorate, led by an Associate Clinical Director, is accountable for the LUH Gynaecology Service. The Women and Infants Directorate reports into the LUH Hospital Executive Board (HEB).

Service Provision

LUH provides a gynaecology service comprising in-patient, day case and out-patient care. In-patient gynaecology services are provided within a complement of notional beds incorporated into an 11-bedded gynaecology ward, to in-patients on outlier wards, and also consultations on referrals from other teams. Day case patients are typically admitted for the following procedures: Examinations under Anaesthetic (EUA), hysteroscopy, and dilation & curettage (D&C). Each Consultant Gynaecologist has one half-day of theatre time per week, on average. There are four theatres in the main theatre block; three of which are operational for general service and one which is used solely for obstetric emergencies. There is a theatre in the Obstetric Department which has been decommissioned since 2011. There are 4 gynaecology out-patient clinics each week, a Consultant-led outreach clinic each fortnight, and a weekly Post-Menopausal Bleeding Clinic. The number of women waiting to be seen as an in-patient, day case or out-patient is detailed in Figure 1 and Figure 2. At the time of this review, two patients were waiting for an urgent in-patient appointment for 36-48 months. In 2019, the Consultant Clinic 'Did Not Attend' (DNA) rate was 9-29%, though this is not monitored on a regular basis (Figure 3).

Patients with diagnosed gynaecological cancers are referred to St. James's Hospital for a multi-disciplinary assessment to determine their plan of care. LUH do not track how many referrals are sent to St. James's Hospital. No referrals for gynaecological cancer are sent to Galway University Hospital.

Gynaecology Inpatient and Day Services Active Waiting List										
As per Jan 2020	0-3 Months	3-6 Months	6-8 Months	8-12 Months	12-15 Months	15-18 Months	18-24 Months	24-36 Months	36-48 Months	Grand Total
Day Case	**117**	**71**	**26**	**14**	**4**	**2**	**1**			**235**
Routine	12	29	12	9	3	1				66
Urgent	105	42	14	5	1	1	1			169
Inpatient	**31**	**23**	**17**	**15**	**7**	**7**	**9**	**14**	**2**	**125**
Routine	14	12	16	9	1	4	7	7		70
Urgent	17	11	1	6	6	3	2	7	2	55
Grand Total	**148**	**94**	**43**	**29**	**11**	**9**	**10**	**14**	**2**	**360**

Figure 1 Gynaecology Inpatient and Day Service Active Waiting List

Gynaecology Outpatient Active Waiting List											
As per Jan 2020	0-3 Months	3-6 Months	6-9 Months	9-12 Months	12-15 Months	15-18 Months	18-21 Months	21-24 Months	24-36 Months	36-48 Months	Grand Total
Routine	202	77	73	65	70	58	87	69	182	20	903
Urgent	207	103	107	98	105	88	81	39	46		874
Grand Total	**409**	**180**	**180**	**163**	**175**	**146**	**168**	**108**	**228**	**20**	**1777**

Figure 2 Gynaecology Outpatient Active Waiting List

Gynaecology Outpatients: Did Not Attend													
2019	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Grand Total**
Consultant A	18%	24%	24%	13%	15%	20%	19%	17%	19%	11%	18%	12%	17%
Consultant B	19%	11%	20%	23%	20%	11%	22%	29%	20%	19%	12%	14%	19%
Consultant C	11%	15%	20%	13%	17%	14%	22%	23%	13%	16%	17%	17%	16%
Consultant D	18%	9%	16%	15%	20%	18%	16%	16%	11%	20%	14%	10%	16%
Registrar A	7%	2%	0%	0%	13%	9%	4%	4%	6%	1%	1%	7%	4%
Grand Total (%)	**15%**	**13%**	**16%**	**13%**	**17%**	**15%**	**17%**	**18%**	**14%**	**14%**	**13%**	**12%**	**15%**
Grand Total (n)	**53**	**40**	**69**	**52**	**66**	**47**	**67**	**66**	**62**	**51**	**48**	**34**	**655**

Figure 3 Gynaecology Outpatients: Did Not Attend

Staffing

The medical staffing of the Gynaecology Service comprises four Consultant Gynaecologists, one of whom is the Clinical Lead; Senior Registrars; Registrars; and Senior House Officers. All Consultant Gynaecologists are on the Specialist Register of the Irish Medical Council. There is evidence of continuous professional development for the Senior Registrars in relation to general gynaecological conditions, and evidence of attendance at transvaginal ultrasound courses. There is no current training needs analysis completed for medical gynaecology staff.

From a nursing/midwifery perspective, the Gynaecology Service is led by a Director of Midwifery, and is staffed by an Assistant Director of Midwifery; a Clinical Midwife Manager III; Clinical Nurse Managers II (CNMII), including an Oncology Liaison Nurse; Staff Nurses, Student Nurses on placement; and Healthcare Attendants. Other than an annual study day on gynaecology cancer for staff nurses, LUH were unable to provide any other evidence of ongoing education in relation to gynaecology and oncology nursing. There is no current training needs analysis completed for nursing gynaecology staff.

The Oncology Liaison Nurse was seconded into the role in December 2019 from her substantive post as the CNMII of the gynaecology ward. The post-holder has no formal training in oncology. The post of Oncology Liaison Nurse has no funding approval and does not have a description of the role and its responsibilities.

Post-Menopausal Bleeding Clinic

The Post-Menopausal Bleeding Clinic was established in on the 7th December 2018 to address the findings of a report relating to a missed diagnosis of endometrial cancer in the presence of post-menopausal bleeding (Incident Review Reference Number: 15142194). The purpose of the clinic is to assess women referred with post-menopausal bleeding for the presence of endometrial cancer. Assessment comprises a consultation and examination including an endometrial biopsy and a transvaginal ultrasound, in the presence of a chaperone. The results of which will help determine if further examination by hysteroscopy is required, as a day case or in-patient procedure, under general anaesthetic.

The Clinic is overseen by a Consultant Gynaecologist and staffed by two Senior Registrars, an Oncology Liaison Nurse (CNMII), a Healthcare Attendant, and a Clerical Officer. The Consultant Gynaecologist does not review each patient who attends the clinic. The clinic takes place every Friday morning. There are six new patient appointments, and no return patient

appointments. It is located in the Colposcopy Unit, Floor B beside the gynaecology ward. In 2019, there were 255 women seen in the clinic. Further details are in Figure 4.

Post-Menopausal Bleeding Clinic Database	
% Seen within 42 Days of Referral	37%
% Women Pipelle Biopsy Offered	100%
Transvaginal Ultrasound Offered	100%
% Hysteroscopy within 42 Days of PMB Clinic Appointment	25%
ET >4mm AND Histopathology Pipelle Normal; Rescanned in 8 weeks	91%
ET ≤4mm AND Histopathology Pipelle Normal AND on HRT OR Fluid in the Endometrium: Rescanned in 8 weeks	50%
Cancer Detected	3
Note: - Above based on full year referrals for 2019 - Above represents data of n=202 women, though n=255 were seen at clinic. Remaining data being uploaded retrospectively. - ET = endometrial thickness	

Figure 4 Post-Menopausal Bleeding Clinic Data

Findings from Incident Reviews

The following commentary is informed by the findings of six incident reviews conducted by Letterkenny University Hospital (LUH) and reviewed by the Saolta Serious Incident Management Team (SIMT); the findings of Incident Review Reference Number: 15142194; and the findings of Incident Review Reference Number: 19895947. The role of the Clinical Service Review Team was to consider the findings from the incident reviews conducted by LUH to identify key areas in which to inform the subsequent engagement with LUH around the Post-Menopausal Bleeding Pathway and around governance for quality and safety of the Gynaecology Service.

Delay

It is clear that the experience for these women, and the service provided to them, was unsatisfactory. All cases, in one form or another, are typified by delay – delay from an urgent GP referral to a gynaecology outpatient appointment; from gynaecology outpatient appointment to urgent diagnostics, such as ultrasound or hysteroscopy; and/or from diagnostics to intervention. The reasons for which appear to be sub-optimal triage and administrative practices, sub-optimal follow-up practices, and limited fail-safes; underpinned by ineffective communication.

All cases but one reviewed pre-date the establishment of the Post-Menopausal Pathway; i.e. from initial GP referral to LUH. This case occurred a number of days after the establishment of the clinic.

Triage and Administrative Practices

In some cases, there is evidence of incorrect triaging; evidence of not being correctly placed on the patient management system; and evidence of not being booked in for follow up outpatient appointments, diagnostics and/or interventions.

Follow-Up and Fail-Safes

In a number of cases, patients interacted with LUH for a variety of related or unrelated reasons separate to their out-patient appointment for post-menopausal bleeding; such as, attending

the Emergency Department; being admitted for unrelated reasons; or being reviewed by a medical team for optimisation for surgery. It is clear that in these cases the opportunity to follow up and ensure that the patient was booked into their respective diagnostic/interventional appointment before discharge was missed.

Communication

Failure to communicate effectively was a common theme which underlined a number of incidents. In a case that illustrates the point, LUH attempted to contact a vulnerable patient, who did not attend outpatient appointments and a planned procedure, by phone multiple times and failed. LUH did not contact the referring GP as per the LUH 'Did Not Attend' Policy (2017) and relevant national waiting list protocols from the National Treatment Purchase Fund (NTPF), which led to a delayed diagnosis. While the source of the error rested with the triage and administrative processes, this error was compounded by the missed opportunity to follow up a patient who was in the care of LUH with symptoms that indicated endometrial cancer and clear indications for urgent diagnostics.

Post-Menopausal Bleeding Pathway

The Post-Menopausal Bleeding Pathway comprises the Post-Menopausal Bleeding Clinic, which was established on the 7th December 2018; the Clinical Guideline for Assessment and Management of Post-Menopausal Bleeding at Letterkenny University Hospital (LUH)**,** effective from December 2019; and a Post-Menopausal Bleeding Clinic Database. This section of the review will consider the pathway since the introduction of these pieces of work.

Referral

There is a pathway of referral from GP to appointment at the Post-Menopausal Bleeding Clinic, supported by a clinical guideline. All referrals are inputted on the Post-Menopausal Bleeding Clinic database. There are a number of manual and electronic steps in place from GP referral to an appointment being made at the clinic.

Triage

The LUH Gynaecology Service triage their outpatient referrals, including those with post-menopausal bleeding, as 'urgent' and 'routine'. All Consultant Gynaecologists triage their own referrals. The triage process is manual and requires referrals to be sent to and from Consultant Gynaecologists by internal post. Patients identified with post-menopausal bleeding are then referred to the Post-Menopausal Bleeding Clinic which is overseen by a single consultant. The patient, however, remains under the care of the referring Consultant Gynaecologist. There is a procedure in place for triaging to be complete in the event of a consultant being on leave.

Appointment

All patients seen in the Post-Menopausal Bleeding Clinic in 2019 were offered a transvaginal ultrasound and endometrial sampling. There are pathways in place for further diagnostics and/or interventions based on the thickness of the endometrium and histology results. Patients who undergo a transvaginal ultrasound and endometrial sampling are appropriately chaperoned by the Oncology Liaison Nurse or a Healthcare Attendant.

Diagnostics

With respect to histology, LUH has processes in place to forward, receive, review and action histology test results, as appropriate**.** With respect to hysteroscopy, LUH has processes in

place for referral, booking, pre-surgical assessment and undertaking hysteroscopies, though there is insufficient theatre capacity to meet demands for timely hysteroscopies. There are also processes in place for further transvaginal ultrasound assessments in the radiology department, and for examination under anaesthetic, including further endometrial biopsies.

Assurance around these processes are reliant on the newly appointed Oncology Liaison Nurse, whose follow up acts as a fail-safe. This follow up includes receipt of histology reports from the laboratory, ensuring that results are reviewed by a Senior Registrar or the Consultant overseeing the Post-Menopausal Bleeding Clinic, appropriately filing the results in the patient's healthcare record, logging the results on the database, and ensuring actions are taken depending on the findings, such as discharge letters back to the GP or ensuring that a patient is booked into hysteroscopy. The process for booking patients in for hysteroscopy has not changed since the introduction of the Post-Menopausal Bleeding Pathway, with the exception that all patients requiring a hysteroscopy are now given a date for their procedure.

Treatment Plan (including onward referral)

There are clear processes for determining and implementing treatment plans such as hysteroscopy, and onward referral to gynaecology-oncology services. The patient remains under the care of the Consultant Gynaecologist who referred into the Post-Menopausal Bleeding Clinic. It is that Consultant who performs the hysteroscopy, and it is that Consultant who the patient sees in general gynaecology outpatients for the results of her diagnostic tests and to determined her treatment plan.

Patients with a diagnosis of endometrial cancer are referred to St. James's Hospital for a multi-disciplinary assessment to determine their plan of care. Any patient who requires a follow up appointment in LUH after review by St. James's Hospital reverts to the care of the referring Consultant.

Communication, Discharge and Follow Up

The processes for communication, discharge and follow up vary in their robustness. While the processes appear to be satisfactory, it should be noted that the appointment of the Oncology Liaison Nurse is recent and therefore, there is insufficient evidence to comment on the effectiveness of this approach. The Post-Menopausal Bleeding Database, as a simple Excel spreadsheet, is not sufficiently mature to act as a tracker to flag actions that require follow up.

In general, the quality of communication between the patient, the hospital and the GP varies. For example, there is a standard Post-Menopausal Bleeding Clinic Risk Assessment Proforma and a standard Post-Menopausal Bleeding Clinic Patient Information Leaflet. However, there is no standard electronic gynaecology referral form for GPs to use; GPs and patients do not routinely receive an acknowledgement of referral with an indicative wait time; and appointments are sent to the patient but not to the GP. While a letter is issued to the GP on the day the patient attends clinic, there is no evidence of a final management plan communicated either with the GP or with the patient.

The LUH Post-Menopausal Bleeding Clinical Guideline provides a standardised approach for those who are referred from the community with post-menopausal bleeding. It does not consider those patients who attend LUH for a related or unrelated reason; such as attendance to ED or admission to the ward, or those who fail a pre-surgical assessment for hysteroscopy.

Governance for Quality & Safety

As per the Terms of Reference, the Clinical Service Review Team undertook a review of the governance for quality and safety of the Letterkenny University Hospital (LUH) Gynaecology Service. The approach to this part of the review was informed by the HIQA National Standards for Safer, Better Healthcare (2012).

The Saolta Women & Children's (W&C) Managed Clinical and Academic Network (MCAN) is in its early stages of development. The MCANs are clinically-led and professionally-managed governance structures being rolled out across Saolta as part of the Saolta Group Strategy 2019-2023. MCANs will have executive authority, accountability and responsibility for service delivery. The W&C MCAN has recently appointed a Director, General Manager, and Group Director of Paediatric Nursing to complement the Group Director of Midwifery currently in post.

Governance for Quality & Safety Structures

Accountability & Governance

The accountability arrangements for the Gynaecology Service is as follows: the Gynaecology Service is led by a Consultant Gynaecologist (Clinical Lead) who reports into the Associate Clinical Director of the LUH Women and Infant's (W&I) Directorate, who in turn reports into the LUH General Manager, who in turn reports into the Saolta CEO. The Director of Midwifery, who leads the nursing component of the Gynaecology Service, also reports into the LUH General Manager.

The governance arrangements for the Gynaecology Service is as follows: the LUH W&I Directorate reports into the LUH Hospital Executive Board (HEB), which in turn reports into the Saolta Executive Council. There are a large number of sub-groups that report into the LUH W&I Directorate.

In the Terms of Reference of the LUH W&I Directorate, there is a sub-group described as a Quality & Safety Sub-Group. However, its Terms of Reference would suggest that this is an Obstetric Incident Review meeting, though no agenda and minutes were provided by LUH. It is not clear how the purpose of the Quality & Safety Sub-Group differs from the LUH W&I Incident Reporting Group. There is also a separate LUH W&I Safety Incident Management Team (SIMT). There were no gynaecology-related key performance indicator reports or gynaecology-related quality assurance reports mentioned in the agendas or minutes for the LUH W&I Directorate from December 2018 to December 2019**.** The Gynaecology Service 'Waiting Lists' for inpatients, day case and outpatients are not a standing agenda item for each LUH W&I Directorate meeting; and only discussed at four meetings at the end of 2019.

It is not clear if any annual reports where submitted from any sub-group to the LUH W&I Directorate in 2018 or 2019, or from the LUH W&I Directorate to the LUH HEB. LUH provided an annual report to the Saolta W&C MCAN in 2017, 2018 and 2019, which is then collated with annual reports from the other W&I Directorates of other hospitals within Saolta. The gynaecology-specific section of the LUH W&I Annual Report relates to the Colposcopy Clinic and the Urodynamic Clinic.

Strategic Planning, Operational Planning and Change Management

The LUH W&I Directorate has developed a statement of purpose which describes the vision, mission and strategic quality aims of the Women and Infants Directorate. However, there is no strategic plan or operational plan as it relates to the LUH Gynaecology Service.

Governance for Quality & Safety Processes

Quality & Performance Indicators

LUH provided the following quality and performance indicators in relation to the Gynaecology Service: Waiting List (Inpatient and Day Case; and Outpatient); the rate and number of people who did not attend (DNA) an outpatient clinic; urodynamic statistics; Colposcopy Clinic statistics; and indicators generated from the Post-Menopausal Bleeding Clinic database.

LUH do not use a suite of standardised, benchmarked gynaecology-related indicators that is regularly produced, and regularly monitored at the LUH W&I Directorate.

Learning and Sharing Information

There are a number of structures in place for the monitoring of, and learning from, patient safety incidents, such as the LUH W&I Directorate, and its Quality & Safety Sub-Group; the LUH W&I Directorate SIMT; and the LUH W&I Incident Reporting Group.

LUH W&I Directorate and Saolta W&C SIMT has a process for the review and management of serious incidents and sharing of that learning within LUH. This includes a monthly meeting of the senior medical and midwifery staff to review incidents from the prior month, and to agree and monitor improvement actions, as well as a review of serious incidents prior to Saolta W&C SIMT meetings.

LUH Quality & Patient Safety Department submits a hospital-wide Quality & Patient Safety End of Year Report to the LUH Quality & Patient Safety Committee (QPSC). While gynaecology-related information is contained within the report, there is no specific quality and patient safety report submitted from the LUH W&I Directorate to the LUH QPSC.

Notwithstanding the review of serious incidents at the Saolta W&C SIMT meetings, there is no evidence of formal or informal networking to support learning and sharing of information between the LUH Gynaecology Service and other gynaecology services within the Group.

Risk Management and Incident Management

LUH established a Risk Committee in 2019 which reports into the LUH Quality & Patient Safety Executive. A hospital-wide risk register monitors all the hospitals' risks**.** The LUH W&I Directorate does not have its own risk register, though gynaecology risks on the hospital-wide risk register are a standing agenda item at the monthly LUH W&I Directorate meetings. Emergent risks are also reviewed at this meeting and sent to the LUH Risk Committee for consideration.

LUH has a range of governance groups, as described above, which focuses on patient safety incidents. The hospital has clear management processes for incidents, serious incidents and serious reportable events, and uses the National Incident Management System to record all incidents**.** LUH has implemented the HSE Open Disclosure Policy 2019. The Quality & Patient Safety Department in LUH provide ongoing training to frontline staff members on the HSE Incident Management Framework 2018.

Clinical Effectiveness and Audit

There is no structured programme of clinical audit for the LUH Gynaecology Service. The LUH W&I Directorate has a Policy, Procedure, Protocol and Guideline (PPPG) sub-group, and there is also a PPPG sub-group of the LUH Quality & Patient Safety Committee. Saolta also has a PPPG and Audit Group. The Colposcopy Unit completes annual, quarterly and monthly audits as part of quality assurance procedures set out by the National Cancer Control Programme

(NCCP) as a CervicalCheck satellite unit. There were two audits completed in 2019 by the Gynaecology Service which were undertaken in response to the findings of Incident Review Number 15142194; one audit was completed in 2018; and one audit (and re-audit) was completed in 2017. There has been no recent audits of compliance with the HSE Incident Management Framework (2018), the HSE Integrated Risk Management Policy (2017) or the LUH Policy for Did Not Attend or Patient Cancellation.

An audit of LUH inpatient, day case and outpatient waiting lists was conducted by the National Treatment Purchase Fund (NTPF) in October 2018 of a random sample of healthcare records, which included gynaecology patients. It found that LUH had a number of suboptimal practices in relation to The Management of Outpatient Services Protocol (2014, v2.1) and the National Inpatient, Day Case, Planned Procedure Waiting List Management Protocol (2017). The NTPF concluded that only limited assurance could be offered that the overall waiting list and planned procedure patient pathways are managed in part within national protocols. The NTPF made 10 recommendations to improve adherence to both policies. LUH noted that a new booking form for inpatient, day case and planned procedures which was recommended in the report was implemented in January 2020. However, no other evidence of the implementation of these recommendations was provided.

Capacity, Capability & Access

The Clinical Service Review Team was informed that access to theatre is a continuing issue for the LUH Gynaecology Service. Each Consultant has only a single half-day theatre session per week, on average, for both inpatient and day case surgeries. Gynaecology theatre sessions are held on a Monday which reduces capacity throughout the year due to bank holidays. As a result of the decommissioning of the theatre on the labour ward in 2011, one theatre in the main theatre block is used solely for emergency obstetric events. LUH provided a business case that the Clinical Service Review Team were informed was submitted to Saolta for approval of funds to reopen the obstetric theatre.

The Post-Menopausal Bleeding Clinic is shared with the Colposcopy Clinic, whilst superior facilities are available in the out-patient area used for ante-natal and general gynaecology outpatient activity.

LUH has four Consultant Gynaecologists (including one locum) and identified a requirement for a fifth Consultant, and noted long-term and ongoing challenges in recruiting Consultant staff. LUH were unable to provide a strategic workforce plan, including a training needs analysis, which would meet the needs of the Gynaecology Service in LUH.

In addition to triaging their outpatients referrals as ‘urgent’ and ‘routine’, as per national waiting list protocols, the Gynaecology Service also use an additional ‘very urgent’ triage category, which is outside the NTPF protocol, to identify those who require immediate review as the wait times for ‘urgent’ review would be deemed too long. There are no locally agreed maximum waiting times for this triage category, nor are the wait times for this category monitored. The Gynaecology Service overbook their clinics with ‘urgent’ or ‘very urgent’ referrals, and rely on other patients not attending (DNA rates of 9-29%) to manage the overflow. Over 60% of patients had to wait more than 6 weeks for a first appointment at the Post-Menopausal Bleeding Clinic (Figure 4).

Discussion

All healthcare service providers should have robust governance structures and governance processes to ensure that the service provided is safe, effective and person-centred. Services should use clinical pathways for specific health conditions as one tool among many to deliver safe, effective and person-centred care. Incidents, such as missed and/or delayed diagnosis, should therefore be seen as a balancing measure – a serious and costly balancing measure – to alert the healthcare service providers that the pathways used to provide care need to be reviewed; and that any learning from such an incident is extracted, considered and incorporated into the governance of the service so that the chances of such an incident happening to another patient is reduced.

The Clinical Service Review Team acknowledges that many women have been successfully treated within the Letterkenny University Hospital (LUH) Gynaecology Service by dedicated, committed and highly trained healthcare professionals in a challenging environment. It should be noted that these incidents were of patients who had already accessed the service and who did not received the care they should have. Our review of the findings of these incidents, and the factors which contributed to the delay experienced by these women, were used to guide our investigation of the LUH Gynaecology Service. As such, the improvements that are required to reduce the risk of reoccurrence of these incidents is comprehended within our analysis and subsequent recommendations, as described below.

In this section of the report, the Clinical Service Review Team provides an analysis of a particular area and a recommendation. Under each recommendation, there are a number of suggested improvements that the Clinical Service Review Team suggests, that if implemented, would satisfy the relevant recommendation.

Post-Menopausal Bleeding Pathway

A clinical pathway is a device which facilitates the implementation of evidence-based practice to achieve optimal healthcare outcomes, while minimising healthcare-acquired complications. At the time of this report, and since the introduction of the LUH Post-Menopausal Bleeding Pathway, the *Investigation of Post-Menopausal Bleeding Clinical Practice Guideline* (IOG, RCPI & HSE, 2013) is beyond its revision date and has been withdrawn from the RCPI website. It is not within the Terms of Reference for the Clinical Service Review Team to conduct an audit on compliance with these guidelines. However, notwithstanding the Terms of Reference or the removal of the Clinical Practice Guideline, the Clinical Service Review Team used the recommendations described in the Clinical Practice Guideline as a framework to understand the structures and processes of the Post-Menopausal Bleeding Pathway so as to identify areas of strength and areas for improvement.

The Clinical Services Review Team found evidence that the LUH Gynaecology Service was substantially compliant in the adherence to these guidelines. However, the LUH Gynaecology Service need to review and improve upon the guidelines which recommended prompt referral and assessment of patients who present with post-menopausal bleeding; and effective communication with patients and GPs.

While the introduction of the Post-Menopausal Bleeding Clinic is commendable, the processes which support the functioning of the clinic are not sufficiently different than what existed before its introduction. LUH should develop the Post-Menopausal Bleeding Clinic further by building its capacity and investing in its capability to deliver a safe, effective and person-centred service to women who present with symptoms of post-menopausal bleeding.

The functioning of the clinic is reliant on the introduction of the Post-Menopausal Bleeding Database and the Oncology Liaison Nurse, who has been seconded into post since December 2019 from her substantive post as CNMII of the gynaecology ward. Considering its importance to the clinic, the Database is not sufficiently robust to provide the key performance indicators required to effectively monitor the clinic, or sufficiently mature to act as a tracker for follow up. A significant amount of responsibility rests with the Oncology Liaison Nurse, who does not have sufficient post-graduate training in oncology nursing, nor has a written description of her role and responsibilities. As it currently stands, this role is one of 'coordinator', rather than Oncology Liaison.

As the clinic is not consultant-based, a significant amount of responsibility also rests on the Senior Registrars. Though the purpose of the clinic is to assess women referred with post-menopausal bleeding for the presence of endometrial cancer, medical staff in the clinic should have sufficient up-to-date oncology knowledge and experience to identify, assess and manage any gynaecological cancer that may present to the clinic. As noted by LUH, not all women who attended the Post-Menopausal Bleeding Clinic in 2019 had post-menopausal bleeding; and not all women who attended the Post-Menopausal Bleeding Clinic in 2019 were seen by a Consultant Gynaecologist.

The capacity of the clinic is limited. Only six new patients are seen each week, and no return patients. Patients receive the results of their endometrial biopsy and other diagnostics tests, such as a hysteroscopy, in the general gynaecology outpatient clinic by a Consultant Gynaecologist who undertook the triage on referral to LUH, instead of returning to the Post-Menopausal Bleeding Clinic. The physical infrastructure does not lend itself to an increase in capacity as the clinic is shared with the colposcopy service. The area where ante-natal and general gynaecology out-patients are seen has superior facilities, and more rooms to see more patients.

The establishment of the Post-Menopausal Bleeding Clinic and the development of the Post-Menopausal Bleeding Pathway requires specific skill sets in service improvement, leadership and change management that are integral to effective change.

Recommendation

Letterkenny University Hospital should build capacity in its Post-Menopausal Bleeding Clinic, and build the capability of staff working in the Post-Menopausal Clinic.

Suggested Improvements

The Post-Menopausal Bleeding Clinic should:

- be consultant-based
- be moved to the area used for ante-natal and general gynaecological out-patients, which has superior facilities and increased physical capacity.

- increase the numbers of new patients who attend the clinic. Patients who require a return appointment should also be seen at this clinic, and not at general gynaecology outpatients. Patients who require a hysteroscopy can be referred onto theatre lists of other Consultant Gynaecologists but should come back to the clinic for their results.

Letterkenny University Hospital should:

- develop a more robust database that can act as a tracker to flag actions for follow up and to generate key performance indicators so that it can be utilised not only by the Oncology Liaison Nurse but also by the wider Post-Menopausal Bleeding Clinic team.
- support the development of staff working in the Post-Menopausal Bleeding Clinic
    - The Oncology Liaison Nurse should undertake specific post-graduate training in oncology nursing. The role of the Oncology Liaison Nurse should have a clear description of the role and its responsibilities.
    - The Senior Registrars should have appropriate and ongoing training in oncology.
    - The Senior Clinical Staff should undertake training in quality improvement, change management and leadership skills so as to act on opportunities to continually improve the quality, safety and reliability of its gynaecology services.

Overview of Gynaecology Service

As well as the capacity issues in the Post-Menopausal Bleeding Clinic highlighted above, Letterkenny University Hospital (LUH) Gynaecology Service also needs to build its capacity to undertake inpatient, day case and planned procedures. The use of one theatre in the main theatre block for emergency obstetric surgeries has the effect of reducing LUH general theatre access by 25% which significantly impacts on the ability of LUH to provide timely diagnostics and interventions to women in the care of the Gynaecology Service leading to long waiting lists.

LUH noted the requirement for a fifth Consultant Gynaecologist, and identified long-term challenges in recruitment. While undoubtedly required for the service, LUH has not conducted a strategic workforce plan for the entire gynaecology workforce which should include enabling staff such as quality and patient safety advisors and administrative staff, as well as medical and nursing staff. A workforce plan for the gynaecology service could also consider the current LUH Clinical Nurse Specialists in Oncology, who report to the Director of Nursing, and who do not review gynaecology cancer as part of their service provision. In the absence of such a plan LUH are also unable to determine the ongoing educational needs of staff to be assured that staff can maintain their competencies.

Though physical and human capacity is an issue, LUH Gynaecology Service are not validating and monitoring their inpatient and outpatient waiting lists sufficiently to ensure that those who need to be seen are seen within a reasonable timeframe. There are nine women who are waiting between 2 and 4 years for an urgent inpatient or day case procedure, while routine patients are seen within that time (Figure 1). Similarly, there are 46 women waiting over 2 years for an urgent outpatient appointment and a further 202 women waiting for a routine outpatient appointment within the same timeframe (Figure 2). In 2019, there were 655 patients who did not attend (DNA) their appointment (Figure 3), which equates to 15% of all gynaecology outpatients. In August 2019, nearly 30% of all patients booked to see Consultant

B did not attend for their appointment. LUH Gynaecology Service do not routinely monitor their DNAs.

The triage system for the LUH Gynaecology Service is cumbersome, inefficient and represents a significant opportunity for error and delay. Furthermore, in addition to triaging their outpatients referrals as 'urgent' and 'routine', as per national waiting list protocols the Gynaecology Service also use an additional 'very urgent' triage category, which is outside the NTPF protocol, to identify those who require immediate review as the wait times for 'urgent' review would be deemed too long. There are no locally agreed maximum waiting times for this triage category, nor are the wait times for this category monitored. The Gynaecology Service overbook their clinics with 'urgent' or 'very urgent' referrals, and rely on other patients not attending (DNA rates of 9-29%) to manage the overflow. Reducing DNAs reduces costs, improves service efficiency, enables more effective booking of slots, reducing mismatch between demand and capacity, and increases productivity.

While only 3 of the 40 healthcare records sampled in the NTPF audit on the management of waiting list were gynaecology patients, it points to a wider issue of compliance with national protocols and policies in the management of waiting lists that must be considered. While these protocols are technical in nature, they are important for ensuring that no patient is missed due to sub-optimal administrative practices. LUH noted that low numbers of administrative staff was limiting their ability to provide an effective administrative service.

Communication, between the hospital, the GP, and the patient, requires improvement. Standard electronic gynaecology referral forms, routine electronic acknowledgement of referrals with an indicative wait time would improve communication between the hospital and the GP. Patients would benefit from a letter of assurance sent from LUH when their results are available or a letter advising them to contact their GP to discuss their results.

Recommendation

Letterkenny University Hospital should review their referral and triage system for gynaecology patients; which should be robust, with built-in fail-safes and be monitored regularly.

Letterkenny University Hospital should build their capacity and capability for inpatient, day case and planned procedures; and should build their capacity and capability for outpatients; both of which should include a review as to how LUH manage their waiting lists.

Letterkenny University Hospital Gynaecology Service should review and improve upon their communication processes with service users and service referrers.

Suggested Improvements

LUH Gynaecology Service should:

- conduct triage in one place in the hospital and have all gynaecology doctors trained on the triage procedures. The Post-Menopausal Bleeding triage should be 'top-sliced' and the remaining referrals sent to relevant Consultants. This is the procedure already in use for colposcopy.

Letterkenny University Hospital should:

- develop clear flow charts of the processes that must be undertaken, by whom, by when, and on what system, of all stages of patient administration from GP referral to discharge. These flow charts should be reviewed to identify steps that can be reduced, and fail-safes that can be added. Consideration should also be given to whether there is sufficient administrative capacity and oversight to provide an effective administrative service.
- consider utilising more effective technological solutions such as the development of a standardised electronic gynaecology referral form, and developing electronic closed loop processes.

Letterkenny University Hospital should:

- increase their theatre capacity in light of the long waiting lists for inpatient, day case and planned procedures.
- conduct a strategic workforce plan to ensure that the Gynaecology workforce is the right size, with the right skills, to deliver a gynaecology service in Donegal. Any plan should include the medical, nursing, administrative, and quality and patient safety staff; a population needs assessment; and a training needs analysis. The service provision of the current Clinical Nurse Specialists in Oncology should also be reviewed and their role with respect to gynaecology-oncology should be considered.
- formally describe their triage system to include 'very urgent'; identify the timelines that they are bound to for each triage category; and to monitor this data regularly to ensure compliance.
- limit the practice of overbooking patients and relying on patients not attending to provide a service to patients deemed 'very urgent' or 'urgent'.
- review the findings and recommendations of the NTPF audit and develop a documented quality improvement plan to improve processes and procedures relating to waiting list protocols.
- regularly monitor and triage Inpatient and Day Services Active Waiting Lists and Out-Patient Active Waiting List; as well as track and regularly monitor DNA rates by clinic and/or consultant.
- undertake a review to determine the reasons for their high DNA rate. The most commonly cited reasons are patients forgetting, administrative error, or communication failure. Other factors that should be considered are: socio-demographic factors; patient factors, such as getting time off work from employer, cost of travel, childcare issues; and hospital factors, such as difficulty cancelling appointments, and poor appointment notification design. A documented quality improvement plan should be developed.
- conduct a survey with service users and service referrers to understand their experience of the gynaecology service and to determine how to improve communication between them and the service. A documented quality improvement plan should be developed.

Governance for Quality & Safety of Gynaecology Services

Governance for Quality and Safety is the system through which healthcare teams and healthcare providers are accountable for the quality, safety and experience of people in the care they deliver. It involves having the necessary structures and processes in place to ensure that safe, effective and person-centred services are delivered.

LUH has a statement of purpose which describes the vision of the service, its mission, and strategic quality aims. However, there is an absence of clear objectives, as well as the strategies and actions that enable the delivery of those objectives; and an absence of a clear plan of how, who, and when, will those objectives be delivered.

The LUH W&I Directorate has a proliferation of sub-groups, and an overemphasis on incidents. In places, the Terms of Reference of some of these sub-groups are confused and it is not clear how their objectives are being met. The LUH W&I Directorate does not use standardised, benchmarked indicators to determine how the Gynaecology Service is performing. Similarly, a service with a sufficient compliment of Non-Consultant Hospital Doctors, and a satisfactory gynaecology nursing complement, should have a much greater number of audits ongoing to determine compliance against key PPPGs. Clinical audit is "the single most important method that any healthcare organisation can use to understand and assure the quality of the service that it provides" (Madden et al., 2008). Systematic monitoring arrangements are important for identifying opportunities to continually improve the quality, safety and reliability of gynaecology services. This needs to be greatly improved in LUH Gynaecology Service.

Another component of effective governance that should be considered and monitored is that of risk. Effective risk management is the cornerstone of effective governance. Risk management is the proactive identification of risks – both strategic and operational - that threaten the achievement of objectives – both strategic and operational. LUH has established a Risk Committee in the past year and holds a hospital-wide risk register. However, managing risk should be considered a day to day business activity and as such, the LUH W&I Directorate should consider conducting its own risk management process; hold and monitor its own risk register; and train senior clinical leaders in risk management.

One of the purposes of incident reviews is to identify the cause of the incident, and to learn lessons on how to reduce the risk of reoccurrence. In a number of cases, there is evidence to suggest that although the incident was noted contemporaneously, it did not appear to prompt an incident review in LUH at that time. In other words, the opportunity to learn from these incidents was not taken promptly by LUH. Since then, LUH and Saolta W&C MCAN have put significant efforts into improving their management and response to incidents and serious incidents, including learning from incidents. This is a commendable piece of work. It would be an opportune time to audit these new structures and processes against the HSE Incident Management Framework (2018) using newly developed audit tools from the HSE.

The relationship between LUH and Saolta is well described in terms of accountability and governance. There does not, however, appear to be a meaningful relationship between LUH Gynaecology Service and the Gynaecology Services in other constituent hospitals in Saolta at a clinical level. There is no evidence of exchanging information, sharing clinical guidelines, conducting joint audits, or engaging in quality improvement initiatives. Although geographically more isolated, the LUH Gynaecology Service must make a greater effort to integrate more with other services, as should other services with LUH. The recently established Saolta W&C MCAN will be key in developing these clinical relationships so as to leverage the knowledge and experience of all staff working in gynaecology across Saolta.

Recommendation

The Letterkenny University Hospital Women and Infant's Directorate should review its Governance for Quality & Safety structures, and improve the robustness of its Governance for Quality and Safety processes.

Suggested Improvements

Letterkenny University Hospital Women & Infant's Directorate should

- complete a full review of its governance structures including its own Terms of Reference; and the number of the sub-groups reporting into it and their Terms of Reference.

Letterkenny University Hospital Gynaecology Service should

- develop a strategic plan and an operational plan, underpinned by appropriate project management structures and processes, that is reviewed regularly at the LUH W&I Directorate meeting and accounted for at the LUH Hospital Executive Board (HEB). Any strategic and operational plan should consider how clinical relationships can be developed with other Gynaecology Services in Saolta.
- develop a suite of structure, process and outcome-related indicators; which are benchmarked, where possible. These indicators should be reviewed regularly at the LUH W&I Directorate meeting and accounted for at the LUH HEB.
- develop and maintain its own risk register, including formal training of the HSE Risk Management Policy (2017) for senior clinical staff.
- identify key policies, protocols, procedures and guidelines (PPPGs) and, alongside its strategic plan, develop a clinical audit programme to determine the effectiveness of its service. This clinical audit programme should take into account the strategic context outlined HSE National Review for Clinical Audit (2019).
- prepare an annual report before the end of the first quarter of the following year, which should be submitted for scrutiny to the LUH HEB.

Letterkenny University Hospital should

- audit their structures and processes for the monitoring of, and learning from, safety incidents to determine their effectiveness.

National Standards for Safer, Better Healthcare

The LUH Gynaecology Service should undertake a robust and comprehensive self-assessment against the HIQA National Standards for Safer, Better Healthcare, 2012 ('the National Standards'). The purpose of the National Standards is to help the people who use healthcare services and the people who provide healthcare services to understand what a high quality, safe healthcare service looks like. The National Standards provide a framework for how services are organised, managed and delivered on a day-to-day basis. This recommendation should be considered as overarching. While it will take time to complete this assessment, it is a worthwhile investment to develop a robust and comprehensive roadmap for improving the quality, safety and reliability of the LUH Gynaecology Service.

Conclusion

The Clinical Service Review Team carried out a detailed investigation of the gynaecological service as described. The Clinical Service Review Team found evidence of good practice by a committed team providing good quality care for the local population. Letterkenny University Hospital (LUH) is beset with large and worsening waiting lists for both inpatient, day case and outpatient services, however, there is evidence that insufficient effort is being made to improve the situation. This is illustrated by high DNA rates and failure to re-commission the Obstetric Theatre. This type of working environment demoralises staff, and makes recruitment and retention of high quality staff very difficult.

With specific reference to the cases which triggered this review, the common theme was delay in diagnosis. There were several causes for this including poor follow up practices, and poor triage and administrative practices; all compounded by ineffective communication. In essence, it was a failure to individualise and provide a person-centred approach to the care of these patients. In response to one of these cases, a Post-Menopausal Bleeding Clinic has been established, however, it relies upon inefficient administrative processes, has unsatisfactory waiting times, insufficient capacity and incomplete pathways.

While there is evidence of structures and processes in place in relation to the governance for quality and safety of the Gynaecology Service, significant effort is required to improve the robustness of the governance processes which support the governance structures so as to assure patients, and the Hospital Executive Board, that safe, effective and person-centred care is being delivered. Furthermore, the relationship between Saolta and LUH at an executive level is clearly defined, however, there was no evidence that LUH Gynaecology Service is clinically engaged with other hospitals within Saolta, and vice versa; and this may account for the isolated impression given.

The Clinical Service Review Team is of the opinion that the recommended actions contained in the body of this report are achievable and, if implemented, will improve clinical outcomes for patients and reduce the risk of delay causing harm to anyone referred to LUH with suspected endometrial cancer.

References

HIQA (2012) National Standards for Safer, Better Healthcare. Health Information and Quality Authority.

IOG, RCPI & HSE (2013) Investigation of Postmenopausal Bleeding. Clinical Practice Guideline No. 26. Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland and Directorate of Clinical Strategy and Programmes, Health Service Executive

Madden, D. (2008) Building a Culture of Patient Safety. Report of the Commission on Patient Safety and Quality Assurance. Department of Health & Children, Ireland.

HSE (2017) Integrated Risk Management Policy. Health Service Executive.

HSE (2018) Incident Management Framework. Health Service Executive.

Recommendations

For each recommendation, there are a number of suggested improvements that the Clinical Service Review Team suggests, that if implemented, would satisfy the relevant recommendation. Please review the body of the report for more information.

1. Letterkenny University Hospital should build capacity in its Post-Menopausal Bleeding Clinic, and build the capability of staff working in the Post-Menopausal Clinic.
2. Letterkenny University Hospital should review their referral and triage system for gynaecology patients which should be robust, with built-in fail-safes and be monitored regularly.
3. Letterkenny University Hospital should build their capacity and capability for inpatient, day case and planned procedures; and should build their capacity and capability for outpatients, both of which should include a review as to how LUH manage their waiting lists.
4. Letterkenny University Hospital Gynaecology Service should review and improve upon their communication processes with service users and service referrers.
5. The Letterkenny University Hospital Women and Infant's Directorate should review its Governance for Quality & Safety structures, and improve the robustness of its Governance for Quality and Safety processes.
6. The LUH Gynaecology Service should undertake a robust and comprehensive self-assessment against the HIQA National Standards for Safer, Better Healthcare, 2012

Acknowledgements

The Clinical Service Review Team wish to acknowledge the courageous and committed women and family members who highlighted these incidents which resulted in this review. The outcome of these incidents had a devastating impact on their lives, and that of their family.

The Clinical Service Review Team would also like to acknowledge and thank the staff of Letterkenny University Hospital for their efforts throughout this review; and their willingness to engage with the Clinical Service Review Team. The Clinical Service Review Team was provided with all requested information in a prompt manner and relevant staff made themselves available to be interviewed at our request.

Appendices

Appendix 1: Terms of Reference

Saolta
Grúpa Ollscoile Cúram Sláinte
University Health Care Group

Review of Gynaecological Clinical Services - Letterkenny University Hospital

Terms of Reference

Background

Through the risk management process, concerns have been raised about the quality and safety of Gynaecological Clinical Services in Letterkenny University Hospital. The quality and safety of services should be assessed against evidence-based quality and patient safety standards. Reviews of individual cases are separate to this report. However, the learning from these reviews will be integrated into the findings of this report.

Scope

The scope of this review will include the Gynaecological Clinical Service; particularly the pathways of care for patients who present with Post-Menopausal Bleeding (PMB) and diagnostic pathways of care for potential gynaecological cancers.

Purpose / Objectives

The purpose / objective of this review is

- To determine the current quality and safety of Gynaecological Clinical Services in Letterkenny University Hospital with a focus on diagnostic pathways of care for potential gynaecological cancers (in particular the pathway of care for women presenting with PMB).
- To make recommendations to improve the quality and safety of Gynaecological Clinical Services in Letterkenny University Hospital.
- To comment on, or highlight for further review, any other areas which are outside of the Gynaecological Clinical Services in Letterkenny University Hospital but which impact the quality and safety of its Gynaecological Clinical Services.

In undertaking this work, reviewers will pay particular attention to the following areas, which have been identified in initial review by the Chief Clinical Director, and informed by previous reviews of serious incidents:

- Assessment & Triage of women referred to the Gynaecological Services at Letterkenny University Hospital with symptoms of post-menopausal bleeding.
- Onward referral patterns and procedures, including timing of further diagnostic procedures such as ultrasound scans, hysteroscopy and endometrial biopsy, follow up of results and referral to gynaecological oncology services.
- Overview of out-patient and in-patient waiting lists, including the governance of such lists.

- Administrative practices and challenges at interfaces of care relevant to points 1.-3. above.
- Monitoring programmes, include KPI use and clinical audit programme
- Hospital and Hospital Group corporate and clinical governance arrangements to support quality and safety of services for users of the Gynaecological Clinical Services

Methodology

To determine the quality and safety of services for users of the Gynaecological Clinical Services, an independent panel of reviewers will undertake an assessment of the service, which will be informed by relevant quality and safety evidence-based standards. A report will be issued to the Review Commissioner

Governance

The Saolta University Health Care Group Chief Clinical Director has commissioned this review, and with the Saolta University Health Care Group CEO will be responsible and accountable for its findings and the implementation of recommendations, if any.
The independent review team will be provided with all relevant information in a prompt manner; and all staff will make themselves available to be interviewed by the review team
The review team will report back to the Chief Clinical Director with their findings within 3 months of the commencement of the review

Standards

IOG (RCPI) & HSE Clinical Practice Guideline: Investigation of Postmenopausal Bleeding (2016) – Appendix I
HSE Clinical Governance Development: As assurance check for Health Service Providers (2012) – Appendix II

Review Team

Dr John Price, Consultant Gynaecologist, Belfast
Ms Anne Kelly, Director of Nursing/Midwifery (retired) Mullingar hospital
Mr Gareth Clifford, Quality and Patient Safety Office, Acute Hospitals Office, HSE

Approach

The reviewers will take the following approach to determine the objective of this review

- Review PPPGs and all relevant documentary evidence (e.g. KPIs etc.)
- Interview relevant people
- 'Walk the floor' Review

Evidence Requests

The information requested may include, but is not limited to:

- Previous self-assessments and audits against the above standards.
- Process map of the complete patient journey
- Organisational chart including relevant governance groups – e.g. Cancer Directorate
- PPPGs related to this service, to risk management and to clinical governance
- Meetings and Minutes of Governance Groups – e.g. Women's and Childrens Directorate
- KPIs

Validation

All those interviewed will be given an opportunity to review the draft report for factual accuracy to ensure due process and fair procedures.

Timeline

The reviewers will complete their report within 3 months of commencement of the review, notwithstanding any delays in receipt of information, or other exigencies. The reviewers will promptly inform the Hospital Group Chief Clinical Director if any delays are anticipated, including a revised timeline for completion. If immediate clinical risks are identified, these should be reported to the Chief Clinical Director as a matter of urgency.

Dr Pat Nash
Chief Clinical Director
Saolta University Health Care Group

Appendix 2: LUH Histology Audit

Clinical Service Review Team Commentary:

On the 12th of June, and again on the 29th June, the Clinical Service Review Team were requested to provide a response on whether an audit of patients diagnosed with endometrial cancer between 2010 and 2019, commissioned by Saolta in September 2019 and completed in June 2020, would have any implications on the findings and recommendations of the *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on Post-Menopausal Bleeding Pathways*, which was submitted to Saolta on 8th May 2020.

The Clinical Service Review Team were furnished with the audit report on 29th June 2020. It would appear that the purpose of the audit was to determine if endometrial cancers, diagnosed in Letterkenny University Hospital between 2010 and 2019, was done so within best practice timelines. The audit described that the LUH histology database was used to identify all patients with an endometrial cancer diagnosis, including atypical or complex hyperplasia; and that there is a probability that some cases of endometrial cancer were secondary to a primary ovarian cancer. That 133 women were diagnosed with endometrial cancer within that time period, and that 38 women were waiting longer than 100 days from initial referral to diagnosis. As part of the Clinical Service Review, the Clinical Service Review Team considered the findings of six incidents reviews conducted by LUH and reviewed by Saolta Serious Incident Management Team; and the findings from Incident Review Reference Number: 15142194 and 19895947, both of whom died, RIP. The Clinical Service Review Team were informed by Saolta that these eight women were included in the histology audit.

The audit does not describe the clinical outcomes for all 38 women who waited longer than 100 days from initial referral to diagnosis, but did describe the clinical outcomes for 15 out of 23 women deemed to have 'no mitigating factors' for delay. The audit report did describe 'tentative explanations' as to what factors contributed to the delay in diagnosis for the 15 women with mitigating factors, which included: "co-morbidities, cardiovascular disease, the need for general medical review, concurrent malignancies, anaesthetic issues and deferrals, appointment DNAs by patients, rescheduling of appointments by patients, extremes of age, young women who did not present with PMB, and the flooding episode at the hospital." The overall impression of the audit report was one of sub-optimal standard as it did not include sufficient descriptions of the histology review, the treatment given, the current status of all women affected, the timelines for attendance, the timelines for diagnosis, and the timelines for initiation of treatment. The Clinical Service Review team were also forwarded 11 preliminary assessment reports of the 15 women 'without mitigating factors'. As per the HSE Incident Management Framework 2018, preliminary assessment reports are used to assist the Serious Incident Management Team in determining the type and level of incident review to undertake, if required. However, the reasons for the causes of the delay have yet to be determined by LUH and Saolta as they require individual incident reviews to be completed.

The Clinical Service Review Team would like to express our disappointment and dissatisfaction that LUH and Saolta did not make the Clinical Service Review Team aware that

this audit was taking place in parallel to the Clinical Service Review, and that an initial draft was completed in May 2020, despite sufficient opportunity to do so.

The Clinical Service Review was commissioned in October 2019. On the 9th January, prior to the site visit on 17th January, Saolta were informed that the Clinical Service Review Team would request evidence from LUH to describe how the effectiveness of the quality and safety of gynaecological pathways in LUH is monitored, evaluated and continuously improved. On the 2nd March, Saolta were specifically asked to provide evidence of how the LUH Gynaecology Service monitors clinical effectiveness, such as audit. A further request for evidence was made to Saolta on 8th April, though not specifically in relation to audit. And finally, both Saolta and LUH were afforded an opportunity for factual accuracy on the 24th April. Indeed, the Clinical Service Review Team were specifically requested to consider the findings of the eight incident reviews mentioned above as part of the Clinical Service Review. It is, therefore, regrettable that the Clinical Service Review Team was not made aware of this audit.

On consideration, it is the view of the Clinical Service Review Team that this audit does not inherently affect the findings and recommendations of our report. However, there are a number of points that we feel are important for the Commissioner of this report, and any other relevant parties, to consider.

The Clinical Service Review was commissioned to assess the current quality and safety of Gynaecological Clinical Services in LUH, in response to eight instances of delayed diagnosis in women with endometrial cancer. The Review Team were informed by LUH that the frequency of women diagnosed with endometrial cancer was not tracked. Therefore, it was difficult for the Review Team to determine the extent of the issue of delayed diagnosis of endometrial cancer in LUH, albeit this was not the function of the review. Notwithstanding that an incident review has yet to be carried out on all women who suffered a delayed diagnosis identified in the audit, it would appear that of the 133 cases of endometrial cancer that 29% (n=38) of women experienced a delay in diagnosis. As noted in direct correspondence with the Saolta MCAN Clinical Director, 19% (n=25) of women had a delay in diagnosis with a potentially serious consequence; though we reiterate that the clinical outcomes of 15 women whose delayed diagnosis were deemed to have ‘mitigating factors’ were not included in the results of the audit. In other words, nearly 3 in every 10 women diagnosed with endometrial cancer in LUH over a 10 year period have had some form of delay in their diagnosis of endometrial cancer; and nearly 1 in every 5 women had a delay with a potentially significant consequence. This is particularly concerning.

The Clinical Service Review Team are of the view that the audit report be considered in the context of the Clinical Service Review report. As such, the categorisation of delays in diagnosis for 38 women as having mitigating or no mitigating factors is problematic. Ultimately, these women did not get a diagnosis of endometrial cancer within a timeframe of 100 days from initial referral, regardless of other factors. If there were factors present at that time which affected timely diagnosis, it is clear from the Clinical Service Review report that LUH were not aware as to what those factors were as they did not do contemporaneous reviews of the reasons for delayed diagnoses; they do not track and audit this information; they do not manage their waiting lists effectively; and they do not manage their DNA rates effectively.

Each delayed diagnosis was an opportunity to learn and to improve, and these opportunities were not taken.

So while the findings and recommendations of our report are not affected with respect to LUH, there must be a consideration as to whether the issues that are present in LUH are replicated in other hospitals around the country. Delay in accessing gynaecology services is not unique to LUH as there are significant waiting lists in all Gynaecology Services across the country. As such, it may be worthwhile to conduct a similar audit of histology in other hospitals to determine if LUH is an outlier with respect to delay in diagnosis for endometrial cancer, or if the same frequency is present elsewhere.

Regardless, there is an absence of national standards for women who present with post-menopausal bleeding, and an absence of clear timelines for assessment, investigation and treatment on presentation. The Clinical Service Review Team would also note that the *IOG, RCPI and HSE (2013) Investigation of Postmenopausal Bleeding. Clinical Practice Guideline No. 26* has been withdrawn from the RCPI website; and that three recommendations were made about its revision, to be completed within 6 months, in the following incident review report: *Investigation of the delayed diagnosis of endometrial cancer related to the time from the patient's referral to gynaecological services in September 2010 to the time of her diagnosis of endometrial cancer in May 2012*. That incident review report was completed in November 2017. National standards, clear timelines, effective quality assurance and monitoring; as well as support for clinicians and services who provide care, are integral to safe, effective and person-centred care for women who present with post-menopausal bleeding.

Finally, while this audit does not change the findings and recommendations of our report, it clearly has implications for LUH and for gynaecology services nationally. For that reason, the Clinical Service Review Team deem it appropriate to addend our report with this commentary as an appendix, and to re-issue the addended report back to the commissioner of the review.