



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Guide: A targeted assurance review of the governance arrangements at national HSE, Saolta University Health Care Group and local hospital level to assure and ensure the quality of gynaecology services at Letterkenny University Hospital

7 April 2021

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

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1. Introduction

Section 8(1)(c) of the Health Act 2007¹ (as amended) confers the Health Information and Quality Authority (HIQA) with the statutory responsibility for monitoring the quality and safety of healthcare. This function is achieved through the monitoring of compliance against the *National Standards for Safer Better Healthcare*.² These national standards provide a framework for service providers to assess and improve the service they provide.

This guide document should be read in conjunction with the following:

- *National Standards for Safer Better Healthcare* (2012)
- The Health Act 2007 (as amended).

1.1 Aim of this review

The aim of this targeted assurance review is to ensure progress in the implementation of recommendations made following an external review into service failures within gynaecology services at Letterkenny University Hospital. It also aims to determine the effectiveness and sustainability of the governance and oversight arrangements at HSE, hospital group and hospital level to assure and ensure the provision of high-quality gynaecology services at Letterkenny University Hospital.

1.2 Purpose of this guide

This guide provides information on HIQA's approach to the review of the governance and oversight arrangements in place at the Health Service Executive (HSE), Saolta University Health Care Group and hospital level to assure and ensure the quality of gynaecology services at Letterkenny University Hospital.

2. Background

2.1. The role of the Health Information and Quality Authority

HIQA was established in 2007 to promote safety and quality in health and social care services for the benefit of the health and welfare of the public.

Under section 8(1)(b) of the Health Act 2007, HIQA has, among other roles, the function of setting standards on safety and quality in services provided by the Health Service Executive (HSE) or a service provider in accordance with the Health Act 2007 (as amended).

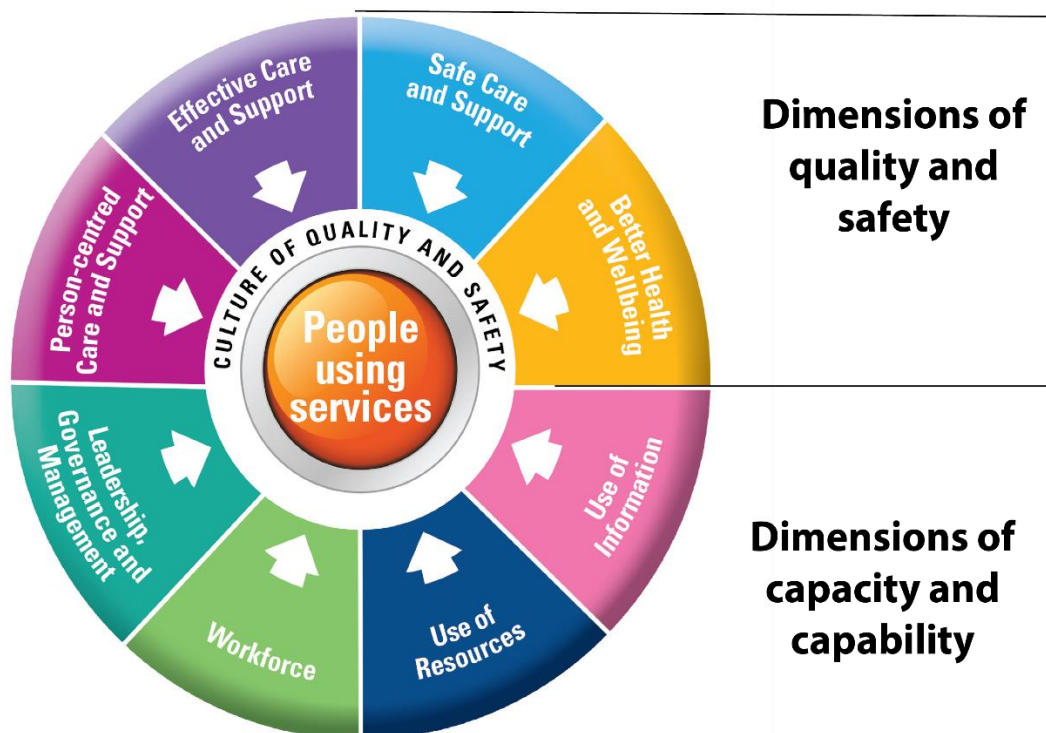
Under section 8(1)(c) of the Health Act 2007, HIQA monitors compliance with nationally mandated standards and advises the Minister for Health and the Health Service Executive accordingly.

2.2. Role of standards and continuous monitoring in improving quality and safety in healthcare

The *National Standards for Safer Better Healthcare* took effect from June 2012. The national standards aim to help promote improvements in the quality and safety of healthcare services in Ireland. Their purpose is to help the public, people who use healthcare services and the people who provide those services to understand what a high-quality, safe healthcare service looks like. Collectively, these national standards describe how a service provides high-quality, safe and reliable healthcare which is centered on people who use the service.

The national standards comprise 45 standards presented under eight themes (see Figure 1). Themes one to four of the national standards describe the dimensions of quality and safety in the delivery of a person-centered healthcare service. Themes five to eight of the national standards describe the capacity and capability factors necessary to deliver high-quality safe care.

Figure 1. The themes in the National Standards for Safer Better Healthcare



The dimensions of quality and safety comprise of four themes:

- Theme 1: Person-centred Care and Support
- Theme 2: Effective Care and Support
- Theme 3: Safe Care and Support
- Theme 4: Better Health and Wellbeing

The capacity and capability factors necessary to deliver high-quality safe care comprise of four themes:

- Theme 5: Leadership, Governance and Management
- Theme 6: Workforce
- Theme 7: Use of Resources
- Theme 8: Use of Information.

Implementing evidence-based standards in healthcare settings, together with continual monitoring of compliance against these standards, is a quality and safety improvement measure. Each service provider needs to assure themselves, people who use the service and the public that it is providing safe, high-quality care by demonstrating that it is meeting the national standards. HIQA, through its monitoring programmes, aims to assure the public that service providers are implementing and meeting the national standards, and making any necessary quality and safety improvements that are required to safeguard people who use healthcare services.

2.3. Gynaecology services in Ireland

In Ireland, gynaecology services are provided in public acute hospitals. In some hospitals, the care is provided by the same consultants and medical staff who provide obstetrical care. A number of private hospitals also provide substantial gynaecology services. Medical staff engaged in the delivery of gynaecology services have expressed a concern that, when compared to other European countries, Ireland has lagged behind in the areas of access to gynaecology surgery and outpatient gynaecological surgical treatment.³ In addition, the provision of gynaecology services has been further impacted by an array of well-documented challenges.³

In 2019, the Health Service Executive (HSE) committed to strengthening the governance and oversight arrangements for maternity and gynaecology services in Ireland. The National Women and Infants Health Programme was established and was tasked with leading the management, organisation and delivery of maternity gynaecology and neonatal services delivered in primary, community and acute care settings. The National Women and Infants Health Programme reports into the Office of the Chief Clinical Officer within the HSE. The Chief Clinical Officer in turn, is accountable and reports to the Chief Executive Officer of the HSE.

2.3.1 Letterkenny University Hospital

Letterkenny University Hospital is a statutory hospital under the governance of the HSE serving a population of approximately 160,000 people in the north-west region of the Republic of Ireland. At hospital level, clinical governance of the gynaecology services at the hospital, rests with the Women and Infants Directorate. This directorate is led by an associate clinical director who reports to the executive board at Letterkenny University Hospital.

Letterkenny University Hospital is a member of the Saolta University Health Care Group. At hospital group level, the gynaecology services are governed by the Women and Children's Managed Clinical and Academic Network led by a consultant

obstetrician and gynaecologist who reports to the Chief Clinical Director of the Saolta University Health Care Group.

2.4. The review of gynaecology services at Letterkenny University Hospital

In 2019, the Chief Clinical Director of the Saolta University Health Care Group commissioned an external review of the gynaecology services at Letterkenny University Hospital, with a particular focus on post-menopausal bleeding pathways⁴ on foot of a number of incidents, over a period of nine years, related to the delay in diagnosing endometrial cancer.

In assessing the quality and safety of gynaecology services at the hospital through this review, the external review team found there was a pattern of delayed diagnosis among some women who accessed services during this time frame arising from poor follow-up practices, sub-optimal triage, and administrative practices, which were further compounded by ineffective communication. The external review team acknowledged how other factors, such as the large and worsening waiting lists for inpatient, day case and outpatient services and a reduced general operating theatre capacity by 25% at Letterkenny University Hospital, significantly impacted on the hospital's ability to provide timely diagnostics and interventions for women attending the gynaecology services.

In early December 2018, Letterkenny University Hospital established a dedicated clinic – the post-menopausal bleeding clinic – as a means to strengthen the structure and process for diagnosing endometrial cancer. However, the external review team recommended that more needed to be done to address the operational inefficiencies and improve the clinical and corporate governance arrangements to assure the delivery of safe, effective and person-centred gynaecology care and services at Letterkenny University Hospital. The review findings and six recommendations relating to operational efficiency, governance arrangements and communication were published in the report of *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways*.⁴ They are also included for reference in Appendix 1 of this guidance document.

2.4.1 HIQA's interactions with hospital, hospital group and national HSE

Initial concerns about gynaecology services at Letterkenny University Hospital relating to both the standard of care received by individual women, and the subsequent investigation of their care at various levels of management within the HSE had been raised with HIQA dating back, in the first instance, to 2018. Since

then, and in accordance with HIQA's current powers under the Health Act 2007 (as amended), HIQA has sought regular assurances from the hospital, hospital group and senior HSE management nationally in relation to concerns around the ongoing quality and safety of gynaecology services at the hospital.

Since that time, and as this engagement continued, it became apparent to HIQA that potential service failures which resulted in delayed diagnoses of endometrial cancer for women were potentially more widespread than initial information may have indicated. Furthermore, it was of significant concern to HIQA that internal governance arrangements at hospital and hospital group level did not appear to have identified this pattern, as might reasonably be expected in a well-governed service. Ultimately, and following continued engagement by HIQA with the HSE, an external review into the totality of post-menopausal bleeding services within the gynaecology services at Letterkenny University Hospital was commissioned by the HSE in 2019.

On the completion of this external review in July 2020, the hospital group and hospital expressed a commitment to fully implement all the recommendations within the report of *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways*.⁴ Responsibility for the operational implementation of the recommendations rests with the hospital group. Enhanced governance arrangements to oversee the implementation of the recommendations was employed at hospital, hospital group and national HSE level.

At hospital group and hospital level, a Special Measures Team (SMT), was convened to ensure the full implementation of the action plan, developed on foot of the recommendations and support service improvement at the hospital. This team reports to, and is accountable to, the Saolta Implementation Oversight Team. This team is chaired by the Clinical Director of Women and Children's Managed Clinical and Academic Network. This oversight team reports directly to the Chief Executive Officer (CEO) of the Saolta University Health Care Group.

At national HSE level, a Letterkenny University Hospital Gynaecological Clinical Service Review: Implementation of Recommendation Oversight Group has likewise been established by the HSE. This oversight group was established under the auspices of the Office of the National Director Acute Operations, and is chaired by a consultant obstetrician and gynaecologist who is independent of services provided at the hospital and the Saolta University Health Care Group. The group is tasked with providing assurance to the HSE's Chief Operations Officer that the recommendations set out in the report of *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways*⁴ are actively implemented and evaluated by the Saolta Implementation Oversight Team. The CEO of Saolta University Health Care Group, and members of the Saolta Executive

Management Team, attend meetings of the HSE's oversight group to account for progress achieved in addressing issues and the implementation of the recommendations in the report of *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways*.⁴

Nine months has now passed since the development and initiation of the action plan and enhanced oversight arrangements by the national HSE, hospital group and hospital. Consequently, HIQA has determined that it is now an appropriate time to conduct a targeted assurance review to establish the level of implementation of recommendations arising from the external review, and determine the effectiveness and sustainability of governance and oversight arrangements at HSE, hospital group and hospital level to assure and ensure the provision of safe, high-quality gynaecology services at Letterkenny University Hospital.

3. Objectives of the review

The primary objective of HIQA's targeted assurance review is to determine and confirm the level of progress made by national HSE, hospital group and hospital in implementing recommendations of the report of *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways*.⁴

HIQA will also look to provide assurance on:

- the effectiveness and sustainability of the governance and oversight arrangements in place at national HSE, Saolta University Health Care Group and hospital level to assure and ensure the delivery of high-quality gynaecology services at Letterkenny University Hospital
- how learning from information relevant to the provision of safe services is promoted and shared at hospital, hospital group and national HSE level.

3.1 Terms of reference

The following terms of reference have been determined for the conduct of this review.

1. Review the progress made by the HSE, hospital group and hospital in implementing recommendations set out in the *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways* report (Price et al. 2020).
2. Review the effectiveness and sustainability of governance and oversight arrangements at national HSE, Saolta University Health Care Group and hospital level to assure and ensure the delivery of high-quality gynaecology services at Letterkenny University Hospital.
3. In undertaking terms 1 and 2, the review team will review the arrangements for providing gynaecology services and care to include, but not limited to:
 - the leadership, governance and management of the hospital, management and use of information, staff skills, teamwork and communication among staff and between staff and women who use the gynaecology services

- how the needs of women using the gynaecology services are being met in the context of the hospital's geographical region, including issues relating to service design and resources available
 - the planning, management and delivery of gynaecology services to include, but not limited to, the assessment and triage, treatment, onward referral and follow up of women using the gynaecology services at Letterkenny University Hospital.
4. Review how learning from information received from women, and or their families, who used or are using gynaecology services at the hospital, and other information relevant to the provision of such services is promoted and supported at hospital, hospital group and national HSE level.
 5. Prepare a report of the findings of the review and make recommendations, if appropriate, as to the governance and oversight arrangements to assure and ensure the quality and standards of gynaecology services at Letterkenny University Hospital. This report will be published in order to promote quality in the delivery of gynaecology services for the benefit of the health and welfare of the public.
 6. If, during the course of the review, it becomes apparent that there are reasonable grounds to believe that there are further or other serious risks to women attending gynaecology services at the hospital, the review team will make a recommendation to HIQA, as appropriate.

4. Review methodology

The review will be conducted in accordance with section 8 and all other relevant provisions set out in the Health Act 2007 (as amended). This review has been devised with a quality improvement outlook, and it is aimed at enabling the HSE, Saolta University Health Care Group and hospital to demonstrate progress in implementing the recommendations from the report of *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways*,⁴ and compliance with national standards.

The review team will comprise of staff from HIQA approved in accordance with section 70(1)(b) and 70(2)(b) of the Health Act 2007 (as amended) as authorised persons. All authorised persons must comply with the HIQA's Code of Conduct, which is available on HIQA's website, www.hiqa.ie.

The methodology for this review will include the issuing of documentation, data and information requests, the on-site inspection and observation of clinical areas, interviews with key persons and a review of patients' healthcare records. A report on the findings will be published on completion of the review.

4.1 Documentation, data and information requests

- The documentation, data and information requirement will be issued by an authorised person under section 73(5) of the Health Act 2007 (as amended).
- Documentation and data will be sought from Letterkenny University Hospital, the Saolta University Health Care Group, and national HSE governing bodies inclusive of the HSE National Acute Operations Office.
- The documentation, data and information required will include, but will not be limited to, data on the service's strategic plan and organograms, minutes of governance meetings, lists of policies and procedures.
- The requested data, documentation and information should be returned, electronically, to HIQA on the date advised. The notification correspondence will confirm the return-by date.
- Authorised persons will review the documentation, data and information provided.

4.1.1 Confidentiality

In line with current data protection legislation⁵ HIQA requests that unless specifically requested to do so, services do not send named patient information or information

that could identify an individual patient to HIQA by email or by post. Hard copy documents provided to an authorised person for removal from the service should not contain data that identifies individual patients.

4.2 On-site inspection, observation and assessment of clinical area

- The review team will conduct an announced inspection to obtain information about the governance and oversight arrangements and the systems and structures in place to support operational performance at Letterkenny University Hospital. Authorised persons will collect evidence of compliance with the 11 specific national standards deemed most relevant to the review (see section 5 for more information on these 11 standards). Evidence of compliance will be collected through inspection and observation of the clinical area, review of documents and data, and meetings with management and staff.
- On arrival at the hospital, the review team will meet with the person with overall accountability and responsibility for the hospital. The hospital will be asked to nominate a liaison person who will be responsible for engaging with authorised persons during the course of the on-site inspection.
- Authorised persons will:
 - request to review documentation and data during the on-site inspection
 - talk with members of staff
 - request an office for use during the duration of the on-site inspection to accommodate scheduled meetings and on-site documentation review.

4.3 Public health precautions during inspection

Authorised persons will take all necessary precautions, in line with public health advice to reduce risks associated with COVID-19. These will include:

- the observation of physical distancing at all times throughout the onsite inspection
- monitoring authorised persons for symptoms of COVID-19, including temperature taking and check prior to entering the hospital
- a declaration by authorised persons to the person with overall responsibility for the hospital that they have no symptoms of illness or a raised temperature
- the observation of good hand hygiene by authorised persons at all times

- compliance with respiratory hygiene and cough etiquette by authorised persons at all times
- the appropriate use of personal protective equipment by authorised persons in accordance with HSE guidance and any national recommendations
- compliance with any additional measures hospitals have in place as appropriate.

Furthermore, authorised persons will be familiar with the most recent guidance and guidelines from the Health Service Executive and the Health Protection Surveillance Centre.

4.4 Interviews

- Individual interviews will be conducted with relevant staff members from Letterkenny University Hospital, Saolta University Health Care Group and national HSE. These interviews will be conducted remotely using videoconferencing technology, on a date or dates after the completion of the on-site inspection at Letterkenny University Hospital.
- Details in relation to these interviews will be communicated in advance so that necessary arrangements can be made to ensure staff availability on the day of interview.

4.5 Patient healthcare record review

- In accordance with section 73 of the Health Act (2007) (as amended), the review team may select and review the healthcare records of a number of women who received gynaecology services and care at Letterkenny University Hospital. This review of healthcare records will inform the review about the women's experience and understand the patient pathway. It should be noted that no specific details of the care received by women will be identifiably included within the subsequent review report that will be compiled by HIQA on conclusion of this review. Rather, the information reviewed through this process will be used to inform HIQA's broader judgments and findings in accordance with the terms of reference of the review.

5. National standards to be monitored during the review

The terms of reference for the review will focus on 11 specific national standards within four of the seven themes of the standards, spanning both the dimensions of capacity and capability and quality and safety.

Capacity and Capability Dimension
Theme 5: Leadership Governance and Management
Standard 5.2 Service providers have formalised governance arrangements for assuring the delivery of high quality, safe and reliable healthcare.
Standard 5.8 Service providers have systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of healthcare services.
Theme 6: Workforce
Standard 6.1 Service providers plan, organise and manage their workforce to achieve the service objectives for high quality, safe and reliable healthcare.
Theme 7: Use of Resources
Standard 7.1 Service providers plan and manage the use of resources to deliver high quality, safe and reliable healthcare efficiently and sustainably.
Theme 8: Use of Information
Standard 8.1 Service providers use information as a resource in planning, delivering, managing and improving the quality, safety and reliability of healthcare.

Quality and Safety Dimension

Theme 1: Person-Centred Care and Support

Standard 1.2 Service users have equitable access to healthcare services based on their assessed needs.

Theme 2: Effective Care and Support

Standard 2.6 Care is provided through a model of service designed to deliver high quality, safe and reliable healthcare.

Standard 2.8 The effectiveness of healthcare is systematically monitored, evaluated and continuously improved.

Theme 3: Safe Care and Support

Standard 3.1 Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.

Standard 3.2 Service providers monitor and learn from information relevant to the provision of safe services and actively promote learning both internally and externally.

Standard 3.3 Service providers effectively identify, manage, respond to and report on patient-safety incidents.

6. Assessment-judgment framework

HIQA is responsible for assessing whether the service provider is in compliance with the national standards under section 8 (1)(c) of the Health Act 2007 (as amended).

In order to carry out its functions as required by the Health Act 2007 (as amended), HIQA has adopted a common Authority Monitoring Approach (AMA).⁶ All HIQA staff involved in the regulation of services or their monitoring against national standards are required to use this approach and any associated policies, procedures and protocols. HIQA's monitoring approach does not replace professional judgment. Instead, it gives a framework for staff to use professional judgment and supports them to do this. The aim of AMA is to:

- ensure a consistent and timely assessment and monitoring of compliance with regulations and standards
- ensure a responsive and consistent approach to regulation and assessment of risk within services
- contribute to the improvement of the service being inspected through application of the inspection process.

In order to improve the quality and safety of healthcare services, service providers are encouraged to continually seek improvements in the services they provide to people who use their healthcare services.

The review team will use an assessment-judgment framework to guide them in assessing and judging compliance with specific 11 national standards monitored during the targeted assurance review. It sets out the lines of enquiry to be explored by authorised persons in order to assess compliance with the standards being assessed. When the evidence is gathered and reviewed, authorised persons will make a judgment on the service's performance. The judgment descriptors on the following page will be used when describing compliance with the 11 national standards.

Compliant	Substantially compliant	Partially compliant	Non-compliant
<p>A judgment of compliant means that, on the basis of this inspection, the service is in compliance with the relevant national standard.</p>	<p>A judgment of substantially compliant means that the service met most of the requirements of the national standard but some action is required to be fully compliant.</p>	<p>A judgment of partially compliant means that the service met some of the requirements of the relevant national standard while other requirements were not met. These deficiencies, while not currently presenting significant risks, may present moderate risks which could lead to significant risks for people using the service over time if not addressed.</p>	<p>A judgment of non-compliant means that this inspection of the service has identified one or more findings which indicate that the relevant national standard has not been met, and that this deficiency is such that it represents a significant risk to people using the service.</p>

7. Risk identification, assessment and notification

During the review, the review team may identify specific issues that they believe may present a risk to the health and or welfare of women using the gynaecology services at Letterkenny University Hospital. If risks are identified, the review team will use HIQA's risk matrix (see Appendix 2) to assess the likelihood and the impact of the identified risks. High risks will be raised with the hospital, hospital group and or HSE in line with HIQA's escalation process (see Appendix 3).

High risks which require immediate mitigation, will be brought to the attention of the manager in overall charge to allow them to implement the actions necessary to mitigate such risks. Formal written notification of any identified risk will also be issued to the accountable person* for the service by email within two working days of identifying the risk. The accountable person will be required to report back to HIQA stating how the risk has been mitigated within two working days of receipt of the notification from HIQA.

In the case of high risks whereby immediate mitigation may not be reasonably achievable, formal notification of the identified risk will be issued to the accountable person by email within two working days of the risk being identified. The accountable person will be required to formally report back to HIQA with an action plan to reduce and effectively manage the risk within five working days of receipt of the notification from the HIQA.

8. Review report

A report of the review's findings will be generated on completion of the review and published on HIQA's website at www.hiqa.ie. The purpose of the report is to:

- provide an update on the progress made in implementing the actions to address the recommendations from the various reviews of the gynaecology services at Letterkenny University Hospital.
- provide assurances, where possible, to women and the wider public that the governance and oversight of gynaecology services at the hospital is compliant with relevant national standards.

* Identified individual or individuals with overall executive accountability, responsibility and authority for the delivery of high-quality, safe and reliable services.

- provide information and share learning across service providers to inform the governance, oversight and delivery of gynaecology services.
- Details of any risks identified will be included in the review report. This will include copies of notification of high risks and the response from the hospital, hospital group, and or national HSE to these risks.
- To allow for due process and to provide an opportunity to provide feedback on the confidential draft report, identified accountable person(s) will be provided with a copy of the draft report. A factual accuracy and feedback form will also be sent to identified accountable person(s).
- The accountable person can provide feedback on the draft report by submitting the completed factual accuracy and feedback form to HIQA within **15 working days** of its receipt.
- Authorised persons will review the feedback, and may make changes as a result of the feedback provided, prior to finalising the report for publication.
- The report will be published on HIQA's website, www.hiqa.ie.
- Relevant stakeholders and the Health Service Executive will be notified five days in advance of the report being published.

9. Freedom of Information

HIQA is subject to the Freedom of Information Acts and the statutory Code of Practice regarding Freedom of Information.

References

1. Health Act 2007. Dublin: The Stationery Office; 2007. [Online]. Available online from: <http://www.oireachtas.ie/documents/bills28/acts/2007/a2307.pdf>.
2. Health Information and Quality Authority. *National Standards for Safer Better Healthcare*. 2012. Dublin: Health Information and Quality Authority. [Online]. Available online from: <http://www.hiqa.ie/standards/health/safer-better-healthcare>.
3. Institute of Obstetricians and Gynaecologists. *The Future of Maternity and Gynaecology Services in Ireland 2006-2016*. 2006. Dublin: Institute of Obstetricians and Gynaecologists; 2016. [Online]. Available online from: <https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/>.
4. Saolta University Health Care Group. *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways*. 2020 Galway: Saolta University Health Care Group. [Online]. Available online from: <https://www.saolta.ie/sites/default/files/publications/LUH%20Gynaecology%20Clinical%20Service%20Review%20FINAL%2020200508%20-%20Addended%2020200707.pdf>
5. Data Protection Act 2018. Dublin: The Stationery Office; 2018. [Online]. Available online from: <http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/html>.
6. Health Information and Quality Authority. *Enhanced Authority Monitoring Approach Guidance*. Dublin: Health Information and Quality Authority; 2017. [Online]. Available online from: https://www.hiqa.ie/sites/default/files/2018-02/Enhanced-Authority-Monitoring-Approach_Guidance.pdf.

Appendix 1 — List of recommendations from the review into the gynaecology services at Letterkenny University Hospital

The following recommendations are those set out in the report of *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleedings pathways*.

No	Recommendation
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 Letterkenny University Hospital manage their waiting lists.
4	Letterkenny University Hospital 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 Letterkenny University Hospital Gynaecology Service should undertake a robust and comprehensive self-assessment against the HIQA National Standards for Safer, Better Healthcare, 2012.

Appendix 2 – Risk matrix

Risk assessment process: authorised persons from the Health Information and Quality Authority (HIQA) will assess the consequence of the risk to patients and the probability of reoccurrence to determine the level of risk, using the tables below. The consequence of the risk and the probability of occurrence are both assessed and given a score from 1 to 5. The risk matrix is then used to give an overall risk score. This score then corresponds with the classification of risk table.

Consequence of the risk: what is the actual impact of the risk?

Consequence category	Impact on individual or future patients
1 Negligible	<ul style="list-style-type: none"> ▪ no obvious harm ▪ no injury requiring treatment.
2 Minor	<ul style="list-style-type: none"> ▪ minor injury ▪ no permanent harm.
3 Moderate	<ul style="list-style-type: none"> ▪ significant injury or ill health ▪ some temporary incapacity.
4 Major	<ul style="list-style-type: none"> ▪ major injuries or long-term incapacity or disability ▪ major permanent harm as result of clinical or non-clinical incident injuries or long-term incapacity or disability ▪ major permanent harm.
5 Catastrophic	<ul style="list-style-type: none"> ▪ death.

Probability of reoccurrence: what is the chance of this event occurring or reoccurring? Identify the 'probability rating' for reoccurrence from the following table:

Probability Score	Descriptor	Frequency
1	Rare	This will probably never happen or reoccur
2	Unlikely	Do not expect it to happen or reoccur again but it is possible
3	Possible	Might happen or reoccur occasionally
4	Likely	Will probably reoccur, but it is not a persistent issue
5	Almost certain	Will undoubtedly recur, possibly frequently.

The lead person classifies the risk using the risk matrix below and documents the findings that indicate the risk.

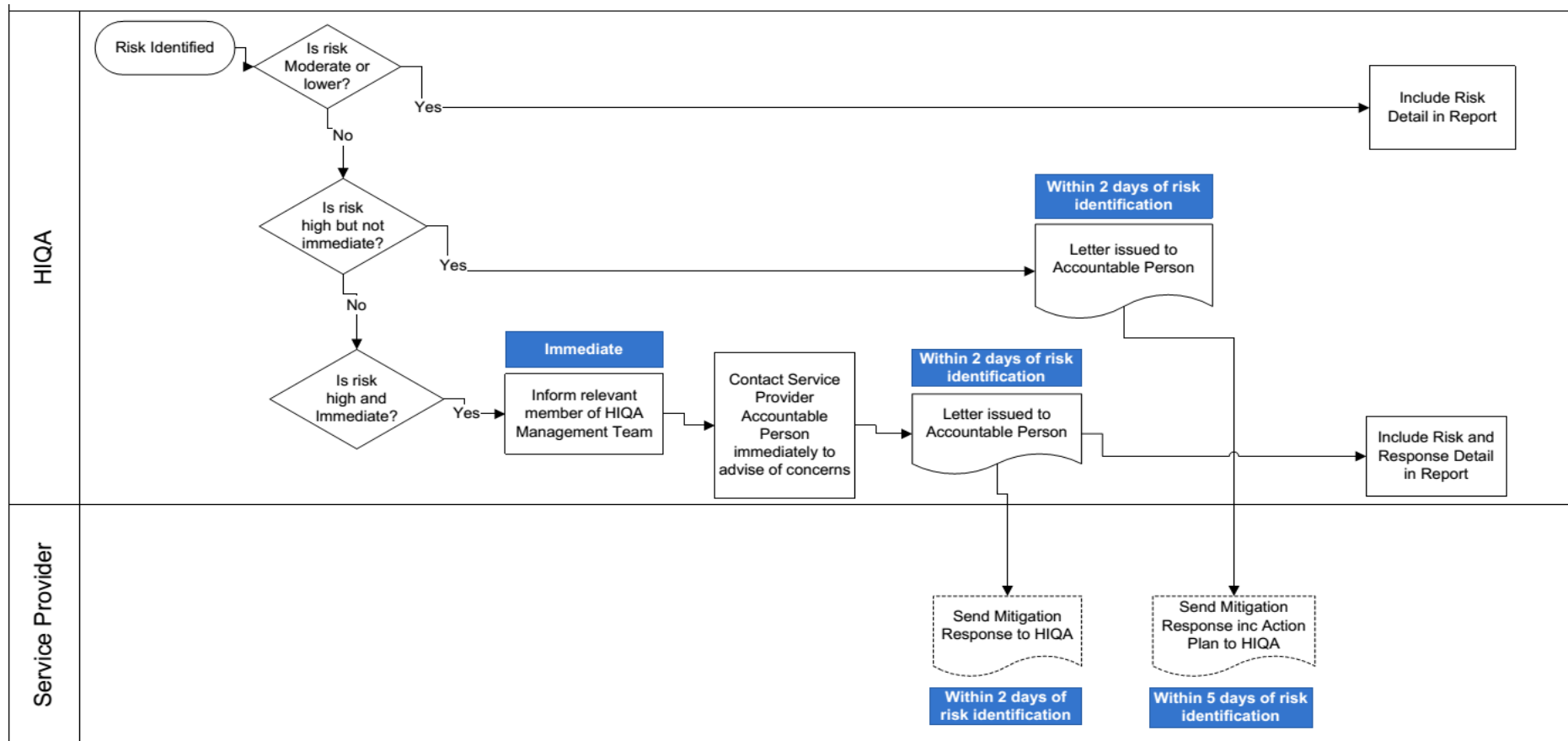
Risk Matrix

Probability ↓	Consequence category →				
	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Almost certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare (1)	1	2	3	4	5

The risk is then classified as high, moderate, low or very low as per the risk matrix score. See classification of risk table below.

Classification of risk	Risk matrix score
High risk (red)	15, 16, 20 or 25
Moderate risk (orange)	8, 9, 10 or 12
Low risk (yellow)	4, 5 or 6
Very low risk (green)	1, 2 or 3

Appendix 3 – Risk escalation process map



Note: Accountable Person: identified individual who has overall executive accountability, responsibility and authority for the delivery of high quality, safe and reliable services.

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