



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

**Report of the targeted assurance review of
the governance arrangements of
gynaecology services at Letterkenny
University Hospital**

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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 Health Service Executive.

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Executive summary

Introduction and background

This report presents the findings from the Health Information and Quality Authority's (HIQA's) targeted assurance review of the governance arrangements at national Health Service Executive (HSE), Saolta University Health Care Group (Saolta Group) and Letterkenny University Hospital levels to assure and ensure the quality of gynaecology services at the hospital.

HIQA has engaged with Letterkenny University Hospital, the Saolta Group and the HSE at a national level about gynaecology services at the hospital since 2018.

Initial concerns about gynaecology services at the hospital were raised with HIQA in 2018 following an incident of delayed diagnosis of endometrial cancer experienced by a woman who had been referred to the hospital with post-menopausal bleeding. This woman subsequently passed away with endometrial cancer. In 2019, HIQA became aware of another woman who had experienced a similar delay in diagnosis. Similarly, this woman also passed away with endometrial cancer.

In response, and in line with HIQA's current powers under the Health Act 2007 (as amended), HIQA engaged with senior management at Letterkenny University Hospital, Saolta Group and nationally in the HSE. This engagement aimed to seek assurances relating to concerns about the governance and ongoing quality and safety of gynaecology services, the standard of care provided at the hospital and the ineffective approach to the investigation of the cases that were the subject of HIQA's concerns.

During HIQA's engagement with the hospital group, it became apparent to HIQA that service failures, which resulted in delayed diagnoses of endometrial cancer for women, were potentially more widespread than just two cases. Furthermore, it was of significant concern to HIQA that internal governance structures and processes in the hospital and Saolta Group had not identified these service failures through the normal oversight assurance processes, as might reasonably be expected in a well-governed service.

To address HIQA's concerns, the Saolta Group implemented external measures to support management and improve the quality of gynaecology services at the hospital from November 2018 to early 2020. However, despite these measures and the assurances provided to HIQA, HIQA became increasingly concerned about the internal governance structures and processes at the hospital and in the Saolta Group through its monitoring activity.

HIQA continued to engage with the Saolta Group regarding the ongoing concerns about the governance, management and quality of gynaecology services at Letterkenny University Hospital, and in 2019 the Chief Clinical Director of the hospital group commissioned an external review (the Price report) into gynaecology services at the hospital, with a focus on pathways for women referred with post-menopausal bleeding. This external review team considered the findings from the case reviews of eight women reported to have experienced a delayed diagnosis of endometrial cancer, including the cases of the two women who had subsequently passed away.

The Price report found that there was significant scope for improving the governance and management of gynaecology services both at the hospital and more widely at Saolta Group level. The report identified several causes for the delay in diagnosis of endometrial cancer, including:

- poor follow-up practices in the referral, assessment and diagnosis processes for women referred to the hospital's gynaecology services with post-menopausal bleeding
- increasing waiting list numbers which impacted on timely access to services for new referrals to the hospital's gynaecology services
- poorly defined and inefficient pathways of care for women referred to the hospital with post-menopausal bleeding
- an overall poor approach to the governance and oversight of gynaecology services at the hospital.

The Price report made six recommendations to improve the quality and safety of services for women attending the hospital's gynaecology services.

HIQA's target assurance review of the governance arrangements of the gynaecology services at Letterkenny University Hospital

Nine months after the publication of the Price report, HIQA commenced a targeted assurance review of the governance arrangements at national HSE, Saolta Group and Letterkenny University Hospital levels to assure and ensure the quality of gynaecology services at the hospital.

HIQA conducted its review over a six-month period from April to September 2021 in line with the review's terms of reference (for further details on the terms of reference see Appendix 1) and the *National Standards for Safer Better Healthcare*.

The review aimed to determine the level of progress made by the national HSE, hospital group and hospital in implementing the Price report's recommendations, and to provide assurance on:

- the effectiveness and sustainability of the governance and oversight arrangements in place at national HSE, Saolta Group and hospital levels 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 in the hospital, hospital group and national HSE.

It should be noted that prior to and over the course of HIQA's review, the health service was working to manage and deal with the unprecedented impact of the COVID-19 global pandemic. The crisis has had a profound impact on Ireland's healthcare system and has caused extraordinary strain on acute healthcare services. It continues to present significant challenges for the health system. Furthermore, HIQA acknowledges that the hospital and county Donegal was one of the most affected hospitals and geographical areas impacted by COVID-19.

The impact of COVID-19 was further compounded by the cyberattack on the HSE's information technology systems in May 2021. This unprecedented event also invoked a crisis management response by the hospital and hospital group. HIQA recognises the significant challenges that these two unprecedented events have had and continue to have on the healthcare system and the provision of services. Despite COVID-19 and the cyberattack, the hospital and hospital group facilitated HIQA in the efficient conduct of its review.

HIQA's findings related to the implementation of the Price report's recommendations

HIQA found that both the hospital and Saolta Group were substantially supported and resourced — financially and with respect to staffing — to implement the Price report's recommendations and bring about changes with the intention to improve efficiencies in the governance and management of gynaecology services at the hospital. Responsibility for the implementation of the recommendations rested with the Saolta Group with structures established at hospital group and national HSE levels to ensure and oversee the implementation of the recommendations.

The Saolta Group developed a plan for the implementation of the recommendations from the Price report, which included 51 actions to be implemented. Each of the 51 actions had a named person who was assigned responsibility for its implementation within a designated timeline. The progress of implementation of the various actions

set out in the plan was monitored every month at hospital, Saolta Group and national HSE levels. Towards the end of HIQA's review, the hospital and Saolta Group had estimated that the majority of actions (84% - 43 actions) were completed, seven actions (14%) were still to be fully completed and one action (2%) had not been started. However, there is some discrepancy in the level of progress estimated to have been achieved and that found by HIQA during the course of its review.

Special Measures Team

A special measures team was convened by the Chief Executive Officer (CEO) of Saolta Group to promote and implement changes at hospital level to improve efficiencies within the gynaecology services, to ensure compliance with best practice clinical guidelines and ensure the provision of safe and reliable gynaecology services for women attending the hospital. This was the second external support measure introduced to support management and improve gynaecology services at the hospital since HIQA raised initial concerns related to governance at the hospital with the hospital group in 2018.

It was evident to HIQA that the special measures team had played an important part in leading and driving the changes to improve the gynaecology services at Letterkenny University Hospital. The special measures team was stood down in April 2021. Thereafter responsibility for the implementation of further initiatives and changes to bring about efficiencies and improvement in gynaecology services was assigned to the local management team at the hospital and the governance structure assigned responsibility for women and children's services at Saolta Group level. HIQA was concerned that Saolta Group had stood down the special measures team before the necessary arrangements and managerial measures were in place at hospital level to further implement changes to improve efficiencies in the governance and management of gynaecology services. Furthermore, HIQA identified a need for enhanced leadership arrangements at Saolta Group and Letterkenny University Hospital to continue to further drive the necessary changes within gynaecology services.

Changes and initiatives to improve efficiencies in and quality of gynaecology services

During the nine months following the Price report, the hospital had introduced a number of changes and initiatives to improve efficiencies in the delivery and the overall quality and safety of gynaecology services. These changes included:

- the introduction of a new ambulatory (outpatient) gynaecology service

- revised procedures for the referral and triage of referrals to the hospital's gynaecology services
- the setting of timelines for the timely review and diagnosis of women referred to the hospital with post-menopausal bleeding.

Ambulatory gynaecology service

An ambulatory gynaecology service is intended to be a one-stop, review-and-treat service provided in an outpatient setting. It is estimated that approximately 70% of general gynaecology referrals are likely to be suitable for management in an ambulatory gynaecology service. Intended benefits for women include a shorter care pathway and quicker recovery period. During HIQA's review, the service was being promoted and prioritised for implementation by the HSE across the country as an alternative approach to the traditional inpatient way of delivering gynaecology services. The service is being implemented on a phased basis across the health system since 2020 and will continue over 2021 and 2022.

At the time of HIQA's review, while work had begun to establish an ambulatory gynaecology service, this was not fully implemented at Letterkenny University Hospital and was working at 50% of its potential capacity. Furthermore, no specific key performance indicators had been developed for the service at local or national HSE levels so the hospital was not monitoring or measuring the performance of the gynaecology service. However, towards the latter end of HIQA's review, the HSE had started to develop specific key performance indicators for the service.

To enable the delivery of the new ambulatory gynaecology service, the hospital had received approval for six whole-time equivalent permanent clerical, nursing and support staff posts. These new posts were in addition to the existing complement of staff providing gynaecology services at the hospital. However, the hospital was unable to fill all six posts on a permanent basis and was dependent on staff employed on locum and agency contracts to sustain the delivery of the service.

Revised referral and triage procedures at Letterkenny University Hospital

Changes to the hospital's referral and triage procedures implemented following the Price report had led to efficiencies in the process. These enabled the tracking of referrals against defined timelines for the processing and triaging of new referrals to the gynaecology services. Adherence to timelines were reviewed weekly and the hospital had a process in place to manage cases where the timelines were not met. However, HIQA found that adherence to process and timelines were not being routinely monitored as part of a structured audit plan.

Additional general gynaecology clinics at Letterkenny University Hospital

Over the three years between 2017 and 2020, waiting times for gynaecology services at Letterkenny University Hospital had increased by 17%. However, from mid-2020, there was a steep decrease in this number. The decline in numbers correlated with the timing of the input of additional resourcing and supports to support the implementation of the Price report's recommendations at the hospital. It is evident that the additional resources and supports had directly impacted on waiting times for gynaecology services at the hospital.

The hospital received additional funding from the National Treatment Purchase Fund, which enabled the scheduling of additional general gynaecology clinics. Extra clinics were provided by medical, nursing and clerical staff from Letterkenny University Hospital and a visiting consultant obstetrician and gynaecologist from University Hospital Galway. These additional clinics helped reduce waiting times for women referred to the gynaecology services. However, while this decline in waiting times is a positive development, it has only managed to align waiting list numbers for gynaecology services at the hospital to the ever increasing waiting list numbers for gynaecology services manifesting across the healthcare system in Ireland.

Additional funding provided by the National Treatment Purchase Fund also enabled the outsourcing of diagnostic procedures for women referred with post-menopausal bleeding to other, mainly private, hospitals. This helped to facilitate timely diagnostics and interventions for women referred to Letterkenny University Hospital. Furthermore, increased operating theatre capacity for gynaecological cases at the hospital is a positive development that has the potential to further facilitate timely diagnosis, management and treatment for women referred to the hospital's gynaecology services. However, with the ambulatory gynaecology services working at 50% of its potential capacity and without the option of outsourcing diagnostic procedures, HIQA is concerned that waiting times for such procedures could again increase and impact on the timely diagnosis of endometrial cancer for women referred with post-menopausal bleeding.

Communication processes with women who use the gynaecology services and those that refer women to the services

The hospital had implemented measures to improve communications with general practitioners (GPs) from the northwest region who refer women to the hospital's gynaecology services. However, at the time of HIQA's review there was limited evidence that the hospital had collaborated with women who had used or were using the gynaecology services so as to make improvements and ensure better experiences for women. As part of its review, HIQA conducted a survey of women who had recently used the service to take feedback on their experience. Notably, the

majority of women who responded to the survey provided positive feedback on their experiences of accessing gynaecology services and care at Letterkenny University Hospital. However, women also identified a number of potential areas for service improvement which were passed on to the hospital. It is important that the hospital and hospital group more comprehensively seek the experiences and views of women using the service in line with the Price recommendation.

Timelines for the timely review and diagnosis of women referred to Letterkenny University Hospital with post-menopausal bleeding

Following the Price report, specific timelines for the timely review and diagnosis of women referred to the hospital with post-menopausal bleeding were set by the hospital, Saolta Group and HSE.

The hospital set a target that required women to be seen and reviewed within 28 days of referral. It also required that within a further 28 days, the woman will receive a diagnosis. At a national level, the HSE had set out that 100% of women with post-menopausal bleeding were to be seen and receive results of tests within 12 weeks of referral. The hospital expressed confidence that the new processes and resourcing levels deployed to this service — together with the revised governance and quality assurance mechanisms introduced following the Price report — would enable it to meet the timelines set for women referred to the gynaecology services, and properly oversee achievement of the timelines.

However, HIQA identified incidents of non-adherence to the timelines for the timely review and diagnosis of women with post-menopausal bleeding. This had not been identified by the hospital or hospital group through its service oversight arrangements. In a small sample of 25 women who had accessed services in the previous months, HIQA identified one instance where targets had not been met, and where, crucially, the hospital's oversight mechanisms had not identified this. In this woman's experience of access to services, the timelines were protracted and were not explainable by any extenuating factors.

The Price report identified major failings in oversight of service performance at the hospital as a key cause of delay for women in receiving a diagnosis of endometrial cancer. Therefore, the failure of the updated oversight arrangements to identify non-adherence to timelines was of significant concern to HIQA.

HIQA sought assurances about these concerns from the CEO of Saolta Group. In response, the CEO acknowledged that the case had highlighted a failure in the governance and quality assurance mechanisms at hospital and Saolta Group levels. Subsequently, the hospital conducted an internal review of all women referred to the hospital's gynaecology service between January 2020 and August 2021. This

revealed a further four cases where the timelines for the timely review and diagnosis of women referred to the hospital's gynaecology services was outside set timelines, and which had not been previously flagged by hospital oversight mechanisms. This further validated HIQA's findings that governance and assurance mechanisms that had been introduced to make gynaecology services safer were not fully effective. Following these findings, a revised approach to oversight was employed by the hospital and Saolta Group. Assurances were provided to HIQA that lessons had been learnt and applied, and that full open disclosure had occurred with all five women identified through this process.

Other concerns about the day-to-day operations of the gynaecology services at Letterkenny University Hospital

Notwithstanding the changes and initiatives that had been introduced at the hospital to improve efficiencies and the quality and safety of gynaecology services, HIQA was concerned that these had only resulted in some improvements for women using the services. The ambulatory gynaecology services was not fully established. As such, while there was an increase in the capacity of the service, this was achieved through the holding of extra general gynaecology clinics that were resourced through funding from the National Treatment Purchase Fund. Furthermore, the revised procedures introduced to improve efficiencies in the referral and triage processes involved multiple manual methods that were labour and time intensive. More importantly, compliance with the processes was not formally monitored or evaluated as part of the annual audit plan at the hospital or Saolta Group. This, together with the shortfalls in the approach to oversight of service performance related to the timely review and diagnosis of women referred with post-menopausal bleeding, raised questions around the effectiveness and sustainability of the changes introduced at the hospital and Saolta Group following the Price report.

In addition, at the time of writing this review report, Letterkenny University Hospital continues to struggle to recruit and retain staff. The hospital had not filled the additional six whole-time equivalent nursing and clerical posts on a permanent basis. The gynaecology services were being sustained through a reliance on locum and agency medical and clerical staff, which has had significant financial implications for the hospital and affects the sustainability of gynaecology services.

Changes implemented to enhance governance of gynaecology services at Letterkenny University Hospital

The Saolta Group had introduced revised governance structures and accountability arrangements at hospital group and hospital levels following the Price report. These aimed to enhance and strengthen the governance arrangements and ensure

effective management at the hospital, and better oversight by the senior management at the Saolta Group.

At the time of HIQA's review, these revised governance structures and accountability arrangements were still in the introductory phase. A committee with responsibility for the management of risk at the hospital had also been recently established. However, HIQA did find issues of concern with some structures governing gynaecology services at the hospital. Two key governance structures had either no terms of reference or had outdated terms of reference. Therefore, HIQA's review team could not determine the effectiveness of the governance structures when compared to their defined purpose and responsibilities. Along with the shortfalls in the approach to oversight of service performance and concerns regarding leadership, this did not provide HIQA with assurance of the hospital's or Saolta Group's effectiveness in ensuring and promoting sustainable quality gynaecology services at Letterkenny University Hospital.

Ineffectiveness of governance assurance structures and processes identified by HIQA

Effective governance cannot be measured through the existence of structures and processes alone. Structures and processes need to work effectively in an integrated way for good governance and management of a service.

At the time of HIQA's review, the implementation of revised governance structures at the hospital and Saolta Group was ongoing. HIQA escalated concerns around weaknesses in the governance and quality assurance mechanisms to the CEO of Saolta Group. In response, the hospital group told HIQA of its intention to introduce an intervention, which included the commissioning of an external, independent team to review the main issues that exist in relation to the management and governance of services at the hospital and to make recommendations to address these issues. Allied to this, the Saolta Group committed to providing on-site managerial support to hospital management. Notably however, this will be the third time since 2018 that external support measures aimed at improving governance structures and processes and supporting management at Letterkenny University Hospital have been implemented by the Saolta Group.

The intervention to improve management and governance of services at the hospital was starting as HIQA's review concluded. In the interim, the Saolta Group committed to implementing corrective actions to address the weaknesses in the governance and quality assurance mechanisms identified during the course of HIQA's review. These actions included that:

- All new referrals to the general gynaecology clinic at Letterkenny University Hospital will be seen by a consultant obstetrician and gynaecologist or non-consultant hospital doctor at registrar grade.
- The hospital's induction programme for incoming locum consultants will be strengthened with particular reference to patient pathways in respect of potential endometrial cancer cases.
- All incidents where appointment timelines set out in the key performance indicators are not met will be reported and reviewed by the Saolta Group.
- A sample of healthcare records of all women who attend the gynaecology services will be reviewed each month to ensure compliance with timelines and key performance indicators.

The recent implementation of these actions should provide additional confidence for women using the gynaecology services at Letterkenny University Hospital that the governance and management issues HIQA identified are being actively addressed.

Compliance with the *National Standards for Safer Better Healthcare*

In conducting this review, HIQA assessed compliance with 11 of the 45 national standards from the *National Standards for Safer Better Healthcare*. Five of the 11 national standards were under the dimension of 'capacity and capacity' in the four themes of leadership, governance and management, workforce, use of resources and use of information.

The remaining six national standards were under the dimension of 'quality and safety' in the three themes of person-centred care and support, effective care and support and safe care and support.

Letterkenny University Hospital was found to be only partially compliant with seven of the 11 national standards assessed (national standards 2.8, 3.1, 3.3, 5.2, 5.8, 6.4 and 8.1). In contrast, it was found to be substantially compliant in the remaining four national standards (national standards 1.2, 2.6, 3.2 and 7.1) assessed during this review.

Overall conclusion

Letterkenny University Hospital and the Saolta Group were substantially supported and resourced to implement the six recommendations from the Price report. HIQA found that while efforts were made to implement the recommendations, these efforts were still a work in progress. With the support and guidance of the special measures team, some important changes and initiatives had been introduced to improve efficiencies and the quality, safety and reliability of gynaecology services at

the hospital but the impact of these changes had yet to be fully realised. HIQA was concerned that the special measures team had been stood down before the necessary local hospital arrangements and managerial controls were in place to implement further improvements in the governance and management of gynaecology services at Letterkenny University Hospital.

The Saolta Group had introduced revised governance and accountability arrangements with the intention to enhance and strengthen governance and oversight of the gynaecology services. During the course of this review, HIQA identified significant weaknesses in the mechanisms. Consequently, HIQA was not assured of the effectiveness of the revised governance structures and processes and oversight arrangements introduced at hospital or Saolta Group levels to assure and ensure the quality of gynaecology services at the hospital following the Price report.

The Saolta Group has introduced an intervention to identify how the approach to governance, management and oversight of all services at the hospital can be improved and supported. HIQA believes it is essential that there is a concerted effort, both at hospital and Saolta Group levels, to ensure that measures implemented now to improve the governance and management of gynaecology services at Letterkenny University Hospital are truly effective and sustained. If sustainable improvements in the governance structures and processes at hospital level and quality assurance mechanisms at Saolta Group level are not achieved with this further external independent intervention, then the Saolta Group need to be held to account by the HSE.

Chapter 1 Introduction

1.0 Introduction

This report presents the findings from the Health Information and Quality Authority's (HIQA's) targeted assurance review of the governance arrangements at national Health Service Executive (HSE), Saolta University Health Care Group (Saolta Group) and Letterkenny University Hospital (LUH) levels to assure and ensure the quality of gynaecology services at the hospital.

Initial concerns about gynaecology services at Letterkenny University Hospital were raised with the HIQA in 2018 following an incident of delayed diagnosis of endometrial cancer, experienced by a woman who had been referred to hospital with post-menopausal bleeding. This woman subsequently passed away with endometrial cancer. In 2019, HIQA became aware of another woman who had experienced a similar delay in diagnosis and who had also passed away with endometrial cancer. Post-menopausal bleeding* is one of the most common reasons for referral to gynaecology services, mainly because of the potential risk of endometrial cancer which is reported to occur in approximately 10% of women who experience post-menopausal bleeding.

In response, and in line with HIQA's current powers under the Health Act 2007 (as amended), HIQA acted upon the unsolicited information that it received and engaged with senior management from Letterkenny University Hospital, Saolta Group and nationally in the HSE. HIQA sought assurances relating to the governance and ongoing quality and safety of gynaecology services at the hospital, the standard of care provided at the hospital and the ineffective approach to the investigation of the cases that were the subject of HIQA's concerns.

Through this engagement with the hospital and Saolta Group, it became apparent to HIQA that potential service and governance failures — which had resulted in a delayed diagnosis of endometrial cancer for a number of women attending the hospital — were potentially greater than the initial information had suggested. Furthermore, it was of significant concern to HIQA that internal governance structures and processes in the hospital and Saolta Group had not identified these service failures through the normal oversight assurance processes, as would be expected in a well-governed service. Following continued engagement by HIQA, an external review into the gynaecology services at Letterkenny University Hospital was

* Post-menopausal bleeding is defined as an episode of bleeding 12 months or more after the woman's last menstrual period.

commissioned by the Chief Clinical Director of the Saolta Group in 2019, with a focus on pathways for women referred to the hospital with post-menopausal bleeding.

The report of this external review —*Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways*¹ (referred in this HIQA report as the Price report) — found that women who were the subject of the review had experienced a delay in diagnosis of endometrial cancer and that there was significant scope for improving the governance and management of gynaecology services at Letterkenny University Hospital and more widely at Saolta Group level.

The Price report found that the delayed diagnosis was caused by a number of contributory factors which included sub-optimal triage and administrative processes, and ineffective follow-up practices for women referred to gynaecology services at the hospital. The report also found insufficient communication among clinicians and across different departments in the hospital, and with women who use the gynaecology services and those who refer women to the services. The report acknowledged that other factors, such as the large and worsening waiting lists for inpatient, day case and outpatient gynaecology services and a general operating theatre capacity reduction of 25% at the hospital, further impacted on its ability to provide timely diagnostics and interventions for women attending gynaecology services at the hospital. The Price report made six recommendations to improve the quality and safety of gynaecology services at the hospital.

Following the publication of the Price report in August 2020, the Saolta Group and Letterkenny University Hospital committed publicly to fully implementing all the recommendations within the report. Responsibility for the operational implementation of the recommendations rested with the Saolta Group, with governance structures established at hospital-group and national-HSE levels to ensure and oversee the implementation process.

HIQA commenced a targeted assurance review of the governance arrangements at national-HSE, Saolta-Group and Letterkenny University Hospital levels to assure and ensure the quality of gynaecology services at the hospital (referred to as HIQA's review in this report) in April 2021. HIQA's review assessed the progress that had been made in implementing recommendations contained in the Price report and reviewed the effectiveness and sustainability of changes introduced with the intention of improving services, enhancing and strengthening governance arrangements at national HSE, Saolta Group and hospital levels to assure and ensure the quality of gynaecology services at Letterkenny University Hospital. HIQA carried out the review in line with its terms of reference (see Appendix 1)² and the *National*

*Standards for Safer Better Healthcare.*³ The review was conducted over six months from April to September 2021.

HIQA's review was carried out nine months after the publication of the Price report. During those nine months and over the course of HIQA's review, the health service was working in crisis mode to manage and deal with the unprecedented impact of the COVID-19 global pandemic. COVID-19 has had a profound impact on Ireland's healthcare system and has caused extraordinary strain on acute healthcare services. It continues to present significant challenges for the health system. Healthcare services and those that work within it, have shown remarkable resilience under unprecedented stress and pressure in managing the COVID-19 pandemic. Indeed, the pandemic has fundamentally changed Ireland's healthcare system.

Inevitably, COVID-19 has had an impact on the organisation and delivery of services at Letterkenny University Hospital. Management of Saolta Group highlighted to HIQA that during the nine month period prior to HIQA's review, the hospital and the Saolta Group had to manage two major surges of COVID-19. Furthermore, the hospital and county Donegal was one of the most affected hospitals and geographical areas impacted by COVID-19. HIQA was told that the surge of COVID-19 at the beginning of 2021 had significantly impacted clinical services at the hospital. For the majority of the nine months before HIQA's review started, the hospital was in crisis escalation mode and the focus was predominantly on managing COVID-19 and maintaining emergency and urgent care. This inevitably had an impact on the progress of implementation of the Price report's recommendations. In addition, Saolta Group management said that the travel restrictions during the nine month period further impacted on the ability of the hospital group management team to provide on-site support to management and staff at the hospital.

The impact from COVID-19 was further compounded by the cyberattack on the HSE's information technology systems, which occurred in May 2021. This unprecedented event also invoked a crisis management response by the hospital and hospital group. HIQA was told that the cyberattack affected all aspects of service delivery including quality improvement initiatives. HIQA recognises the significant challenges that these two unprecedented events have had and continue to have on the healthcare system and the provision of services. Despite the challenges of COVID-19 and the cyberattack, the hospital and hospital group facilitated HIQA in the efficient conduct of its review.

1.1 Structure of the review report

Findings of HIQA's review have been informed by a number of sources of evidence. These include a review of relevant data, documents and information. HIQA also conducted a three-day on-site inspection at Letterkenny University Hospital, and concluded its review with interviews with staff and senior managers at the hospital, and with senior management in the Saolta Group and national HSE. Full details of the review methodology are outlined in Appendix 1.

The report concludes with an overall assessment of progress made at the hospital and Saolta Group in implementing the six recommendations made in the Price report and HIQA's assessment of the level of compliance at the hospital by the HSE with relevant national standards from the *National Standards for Safer Better Healthcare*.

The report also contains a number of appendices which provide additional information on the conduct of the review and the *National Standards for Safer Better Healthcare*. In addition, explanatory footnotes are included throughout the report, and references are identified by a superscript number in the body of the report.

Chapter 2 Placing this review in context

2.0 Introduction

This chapter sets out the context for HIQA's review of the relevant governance arrangements in place in the HSE, Saolta Group and hospital to assure and ensure the quality of gynaecology services at Letterkenny University Hospital. It differentiates between the role of the Department of Health, HSE and hospital group in the governance, management and provision of healthcare services, including gynaecology services. It describes HIQA's role in regulating healthcare services and briefly describes the model and provision of gynaecology services across Ireland. The hospital is profiled, with a specific focus on gynaecology services there.

2.1 Governance and regulation of healthcare and gynaecology services in Ireland

Public healthcare services in Ireland, which include emergency, diagnosis, treatment and rehabilitation services are provided by 49 publicly-funded acute hospitals across the country. These hospitals are categorised according to the type of activity and clinical services they provide. In 2010, the HSE's National Acute Medicine Programme⁴ described four different models[†] of hospitals. These models defined the level of service that can be safely provided in a hospital and are based on the hospital's capacity, capability, staffing level and resources.

The role and functions of the four different models was further described and elaborated in the HSE and Department of Health's report *Securing the Future of Smaller Hospitals: a Framework for Development*.⁵ With each of the 49 publicly-funded acute hospital organised into one of the four models, there is an expectation that the HSE would ensure that each hospital is structured and resourced to provide care and services in line with its categorisation.⁶

[†] Model 1 hospitals – these are community hospitals where patients are under the care of the resident medical officer(s). These hospitals do not have surgery, emergency care, acute medicine (other than a select group of low-risk patients) or critical care. Model 2 hospitals – these hospitals provide the majority of a hospital's activity, including extended day-surgery, selected acute medicine, local injuries, a large range of diagnostic services (including endoscopy, laboratory medicine, point-of-care testing, and radiology [CT, US and plain film X-Ray]) specialist rehabilitation medicine and palliative care. Model 3 hospitals – these hospitals provide 24/7 acute surgery, acute medicine, and critical care. Letterkenny University Hospital is categorised as a Model 3 hospital. Model 4 hospitals – will be similar to Model 3 hospitals, but these hospital also provide tertiary care and, in certain locations, supra-regional care.

2.1.1 Role of Department of Health and Health Service Executive

At a national level, the Department of Health provides leadership and policy direction for the healthcare sector.

Operationally, the structure and provision of healthcare service in Ireland has undergone very significant change over the past 17 years, with the dissolution of the health board structure in 2004 and the establishment of the HSE in 2005.

Established under the Health Act 2004,⁷ the HSE is the agency assigned with the statutory responsibility for the management and delivery of health and personal social care services for the population of Ireland. Overall executive responsibility and accountability rests with a Chief Executive Officer (CEO) who reports to the board of the HSE. The CEO is supported by the Chief Operations Officer and the Chief Clinical Officer. Responsibility for the overall operational performance management and delivery of healthcare services, including the acute hospitals rests with the Chief Operations Officer, while the Chief Clinical Officer provides clinical leadership across the HSE.

The HSE established the National Women and Infants Health Programme in 2017 to lead the management, organisation and delivery of maternity, gynaecology and neonatal services delivered in primary, community and acute care settings. In 2020, following on from the recommendations of HIQA's review of maternity services,⁸ the HSE committed to strengthening the governance and oversight of maternity and gynaecology services in Ireland. Consequently, the reporting structures of the National Women and Infants Health Programme were further defined. Following this, the programme now reports to the HSE's Office of the Chief Clinical Officer. The Chief Clinical Officer in turn reports upwards to the CEO of the HSE.

In its 2021 national service plan,⁹ the HSE committed to working with the Department of Health to improve women's health outcomes and experiences of healthcare, with a particular focus on the priorities set out by the Department of Health's Women's Health Taskforce.¹⁰ These priorities included:

- gynaecological health
- supports for the menopause
- review existing national clinical guidelines in the areas of maternity and gynaecology and develop new ones
- develop further key performance indicators in the areas of maternity and gynaecology services.

The plan sets out how the HSE intends to build capacity, enhance access, reform women's health services and improve gynaecology and fertility services. This increased capacity and reform was to be achieved through a schedule of focused investment, which included €12 million for the implementation of *the National Maternity Strategy—Creating a Better Future Together 2016-2026*.¹¹ A further €10 million was assigned for health screening services, which included CervicalCheck.

Furthermore, as part of the HSE's national service plan, the National Women and Infants Health Programme was allocated an additional €4.683 million to enable the rollout of the ambulatory (outpatient) gynaecology model of care, which started in 2020 across the health system. The funding was to also assist the progression and rollout of phase one of the model of care for infertility. In addition, in 2020 the HSE's National Women and Infants Health Programme secured a further €2.055 million for gynaecology services from the Department of Health's Women's Health Taskforce to further progress the rollout of the ambulatory gynaecology model of care and expansion of gynaecology services across the country.

2.1.2 Hospital groups

The 49 public acute hospitals across Ireland are currently organised into six hospital groups and Children's Health Ireland[‡] established following the publication of the report of the *Establishment of Hospital Groups as a transition to Independent Hospital Trusts*.¹² These hospital groups work with the HSE's acute operations division to deliver healthcare services. Executive accountability and responsibility for the HSE's acute operations division rests with the National Director for Acute Operations. The HSE has devolved responsibility and accountability for the management and delivery of public healthcare services, which includes gynaecology services across the State, to the CEOs of each of the six hospital groups. General gynaecology and maternity services are provided across all six hospital groups (see Appendix 2). Letterkenny University Hospital is a member of and accountable to the CEO of the Saolta University Health Care Group.

2.1.3 Saolta University Health Care Group

The Saolta University Health Care Group (Saolta Group) provides acute and specialist hospital services in the west and northwest of Ireland — counties Galway, Mayo, Roscommon, Sligo, Leitrim, Donegal and adjoining counties — providing healthcare services to a population of approximately 830,000 people in these regions. The hospital group employs 10,653 staff (October 2019) and had an allocated budget of

[‡] The six hospital groups are: Ireland East Hospitals Group; Royal College of Surgeons in Ireland (RSCI) Hospital Group; Dublin Midlands Hospital Group; South/Southwest Hospital Group; Saolta University Health Care Group; University Limerick (UL) Hospitals Group. Children's Health Ireland is an entity established under Section 38 of the Health Act 2004.

€868 million in 2019.^{13,14} The Saolta Group comprises six hospitals across eight sites (see Table 1) and, from an academic perspective, it is partnered with the National University of Ireland Galway (NUIG).

Table 1 Hospitals in Saolta University Health Care Group

Hospital/Academic partner	Model	No. of inpatient beds
Letterkenny University Hospital	Model 3	332
Mayo University Hospital	Model 3	332
Portiuncula University Hospital	Model 3	220
Roscommon University Hospital	Model 2	115
Sligo University Hospital incorporating Our Lady's Hospital Manorhamilton	Model 3	281
University Hospital Galway incorporating Merlin Park University Hospital	Model 4	627

2.1.3.1 Governance of gynaecology services by Saolta University Health Care Group

The CEO of Saolta Group has executive responsibility and accountability for the delivery of services as set out in the HSE's annual service plan, and the Saolta Group's operational plan. The CEO of Saolta Group is accountable and reports to the HSE's National Director of Acute Operations.

Prior to 2020, governance and oversight of gynaecology services at Saolta Group level had been the responsibility of a Women's and Children's Directorate, which had been established within the hospital group's governance structures. The Directorate published annual reports that presented information on the activity and clinical outcomes for each maternity unit in the hospital group.¹⁵

The Saolta Group told HIQA that, in 2020, pre-existing governance structures had been changed with the introduction of a revised management structure called the Women's and Children's Managed Clinical and Academic Network. Its aim was to take a more integrated approach to delivering women's and children's services across the hospital group. The Women's and Children's Directorate was replaced by the Women's and Children's Managed Clinical and Academic Network, which was established to:

- facilitate the effective collaborative workings of the five maternity units[§] within the hospital group
- improve quality and outcomes for women and babies using services
- work closely with individual hospitals to develop and implement strategy, hospital-group-wide clinical policies, procedures, guidelines and pathways to improve services for women and babies
- integrate education, research and training across hospitals within the hospital group to improve the recruitment and retention of staff and support the development of highly skilled multidisciplinary teams.¹⁶

The Saolta Group outlined its plans to improve the range of services for women accessing gynaecology services across the hospital group in its strategic plan 2019–2023.¹⁴ These included the development, establishment and or expansion of a:

- dedicated ambulatory gynaecology service alongside early pregnancy assessment units on each hospital site in the hospital group
- hospital group regional referral service for gynaecology-oncology at University Hospital Galway
- tertiary referral centre in University Hospital Galway, which includes the development of a maternity and gynaecology operating theatre suite
- gynaecology-oncology surgical programme at University Hospital Galway.

2.1.4 HIQA's role in regulating healthcare services in Ireland

HIQA is an independent authority established under the Health Act 2007 (as amended) in May 2007.⁷ Part of HIQA's statutory role includes promoting safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

In line with section 8(1)(b) of the Act, HIQA, among its other functions, sets standards on safety and quality in relation to services provided by the HSE or a service provider in line with the Health Acts 1947 to 2007 (as amended).^{7,17} Section 8(1)(c) also confers the HIQA with statutory responsibility for monitoring the quality and safety of healthcare.⁷

[§] The five maternity units in the Saolta University Health Care Group are Letterkenny University Hospital, Sligo University Hospital, Mayo University Hospital, Portiuncula University Hospital and University Hospital Galway.

The *National Standards for Safer Better Healthcare*³ were developed by HIQA and subsequently mandated by the Minister for Health in June 2012. The national standards aim to 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, reliable healthcare service looks like. The national standards apply across hospital, regional and national health services, and to both the service provider and the HSE as the commissioner of services. For more details on the *National Standards for Safer Better Healthcare* see Appendix 3.

At the time of writing this review report, HIQA does not have the legal remit to enforce compliance with national standards or recommendations arising from investigations or reviews that it conducts in hospitals. HIQA's enforcement powers for healthcare services are limited to services providing medical exposures to ionising radiation (such as X-ray and radiotherapy services). However, where HIQA identifies risks, it escalates these to either the HSE or to the Department of Health. In the future, HIQA's role and function in the monitoring of healthcare services will be significantly expanded with the enactment of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019¹⁸ and the Patient Safety (Licencing) Bill.¹⁹

Furthermore, at the time of writing, HIQA does not have the statutory remit to review or investigate individual complaints about health and social care services. HIQA directs people with individual complaints to the HSE, which has the statutory responsibility to review or investigate them and or the Office of the Ombudsman. HIQA does, however, review all information received about the safety, quality and standards of health and social care services to determine if the information indicates non-compliance with national standards and to assess if there is a serious risk to the health and welfare of people who use the services.

2.2 Model of gynaecology services in Ireland

The model, configuration and provision of general gynaecology services in Ireland are closely aligned to maternity services. Many — if not most — of the same workforce are employed across both services. Gynaecology services are provided in publicly-funded acute hospitals and, in some hospitals, the care is provided by the same medical consultants and medical staff who provide obstetric care. A number of private hospitals also provide substantial gynaecology services. A woman's access to gynaecology services is mostly through their general practitioner (GP), to a lesser

extent through Well Woman Centres** and less often via a hospital's emergency department.

Women may present or be referred to gynaecology services with a variety of presentations or complications, including but not limited to:

- menorrhagia^{††} (heavy menstrual bleeding, endometriosis, other)
- pelvic pain (polyps, cyst, other)
- urinary incontinence issues (associated with childbirth or with the menopause)
- fertility issues
- pre-, peri- and post-menopausal symptoms.

Gynaecology services are provided in all 19 publicly-funded maternity hospitals and units. Four of the 19 maternity hospitals or units are stand-alone hospitals:

- The Rotunda Hospital Dublin
- The National Maternity Hospital
- Coombe Women and Infants University Hospital
- University Maternity Hospital Limerick.^{‡‡}

These four hospitals are not co-located with an acute general hospital with ready access to on-site surgical and medical specialties and intensive care facilities. Such facilities, when required, are accessed through arrangements with an acute hospital usually within their assigned hospital group. The remaining 15 maternity units are co-located with an acute general hospital on site, which enables access to on-site surgical and medical specialties and intensive care facilities.

Specialised gynaecology services are also provided within model 4 general acute hospitals. Such services are led and or provided by consultant obstetrician and gynaecologists. Some of these consultant obstetrician and gynaecologists have joint

** Founded in 1978 and predominantly based in urban settings in Ireland, Well Woman centres provide contraception, sexual health screening, counselling, cervical health screening and advice, support and screening for menopausal conditions.

†† Menorrhagia is a medical term to describe menstrual bleeding lasting for longer than seven days.

‡‡ A colposcopy service is provided in University Maternity Hospital Limerick only; all other gynaecology services are provided in the University Hospital Limerick.

contracts of employment with the model 4 general acute hospital and the specialist maternity hospital.

The provision of gynaecology services across Ireland has been impacted by an array of well-documented challenges, key among them being:

- challenges in recruiting and retaining medical, nursing and midwifery staff
- career development and advancement for medical staff
- poor facilities and equipment in gynaecology operating theatres in maternity hospitals compared to general acute hospitals
- inadequate outpatient hysteroscopy^{§§} facilities
- infrastructural and environment challenges across hospitals in the healthcare sector.^{20,21}

The Institute of Obstetricians and Gynaecologists proposed several initiatives and recommendations to address the challenges in 2006, which included:

- dedicated adequate operating theatre sessions for gynaecology (separate from emergency obstetrics)
- dedicated separate gynaecology wards (staffed by nursing and midwifery staff trained in gynaecology)
- a dedicated 24-hour assessment area for obstetrics and gynaecology emergency cases
- a dedicated outpatient area for obstetrics and gynaecology, to encompass specific facilities for colposcopy clinic, outpatient hysteroscopy and ultrasound scanning
- increased and improved day surgery facilities
- increased and improved outpatient facilities, inpatient and day surgery operating theatre list for each consultant

^{§§} Hysteroscopy is a procedure used to examine the inside of the womb (uterus) in order to diagnose and treat causes of abnormal bleeding. Hysteroscopy is done using a hysteroscopy, a thin, lighted tube that is inserted into the vagina to examine the neck of the womb (cervix) and inside of the womb.

- 24-hour laboratory services, including for example, haematology, biochemistry, microbiology, access to advanced imaging, access to an intensive care unit
- the development of gynaecology services based on the network system
- that complex elective gynaecology cases should be managed in hospitals where the full range of medical and surgical specialties are available
- that each maternity and gynaecology unit should have at least one consultant with a special interest in:
 - urogynaecology
 - minimal access surgery
 - reproductive medicine
 - colposcopy
- the establishment of joint gynaecological audit meetings for hospitals within the network, at least twice yearly.²⁰

Despite these initiatives and recommendations, with the exception of outpatient hysteroscopies, many of the challenges in gynaecology services identified more than 15 years ago continue to challenge the provision of gynaecology services in Ireland today.

2.2.1 Staffing of gynaecology services in Ireland

Gynaecology services across Ireland are delivered by multidisciplinary teams comprising obstetrician and gynaecologists, non-consultant hospital doctors, nurses, midwives, GPs, physiotherapists, radiologists, radiographers, public health nurses, pharmacists, and other health and social care professionals, such as social workers and administrative staff.

Non-consultant hospital doctors who successfully complete basic specialist training in obstetrics and gynaecology and who gain additional clinical experience can apply for the higher specialist training programme in obstetrics and gynaecology. This specialist training programme is five years long. Those on training programmes rotate to different hospitals to facilitate the development and acquisition of core skills and competencies in obstetrics and gynaecology. Training programmes are overseen and managed by the Institute of Obstetricians and Gynaecologists of Ireland and the Royal College of Physicians of Ireland.

Currently, there are no formally agreed national recommendations in Ireland outlining requirements for the number of obstetrician and gynaecologists that should be employed in any hospital providing maternity and gynaecology services. In 2013, the Organisation for Economic Co-operation and Development (OECD) identified that Ireland had the lowest number of consultant obstetrician and gynaecologists per 100,000 women in the European Union.²² At that time, the number of consultant obstetrician and gynaecologists employed in the Irish public healthcare service was 135. Following this, the HSE's National Clinical Programme for Obstetrics and Gynaecology^{***} recommended that the number of consultant obstetrician and gynaecologists in Ireland needed to increase by 100 to reach the United Kingdom's rate of 9.22 consultant obstetricians for every 1,000 live births.^{20,23,24} Between 2015 and 2019, 26 consultant obstetrician and gynaecologists⁺⁺⁺ were recruited to the Irish public healthcare service and in 2020 the number of consultant obstetrician and gynaecologists reported to be employed by the HSE was 189.²⁵ Despite this uplift in consultant obstetrician and gynaecologist numbers, the number still falls short of that recommended by the HSE's National Clinical Programme for Obstetrics and Gynaecology.

Nurses and midwives also work as part of the multidisciplinary team providing gynaecology services. Nurses and midwives have options to further specialise as a clinical nurse or midwife specialist in areas such as colposcopy,⁺⁺⁺ urodynamics^{§§§} and gynae-oncology.^{****} The number of nurses and midwives employed in the Irish public healthcare system in 2017 was high, at 12.2 per 1,000 population, when compared to the EU average of 8.5 per 1,000 population.²⁶ However, this number has decreased year-on-year since.⁸

Furthermore, staffing of gynaecology services is impacted by the ongoing issues of recruitment and retention that has led to shortages within the nursing, midwifery and medical workforce. Efforts by the HSE to address the issue of medical, nursing and midwifery staff shortage included:

*** The HSE established a range of national clinical programmes since 2010. The clinical programmes were established as a joint initiative between the HSE and the Forum of Irish Postgraduate Medical Training Bodies with the objective of improving quality of care. National Clinical Programmes develop evidence-based practice within their respective programme, produce guidelines and integrated care pathways in their specific areas.

+++ This number includes consultant obstetricians and gynaecologists who are employed in maternity units and hospitals as well as acute hospitals that provide gynaecology services.

+++ Colposcopy is a procedure to examine the reproductive tract — cervix, vagina and vulva — for signs of disease.

§§§ Urodynamics is a series of tests that evaluate the function of the bladder.

**** Gynae-oncology services diagnoses and treats women with cancers of the reproductive tract.

- the convening of two separate taskforces that looked at nursing and medical staffing^{27,28}
- increasing the number of nurses, midwives and medical staff employed in the public healthcare system year on year. The number of nurses and midwives (including nursing and midwifery students and public health nurses) employed by the HSE has increased from 24,776 (December 2018) to 47,450 (August 2021).^{29,30} Similarly, the medical workforce (consultants and non-consultant hospital doctors, excluding dental) within the HSE has increased from 6,011 to 11,865 over the same period of time^{29,30}
- increasing the number of doctors in training in Ireland. Between 2019 and 2020 the number in training increased by 15%.²⁵

2.2.2 Provision of evidence-based gynaecology care in Ireland

The HSE's National Clinical Programme for Obstetrics and Gynaecology in collaboration with the Irish Institute of Obstetricians and Gynaecologists of Ireland have developed a number of clinical guidelines to assist clinicians in their decision-making about appropriate care for women attending gynaecology services, including those referred with post-menopausal bleeding. However, the majority of these guidelines need to be revised and updated because they are past their revision dates. The guidelines available to clinicians are:

- Investigation and Management of Menorrhagia (2015).³¹
- Investigation of Postmenopausal Bleeding (2013).³²
- Investigation and Management of Ovarian Cysts in Postmenopausal Women (2017).³³
- Management of urinary retention in pregnancy, post-partum and after gynaecological surgery (2018).³⁴
- Medication Guidelines for Obstetrics and Gynaecology First Edition Volume 1: Antimicrobial Prescribing Guidelines (2017).³⁵
- Medication Guidelines for Obstetrics and Gynaecology First Edition Volume 2: Antimicrobial safety In Pregnancy and Lactation (2017).³⁶
- Diagnosis and staging of patients with ovarian cancer (2019).³⁷

Internationally, the Royal College of Obstetricians and Gynaecologists (RCOG) has developed standards for gynaecology care and published a number of clinical

guidance documents relevant to gynaecology care.^{38,39} Four of its clinical guidelines specifically reference post-menopausal bleeding. These are:

- Management of endometrial hyperplasia.^{††††40}
- Hysteroscopy, best practice in outpatient.⁴¹
- Guidance for management of abnormal uterine bleeding in the evolving Coronavirus (COVID-19) pandemic.⁴²
- Uterine Cancer Guidelines: Recommendations for Practice.⁴³

In addition, as outlined in Table 2, the RCOG identified key indicators that characterise a well-functioning gynaecology service.³⁹

Table 2 RCOG's Indicators of a well-functioning gynaecology service

RCOG's indicators of a well-functioning gynaecology service
■ Clear referral pathways and evidence-based clinical guidelines and practices benchmarked to national and international guidance.
■ Multidisciplinary care and team working.
■ Well-developed clinical governance structure incorporating: clinical guidelines, clinical incident reporting, training, responding to national alerts and patient feedback.
■ Nominated lead for clinical governance in gynaecology and effective risk management systems.
■ Effective communication strategy and mechanisms for handover of care.
■ Use of operating-theatre safety checklists.
■ Review of services provided, and an annual plan for audit and quality improvement.
■ Electronic systems to capture and share information to support risk identification and allow data to be collected and made available for audit and research purposes.

With regard to the referral and diagnosis of endometrial cancer, the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) has developed guidance,⁴⁴ which recommended that:

†††† Endometrial hyperplasia is defined as irregular proliferation of the endometrial glands with an increase in the gland to stroma ratio when compared with proliferative endometrium. Endometrial hyperplasia is estimated to be at least three times higher than endometrial cancer and if left untreated it can progress to cancer. The most common presentation of endometrial hyperplasia is abnormal uterine bleeding, including post-menopausal bleeding.

- women aged 55 and over presenting with post-menopausal bleeding and suspected as having endometrial cancer are seen and reviewed by a clinician within two weeks
- women aged under 55 presenting with post-menopausal bleeding be seen and reviewed by a clinician within two weeks.

At European level, the European Board and College of Obstetrics and Gynaecology (EBCOG) developed standards of care with the aim of standardising and improving the quality of gynaecology care for women across Europe.^{45****}

Notably, despite the existence of international and European guidance, the HSE had not set out specific standards for the referral and diagnosis of endometrial cancer at the time of this review. There are defined standards for the referral and diagnosis of breast, lung and prostate cancer. However, following the Price report, the HSE's National Women and Infants Health Programme did develop clinical guidance on the appropriate time frame for the investigation of post-menopausal bleeding in August 2020.⁴⁶

2.3 Profile of gynaecology services at Letterkenny University Hospital

Letterkenny University Hospital is a statutory model 3 hospital under the governance of the HSE and serving a population of approximately 161,000 in the northwest region of the Republic of Ireland. Letterkenny University Hospital is a member of the Saolta Group, which provides healthcare services on behalf of the HSE to populations in the west and northwest of Ireland. The 332-bed hospital provides a broad range of acute general and maternity services (see Table 3) on an inpatient, day case, and outpatient basis. The hospital is a teaching hospital for medical, nursing, midwifery and other health and social professionals and training is linked with the University of Ireland Galway (NUIG), Royal College of Surgeons in Ireland (RCSI) and Letterkenny Institute of Technology (LYIT).

**** The European Board and College of Obstetrics and Gynaecology standards of care comprise 25 standards that reference various gynaecology conditions. Standard 15: Menopause and Hormonal Therapy makes reference to post-menopausal bleeding, recommending how the management of post-menopausal bleeding in women should be informed by evidence-based guidelines.

Table 3 Services provided at Letterkenny University Hospital

Healthcare services provided in Letterkenny University Hospital	
General Surgery	Orthopaedics
General Medicine	Urology
Emergency Department	Oncology
Coronary Care	Obstetrics
Intensive Care	Gynaecology
Haematology	Renal Services – Regional Centre (Including dialysis)
Radiology	Paediatrics (Including neo-natal services)
Pathology	Psychiatry
Visiting consultants: Neurology; Dermatology; Oral and Maxillofacial; Paediatric Cardiology; Ear Nose and Throat (ENT); and Ophthalmology	

Table 4 sets out activity at Letterkenny University Hospital for the years 2016 to August 2020 as based on publicly available information.^{47,48,49,50} Information on the hospital's activity for quarter 4 of 2020 was not publicly available at the time of HIQA's review. During the COVID-19 pandemic, services had been reconfigured, which had a profound impact on the delivery of scheduled and unscheduled care, especially scheduled care. Staff redeployment meant that some normal activities, such as the collation and publication of hospital activity data, other than COVID-19 data, was delayed or deferred.

The information on hospital activity shows that inpatient cases and day case numbers were consistent year on year for Letterkenny University Hospital. However, emergency inpatient discharge numbers have increased year on year, as have the number of inpatient and day case discharges for people aged 75 years old or older. The total number of births at the hospital has decreased, which is consistent with the decrease in the national birth rate.

Table 4 Management data for activity in Letterkenny University Hospital for 2016 to August 2020

Management data	2016	2017	2018	2019	To Aug 2020
Discharge activity	Discharge activity	Discharge activity	Discharge activity	Discharge activity	Discharge activity
Inpatient cases	24,703	23,723	24,366	24,141	13,794
Day case (includes dialysis)	30,855	30,814	31,008	30,213	16,801
Emergency inpatient Discharges	18,311	17,726	17,932	18,856	10,679
Elective inpatient Discharges	2,061	1,921	2,194	1,946	916
Maternity inpatient Discharges	4,331	4,076	4,240	3,839	2,199
Inpatient discharges ≥ 75 years	4,636	4,712	4,807	5,116	3,003
Day case discharges ≥ 75 years	6,209	6,210	6,350	6,694	3,871
Patient and day case profile (public/private profile)	91.6% Public	91% Public	91% Public	92% Public	92.5% Public
Emergency Care	ED	ED	ED	ED	ED
ED - all emergency presentations	41,847	41,872	45,573	39,832	23,768
New ED attendances	38,084	38,054	40,093	40,903	26,588
Return ED attendances	-	1,780	1,580	1,820	1,320
Other emergency presentations	-	2,038	3,900	3,349	2,200
Births	Births	Births	Births	Births	Births
Total number of births	-	1,668	1,713	1,644	1,159
Outpatients	Outpatients	Outpatients	Outpatients	Outpatients	Outpatients
Number of new and return OPDs	-	63,210	65,968	62,902	45,541

2.3.1 Gynaecology services and pathways at Letterkenny University Hospital

Letterkenny University Hospital provides a gynaecology service comprising inpatient, day case and outpatient care. Inpatient gynaecology services are provided within the complement of the 332 inpatient beds to women admitted to the 11-bed gynaecology ward. Women admitted for gynaecological procedures may also be admitted to other wards in the hospital.

The hospital has four operating theatres in the main operating theatre block; three of these are used for general services and the fourth was, until December 2020, assigned solely for obstetric emergencies. In December 2020, a pre-existing operating theatre at the hospital that was previously decommissioned was recommissioned and this operating theatre was designated for obstetric emergencies. The recommissioning of this operating theatre resulted in additional operating theatre capacity for gynaecological cases.

2.3.1.1 Inpatient, day case waiting lists at Letterkenny University Hospital

The hospital's long and worsening waiting lists for both inpatient, day case and outpatients gynaecology services had been identified in the Price report as a significant contributor to the delay in diagnosing endometrial cancer for some women attending gynaecology services.¹

In February 2021, almost 5,339 women were waiting for an inpatient and or day case gynaecology appointment across the public healthcare sector in Ireland.⁵¹ This number represented 7% (just over 1 in every 14) of the national inpatient and or day case waiting list number (80,936) at that time. Letterkenny University Hospital was one of four hospitals with the highest numbers of women waiting for an appointment for the inpatient and or day case gynaecology services at that time.^{§§§§} A total of 423 women were waiting for an appointment in the gynaecology services at the hospital, which overall represented 8% (just over 1 in 12) of the total number of women (5,339) waiting for an appointment in the inpatient and or day case gynaecology services within the public healthcare system in Ireland.⁵²

2.3.1.2 Outpatient waiting lists at Letterkenny University Hospital

In February 2021, one year following the onset of the COVID-19 pandemic, 31,009 women were reportedly waiting for an appointment in the outpatient gynaecology services across the Irish public healthcare system.⁵² Of these women, 4,544 (15%) were waiting over 18 months for an appointment.⁵²

The number of women waiting over 18 months for gynaecology outpatient services at Letterkenny University Hospital dramatically increased from two women in 2015 to 458 women by end of 2020. However, this increase is consistent with the national waiting list numbers for outpatient gynaecology services (see Table 5).⁵² The number of women waiting longer than 18 months at Letterkenny University Hospital had increased to 461 women in February 2021, which accounted for 36% (just over

^{§§§§} The four hospitals reported to have the highest waiting lists for inpatient hospital gynaecology appointments were – Cork University Maternity Hospital; St Luke's General Hospital, Kilkenny; Mayo University Hospital; and Letterkenny University Hospital.

1 in 3) of the total number of women waiting for an outpatient appointment for gynaecology services at the hospital.

Table 5 Outpatient waiting list for gynaecology services at Letterkenny University Hospital

Outpatient Waiting List for Gynaecology Services at LUH						
Year	Dec 2015	Dec 2016	Dec 2017	Dec 2018	Dec 2019	Dec 2020
Total LUH numbers	1,265	1,102	1,299	1,599	1,777	1,340
0-3 months	334	357	317	408	409	379
3-6 months	266	218	248	261	180	109
6-9 months	265	188	188	221	180	66
9-12 months	185	158	152	165	163	142
12-15 months	199	108	106	118	175	115
15-18 months	14	36	98	105	146	71
18+ months	2	37	190	321	524	458

Rising waiting list numbers is not unique to Ireland. The demand for gynaecology services is comparable per capita when compared to the United Kingdom. There, the National Health Service (NHS) is also experiencing significant pressure and unprecedented levels of demand for elective care, with referrals for gynaecology services accounting for almost 4% of all outpatient attendances.⁵³ This demand has further increased due to the impact of the COVID-19 pandemic.

2.3.1.3 Comparison of national and Letterkenny University Hospital waiting list numbers for 2017–2020

Analysis of waiting list information reported to the National Treatment Purchase Fund for the period 2017–2020 showed that waiting lists for all specialties increased across Ireland, with the waiting list for gynaecology services also increasing but at a lower rate.

Figure 1 shows the monthly national trend of waiting lists for the aggregate of all speciality services and gynaecology services for 2017–2020. The aggregate of all speciality services shows a steady increase (up by 36%) over this period, from 445,701 patients in January 2017 to 606,230 in December 2020. In gynaecology services, while there was greater instability month to month, the overall increase was smaller (17% increase) from 24,517 in January 2017 to 28,778 in mid-2020.

Figure 1 Monthly national trend of waiting lists for all speciality services and gynaecology services for 2017-2020

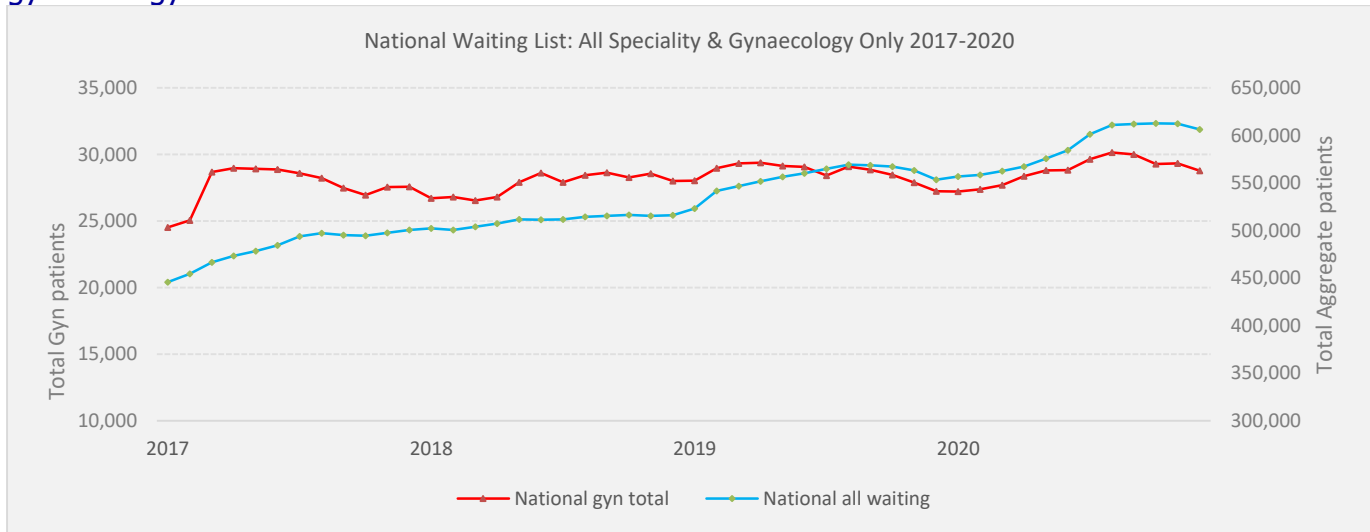
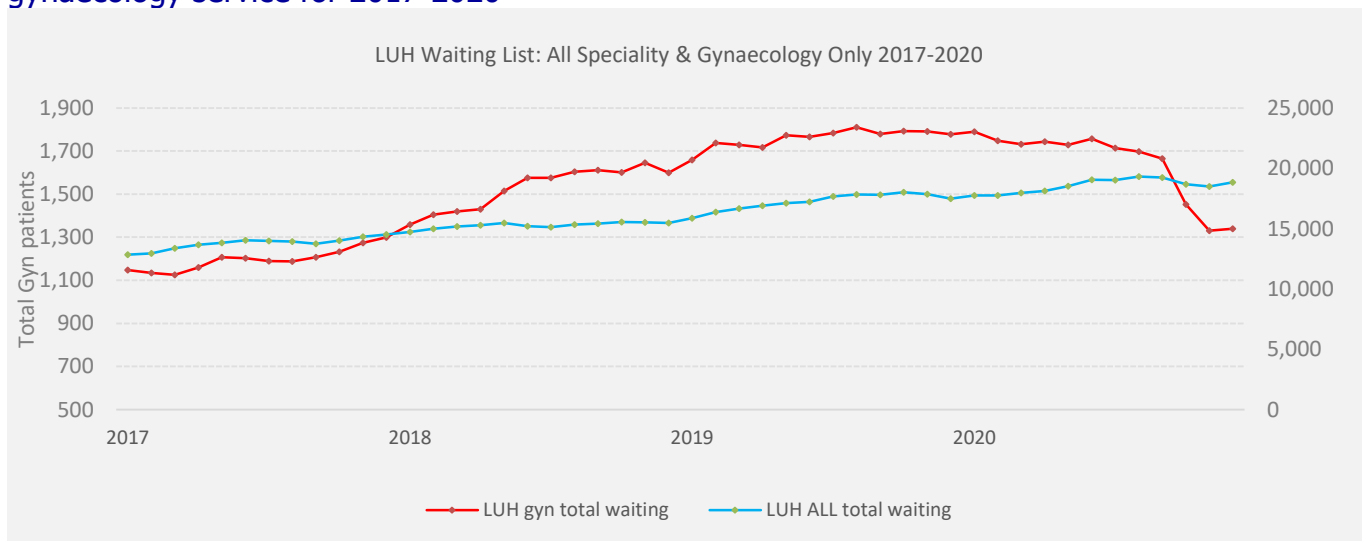


Figure 2 shows the comparable trend for Letterkenny University Hospital. Here, the aggregate for all speciality services increased from 12,842 to 18,832 (a 47% increase) between 2017–2020. Gynaecology services also increased from 1,148 to 1,340 (a 17% increase) over this period too. However, there was a steep decline in this figure from mid-2020, which correlates with the additional resourcing received by the hospital, and other changes and measures introduced at the hospital to implement the Price report’s recommendations. These changes and measures included the introduction of a new ambulatory gynaecology service, regular clinical validation of waiting lists and the scheduling of extra general gynaecology clinics.

Figure 2 Letterkenny University Hospital waiting lists for all speciality services and gynaecology service for 2017-2020



Waiting lists for all speciality services at Letterkenny University Hospital were relatively stable between 2017 and 2020, in the range of 2.7% to 3.2% of the

national total. However, for gynaecology services, the numbers were both higher and fluctuated more, with a range of 4% to 7%, peaking in early 2020 and declining steadily thereafter (see Figure 3). This decline in waiting list numbers for gynaecology services at the hospital continued in 2021 (this is discussed further in section 3.4 of this report).

Figure 3 Letterkenny University Hospital as a percentage of national waiting lists

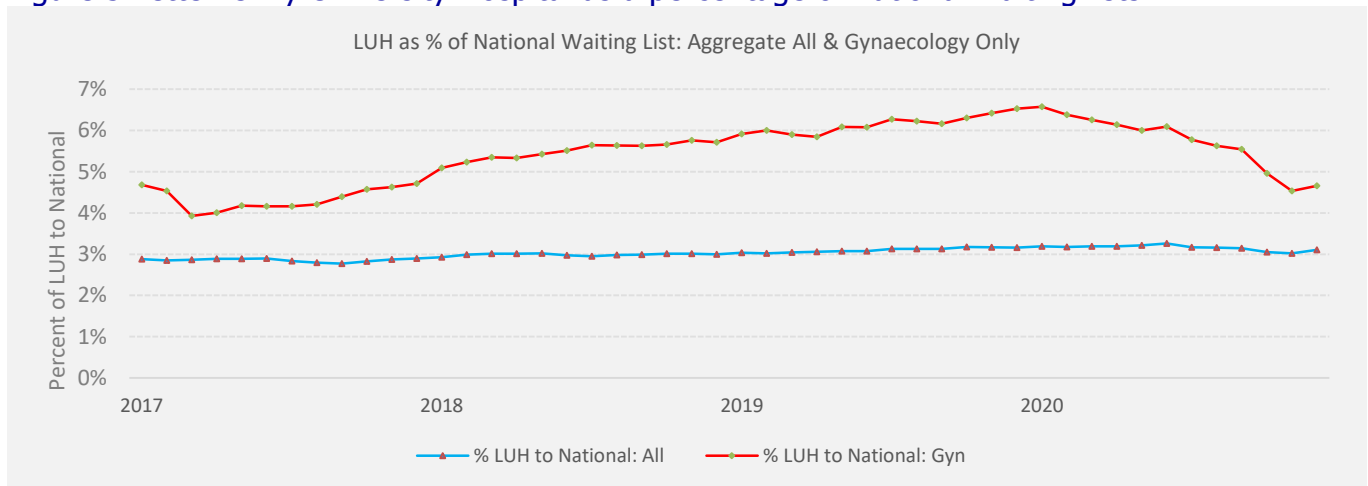


Figure 4 shows the proportion of the gynaecology services waiting list at Letterkenny University Hospital to the waiting list for all speciality services and compares this to the proportion nationally and within the Saolta Group. This shows that, for the Saolta Group and nationally, the proportion of waiting lists that gynaecology services account for vary between 4.5% and 6%. For Letterkenny University Hospital, however, this proportion is higher, between 7% and 11%. For all three parameters (Letterkenny University Hospital, Saolta Group and nationally), the gynaecology services waiting lists declined as a proportion of the total from early 2019.

Figure 4 Proportion of Letterkenny University Hospital's gynaecology waiting list compared to national and Saolta University Health Care Group waiting lists

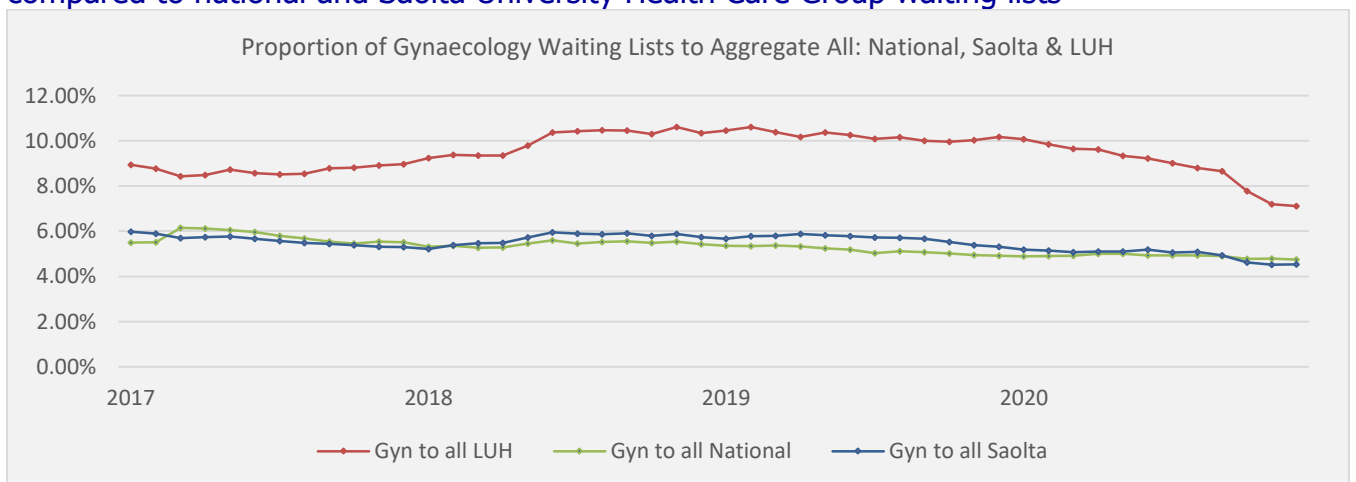
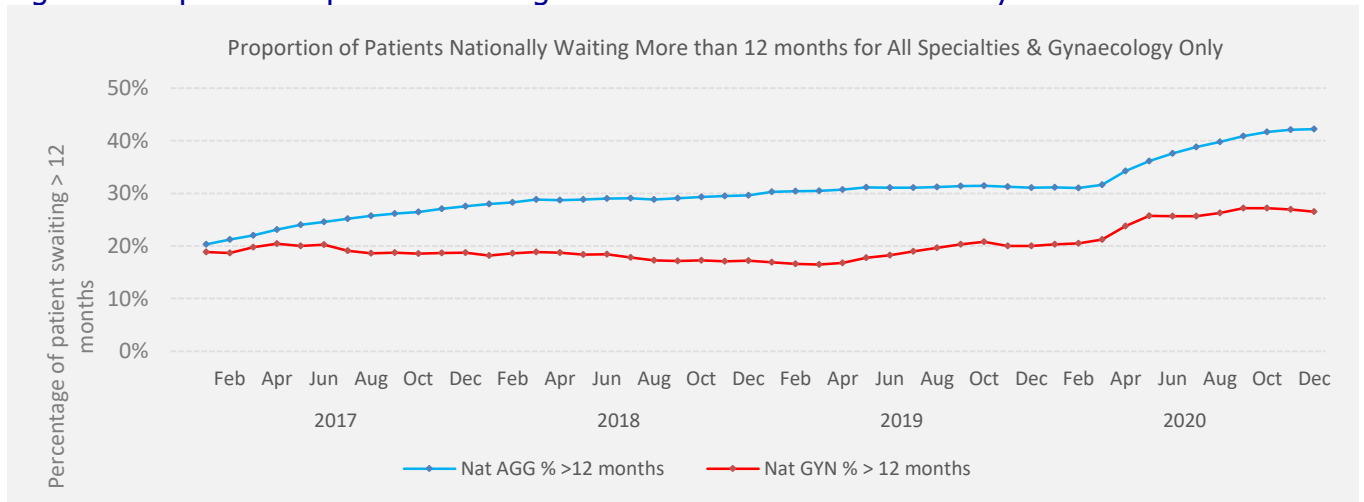


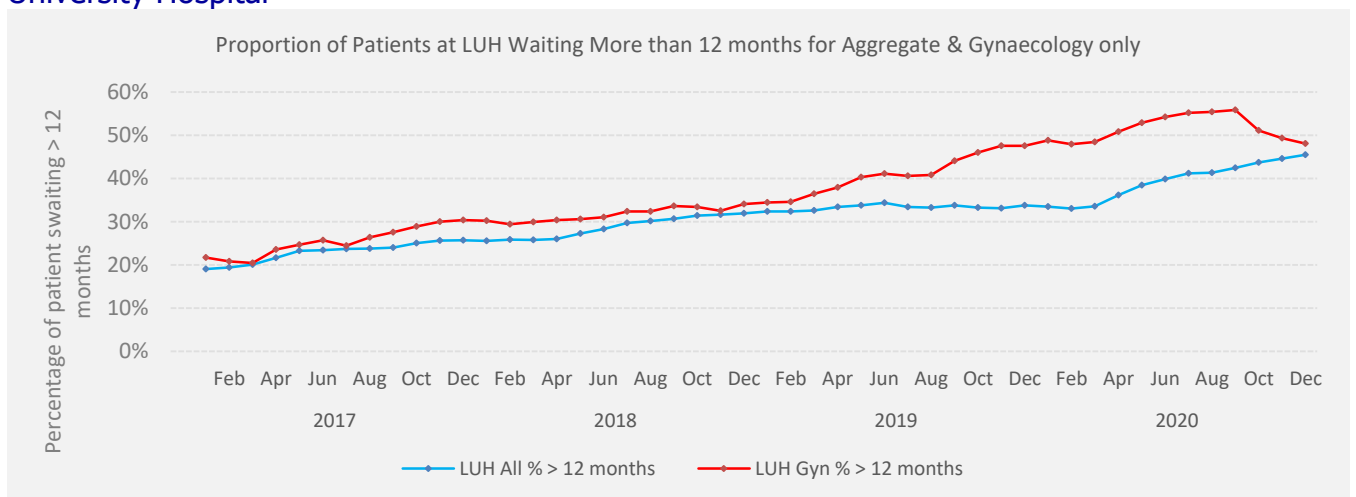
Figure 5 shows the proportion of patients on waiting lists for more than 12 months nationally, for all specialties and for gynaecology services only. This illustrates that a smaller proportion of gynaecology patients nationally were waiting more than 12 months by comparison with patients attending all specialties. Notably, since March 2020, the proportion of women waiting more than 12 months has markedly increased for both groups. Inevitably, COVID-19 has impacted and contributed to this increase in waiting times.

Figure 5 Proportion of patients waiting more than 12 months nationally



The proportion of women waiting more than 12 months for gynaecology services at Letterkenny University Hospital was higher than those for all specialties, and was higher at each time interval than the national equivalent (as shown in Figure 6).

Figure 6 Proportion of patients waiting more than 12 months at Letterkenny University Hospital



In summary, the analysis of waiting list numbers for 2017-2020 showed that the waiting lists for all specialties at Letterkenny University Hospital — and until August 2020, gynaecology services — had increased. The analysis also showed that:

- Letterkenny University Hospital had a higher proportion of the national gynaecology services waiting list.
- Gynaecology services accounted for a higher proportion of Letterkenny University Hospital's total waiting list, which is higher than the national picture or other hospitals in the Saolta Group.
- A higher proportion of those waiting for an appointment for gynaecology services at Letterkenny University Hospital were waiting more than 12 months, compared to both the national waiting lists or Saolta Group waiting lists for gynaecology services.
- There was a marked reduction in the overall trending difference for gynaecology services waiting lists between Letterkenny University Hospital and national waiting lists since mid-2020. Letterkenny University Hospital's total waiting list for gynaecology services declined at this time. This was the direct result of the substantial input of resources and changes introduced at the hospital to increase the capacity of the gynaecology services and improve the organisation, governance and quality of services at the hospital.

2.3.2 Governance of gynaecology services at Letterkenny University Hospital

Corporate governance, managerial responsibility and executive accountability for gynaecology services at Letterkenny University Hospital rests with the General Manager who reports upwards to the CEO of the Saolta Group.

Clinical governance of the gynaecology services, rests with the hospital's Women's and Children's Managed Clinical and Academic Network, which is led at hospital level by an Associate Director of Network, appointed on a rotational basis. The Associate Director of Network — Women's and Children's Managed Clinical and Academic Network reports to the hospital executive board and the Clinical Director of the Saolta Group's Women's and Children's Managed Clinical and Academic Network.

2.3.3 Findings of the external review of gynaecology services at Letterkenny University Hospital (the Price report)

The Price report found that Letterkenny University Hospital had sub-optimal triage and administrative processes with ineffective follow-up practices. It also found there was insufficient communication with women who had attended gynaecology services and those who had referred women to the services. The Price report described the triaging of gynaecology cases at the hospital as cumbersome and inefficient and had concluded that the process provided the opportunity for error and delay. In addition, the report found that large and worsening waiting lists for inpatient, day case and

outpatient services and a general operating theatre capacity reduction of 25% had significantly impacted on the hospital's ability to provide timely diagnostics and interventions for women attending the gynaecology services. Furthermore, Letterkenny University Hospital had not tracked or trended the number of onward referrals sent to the gynae-oncology specialist in St James' Hospital, Dublin for further review and investigation.

Before the Price report, the hospital had put in place some measures to strengthen the structure and process for reviewing and assessing women who were presenting with post-menopausal bleeding. Despite these measures, the Price report 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 person-centred gynaecological care and services at Letterkenny University Hospital. Table 6 sets out the six recommendations relating to operational efficiency, governance arrangements and communication that are contained within the Price report.

Table 6 Six recommendations from *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleedings pathways* (Price report)

Recommendation 1	Letterkenny University Hospital should build capacity in its post-menopausal bleeding clinic and build the capacity of staff working in the post-menopausal bleeding clinic.
Recommendation 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.
Recommendation 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.
Recommendation 4	Letterkenny University Hospital Gynaecology Service should review and improve upon their communication processes with service users and service referrers.
Recommendation 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.
Recommendation 6	The Letterkenny University Hospital gynaecology service should undertake a robust and comprehensive self-assessment against the HIQA <i>National Standards for Safer Better Healthcare</i> , 2012.

2.4 HIQA's previous engagement with Letterkenny University Hospital, Saolta University Health Care Group and national HSE

Initial concerns relating to both the standard of care received by a person who had attended the gynaecology services at Letterkenny University Hospital and who had a delayed diagnosis of endometrial cancer, and the subsequent investigation of their care were brought to the attention of HIQA in 2018. The approach taken by the HSE to investigate this individual's care was subsequently acknowledged by the HSE to have been sub-optimal, and a repeat investigation with input from the HSE's National Women and Infants Health Programme was conducted.

In addition, a second serious incident involving a surgical patient, which related to poor clinical governance emerged in 2018. At that time, and following consideration of these two incidents alongside HIQA's own experience of prior inspections at the hospital,^{54,55,56,57,58} HIQA raised concerns with the CEO of the Saolta Group around the overarching governance arrangements to ensure a sustainably safe, quality service at the hospital. The hospital group committed to addressing HIQA's concerns regarding the governance arrangements through the implementation of special measures and additional managerial supports. This was initially planned for six months from November 2018 to May 2019, but was extended for more than 12 months. In early 2020, with the onset of the COVID-19 pandemic, there was an understandable change in focus as the hospital and hospital group responded to the pandemic.

In September 2019, HIQA became aware of a second serious incident relating to delayed diagnosis of a woman with endometrial cancer at Letterkenny University Hospital. HIQA sought information on the plan to investigate the care provided and assurance on the safety of gynaecology services more generally from the CEO of the Saolta Group. Since that time, and as this engagement continued, it became apparent that potential service failures, which resulted in delayed diagnoses of endometrial cancer for women, were potentially more widespread than just two incidents and contrary to what initial information of concern may have indicated. Furthermore, it was of significant concern to HIQA that internal governance arrangements at both the hospital and Saolta Group did not appear to have identified this pattern of service failures. Ultimately and following continued engagement by HIQA with the Saolta Group and HSE, an external review into the totality of post-menopausal bleeding services within the gynaecology service at Letterkenny University Hospital was commissioned by the Chief Clinical Director of the Saolta Group in October 2019, leading to the publication of the Price report.

In October 2020, the Saolta Group issued HIQA with a copy of the report of the commissioned review along with a report on the audit of the histology database

completed by the hospital. At the time, HIQA sought additional information regarding both reports and an assurance from management of the hospital group that all women whose cases had been included in the review of the histology database had been communicated with and informed. Subsequently, HIQA received a detailed implementation plan from the Saolta Group comprising 51 actions that, when implemented, would aim to address the six recommendations made in the Price report. During the course of HIQA's review of the governance structures to assure and ensure the quality of gynaecology services at Letterkenny University Hospital, HIQA continued to receive unsolicited information about services at the hospital. This information was reviewed and given due and reasonable consideration. Furthermore, HIQA sought assurances around the ongoing quality and safety of services at the hospital from hospital management and senior management in the Saolta Group when required.

2.5 Conclusion

This chapter described the background and context for HIQA's review of governance arrangements in place at national HSE, hospital group and hospital levels to assure and ensure the quality of gynaecology services at Letterkenny University Hospital.

The Price report — *Letterkenny University Hospital: Review of the Gynaecology Service, with a particular focus on post-menopausal bleeding pathways*¹ — set out six recommendations to improve the quality and safety of gynaecology services at Letterkenny University Hospital. In response, Saolta Group in collaboration with the hospital developed an implementation plan comprising of 51 actions. Each action had a designated person responsible for its implementation. The majority of actions were hospital focused and a small minority were to be implemented by the Saolta Group.

The primary objective of HIQA's review was to determine the level of progress made by the national HSE, hospital group and hospital in implementing the recommendations of the Price report, and to provide assurance on:

- the effectiveness and sustainability of the governance and oversight arrangements in place at national HSE, Saolta Group and hospital levels 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 in the hospital, hospital group and national HSE.

The terms of reference for HIQA's review and a full description of the review methodology are outlined further in Appendix 1. Chapters 3 and 4 of this report sets

out the findings of HIQA's review. Chapter 5 set outs the overall conclusion of HIQA's review.

Chapter 3 HIQA's findings on the progress in implementation the recommendations from the Price report

3.0 Introduction

This chapter describes the changes introduced at Letterkenny University Hospital and within the Saolta Group to implement five of the six recommendations (1, 2, 3, 4 and 6) from the Price report. These five recommendations focused on the need to increase the capacity and capability, and improve quality and safety of gynaecology services at the hospital. The remaining recommendation (recommendation 5) focused on the structures and processes governing the gynaecology services at the hospital. Changes introduced with the intention to improve and strengthen the governance structures and processes at both hospital and Saolta Group level are presented in Chapter 4 of this report.

Each section in this chapter begins with a summary of the relevant findings from the Price report and the related recommendation. Then, the changes introduced at hospital and or Saolta Group level to support the implementation of the recommendation are described. Judgments on compliance with the 11 national standards from the *National Standards for Safer Better Healthcare* which were monitored during the course of HIQA's review are presented at the end of both Chapters 3 and 4.

3.1 Project plan to implement recommendations from the Price report

Following the publication of the Price report, the hospital and Saolta Group committed to implementing all of its recommendations. The hospital group developed a comprehensive project plan for the implementation of the recommendations from the Price review that detailed the approach to the implementation process and actions to be implemented to improve the gynaecology services. This project plan set out the 11 work streams that were key to the success of the implementation process and clearly identified the key elements, deliverables, risks, opportunities and governance of each work stream.

The Saolta Group, in collaboration with Letterkenny University Hospital, also developed a 51-point implementation plan, setting out specific actions to be implemented under each of the six recommendations. Each action had a named person who was assigned responsibility for its implementation within a designated timeline. The hospital received substantial support and resources, both financially and with respect to staffing, from the Saolta Group and national HSE to implement the 51-point implementation plan. The progress of implementation of the various

actions set out in the 51-point implementation plan was monitored every month at hospital, Saolta Group and national HSE levels. The progress or otherwise was recorded on an action tracker, which facilitated the tracking of progress or lack of progress, month on month. Overall operational responsibility for the implementation of the recommendations rested with the senior management team at the hospital and the executive management team of the Saolta Group. Towards the end of HIQA's review, the hospital and Saolta Group had estimated that the majority of actions (84% - 43 actions) tracked on the action tracker were completed, seven actions (14%) were still to be fully completed and one action (2%) had not been started.

The level of progress estimated to have been achieved by the Saolta Group and hospital is notable, especially when considering the competing demands caused by the extraordinary challenges caused by COVID-19 and the cyberattack on the HSE's information technology system. However, there is some discrepancy in the level of progress estimated to have been achieved and that found by HIQA during the course of its review.

3.2 Building capacity within the post-menopausal bleeding clinic and personnel working in the clinic

Table 8 presents a summary of the key findings and the related recommendation from the Price report focusing on the need to build the capacity of the post-menopausal bleeding clinic. This was the clinic where women referred to Letterkenny University Hospital with post-menopausal bleeding were seen and reviewed.

Table 8 Findings and recommendation from the Price report focusing on building capacity of the post-menopausal bleeding clinic and staff working in the clinic

- Processes which supported the functioning of the post-menopausal bleeding clinic were no different than those that existed before the clinic was introduced.
- Clinic was not consultant-based. A significant amount of responsibility for the clinic rested with non-consultant hospital doctors at senior registrar grade.
- Functioning of the clinic was dependent on the introduction of a post-menopausal bleeding database. The database was 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.
- The clinic was reliant on an oncology liaison nurse, who went into post in December 2019 from a substantive post as clinical nurse manager grade 2 of the gynaecology ward.
- Capacity of the clinic was limited — only six new and no return patients were seen each week.

- Establishment of the post-menopausal bleeding clinic and the development of the post-menopausal bleeding pathway required specific skill sets in service improvement, leadership and change management that were integral to effective change.

Price report's Recommendation 1: Letterkenny University Hospital should build capacity in its post-menopausal bleeding clinic and build the capacity of staff working in the post-menopausal bleeding clinic.

Progress in implementing Price report's Recommendation 1

HIQA found that significant progress had been made at Letterkenny University Hospital to build capacity in the gynaecology services in order to manage women referred to the hospital with post-menopausal bleeding. The progress was achieved in part due to the significant increase in resourcing of the services, and as a consequence of the leadership, direction and support provided by a special measures team and oversight from the Saolta Group's governance structure assigned responsibility for the women and children's services — the Saolta Group's Women's and Children's Managed Clinical and Academic Network.

3.2.1 Special measures team

A special measures team was convened by the CEO of the Saolta Group to promote and implement changes at hospital level to improve efficiencies within the gynaecology services, to ensure compliance with best practice clinical guidelines and ensure the provision of safe and reliable services for women attending the hospital. Membership of the special measures team comprised two people:

- a senior clinical advisor and clinical lead (a retired consultant obstetrician and gynaecologist) who was independent to Letterkenny University Hospital and the Saolta Group, and
- a senior manager from the hospital group.

The special measures team lead out on four of the 11 work streams of the implementation process. The team reported to the chairperson of the implementation group that had been established by the Saolta Group to implement the recommendations of the Price report. The chairperson of the implementation group in turn reported to the CEO of the Saolta Group.

Documented evidence submitted to HIQA indicated that the special measures team had provided substantial clinical and administrative direction, guidance and support at the hospital from July 2020 to April 2021. With the support and guidance of the

special measures team, changes had been introduced across the gynaecology services to strengthen governance arrangements, increase capacity and improve the quality, safety and reliability of the service. Changes had also been introduced to improve the administration processes, clinical practice and upskilling of staff. Initiatives had been introduced to improve communication across specialties and departments within the hospital with women who use the service and service referrers. The special measures team was stood down on 23 April 2021, with full responsibility for the implementation of further initiatives and changes handed over to the local management team in Letterkenny University Hospital and the Saolta Group's Women's and Children's Managed Clinical and Academic Network (this structure is discussed further in section 4.1.1 of this report).

At the time of HIQA's review, in terms of capacity, the post-menopausal bleeding clinic was functioning similarly to that described in the Price report. However, the hospital was progressing with the introduction of a new ambulatory (outpatient) gynaecology model of care and had plans to integrate the post-menopausal bleeding clinic into the new service.

3.2.2 Ambulatory gynaecology service at Letterkenny University Hospital

The hospital introduced a new one-stop, review-and-treat ambulatory gynaecology service on 29 March 2021. This model of care aligned with the approach to gynaecology services for model 3 hospitals (second-level clinics)^{****} promoted and prioritised by the HSE's National Women and Infants Health Programme.⁵⁹

The ambulatory gynaecology service provides an alternative to the traditional inpatient pathway for women presenting with gynaecological symptoms.⁺⁺⁺⁺ The documented benefits and efficiencies of an ambulatory gynaecology model of care include:

- a shortened care pathway for women attending with gynaecology symptoms
- improved clinical outcomes for women attending the service
- quicker recovery period and return to work and family life

**** Second-level ambulatory gynaecology service clinics are the level of clinics developed and available to women accessing gynaecology service in model 3 hospitals in 12 areas: Portlaoise, Mullingar, Kilkenny, Wexford, Drogheda, Cavan, Mayo, Letterkenny, Sligo, Waterford, Kerry and Clonmel.

++++ In the traditional model of care, women were referred for review to the outpatient general gynaecology services. If further investigations were required, the woman was then admitted to the hospital as an inpatient to have the investigations.

- increased outpatient procedures
- increased day case activity and rates
- increased capacity for inpatient theatre lists
- reduction in the number of elective surgeries
- increased rate of satisfaction with the service.^{60,61,62}

The HSE estimated that approximately 70% of women referred to general gynaecology services are likely to be suitable for management in the ambulatory gynaecology service.⁵⁹ However, management at Letterkenny University Hospital stated to HIQA that they estimated only 30% of women referred to their gynaecology services were suitable for review and treatment at the ambulatory gynaecology service. Therefore, there would appear to be a discrepancy between the national HSE's expectation of the number of women who might be reviewed and treated through this model of care and that which is achievable at Letterkenny University Hospital.

The service was consultant led and women referred to the service were assessed, treated and discharged from the service or, if required, referred to the specialist gynae-oncology services in a tertiary hospital — St James' Hospital, Dublin. HIQA's review found that referral of women to the gynae-oncology specialists at University Hospital Galway was not common. Given that referral to St James' Hospital, Dublin meant that women within the Saolta Group area were being referred for gynae-oncology services outside of the group area, HIQA requested an explanation for this situation from the hospital and Saolta Group. In response, the CEO of Saolta Group said that capacity of the gynae-oncology service at University Hospital Galway for women referred from Letterkenny University Hospital is limited. The hospital had an historic arrangement for women requiring gynae-oncology services to be referred to St. James' Hospital, Dublin. It was further highlighted to HIQA by management at the hospital and Saolta Group that the travel time to Dublin is shorter than that to Galway. Furthermore, it was also expressed that it has been women's preference to receive care in Dublin. There are plans to expand the gynae-oncology service at University Hospital Galway to incorporate women referred from Letterkenny University Hospital and when the resources are recruited and service expanded, the pathway for these women will change from St James' Hospital, Dublin to University Hospital Galway.

The ambulatory gynaecology service was provided in a designated unit located in the gynaecology ward. The hospital was substantially resourced to support the repurposing of the clinical area. The ambulatory gynaecology unit is comprised of

two clinical treatment rooms located on the general gynaecology ward. A range of investigations and treatments, including hysteroscopy,⁺⁺⁺⁺ were provided in the service. A total of four ambulatory gynaecology clinics were undertaken each week (Monday – Thursday). Four to six women, comprising new patients and recall visits on a ratio of 2:1, were reviewed and assessed at each clinic.

At the time of HIQA's on-site inspection in May 2021, the unit was not fully established. Only one of the two clinical treatment rooms was fully commissioned and functioning. Hospital management informed HIQA that the second room would be opened and functional in mid-November 2021. Management at Saolta Group told HIQA that when the service was fully functional, the hospital would be able to meet demand for their gynaecology services and the need to schedule additional general gynaecology clinics would be negated. In the first three months since its opening (between April and June 2021), a total of 174 women had attended the ambulatory gynaecology service at Letterkenny University Hospital. This attendance was with the unit working on 50% of its potential capacity, so when the service is fully operational, the number of women seen in the unit has the potential to increase greatly so long as suitable candidates can be identified.

3.2.3 Post-menopausal bleeding clinic at Letterkenny University Hospital

Women experiencing post-menopausal bleeding were reviewed in the hospital's post-menopausal bleeding clinic. Investigations provided in the clinic included transvaginal ultrasound,^{§§§§§} pipelle sampling^{*****} and dilation & curettage (D&C).

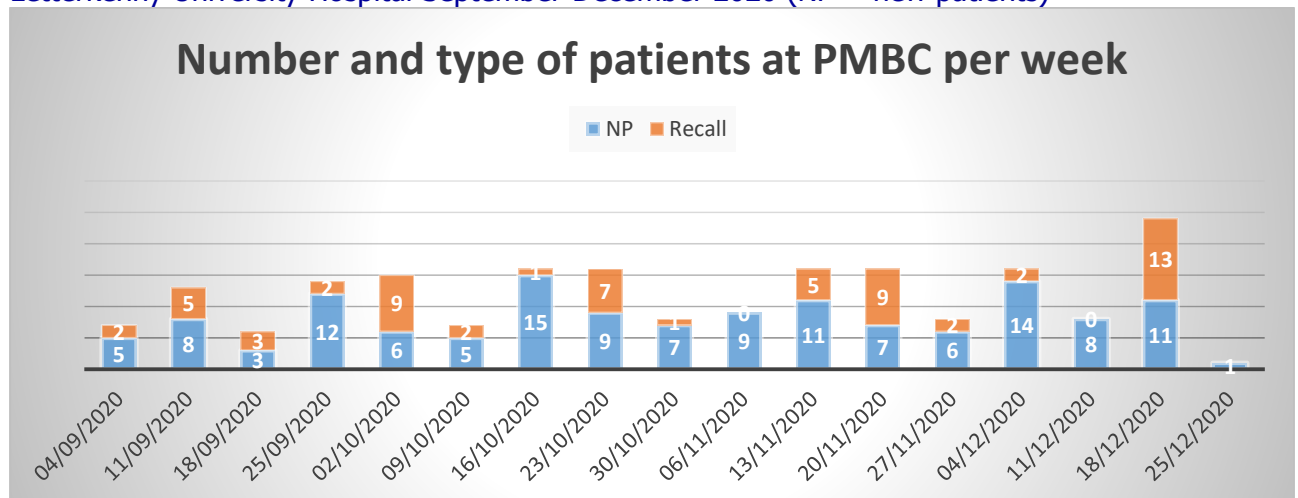
One post-menopausal bleeding clinic was held each week on a Friday. At the time of HIQA's review, the hospital was planning to integrate the post-menopausal bleeding clinic into the one-stop, review-and-treat ambulatory gynaecology service when the service was fully established. Six to eight women were reviewed and assessed at each post-menopausal bleeding clinic. These comprised of new patients and recall visits on a ratio of 3:1. Occasional extra post-menopausal bleeding clinics had been scheduled to meet any surge in demand. Figure 7 details the number and type of women seen at the post-menopausal bleeding clinic(s) each week from early September to late December 2020. Over the 17-week period between September and December 2020, a total of 137 new patients had attended and 62 recall visits had occurred at the post-menopausal bleeding clinic(s).

⁺⁺⁺⁺ Hysteroscopy is a procedure that enables clinicians to look inside the uterus in order to diagnose and treat causes of abnormal bleeding.

^{§§§§§} A transvaginal ultrasound is a type of pelvic ultrasound used by doctors to examine female reproductive organs.

^{*****} Endometrial pipelle sampling, also known as endometrial biopsy, scratching, or injury, is a procedure performed in women with abnormal uterine bleeding.

Figure 7 Number of women referred to the post-menopausal bleeding clinic (PMBC) at Letterkenny University Hospital September-December 2020 (NP = new patients)



The capacity of the post-menopausal bleeding clinic was similar to that identified during the Price report. In the nine months since the Price report, the number of women seen at each clinic had only increased by two. The additional two slots were used for recall visits so the overall capacity of the clinic had only increased in a limited way.

3.2.4 Referral pathway for ambulatory gynaecology service and post-menopausal bleeding clinic

The hospital had defined and established pathways for the assessment, management and treatment of women who attended the ambulatory gynaecology service. These were consistent with the operational guidelines for the service reviewed by HIQA. There was one point of access to the ambulatory gynaecology service. Women on the general gynaecology inpatient or day case waiting lists were reviewed, and those categorised as 'urgent' and suitable for ambulatory gynaecology service were prioritised for review and treatment in the service. HIQA was told that GPs will not refer women directly to the ambulatory gynaecology service because there are very specific criteria for that service. Instead, GPs will refer women to the gynaecology services and a consultant obstetrician and gynaecologist will then triage women to either the ambulatory gynaecology service, post-menopausal bleeding clinic or general gynaecology outpatients as appropriate.

The hospital also had defined and established pathways for the assessment of women attending the post-menopausal bleeding clinic. Women were referred to the clinic via different pathways — external referral from their GP or internal referral from the hospital's emergency department, gynaecology outpatient clinic or from inpatient services.

The hospital had a defined pathway for women who presented for unscheduled care with gynaecological conditions to its emergency department. At the time of HIQA's review, this pathway was recently developed and HIQA was told that the hospital had communicated with GPs to inform them that women with gynaecological symptoms attending the hospital for unscheduled care should present to the emergency department. Women presenting to the emergency department were booked under the care of the consultant obstetrician and gynaecologist on call. Women were then reviewed by the registrar in obstetrics and gynaecology in the emergency department or on the general gynaecology ward. If the woman's condition was unstable, she was stabilised in the emergency department and all necessary treatment was provided there, which included a review by a non-consultant hospital doctor in obstetrics and gynaecology.

Previous to the development of the pathway for unscheduled care, some GPs referred women with gynaecological symptoms directly to the general gynaecology ward in Letterkenny University Hospital. Referrals received and reviewed in this way were termed 'ward attendees'. Ward attendees were usually discharged home following review with a follow-up review arranged in the hospital's general gynaecology outpatient clinic.

The practice of women attending the ward for review ('ward attendees') would not be consistent with best practice for women presenting for unscheduled care. HIQA was informed that the hospital had plans in place to cease the practice. The hospital was engaging with GPs in the northwest region to inform them of the change in practice and pathway.

3.2.5 Extra general gynaecology clinics and post-menopausal bleeding clinics

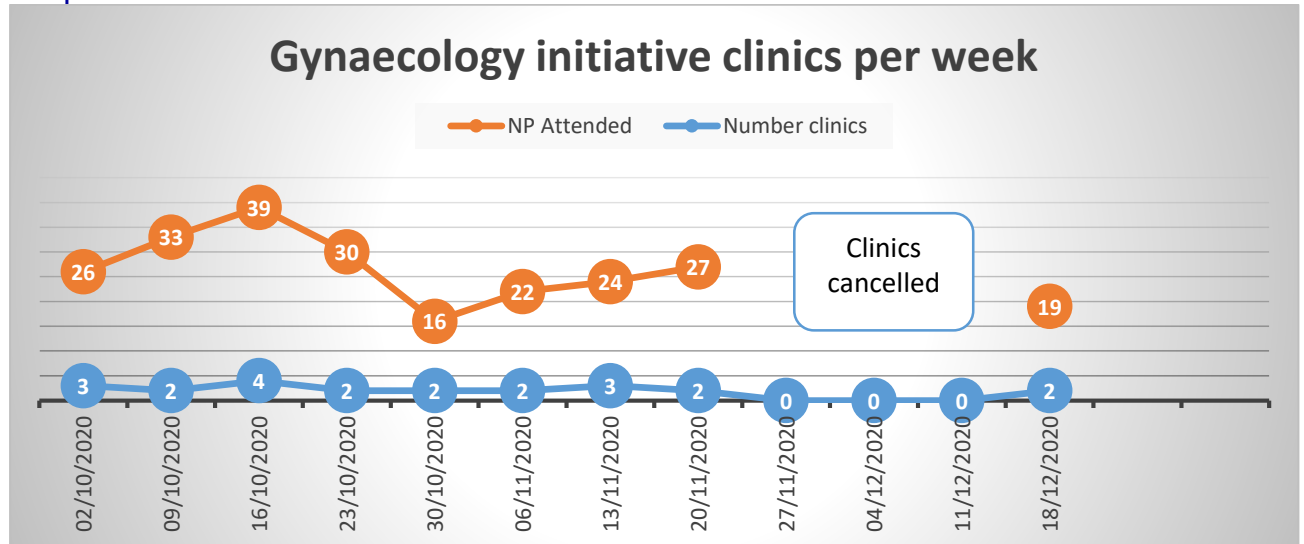
The hospital received additional funding from the National Treatment Purchase Fund,⁺⁺⁺⁺⁺ which supported the scheduling and delivery of extra general gynaecology clinics at the hospital. Additional general gynaecology clinics were provided in the evenings by consultant obstetrician and gynaecologists from Letterkenny University Hospital and a visiting consultant obstetrician and gynaecologist from University Hospital Galway. The additional payroll cost arising from these extra clinics was covered by the funding received from the National Treatment Purchase Fund.

A total of 37 additional general gynaecology clinics were held for new referrals to the hospital's general gynaecology service between October 2020 and July 2021.

⁺⁺⁺⁺⁺ The National Treatment Purchase Fund is an independent statutory body with functions such as: making arrangements for the provision of hospital treatment to such classes of persons as may be determined by the Minister, from time to time; and collecting, collating and validating information in relation to persons waiting for hospital treatment.

Twenty-two clinics were held from October to December 2020. Figure 8 details the number of additional gynaecology clinics held each week from October to December 2020 and the number of women who attended each clinic. A further 15 additional general gynaecology clinics were held between January and July 2021.

Figure 8 Number of additional general gynaecology clinics in Letterkenny University Hospital from October-December 2020



The scheduling of extra clinics had not been overly impacted by COVID-19. Clinics were cancelled for a three-week period between November and December 2020. The extra clinics have helped to address the backlog of referrals for the general gynaecology services at Letterkenny University Hospital, but this initiative was heavily reliant on external funding from the National Treatment Purchase Fund and members of the multidisciplinary team working additional shifts (with associated payroll costs), which was not sustainable. Senior management at the hospital and Saolta Group anticipated that extra clinics would no longer be needed when the ambulatory gynaecology service was fully operational in mid-November 2021. However, as it is anticipated that the ambulatory gynaecology service will cater for the needs of only 30% of women referred to the general gynaecology services rather than 70%, it remained unclear to HIQA if the need for extra clinics until mid-November 2021 is reasonable or if extra supports will be needed for a longer period.

As well as extra general gynaecology clinics, additional post-menopausal bleeding clinics were scheduled when there was a surge in demand for that clinic. The aim was to ensure that all women referred to the hospital with post-menopausal bleeding were seen and reviewed within defined timelines for the review, testing and receipt of results as set by the hospital, the Saolta Group and national HSE. These timelines are discussed further in chapter 4 of this report. Additional post-menopausal bleeding clinics were provided by the consultant with assigned

responsibility for the post-menopausal bleeding clinic supported by nursing and administrative staff.

3.2.6 Expected timelines when demand can be met by service capacity

Projections submitted to HIQA by Saolta Group show that it expected Letterkenny University Hospital to reach a steady state by mid-November 2021, whereby demand for general gynaecology services at the hospital would be met within normal service capacity and extra general gynaecology clinics would no longer be needed. For the hospital to meet the demand for the gynaecology services and to review women categorised as 'routine' or 'urgent' within the defined timelines as set by the Saolta Group and national HSE,^{*****} the hospital's outpatient waiting list numbers should not exceed 500 women. Saolta Group expects that the target of not exceeding 500 women would be achieved by mid-November 2021.

The projections submitted to HIQA were based on a number of assumptions. The first was that a total of 38 women would be seen in the gynaecology outpatient department and post-menopausal bleeding clinic each week. Analysis conducted by HIQA on attendance levels at general gynaecology clinics would suggest this is achievable. The second assumption was that extra general gynaecology clinics would be needed until mid-November 2021 to reduce the backlog in outpatient waiting list numbers for gynaecology services. These extra clinics would continue to be funded by the National Treatment Purchase Fund, with 18 women seen in each clinic per week. At the time of HIQA's review, the hospital and Saolta Group expected that the additional funding from the National Treatment Purchase Fund would continue. The projections do take account of potential risks, such as COVID-19 and contingencies were planned for to control these risks.

However, it was not clear to HIQA if the projections set out above were based on the assumption that 30% of women referred to the general gynaecology services would be suitable for the ambulatory gynaecology service or if it was based on the 70% national HSE expectation for such a service. If it's the latter, then it's unclear if a steady state will be achievable as predicated in mid-November 2021 especially considering this timeline is based on the hospital's outpatient waiting list numbers not exceeding 500 women.

3.2.7 Outsourcing of hysteroscopies

In addition to extra general gynaecology clinics, the hospital, with support from the National Treatment Purchase Fund, availed of additional capacity in other, mainly private hospitals, to conduct hysteroscopies. These hysteroscopies were mainly

^{*****} 12 months for 'routine' referrals, six weeks for 'urgent' referrals and four weeks for the post-menopausal bleeding clinic.

performed by the consultant obstetrician and gynaecologist from Letterkenny University Hospital with the assigned responsibility for the post-menopausal bleeding clinic. Women who had hysteroscopies done in other hospitals were reviewed post-procedure in the referring consultant's general outpatient clinic at Letterkenny University Hospital, where results and a follow-up plan of care were discussed. HIQA was informed that since August 2020, the hospital had arranged for 100 women to have their hysteroscopies carried out in other hospitals. However, less than 50% of women who were offered an appointment for a hysteroscopy in another hospital attended for appointment. Hospital management stated that women had concerns about the transmissibility and risk of infection from COVID-19 and travelling outside the county when COVID-19 public health restrictions were in place. Management at the hospital stated that these concerns had impacted on the level of uptake of hysteroscopies.

3.2.8 Anaesthetic pre-assessment pathway for women attending gynaecology service

The hospital had a formal process in place for the referral and review of women unable to have hysteroscopies in the ambulatory gynaecology service. Women were referred to the enhanced recovery unit (ERU) where a detailed anaesthetic pre-assessment was conducted by an anaesthesiologist or a nurse. The woman was then offered a hysteroscopy in the day service unit or in the main operating theatre. This process was consistent with the relevant standard operating procedure (dated August 2020) reviewed by HIQA. However, at the time of HIQA's on-site inspection to the hospital, this standard operating procedure remained in draft format, and had not been ratified by the relevant governance structures at Letterkenny University Hospital. Non-ratification of procedures would not be consistent with a well-governed service.

3.2.9 Capacity of radiology services at Letterkenny University Hospital

The efficiency of the gynaecology services was further impacted by the diminished capacity in radiology services at the hospital. Staffing issues in the radiology department and increasing demand for radiological services from all specialties were the two main reasons given to HIQA to explain the decrease in capacity in the radiology services. The hospital had a three to four-week wait across all specialties for radiology services such as CTs,^{§§§§§} MRIs^{*****} and ultrasound. HIQA was concerned that this backlog could impact on the timely review, diagnosis and treatment of women with suspected endometrial cancer.

^{§§§§§} An X-ray is an image made using a form of tomography in which a computer controls the motion of the X-ray source and detectors, processes the data, and produces the image.

^{*****} An MRI is an image obtained by magnetic resonance imaging.

This was a known risk that had been escalated by the Radiology Services Manager at the hospital to the hospital's General Manager and the Radiology Directorate at Saolta Group level. The risk was also recorded on the hospital's risk register and corrective actions, such as outsourcing of services, recruiting of additional staff and scheduling of additional radiology sessions, were being considered by the hospital at the time of HIQA's review to militate against the risk. At the time of HIQA's review, the hospital was outsourcing gynaecology ultrasound. Furthermore, the hospital had set a target that ultrasounds categorised as 'urgent' were to be completed within two weeks and 'non-urgent or routine' ultrasounds were to be completed within six weeks of being requested. Compliance with this target was to be regularly reviewed by the radiology services manager.

3.2.10 Communication among multidisciplinary teams

Engagement and buy-in of staff was important for the successful implementation of the Price report's recommendations. Following the Price report, the hospital and hospital group recognised the need to improve and provide opportunities for better communication between departments and services within Letterkenny University Hospital. Formal processes were implemented to facilitate effective communication among the multidisciplinary team providing gynaecology services. The processes were supported by clinical policies, developed by the hospital and Saolta Group, which had endorsed the use of the Identify-Situation-Background-Assessment-Recommendation (ISBAR) tool.⁺⁺⁺⁺⁺ The hospital policy⁺ reviewed by HIQA was being developed and had not been ratified by relevant governance structures at Letterkenny University Hospital or the Saolta Group.

The following multidisciplinary meetings were established to improve communications amongst clinicians across specialties following the Price review:

- gynaecology multidisciplinary meeting
- gynaecology/post-menopausal bleeding-ambulatory gynaecology meeting.

3.2.10.1 Gynaecology multidisciplinary meeting

The gynaecology multidisciplinary meeting was held every week. This meeting was chaired by the Associate Director of the hospital's Women's and Children's Managed Clinical and Academic Network. During COVID-19, the meeting attendance was limited to the key speciality consultants (gynaecology, radiology, histopathology and

⁺⁺⁺⁺⁺ The ISBAR (Identify -Situation-Background-Assessment-Recommendation) tool is a simple way to plan and structure communication.

⁺ LUH Escalation of Care in the Gynaecology Department - Communication Policy (ISBAR).

oncology as needed), the advanced nurse practitioner (candidate)^{*****} and a small number of non-consultant hospital doctors and others.

Cases of interest were reviewed at the meeting and learning was promoted to enhance the management of similar cases that may present subsequently to the service. Documentation received by HIQA showed that seven meetings had occurred over the 13-week period from early October to the end of December 2020. At times, these meetings had been reasonably well attended, but attendance levels at meetings could have been better. HIQA acknowledges that during 2020 and early 2021, the COVID-19 pandemic could have impacted on attendance at meetings and that Letterkenny University Hospital was especially challenged in December 2020 and January 2021 with very high numbers of inpatient cases of COVID-19.

3.2.10.2 Gynaecology/post-menopausal bleeding-ambulatory gynaecology meeting

A multidisciplinary post-menopausal bleeding ambulatory gynaecology meeting was held every two weeks with a focus on day-to-day operational issues. HIQA did not receive a terms of reference for this meeting but did receive copies of the meeting minutes for January to April 2021. These minutes showed that a variety of issues, including staffing and staff education and training, had been discussed at these meetings. The reviewed minutes indicated that attendance levels at the meetings was reasonably good.

HIQA noted that adherence to set timelines for the triage of women referred to the hospital's gynaecology services was recorded in the minutes as having been reviewed. However, there appeared to be no recording in the minutes of the consideration and deliberation that occurred regarding the level of adherence or non-adherence to set timelines for the review, testing and receipt of results (diagnosis) for women referred to the service with post-menopausal bleeding.

While the staff who attended and deliberated at these meetings are to be commended for their efforts, the hospital should review the organisation of the meetings to ensure there is an up-to-date terms of reference and the meeting functions according to the stated purposes. Measures should be introduced to improve attendance at meetings to ensure input from all specialties. Input from all specialties would assist in more effective and informed clinical decision-making, the sharing of information across specialties and improve the quality of care for women referred to the gynaecology services.

^{*****} Advanced nurse practitioner (candidate) is a registered nurse undertaking a formal postgraduate education programme for advanced nurse practitioners.

3.2.11 Policies, procedures, protocols and guidelines for gynaecology services

The integration of best available evidence through the use of policies, procedures, protocols and clinical guidelines ensures that care and service delivery are consistent, up to date and effective.⁶³ Care provided in the gynaecology ambulatory service and post-menopausal bleeding clinic was guided by best available evidence as evident in the range of relevant policies, procedures, protocols and clinical guidelines received by HIQA. These were essential in supporting and informing effective clinical decision-making and consistent effective care. Some of these policies, procedures, protocols and clinical guidelines were developed at local hospital level, such as the investigation and management of post-menopausal bleeding (PMB) policy, while others were developed at Saolta Group level and used locally.

All policies, procedures, protocols and clinical guidelines were accessible electronically to staff through the hospital's quality management system. Despite the overall quality of the documents and guidance submitted, three of the six policies, procedures, protocols and clinical guidelines^{§§§§§§} received and reviewed by HIQA were incomplete and or in draft format. It is imperative that all relevant policies, procedures, protocols and clinical guidelines for gynaecology services are adopted and approved for use by the appropriate governance structures at both Letterkenny University Hospital and Saolta Group level.

3.2.12 Staffing of the ambulatory gynaecology service and post-menopausal bleeding clinic

In implementing changes to improve the structures and processes governing gynaecology services at Letterkenny University Hospital, the hospital and hospital group had identified that additional human resources would be needed. Additional staff were needed to resource the ambulatory gynaecology service and provide administrative managerial support for the Women's and Children's Managed Clinical and Academic Network. The identified staffing requirement for the ambulatory gynaecology service was aligned with the staffing levels proposed for the model of care by the HSE's National Women and Infants Health Programme.⁵⁹

The hospital was substantially resourced to ensure sufficient and appropriate levels of clerical, medical and nursing staffing to service the ambulatory gynaecology unit and post-menopausal bleeding clinic. However, at the time of HIQA's review, the

^{§§§§§§} The three policies that were incomplete or in draft format were - Operational Policy for Gynaecology Services, Letterkenny University Hospital [this guideline was incomplete]; Emergency gynaecology service – discussion document draft V1 (March 2021); Pathway for Gynaecology Patients requiring surgical procedure.

hospital was dependent on medical staff and administrative staff employed on locum or agency contracts.

The staffing profile for the ambulatory gynaecology service inclusive of the post-menopausal bleeding clinic comprised:

- one whole-time equivalent^{*****} advanced nurse practitioner (candidate)
- two whole-time equivalent clerical officers
- two whole-time equivalent registered general nurses
- one whole-time equivalent healthcare assistant
- consultant obstetrician and gynaecologists
- non-consultant hospital doctors at registrar grade.

3.2.12.1 Administrative staff

At the time of HIQA's on-site inspection, one whole-time equivalent clerical officer had been appointed through an agency for the ambulatory gynaecology service. The hospital was in the process of appointing a second clerical officer. Another 0.5 whole-time equivalent clerical officer had been assigned to the post-menopausal bleeding clinic. This person was transferred to the position from the gynaecology secretary office on a temporary basis. The clerical officers provided a range of administrative supports to the ambulatory gynaecology service and post-menopausal bleeding clinic. They had defined reporting arrangements to the patient services manager. During HIQA's on-site inspection, HIQA was informed that recruitment for the second permanent clerical officer position (one whole-time equivalent) was due to commence through the Health Business Services⁺⁺⁺⁺⁺ division of the HSE.

3.2.12.2 Administrative staff for the hospital's Women's and Children's Managed Clinical Academic Network

Letterkenny University Hospital's Women's and Children's Managed Clinical and Academic Network had a business manager (one whole-time equivalent) appointed on a permanent contract who assumed the position on a full-time basis in July 2021. The business manager was responsible for the operational and strategic

***** Whole-time equivalent (WTE): one whole-time equivalent employee is an employee who works the total number of hours possible for their grade. WTEs are not the same as staff numbers as many staff work reduced hours.

+++++ The Health Business Services was introduced in 2013 to organise and supply internal support services more efficiently and effectively across the healthcare sector.

management of the network and reported to the General Manager at Letterkenny University Hospital.

3.2.12.3 Nursing staff

At the time of HIQA's on-site inspection, an advanced nurse practitioner (candidate) (cANP) (one whole-time equivalent) and one whole-time equivalent registered general nurse were employed in the ambulatory gynaecology service. HIQA was told a second registered general nurse, had been appointed to the service and was due to start employment the week beginning 17 May 2021.

The cANP took up position on 26 March 2021. This position was appointed at clinical nurse manager grade 3 level. The cANP was responsible for the oversight, running and coordination of the ambulatory gynaecology service and post-menopausal bleeding clinic. At the time of HIQA's review, the cANP was undertaking a formal education programme for advanced nurse practitioners. Under the supervision of a consultant obstetrician and gynaecologist, the cANP assessed and reviewed women who attended the ambulatory gynaecology service. This included taking a detailed history and performing hysteroscopies and other procedures.

On successful completion of the formal education programme and registration with the professional regulatory body — the Nursing and Midwifery Board of Ireland — the cANP will be assigned a caseload of women attending the ambulatory gynaecology service. The cANP reported to the Director of Midwifery at Letterkenny University Hospital on operational day-to-day issues, and to the consultant obstetrician and gynaecologist in the hospital providing supervision of clinical practice as part of the formal training for an advanced nurse practitioner.

The cANP met with the Director of Midwifery every week to discuss operational issues related to the ambulatory gynaecology service and the post-menopausal bleeding clinic. The cANP also attended monthly meetings of the gynaecology/post-menopausal bleeding ambulatory gynaecology and quality and patient safety committee.

3.2.12.4 Gynae-oncology registered nurse

The gynae-oncology nurse position was unfilled at the time of HIQA's on-site inspection. HIQA was told that the hospital had commenced a recruitment campaign to fill the position. Expression of interests had been sought from current members of staff. The position was to be integrated with the vacant clinical nurse manager, grade 2 post in the gynaecology outpatients department.

3.2.12.5 Medical consultant staff

The hospital had approval for five permanent consultant obstetrician and gynaecologist positions. Three of the five consultant obstetrician and gynaecologist were permanent appointments. One of these three consultants was the Associate Director of Network — Women’s and Children’s Managed Clinical and Academic Network. Two of the three permanent consultant obstetrician and gynaecologists were due to retire within five years. Two consultant obstetrician and gynaecologists were appointed on locum contracts.

Management at hospital and hospital-group reported that the reliance on agency staff was due to the difficulties in attracting and retaining staff, which they attributed to the hospital’s geographic location and the adverse impact of the shortage and difficulty in recruiting consultant medical staff at national level.

Medical staff – Non-consultant hospital doctors

The consultant obstetrician and gynaecologists at Letterkenny University Hospital were supported by 14 non-consultant hospital doctors in obstetrics and gynaecology. Seven were at senior house officer grade^{*****} and seven at registrar grade.^{§§§§§§§§} Some of the registrars were long-standing appointments who were in post for many years, and were not on a specialist training scheme. The challenges associated with these appointments has been well-documented in previous HIQA reports⁶⁴ but despite measures being identified to address the issue, the challenges still prevail.⁶⁵ Furthermore, management at the hospital highlighted to HIQA that the difficulty in recruiting permanent consultant medical staff had impacted on the hospital’s ability to attract and increase non-consultant hospital doctor training.

The challenges around recruitment of medical and nursing staff experienced by the hospital were recognised and acknowledged to HIQA by senior management at Letterkenny University Hospital, the Saolta Group and national HSE. The hospital group and national HSE were working together to address the issue and associated challenges. The Saolta Group had developed a 15-point plan to improve and sustain medical staffing at the hospital. The hospital was trying to fill the outstanding permanent consultant obstetrician and gynaecologist posts through the public appointments service (PAS).^{*****}

***** A senior house officer (SHO) is a non-consultant hospital doctor who is supervised in their work by consultants and other non-consultant doctors at registrar grade.

§§§§§§§§ A registrar is a senior grade non-consultant hospital doctor in training who is supervised in their work by consultants.

***** The Public Appointment Service is a central recruitment agency for the recruitment to the civil service and a range of other public bodies. The Public Service Management (Recruitment and

3.2.12.6 Training and education for staff

In-house, clinical skills training for medical and nursing staff providing ambulatory gynaecology service was provided by the clinical lead from the special measures team over a four-week period in March and April 2021. Since August 2020, three medical staff had completed formal training and instruction on gynaecology ultrasound scanning.

The cANP was undertaking a formal education programme to attain the requisite theoretical and clinical instruction which, on successful completion, would meet the eligibility criteria for registration on the advanced nurse practitioner register with the Nursing and Midwifery Board of Ireland.

The clerical officer received in-house instruction and training on how to use the Integrated Patient Management System (iPMS), which is the national patient administration system used by the HSE.⁺⁺⁺⁺⁺

Two gynaecology study days had been provided for nursing staff in the 12-month period before HIQA's review. Allied to these, the Director of Midwifery, along with Saolta Group's Chief Director of Midwifery, in partnership with the Centre of Nursing and Midwifery Education, were progressing with the development of a Quality and Qualifications Ireland (QQI)⁺⁺⁺⁺⁺ level 8 postgraduate educational programme on gynaecology nursing. It was anticipated that this programme would be available for nursing and midwifery staff from September 2022.

The Price report had recommended that senior registrars involved in the post-menopausal bleeding clinic should have appropriate and ongoing training in oncology. At the time of this review, HIQA found that that this recommendation had not been progressed at hospital or hospital-group levels. Hospital management told HIQA that the availability of training was impacted by the COVID-19 pandemic. However, this lack of progress — along with the unfilled gynae-oncology nurse post — resulted in a shortfall in aspects of care delivery, especially for women who require onward referral to specialist gynae-oncology services.

Appointments) Acts 2004 to 2013 empowers government departments and other public service bodies to recruit staff directly under licence, as well as through the centralised recruitment system provided by the Public Appointment Services.

⁺⁺⁺⁺⁺ Integrated Patient Management System is the national patient administration system.

⁺⁺⁺⁺⁺ Quality and Qualifications Ireland (QQI) is the national agency responsible for qualifications and quality assurance in further education and training and higher education in Ireland.

3.2.13 Summary of findings on changes implemented to increase the capacity of the post-menopausal bleeding clinic

Overall, significant work has been undertaken by the hospital and hospital group to increase the capacity of the general gynaecology services at Letterkenny University Hospital. The ambulatory gynaecology service should, when fully established, help efficiencies in the service. The impact of this service on the numbers of women waiting for general gynaecology services at the hospital has yet to be determined. Presently, the true impact of the ambulatory gynaecology service on waiting list numbers at the hospital is not easily identifiable due to the parallel utilisation of additional capacity through extra general gynaecology clinics.

Staff recruitment, especially in medical and nursing staff, remains a well-recognised challenge for the hospital, and reliance on agency or locum staff is not sustainable. The successful recruitment and retention of staff across all specialties are critical to the delivery of safe, quality and reliable services at the hospital. It is also imperative that the appropriate governance structures at Letterkenny University Hospital and Saolta Group level ratify and confirm that relevant policies, procedures, protocols and clinical guidelines for gynaecology services meets the standard required.

3.3 Referral and triage system for women attending gynaecology services at Letterkenny University Hospital

Table 9 presents a summary of the key findings and the related recommendation from the Price report regarding the hospital's referral and triage system for gynaecology services.

Table 9 Findings and recommendation from Price report related to referral and triage systems

- The triage system for the gynaecology service was cumbersome, inefficient and represents a significant opportunity for error and delay.
- In addition to triaging outpatient referrals as 'urgent' and 'routine', as per National Treatment Purchase Fund protocols, the gynaecology service also used an additional 'very urgent' triage category, which was not consistent with the National Treatment Purchase Fund protocol.
- There are no locally agreed maximum waiting times for the 'very urgent' triage category, nor are the waiting times for this category monitored.
- The gynaecology service overbooked its clinics with 'urgent' or 'very urgent' referrals, and relied on other patients not attending to manage the overflow. Communication, between the hospital, the GP, and the patient, required improvement.

Price report's Recommendation 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.

Progress in implementing Price report's Recommendation 2

Following the publication of the Price report, Letterkenny University Hospital reviewed its referral and triage pathway for the post-menopausal bleeding clinic and identified opportunities for improvements to streamline the process. A revised procedure for the management of referrals to the general gynaecology services at the hospital was implemented in August 2020.

During HIQA's on-site inspection, the review team followed the pathway of referral from the Central Referral Office, where referrals for all services, including gynaecology services, were received. From here, gynaecology referrals were sent to the gynaecology secretary's office. Referrals for the post-menopausal bleeding clinic were sent to the secretary of that clinic and referrals for general gynaecology services were sent to the gynaecology outpatients department. All referrals were then forwarded to a consultant obstetrician and gynaecologist for review and triage.

The revised referral and triage process offered improvements in terms of defining the roles and responsibilities of each individual involved and increased the transparency of the process. The process enabled the tracking and triaging of referrals against defined timelines.

3.3.1 Processing of gynaecology service referrals at Letterkenny University Hospital

The majority of GP referrals (75%) received by the hospital for the general gynaecology services was via the electronic messaging service used by GPs — Healthmail or Healthlink. The remaining 25% were in hard copy, letter format. GPs who used the electronic format used a standardised referral form and received a routine acknowledgment of receipt of the referral from the hospital. However, GPs who used hard copy letter format did not receive a routine acknowledgment of receipt of referral from the hospital.

In line with hospital procedure, all referrals were entered on the hospital's integrated patient management system within 24 hours of receipt of referral in the Central Referral Office. After being entered on this system, the referral was then sent to the gynaecology secretary assigned to the post-menopausal bleeding clinic or the general gynaecology outpatient department for forwarding to the relevant consultant obstetrician and gynaecologist for triage.

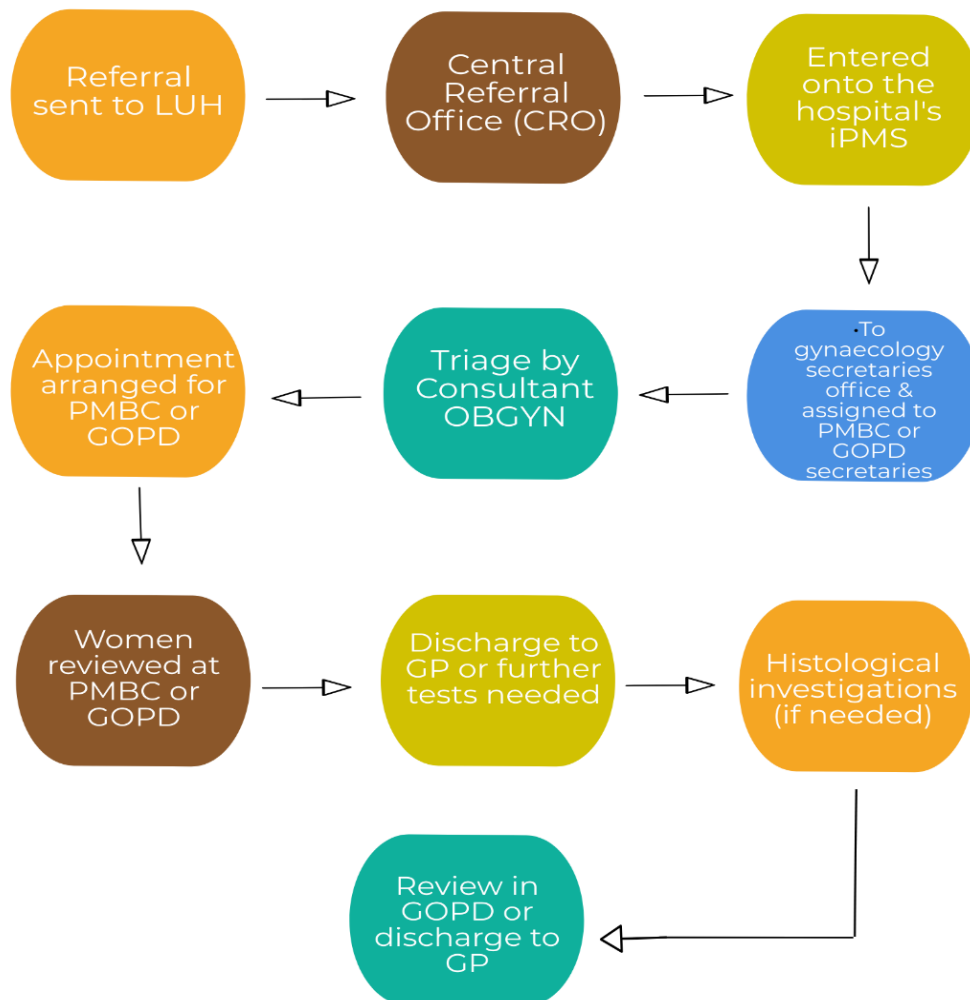
At the time of HIQA's review, this target of 24 hours was met by staff in the Central Referral Office. The success in meeting the target was in part due to the commitment and dedication of staff in the Central Referral Office who at times worked beyond their contracted hours to ensure compliance with the target. However, HIQA found that, going forward, there is a risk that the target will not be achieved due to the increase in the number of referrals received by the Central Referral Office and the lack of contingency planning around staff resourcing in the office. The Central Referral Office was staffed by three whole-time equivalent clerical officers who had defined reporting arrangements to the patient services manager. The risk regarding contingency planning had been escalated through the line management structure. HIQA was told that the hospital had submitted a business case to the Saolta Group seeking approval to recruit and appoint a 0.5 whole-time equivalent clerical staff to add to the existing compliment of staff in the Central Referral Office.

3.3.2 Process for triage of gynaecology referrals to Letterkenny University Hospital

Staff reported improvements in the system for gynaecology referrals and triage since the introduction of the revised referral and triage processes, with better tracking and tracing of referrals throughout the process. The hospital had a set target that all outpatient referrals to the gynaecology service were to be triaged by a consultant obstetrician and gynaecologist within five working days of receipt of referral (see Figure 9 depicting the process for the referral, triage and review of women referred to gynaecology services, as described by the hospital).

The hospital had a process in place to escalate cases where the triage timeline was not met. If the five-day target was not met, this was escalated to the Director of Midwifery who followed up with the relevant consultant. Information on adherence to the timeline was collected and reviewed weekly by the scheduled care manager. The business manager for the Women's and Children's Managed Clinical and Academic Network at Letterkenny University Hospital was to assume this responsibility when in post on a full-time basis. The level of adherence or non-adherence to triage timelines was reviewed at the hospital's operational gynaecology services meeting every two weeks.

Figure 9 Process for the referral, triage and review of women referred to the gynaecology services at Letterkenny University Hospital



Notwithstanding the improvements in the referral and triage system over the past six months, the process was not automated. As a result, it involved multiple manual processes that had resulted in the duplication of tasks and increased the burden on staff in the Central Referral Office. For example, the referral forms were uploaded to a file share and were also scanned and saved to an electronic document management system. While these built-in fail-safes were commendable, the manual process was labour and time intensive. Furthermore, the effectiveness and sustainability of the referral and triage process was dependent on the existence of clear guidance about the process, consistent availability of well-trained staff, and defined contingency plans to ensure familiarity and consistency in the process when existing staff were on leave. In light of HIQA's findings, management at Letterkenny University Hospital should consider implementing an electronic referral and triage

system for the processing of all referrals received by the hospital, which is efficient, cost-effective and time saving.^{66,67}

3.3.3 Procedure for cancelled appointments and non-attenders

The hospital had processes in place for booking, cancelling and rescheduling appointments for the ambulatory gynaecology service and post-menopausal bleeding clinic. Women were offered appointments to the ambulatory gynaecology service and post-menopausal bleeding clinic two weeks in advance. Women who cancelled or did not attend for appointments were re-issued an appointment for the following week (sometimes two weeks). The process was consistent with the hospital's cancellation and 'did not attend' policies. To further improve attendance at general gynaecology clinics, the hospital had introduced a text messaging service, where women were sent a text message with the date and time of their appointment.

3.3.4 Summary of findings on changes implemented to improve the referral and triage system for gynaecology services at Letterkenny University Hospital

Overall, HIQA found that this Price report's recommendation was the most progressed recommendation and there had been substantial gain in achieving efficacy in the process. The hospital had introduced a revised procedure for the management of referrals to the general gynaecology services and had defined timelines for the review and triage of referrals. Service performance was measured against the level of adherence or non-adherence to these timelines. The process had built-in fail-safes, but these were labour and time intensive. The hospital should consider implementing an electronic referral and triage system for the processing of all referrals to the hospital.

3.4 Capacity and capability for inpatient, day case and planned procedures at Letterkenny University Hospital

Table 10 presents a summary of the key findings and the related recommendation from the Price report related to the capacity of general gynaecology service to perform inpatient, day case and outpatient planned procedures.

Table 10 Findings and recommendation from the Price report related to inpatient, day case and planned procedures

- Letterkenny University Hospital gynaecology service should build its capacity to undertake inpatient, day case and planned procedures.
- The use of one operating theatre in the main operating theatre block for emergency obstetric surgeries had the effect of reducing the hospital's general theatre access by 25% which significantly impacted on the ability to provide

timely diagnostics and interventions to women in the care of the gynaecology service leading to long waiting lists.

- Letterkenny University Hospital gynaecology service were 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 time frame.

Price report's Recommendation 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.

Progress in implementing Price report's Recommendation 3

At the time of HIQA's review, similar to other hospitals, demand for gynaecology services at Letterkenny University Hospital was greater than capacity. However, additional resourcing received following the Price report from the National Treatment Purchase Fund facilitated the delivery of extra general gynaecology clinics that helped address the backlog in demand for the outpatient, day case and inpatient gynaecology services. In addition, the hospital introduced measures in the management of the general gynaecology clinics to ensure all clinics were run at maximum efficiency. Consequently, the hospital experienced a decline in waiting list numbers for the outpatient, day case and inpatient gynaecology services. The number of women waiting for an appointment in the hospital's post-menopausal bleeding clinic also declined.

Figure 10 shows the steady decline in the numbers of women waiting for outpatient gynaecology services at the hospital from October to December 2020, which reflects the time after additional resources and supports were provided to the hospital. This steady decline in general gynaecology outpatient waiting list numbers continued month on month to September 2021^{§§§§§§§§§§} (see Figure 11).

^{§§§§§§§§§§} Information on waiting lists numbers for June 2021 was not available due to the cyberattack on the HSE information technology system in May 2021.

Figure 10 General gynaecology outpatient waiting list numbers at Letterkenny University Hospital October-December 2020

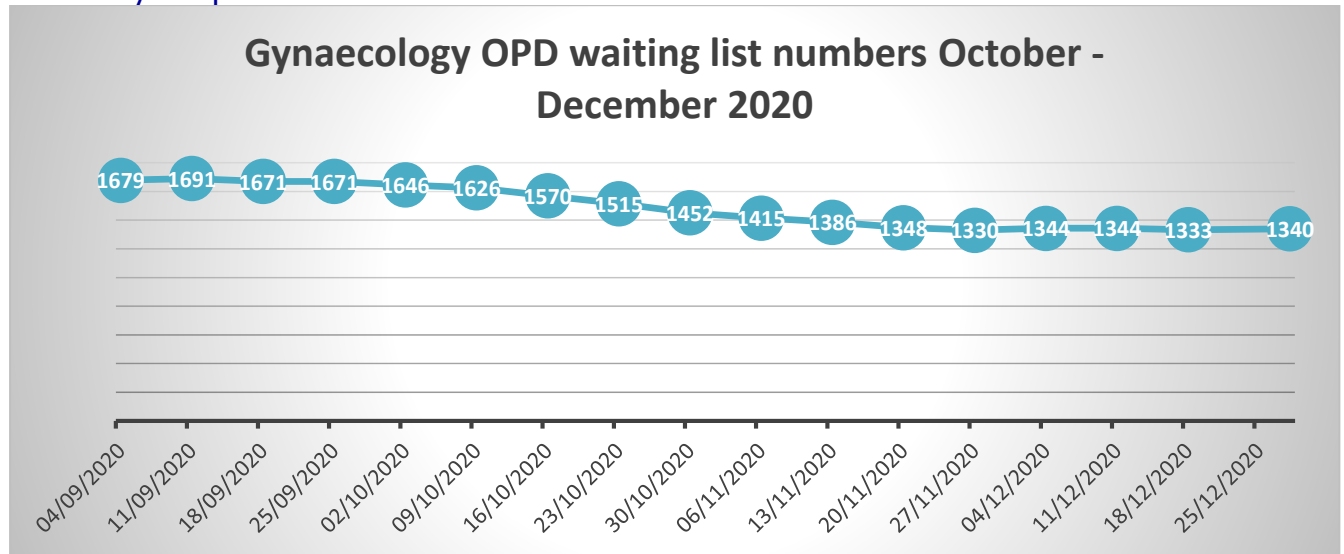
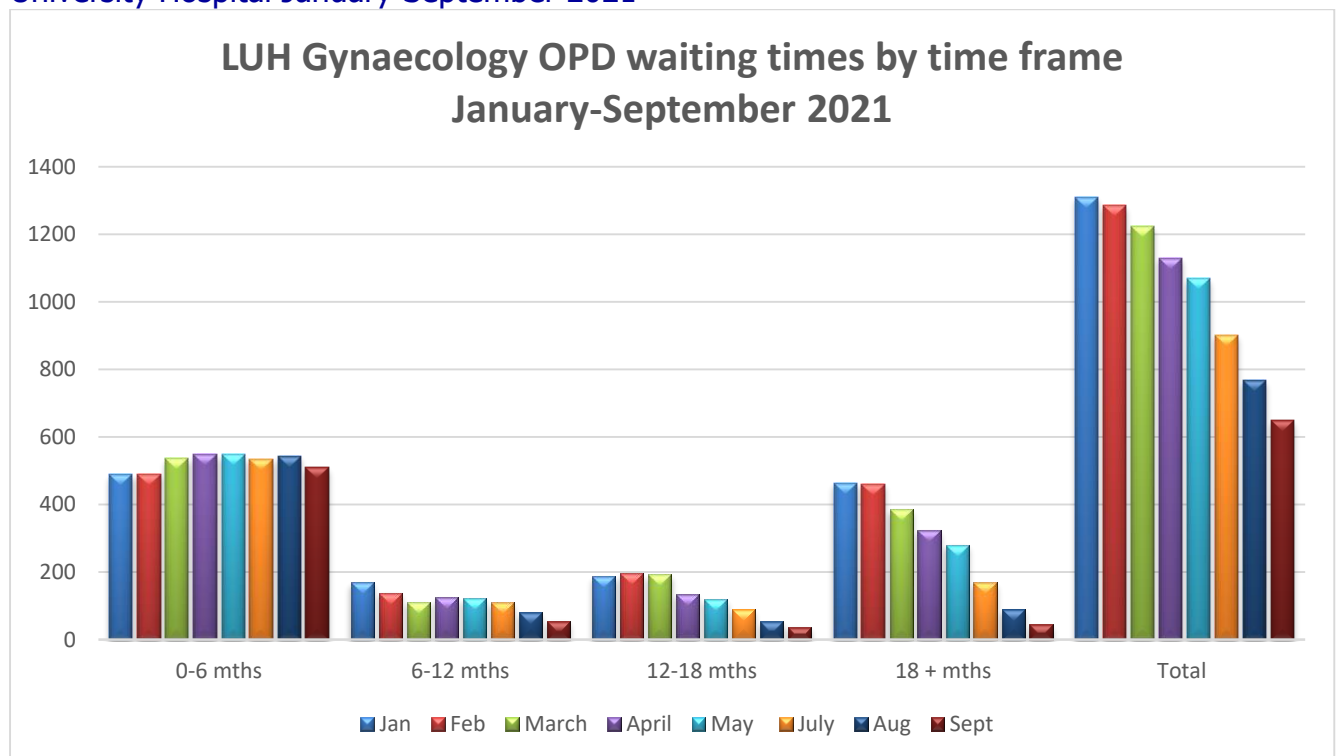
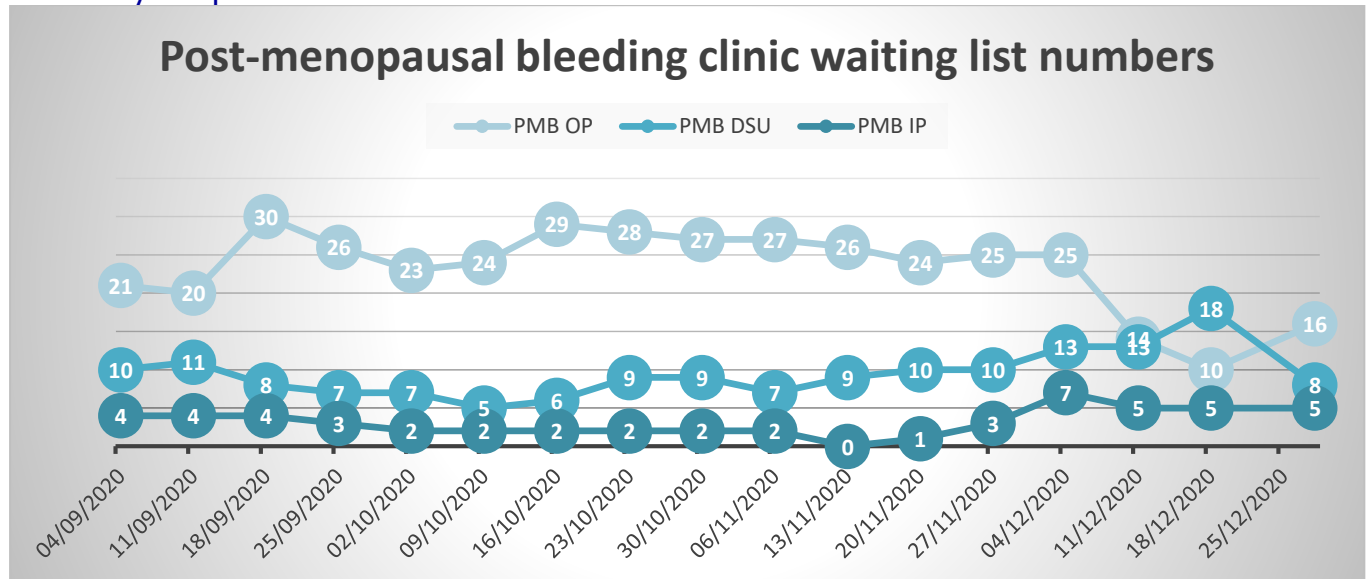


Figure 11 General gynaecology outpatient waiting list numbers at Letterkenny University Hospital January-September 2021



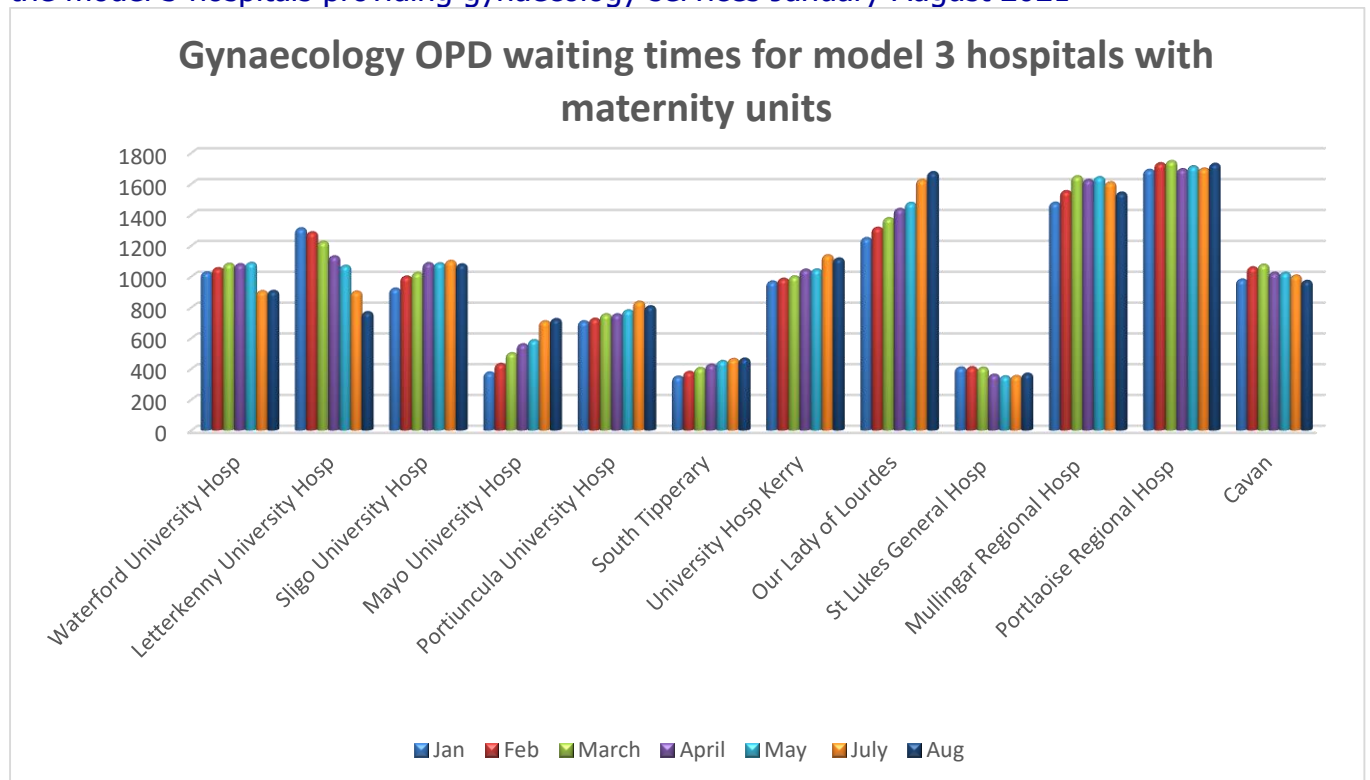
Similarly, the hospital experienced a general decline in the numbers of women waiting for an appointment at the hospital's post-menopausal bleeding clinic from October to December 2020 (see Figure 12).

Figure 12 Post-menopausal bleeding clinic waiting list numbers at Letterkenny University Hospital October-December 2020



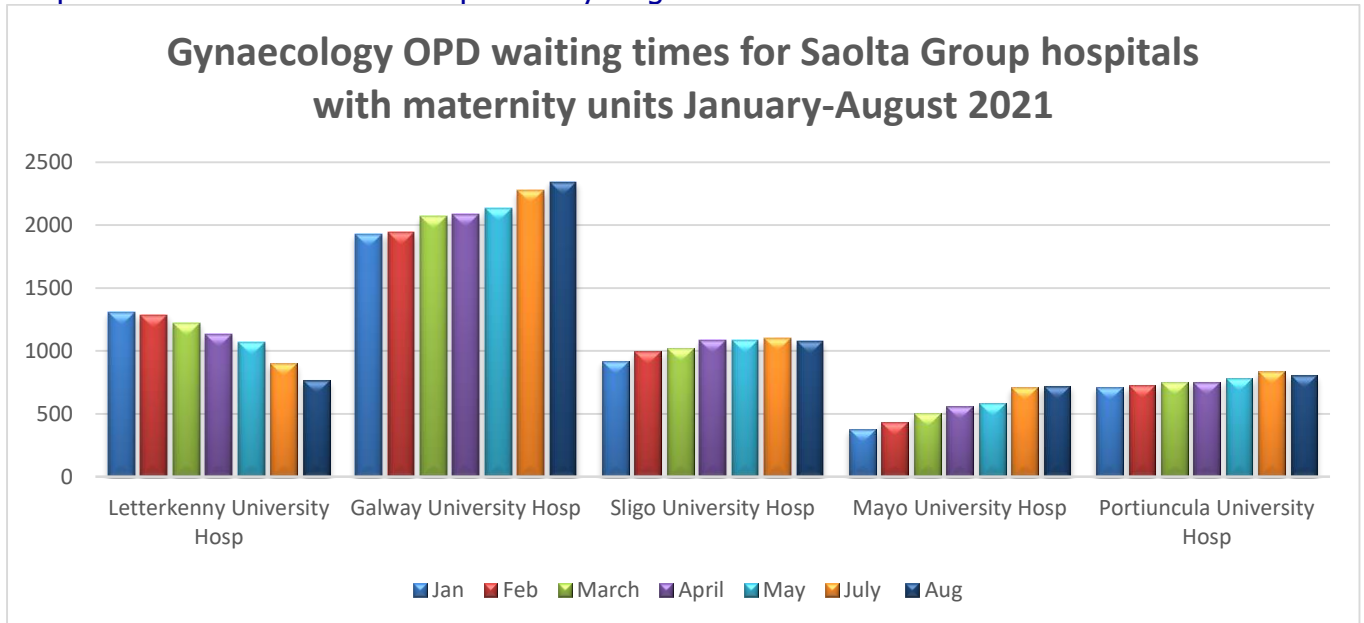
When compared to the other model 3 hospitals providing gynaecology services across the healthcare system, there was a steady decline in the number of women waiting for outpatient general gynaecology services month on month at Letterkenny University Hospital during the period from January to August 2021 (see Figure 13).

Figure 13 Waiting list numbers for general gynaecology outpatient services across the model 3 hospitals providing gynaecology services January-August 2021



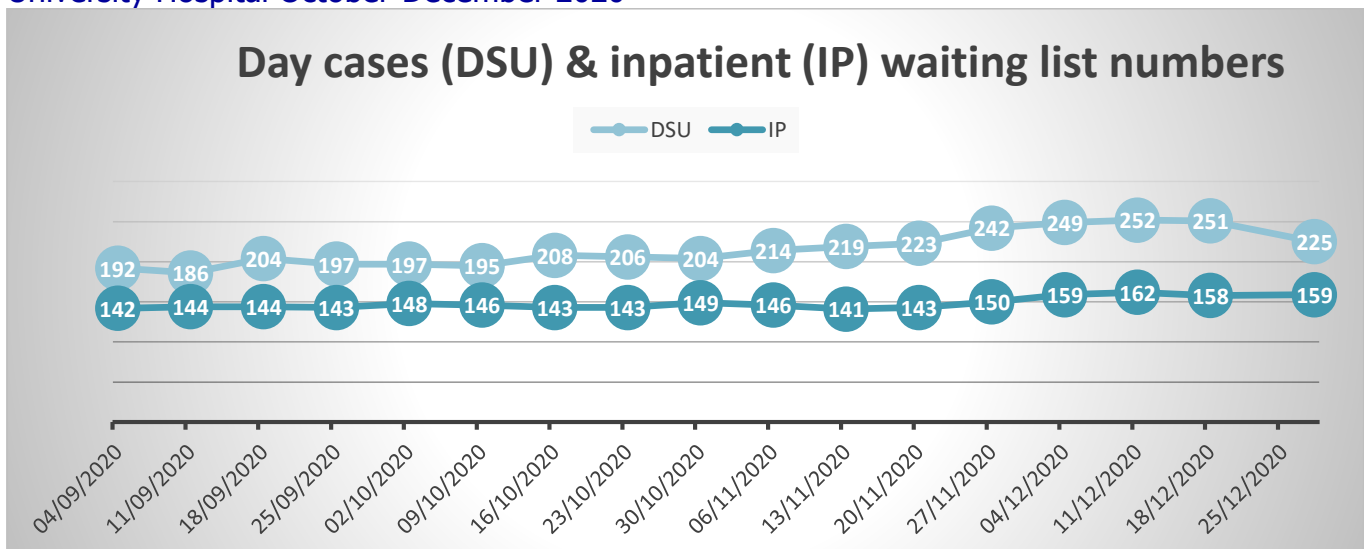
At Saolta Group level, the hospital had the second highest number of women waiting for outpatient general gynaecology services for the first four months of 2021 (January-April), but this changed thereafter, with a steady decline in numbers occurring each month to August 2021 (see Figure 14).

Figure 14 Waiting list numbers for general gynaecology outpatient services in hospitals across the Saolta Group January-August 2021



However, the decline experienced in general gynaecology outpatient waiting list numbers was not evident in the gynaecology day case or inpatient services waiting list numbers for the 17-week period between October and December 2020 (see Figure 15). Here, there was a steady increase in the numbers, but this was consistent with the national waiting list numbers for general gynaecology services.⁵¹

Figure 15 Gynaecology day case and inpatient waiting list numbers at Letterkenny University Hospital October-December 2020



The pattern of increasing waiting list numbers for day cases and inpatient gynaecology services at Letterkenny University Hospital changed in 2021. In the nine months from January to September 2021, waiting list numbers for day cases and inpatient gynaecology services at the hospital declined month on month. The overall waiting list numbers for day cases and inpatient gynaecology services declined from 399 (January 2021) to 245 (September 2021).

The general decline in outpatient, day cases and inpatient waiting list numbers for general gynaecology services and the post-menopausal bleeding clinic at the hospital reflects the impact of the substantive supports and resources provided to the hospital and increased service capacity following the Price report.

3.4.1 Clinical and administrative validation of waiting lists referrals

Checking and confirming the accuracy of waiting lists on a continual basis is an important part of waiting list management, which results in improved waiting times and enables hospitals to better manage waiting lists.⁶⁸

The Price report found that the practice of triaging all cases as 'urgent' contributed to the increasing numbers of women waiting for outpatient, day case or inpatient general gynaecology services at the hospital. Clinical validation can, when conducted periodically by a consultant obstetrician and gynaecologist, ensure that women are triaged and categorised in line with their clinical signs, symptoms and need. Clinical validation of the hospital's gynaecology outpatient, day case and inpatient waiting lists was conducted by the clinical lead of the special measures team.

During this process, every referral categorised as 'urgent' was reviewed to determine the level of urgency and action needed. This work concluded when the special measures team stood down in April 2021. After that, waiting list times were reviewed by the consultant obstetrician and gynaecologists in Letterkenny University Hospital at meetings of the gynaecology/post-menopausal bleeding-ambulatory gynaecology every two weeks. The aim was to reduce 'urgent' waiting lists times for all consultant obstetrician and gynaecologists at the hospital.

Administrative validation of outpatient and inpatient waiting lists was carried out in conjunction with the national centralised validation unit in the National Treatment Purchase Fund using a standardised approach and protocols. The process was impacted by the COVID-19 pandemic and more recently by the cyberattack on the HSE's information technology system. Staff from the scheduled care department were redeployed to other departments in the hospital and or to the HSE's COVID-19 vaccination clinics. Consequently, the administration validation process was suspended for four months but was due to recommence in July 2021.

3.4.2 Operating theatre use at Letterkenny University Hospital

Before the Price report, general operating theatre access was a contributing factor that significantly impacted on the ability to provide timely diagnostics and interventions for women attending the gynaecology services at Letterkenny University Hospital. Significant work had been carried out between August 2020 and April 2021 to increase operating theatre access and capacity for gynaecological cases at the hospital. The opening of the maternity operating theatre in the labour ward in December 2020 resulted in increased capacity in the main operating theatre department.

Consequently, this resulted in additional operating theatre capacity for gynaecological cases, which resulted in a total of five operating theatre lists being available for gynaecological cases each week. This increased capacity in the operating theatre will facilitate timely diagnostics and interventions for women attending the hospital's gynaecology services. The increased operating theatre activity for gynaecological cases was resourced by the recruitment of five whole-time equivalent nurses and two whole-time equivalent anaesthesiologists.

3.4.3 Summary of findings on changes implemented to build capacity and capability for inpatient, day case and outpatient gynaecology services at the hospital

Overall, the changes introduced at hospital level to build capacity for inpatient, day case and planned procedures and achieve efficiencies had significantly reduced the number of women waiting for outpatient general gynaecology appointments at the hospital. As of the end of September 2021, the waiting list numbers for inpatient and day case gynaecology services at Letterkenny University Hospital had also significantly decreased month on month.

3.5 Communication processes with service users and service referrers

Table 11 presents a summary of the key findings and related recommendation from the Price report related to communication, discharge and follow-up processes at Letterkenny University Hospital.

Table 11 Findings and recommendation from the Price report related to communication processes

- The processes for communication, discharge and follow-up varied in their robustness.
- The quality of communication between the woman, the hospital and GP varied.

Price report's Recommendation 4: Letterkenny University Hospital gynaecology service should review and improve upon their communication processes with service users and service referrers.

Progress in implementing Price report's Recommendation 4

During meetings with HIQA, senior management teams from the hospital group and hospital expressed their commitment to implement Saolta Group's patient engagement strategy published in 2020, and to engage with women who use the services at the hospital so as to enhance and improve their experiences of the service. However, HIQA's review team was told that outbreaks of COVID-19 at the hospital had limited opportunities to bring women together to discuss their experiences of using the gynaecology services. There was some evidence, however, that the hospital had collaborated and communicated with service referrers.

3.5.1 Engagement with women who use the gynaecology services

Two service-user representatives and one GP representative were members of the Letterkenny University Hospital Gynaecology Service Review Implementation Group (discussed further in section 4.1.2 of this report). The service-user representatives had reviewed and provided feedback on the patient information leaflet for the post-menopausal bleeding clinic. The hospital had designed patient comment cards for women to relay their experiences of the service — as a result of a self-assessment with the *National Standards for Safer Better Healthcare Services* arising from another recommendation in the Price report (discussed below). These patient comment cards were, however, not in use at the time of HIQA's on-site inspection. Hospital management told HIQA that it had planned to establish a patient forum but had not progressed this due to the COVID-19 pandemic.

3.5.2 Engagement with service referrers

In April 2021, the hospital provided an information session for GPs in the northwest region of Ireland where they shared information about changes introduced to improve gynaecology services at the hospital. The hospital plans to hold information sessions for GPs every six months, with the next session planned for October 2021. At the time of HIQA's review, the hospital was also establishing a GP-hospital gynaecology forum. The hospital had improved on their communication with GPs. Discharge letters were issued to GPs when women attended the ambulatory gynaecology service and post-menopausal bleeding clinic. This process enabled the sharing of accurate, relevant information between the hospital and primary care, which is important for the effective and safe transition of care. Women were also

issued with a copy of the discharge letter at the end of their scheduled appointment. A copy of the letter was also filed in the woman's healthcare records.

3.5.3 Feedback on women's experiences of the post-menopausal bleeding clinic at Letterkenny University Hospital

Complaints and compliments about gynaecology services at Letterkenny University Hospital were tracked by the quality and patient safety department at both the hospital and Saolta Group. However, there was limited evidence from the documentation submitted to HIQA on how the hospital used this information to improve services for women.

As part of its review, HIQA took the opportunity to survey a number of women who had used the post-menopausal bleeding clinic in Letterkenny University Hospital over a six-week period to find out about their experiences of the clinic. Surveys were sent to 76 women, with 49 women completing the survey (response rate of 64%). 70% or 34 of the 49 women who completed the survey rated their overall experience as positive. Positive comments were received about the kindness of staff, efficiency of the service and the hospital's compliance with public health guidance related to COVID-19. Four women (8%) were dissatisfied with the service and care provided. Dissatisfaction was expressed about the level of information received about procedures performed in the clinic, the management of pain when having procedures and the efficacy of the hospital's complaints process.

HIQA shared anonymised findings of the survey with the General Manager of Letterkenny University Hospital in advance of concluding its review so that efforts with respect to feedback on service delivery could be acted on by the hospital. In subsequent correspondence from the hospital, HIQA was informed that the issues highlighted would be brought to the attention of the hospital's quality and patient safety lead and members of the hospital's Women's and Children's Managed Clinical and Academic Network. Corrective actions were to be implemented to improve women's experiences of the service. It is imperative that the hospital commit and introduce creative and innovative processes to collect women's experiences and views of using the gynaecology services in a timely way and that the information gained is used proactively to improve their experiences of the service.

3.5.4 Feedback on GPs' experiences of referring to the post-menopausal bleeding clinic at Letterkenny University Hospital

HIQA also surveyed GPs in the northwest region of Ireland who referred women to the post-menopausal bleeding clinic in Letterkenny University Hospital in the 12 months prior to HIQA's review. The purpose was to find information about the referral process and waiting times, the quality of communication with and from the

hospital, and the availability of services for women referred to the post-menopausal bleeding clinic.

GPs who responded to the survey indicated that the average waiting period for an appointment at the post-menopausal bleeding clinic had improved over the 12-month period before HIQA's review and, at the time of HIQA's review, was averaging about four weeks. Likewise, over the preceding year, GPs said that there was a definite improvement in the communications received from the hospital. GPs described the service as friendly and patient centred. However, areas identified for further improvement included:

- better sharing of information about the new ambulatory gynaecology model of care and plans for the post-menopausal bleeding clinic
- confirmation of receipt from the hospital that GP referrals (hard copy, letter format) to the service had been received
- access to hysteroscopies.

HIQA believes that Letterkenny University Hospital and the Saolta Group should now use the information sessions held with GPs to further inform and share information about the 'one-stop, review and treat' ambulatory gynaecology service and any other initiatives being implemented at the hospital.

3.5.5 Summary of findings on changes implemented at the hospital to improve communication processes with women and service referrers

Overall, this was the one recommendation where the least amount of progress was seen by the HIQA review team. While there was some evidence that the hospital had collaborated and communicated with service referrers, there was little evidence that they did the same with women who had used or were using the gynaecology services. The hospital should collect women's experiences and views of the service. Furthermore, the information gained should be used proactively to improve the experience of women using the gynaecology services.

3.6 Self-assessment of compliance with the *National Standards for Safer Better Healthcare*

Table 12 presents the recommendation from the Price report that Letterkenny University Hospital undertake a self-assessment against the *National Standards for Safer Better Healthcare*.

Table 12 Recommendation from the Price report related to a self-assessment with the *National Standards for Safer Better Healthcare*

Price report's Recommendation 6: The Letterkenny University Hospital gynaecology service should undertake a robust and comprehensive self-assessment against HIQA's *National Standards for Safer Better Healthcare 2012*

Progress in implementing Price report's Recommendation 6

The hospital had completed a self-assessment against the *National Standards for Safer Better Healthcare* and had identified the need to develop 16 quality improvement plans. Quality improvement plans are one of many tools that can improve the quality, safety and reliability of gynaecology services at Letterkenny University Hospital. Documentation received by HIQA suggested that work on developing the quality improvement plans was progressing. The implementation of the quality improvement plans was an action included in the 51-point implementation plan. Overall, HIQA found that progress in implementing the plans could be improved. The hospital should focus on completing and implementing the 16 quality improvement plans to further improve the gynaecology services at the hospital.

Summary of key findings related to the implementation of Price report's recommendations 1, 2, 3, 4, and 6

- Letterkenny University Hospital was progressing with a new ambulatory (outpatient) gynaecology model of care. However, the ambulatory gynaecology unit was not fully operational. Only one of the two clinical treatment rooms was fully commissioned, so the service was working at only 50% of its potential capacity.
- The hospital had defined and established pathways for assessing, managing and treating women who attended the ambulatory gynaecology service and post-menopausal bleeding clinic.
- Letterkenny University Hospital had a defined pathway for women who presented with gynaecological conditions to the hospital's emergency department.
- Thirty-seven additional general gynaecology clinics for new referrals were held from October 2020 to July 2021.
- Women unable to have hysteroscopies in the ambulatory gynaecology service were referred through a formal process to the enhanced recovery unit where a detailed anaesthetic pre-assessment was conducted.
- Many of the standard operating procedures for the ambulatory gynaecology service and post-menopausal bleeding clinic were in draft format and were not ratified by the relevant governance structures at Letterkenny University Hospital.
- The diminished capacity in radiology services at the hospital impacted on the capacity and capability of gynaecology services at Letterkenny University Hospital.

- Letterkenny University Hospital had implemented measures to improve communication between services and different departments within the hospital.
- The hospital had relevant policies, procedures, protocols and guidelines that ensured the care provided in the gynaecology ambulatory service and post-menopausal bleeding clinic was guided by best available evidence.
- Letterkenny University Hospital depended on locum medical staff and administrative staff employed on agency contracts.
- In-house clinical skills training for medical and nursing staff in the ambulatory gynaecology service was provided by the clinical lead from the special measures team (during the team's contracted period of work with the service).
- Letterkenny University Hospital had revised the procedure for managing referrals to the general gynaecology services. However, the process still involved multiple manual processes that resulted in the double checking and duplication of tasks and relied on the existence of clear guidance about the process, consistent and well-trained staff, and defined contingency plans to ensure familiarity and consistency in the process.
- Additional resourcing from the National Treatment Purchase Fund had helped to address the backlog in demand for the outpatient, day care and inpatient gynaecology services and had significantly reduced waiting list numbers for these services at the hospital.
- The process of clinical validation was ongoing to reduce the 'urgent' waiting times for all consultant lists for gynaecology services at Letterkenny University Hospital.
- Significant work had been undertaken between August 2020 and April 2021 to increase operating theatre access and capacity for gynaecological cases at the hospital.
- There was little evidence that the hospital and or hospital group had collaborated or consulted with women who had used or were using the post-menopausal bleeding clinic or gynaecology services.
- The hospital had improved follow-up communications with GPs.
- Complaints and compliments about the gynaecology services at Letterkenny University Hospital were tracked, but there was limited evidence on how the hospital used this information to improve services for women.
- There was limited evidence of the implementation of the 16 quality improvement plans arising from the hospital's self-assessment of gynaecology services against the *National Standards for Safer Better Healthcare*.

3.7 Compliance with the *Nationals Standards for Safer Better Healthcare*

As part of the targeted assurance review, HIQA assessed compliance with 11 national standards from the *National Standards for Safer Better Healthcare*. Tables

13 and 14 presents HIQA's judgments with five of the 11 national standards under the dimensions of 'capacity and capability' and 'quality and safety'.

Table 13 Compliance with the *National Standards for Safer Better Healthcare*

Capacity and capability dimension
Theme 6: Workforce
<p>Standard 6.1 Service providers plan, organise and manage their workforce to achieve the service objectives for high-quality, safe and reliable healthcare.</p> <p>Key findings: The hospital depended on medical staff and administrative staff employed on locum or agency contracts. The hospital had approval for five permanent consultant obstetrician and gynaecologist positions. Five of these posts were filled with three consultants appointed on permanent contracts, while two consultants were appointed on locum contracts. The Saolta Group devised a 15-point plan to recruit and retain medical staff.</p> <p>Judgment: Partially compliant</p>
Theme 7: Use of Resources
<p>Standard 7.1 Service providers plan and manage the use of resources to deliver high-quality, safe and reliable healthcare efficiently and sustainably.</p> <p>Key findings: The ambulatory gynaecology unit was not fully established, with the service only working at 50% of its potential capacity. The hospital was reliant on external funding to resource extra general gynaecology clinics. The hospital depended on the willingness and commitment of staff to work extra hours in order to staff additional general gynaecology clinics.</p> <p>Judgment: Substantially compliant</p>
Theme 8: Use of Information
<p>Standard 8.1 Service providers use information as a resource in planning, delivering, managing and improving the quality, safety and reliability of healthcare.</p> <p>Key findings: Complaints and compliments about gynaecology services at Letterkenny University Hospital were tracked, but there was limited evidence of how the hospital used this information to improve gynaecology services for women. A small number of women who participated in HIQA's survey, conducted as part of HIQA's review, were dissatisfied with aspects of the service, including the efficacy of the hospital's complaints process. The hospital did not collect woman's experiences of gynaecology services in a formal or structured way.</p> <p>Judgment: Partially compliant</p>

Table 14 Compliance with the *National Standards for Safer Better Healthcare*

Quality and safety dimension
Theme 1: Person-Centred Care and Support
<p>Standard 1.2 Service users have equitable access to healthcare services based on their assessed needs.</p> <p>Key findings: Women on the inpatient and day case gynaecology waiting lists were reviewed in the ambulatory gynaecology service. There was no referral pathway to this model of care for GPs. There was a GP referral pathway to the post-menopausal bleeding clinic. The hospital had defined timelines for the review and investigation of women presenting with post-menopausal bleeding. These timelines were collated and reviewed weekly.</p> <p>Judgment: Substantially compliant</p>
Theme 2: Effective Care and Support
<p>Standard 2.6 Care is provided through a model of service designed to deliver high quality, safe and reliable healthcare.</p> <p>Key findings: The ambulatory (outpatient) gynaecology model of care had been introduced at the hospital, and the hospital was planning to integrate the post-menopausal bleeding clinic into this model of care.</p> <p>Judgment: Substantially compliant</p>

3.8 Conclusion

There was evidence that the hospital and Saolta Group were implementing the recommendations (recommendations 1, 2, 3, 4 and 6) in the Price report. The substantial support and resourcing received by the hospital, both financially and with respect to staffing, together with the leadership and direction of the special measures team, enabled the introduction of a new ambulatory gynaecology service. It was evident that the special measures team had played an important role in leading and driving the changes to bring about efficiencies and changes to improve the quality of gynaecology services at the hospital. Allied to this was the additional funding received from the National Treatment Purchase Fund that enabled the scheduling of extra general gynaecology clinics and the outsourcing of procedures. Collectively, these actions helped reduce waiting times for some women referred to outpatient, day case and inpatient gynaecology services at the Letterkenny University Hospital.

However, the ambulatory gynaecology service was not yet fully established. The recruitment and filling of consultant obstetrician and gynaecology, nursing and administrative posts on a permanent, full-time basis was also an ongoing challenge for the hospital and the Saolta Group. The hospital's reliance on staff on agency or temporary contracts is not sustainable due to the related cost to the service and the potential impact on service delivery that may arise due to the temporary nature of a locum or agency contract.

Finally, while there was evidence of some progress in implementing the Price report's recommendations 1, 2 and 3, there was little evidence that any substantive improvement or meaningful engagement had occurred with women who attended or were attending the gynaecology services at the hospital (Price report's recommendation 4). The hospital had implemented initiatives to improve communications with service referrers, but had yet to introduce initiatives to collect women's experiences and views of the gynaecology services, and to use this information to improve their experiences.

There was also limited evidence of the implementation of the hospital's 16 quality improvement plans following its self-assessment against the *National Standards for Safer Better Healthcare* (Price report's recommendation 6). The next chapter presents HIQA's findings regarding the progress made to improve the governance structures and processes implemented before and after the Price report at hospital, hospital group and national HSE levels to assure and ensure the quality and safety of gynaecology services at Letterkenny University Hospital.

Chapter 4 Changes implemented to enhance governance of gynaecology services at Letterkenny University Hospital

4.0 Introduction

A well-governed healthcare service is clear about what it does, how it does it and is accountable for the services it provides. Good governance arrangements recognise the inter-dependencies between organisational arrangements and clinical practice and integrate these to deliver high-quality, safe and reliable services. Healthcare services should have formalised governance arrangements ensuring that there are clear lines of accountability at individual, team and service levels so that everyone working in the service is aware of their responsibilities and accountability. In addition, a well-governed and managed service monitors its performance to identify and act on opportunities to continually improve the quality and safety of services.

Achieving safe, high-quality care depends on the culture of the service in which the care is provided. Leaders at all levels of the service have a key role in strengthening, promoting and protecting the culture of a service. This chapter outlines the changes introduced at hospital, Saolta Group and national HSE levels aimed at improving and strengthening corporate and clinical governance of gynaecology services at Letterkenny University Hospital. It presents HIQA's analysis of the effectiveness and sustainability of the changes made to assure and ensure the quality and safety of gynaecology services at the hospital.

Table 15 details the findings and recommendation from the Price report related to the governance of gynaecology services at Letterkenny University Hospital. It references the Women and Infants Clinical Directorate at Letterkenny University Hospital, which prior to 2020 was the governance structure with the assigned responsibility for the gynaecology services at the hospital. In 2020, the governance structures were revised and the Women's and Children's Managed Clinical and Academic Network was introduced and was assigned responsibility for the delivery of women and children's services at the hospital.

Table 15 Findings and recommendation from the Price report related to governance structures and processes at hospital, hospital group and national HSE levels

- There was no evidence of formal or informal networking to support learning and sharing of information between the Letterkenny University Hospital gynaecology service and other gynaecology services within the hospital group.
- The Women and Infants Directorate at Letterkenny University Hospital did not submit a quality and patient safety report to the hospital's quality and patient safety committee.
- The hospital's Women and Infants Directorate had a proliferation of sub-groups. In places, the terms of reference of some of these sub-groups were confused and it was not clear how their objectives were being met. The hospital's Women and Infants Directorate did not use standardised, benchmarked indicators to determine how the gynaecology service was performing.
- The hospital did not have a suite of standardised, benchmarked gynaecology related key performance indicators that were being regularly monitored to determine the quality and safety of gynaecology service.
- There was no structured programme of clinical audit for the gynaecology service at the hospital.
- There did not appear to be a meaningful relationship at a clinical level between the hospital's gynaecology service and the gynaecology service in other hospitals in the Saolta University Health Care Group. There was no evidence of exchanging information, sharing clinical guidelines, conducting joint audits, or engaging in quality improvement initiatives.

Price report's Recommendation 5: The Letterkenny University Hospital Women and Infants Directorate should review its governance for quality and safety structures, and improve the robustness of its governance for quality and safety processes.

4.1 Corporate and clinical governance at Saolta University Health Care Group

HIQA reviewed the current governance arrangements for the delivery of safe, quality gynaecology services at the national HSE, Saolta-Group and Letterkenny University Hospital levels. HIQA found that a formal review of the governance structures had not taken place following the Price report, and, therefore, recommendation 5 of the Price review had not been implemented in full. However, in January 2021 the Saolta

Group's Women's and Children's Managed Clinical and Academic Network had completed the HSE governance checklist⁶⁹ and updated the actions arising from this process in April 2021. Furthermore, there was evidence that some changes had been introduced at Saolta Group and hospital level with the intention of improving and strengthening the structures and processes governing the gynaecology services at Letterkenny University Hospital.

Overall responsibility for the governance of the gynaecology services at Letterkenny University Hospital lies with the Chief Executive Officer (CEO) of Saolta Group. The CEO of Saolta Group has executive responsibility and accountability for the delivery of services as set out in the HSE's annual service plan, and the Saolta Group's operational plan. The CEO is accountable and reports to the HSE's National Director of Acute Operations, who in turn reports to the HSE's Chief Operations Officer (see section 4.1.10 of this report for further details of the accountability and reporting arrangements with the HSE).

4.1.1 Saolta's Women's and Children's Managed Clinical and Academic Network

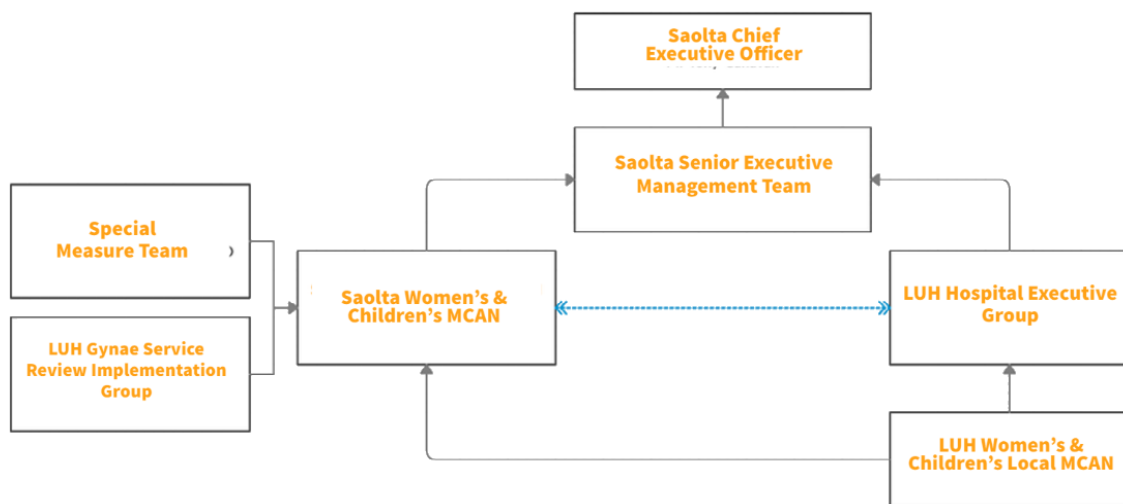
Executive authority, accountability and responsibility for the delivery, quality and safety of maternity, gynaecology and children's services across Saolta Group rests with the Saolta Group's Women's and Children's Managed Clinical and Academic Network. This network approach to the governance of women and children's services was introduced on a trial basis in 2020 with the aim of incorporating an integrated approach to the governance of women and children's services across all six hospital sites in the Saolta Group. At the time of HIQA's review, this revised structure was being trialled and established. The Saolta Group had plans to review the effectiveness of the revised integrative governance approach at the end of 2021.

The Saolta Group's Women's and Children's Managed Clinical and Academic Network was led by a Clinical Director who was a consultant obstetrician and gynaecologist. Administratively, the network had a general manager and a dedicated business manager. The business manager reported to the general manager of the network, who in turn reported to the Clinical Director of the Saolta Group's Women's and Children's Managed Clinical and Academic Network.

Membership of the Saolta Group's Women's and Children's Managed Clinical and Academic Network comprised clinical representatives (medical, nursing and midwifery) from the women and children's services across the Saolta Group, a quality and patient safety manager and representatives from the hospital group's finance and human resource teams. The network had terms of reference that outlined its purpose, objective, membership, roles and responsibilities.

The network had defined reporting arrangements. The Clinical Director of the network reported to the Chief Clinical Director and Chief Operations Officer of Saolta Group. Both were members of Saolta Group’s executive management team and they in turn reported to the CEO of Saolta Group. Letterkenny University Hospital had a local, hospital-based Women’s and Children’s Managed Clinical and Academic Network that was assigned responsibility for the women and children’s services at hospital level. This hospital-based network reported and was accountable to the Saolta Group’s Women’s and Children’s Managed Clinical and Academic Network (see Figure 16).

Figure 16 Reporting and accountability arrangements for Saolta’s Women’s and Children’s Managed Clinical and Academic Network



4.1.2 Letterkenny University Hospital Gynaecology Service Review Implementation Group

Following the Price report, the Saolta Group convened an implementation group — Letterkenny University Hospital Gynaecology Service Review Implementation Group — which was assigned responsibility for implementing the Price report’s recommendations. This group, together with the General Manager and the Women’s and Children’s Managed Clinical and Academic Network at Letterkenny University Hospital, was responsible for:

- ensuring the implementation of the Price report’s recommendations
- reporting on the progress of the implementation of the Price report’s recommendations

- providing assurance on the implementation of the Price report's recommendations to the executive management team of the Saolta Group
- sharing learning across the Saolta Group through the Saolta Group's Women's and Children's Managed Clinical and Academic Network.

The implementation group was chaired by the Clinical Director of the Saolta Group's Women's and Children's Managed Clinical and Academic Network. The group had defined terms of reference setting out its purpose, objective, membership, roles and responsibilities. Membership comprised representation from the Saolta Group's Women's and Children's Managed Clinical and Academic Network, members of the special measures team, senior management from Letterkenny University Hospital, patient representatives and a GP representative.

The implementation group met every month and reported to Saolta Group's executive management team. The CEO of Saolta Group in turn submitted a report outlining the progress made in implementing the Price report's recommendations regularly to the chairperson of the national oversight group convened by the HSE to oversee the implementation of the Price report's recommendations. HIQA was informed by the CEO of Saolta Group that this implementation group will remain in place until all recommendations from the Price report are fully implemented and all actions on the 51-point implementation plan are completed.

4.1.3 Executive management team of Saolta University Health Care Group

The Saolta Group's executive management team was responsible for the operational and strategic direction and management, quality, safety and reliability of services across the hospital group. The executive management team comprised:

- Chief Executive Officer
- Chief Operation Officer
- Chief Financial Officer
- Group Director of Human Resources
- Chief Clinical Director
- Chief Director of Nursing and Midwifery
- Group Service Improvement Lead
- Head of Communications.

The executive management team had terms of reference that outlined the purpose, objective, membership, roles and responsibilities of the team. The team, led by the Chief Executive Officer, met weekly and was provided with operational updates and data on the quality and safety of services across the hospital group. It was evident from documents reviewed by HIQA that the meetings were well attended and were action orientated. The executive management team reported to the hospital group's executive council (see Figure 17), whose role and function is set out below.

Figure 17 Saolta University Health Care Group executive management team's governance structure



4.1.4 Executive council of Saolta University Health Care Group

The executive council was the executive decision-making body within the Saolta Group's governance structure. The executive council was assigned responsibility for ensuring that the hospital group's operational and clinical activities were governed under a single structure, with the primary focus being the delivery of high-quality safe services. The executive council had terms of reference that outlined its purpose, objective, membership, roles and responsibilities. The executive council was led by the Chief Executive Officer and membership comprised, among others:

- the hospital group's executive management team
- general managers from the six acute hospitals in the hospital group, and
- Clinical Director of the Saolta Group's Women's and Children's Managed Clinical and Academic Network.

The executive council met every month and reported to the chairperson of the Saolta University Health Care Group Board. It was evident from documents received by HIQA that the executive council had oversight of risks and service performance of hospitals in the Saolta Group. Furthermore, the general manager from each hospital within the hospital group provided an update on operational issues and service performance at meetings of the council every month.

4.1.5 Revised accountability and performance framework

Following the Price report, the Saolta Group implemented a revised accountability and performance framework in April 2021. The revised processes were to align with the HSE's National Director of Acute Operations Performance meetings. For the women and children's services, performance meetings were to be held every two months between Saolta's executive management team and the Saolta Group's Women's and Children's Managed Clinical and Academic Network.

At local hospital level, performance meetings were also to be held every two months between Saolta's executive management team and senior management from Letterkenny University Hospital. The Clinical Director of the Saolta Group's Women's and Children's Managed Clinical and Academic Network also attended these meetings.

Performance meetings were to focus on day-to-day operational issues and strategic objectives, and each meeting was to be action focused. The meetings had a formalised agenda that included with the following items:

- access and integration of services
- COVID-19 recovery planning
- quality and safety of services and patient experience and engagement
- financial management, governance and compliance
- workload
- strategic developments
- key capital developments
- key critical issues.

The revised accountability and performance processes had been introduced just prior to the commencement of HIQA's review and was in the early stages of implementation and establishment. While the revised accountability and performance

processes aim to formalise and standardise the approach to accountability and performance reporting across the Saolta Group, the effectiveness and impact of the processes had yet to be fully realised, reviewed and evaluated. The hospital group planned to review the effectiveness of the revised accountability and performance processes at the end of October 2021.

4.1.6 Risk management of gynaecology services at hospital-group level

The Saolta Group's Women's and Children's Managed Clinical and Academic Network had arrangements in place that were intended to identify, manage and reduce identified risks related to the gynaecology services escalated from individual hospitals in the Saolta Group. Identified risks were recorded on the Saolta Group's Women's and Children's Managed Clinical and Academic Network risk register. Identified risks was reported to Saolta's executive management team as part of the network's reporting arrangements. Risks were assessed and analysed using the two-dimensional probability and impact risk matrix and corrective measures were identified to control the risk.

At the time of HIQA's review, five of the 14 risks recorded on the Saolta Group's Women's and Children's Managed Clinical and Academic Network risk register related to gynaecology services. These included:

- delayed diagnosis and treatment due to insufficient capacity to manage the demand on the gynaecology service
- dual governance processes during trial of concept of Women's and Children's Managed Clinical and Academic Network
- access to operating theatre for gynaecology services
- difficulty in recruiting and retaining appropriately qualified and skilled clinical staff across the Women's and Children's Managed Clinical and Academic Network
- risks associated with reliance on agency and locum senior clinical decision-makers.

4.1.7 Quality and safety committee of Saolta University Health Care Group

The Saolta Group had a designated overall lead manager for quality and safety of services across the hospital group. The Saolta Group's quality and patient safety committee was responsible for managing and coordinating a structured approach to quality and safety for the group. The committee had terms of reference that outlined its purpose, objective, membership, roles and responsibilities. The committee was

chaired by the Chief Clinical Director of the Saolta Group, and membership comprised of members from the Saolta Group's executive management team. The committee met and reported to the CEO of Saolta Group every month. The committee had oversight of patient safety incidents, reportable serious events and risks escalated from individual hospital sites, including those from Letterkenny University Hospital. The committee considered the report submitted from the quality and patient safety committee at Letterkenny University Hospital every month. It was evident from documents received and reviewed by HIQA that the meetings were well attended and were action orientated. At the time of HIQA's review, the Saolta Group was establishing a quality forum and was working through how the forum would function and integrate alongside the hospital group's existing quality and safety processes.

4.1.8 Monitoring and evaluation of gynaecology services across the Saolta Group

Following the publication of the Price report, the Saolta Group had developed specific key performance indicators for gynaecology services, which were used across the six hospital sites in the hospital group to monitor and evaluate the performance of gynaecology services (see Table 16).

Table 16 Key performance indicators monitored for the gynaecology services at Letterkenny University Hospital

Key performance indicator	Monitored
Percentage of referral of post-menopausal bleeding having histological investigation within 56 calendar days of referral.	Monthly
Percentage of adult women waiting over nine months for inpatient treatment.	Monthly
Percentage of adult women who are waiting over 12 months for an outpatient appointment.	Monthly
All gynaecology oncology patients should have their surgery within four weeks of the clinician's decision to operate.	Monthly

Letterkenny University Hospital's performance against the key performance indicators outlined in Table 16 were discussed as part of the performance meeting held every two months between the Saolta Group's executive management team and senior management from the hospital.

The monitoring and evaluation of performance is essential so that Saolta Group can benchmark and compare the performance of gynaecology services and the quality and safety of those services with other hospitals of a similar size both nationally and internationally. The Saolta Group did not have specific key performance indicators to monitor and benchmark the performance of the ambulatory gynaecology service.

Management of Saolta Group told HIQA that key performance indicators for the ambulatory gynaecology service were being developed by the HSE's National Women and Infants Health Programme and they felt it was better to progress with a standard set of key performance indicators which allows national comparison rather than a standalone set. The hospital was monitoring key metrics as set out in Table 16. At the time of writing this report, the HSE told HIQA that work was ongoing on the development of key performance indicators for the ambulatory gynaecology service.

HIQA recommends a set of key performance indicators for the ambulatory gynaecology service should be developed and made available by the HSE as a matter of urgency. These should be implemented, monitored and evaluated by all hospitals providing an ambulatory gynaecology service. If these are not developed by the HSE in the short term, interim key performance indicators should be developed by the Saolta Group and used to monitor the effectiveness of the service and compare service performance with best practice. Oversight and accountability of service performance against the key performance indicators should form part of the accountability and performance management arrangements between Saolta Group and hospitals in the hospital group, and at national level between the HSE and Saolta Group.

4.1.9 Serious incident management team

Patient safety incidents, serious events and serious reportable events related to women and children's services from across the Saolta Group were considered every month at meetings of the Saolta Group's quality and patient safety committee and at meetings of the Women's and Children's Serious Incident Management Team. The Women's and Children's Serious Incident Management Team was accountable to the Chief Clinical Director of the Saolta Group. Membership comprised, amongst others, the:

- Clinical Director of the Saolta Group's Women's and Children's Managed Clinical and Academic Network.
- Associate Director of Network — the Women's and Children's Managed Clinical and Academic Network at Letterkenny University Hospital.
- Director of Midwifery at Letterkenny University Hospital.

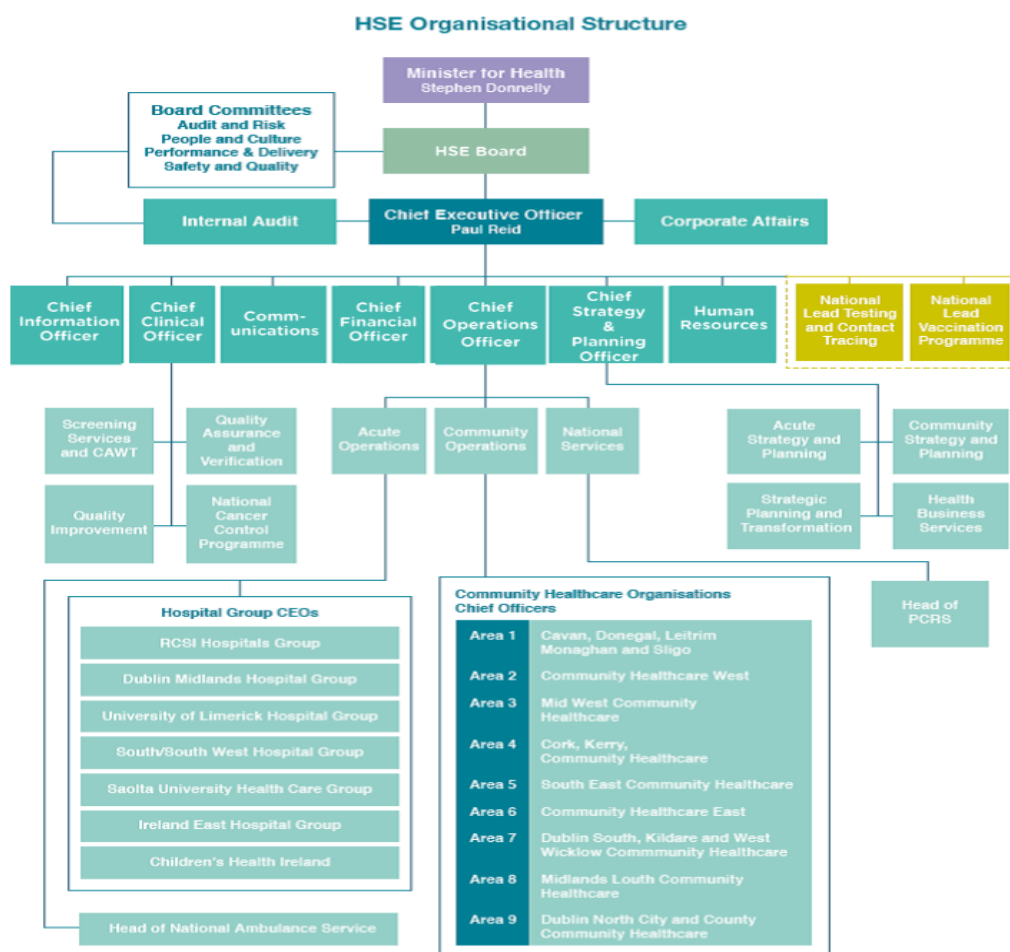
A summary update on the activity of the Women's and Children's Serious Incident Management Team was submitted to the Saolta Group's Serious Incident Management Team. The Saolta Group's Serious Incident Management Team is a

multidisciplinary team that meet every month to manage and monitor serious incidents from all six hospital sites in the hospital group.

4.1.10 Reporting and accountability arrangements between the Saolta University Health Care Group and national HSE

The CEO of Saolta Group is accountable and reports to the HSE's National Director of Acute Operations, who in turn reports to the HSE's Chief Operations Officer (see Figure 18, as provided to HIQA by the HSE).

Figure 18 Reporting and accountability arrangements for the HSE



4.1.10.1 Saolta Group's accountability and performance arrangements with the HSE

The Saolta Group's relationship with the HSE is formalised through the hospital group's governance structure and the performance agreement signed with the HSE. This agreement sets out the scope of what Saolta Group is responsible for and against which they are held to account.⁷⁰ Saolta Group's performance is assessed using a range of indicators across the four domains of: access to and integration of services; quality and safety of services; financial governance and compliance

requirements; and workforce. Performance is monitored and appraised through a formal process comprising monthly financial management and performance review meetings. Through this process, the HSE seeks assurances from Saolta Group that the services it is funded to provide, on behalf of the HSE, are focused on assuring the delivery of high-quality, safe and reliable services.

A senior operational managers meeting is held every month with the CEO of the HSE and the Saolta Group's CEO. A performance review meeting is also held with the HSE's National Director of Acute Operations, and the CEO of Saolta Group every month. Items such as financial and workforce performance, service performance against set targets, patient safety and quality are discussed at these performance review meetings. Minutes of performance management review meetings received and reviewed by HIQA showed that the meetings were well attended and action orientated.

In addition to the monthly senior operational managers and performance review meetings, the HSE's Chief Operations Officer and the HSE's National Director of Acute Operations hold a performance review meeting with the CEO of the Saolta Group every year to review the previous year's organisational performance and to plan for the coming year.

4.1.10.2 Letterkenny University Hospital Gynaecology Clinical Service Review: Implementation of Recommendation Oversight Group

Following the Price report, the HSE convened a national oversight group under the sponsorship of the Office of the National Director of Acute Operations in July 2020. The aim was to provide the HSE with assurance on the implementation of recommendations set out in the Price report. The oversight group was chaired by a consultant obstetrician and gynaecologist who was independent of services provided at Letterkenny University Hospital and the Saolta Group. Membership comprised key people from the HSE's acute operations division (national director, head of quality patient safety, head of scheduled care and the communications lead), members of the HSE's National Women and Infants Health Programme, a further consultant obstetrician and gynaecologist external to the hospital and Saolta Group and a patient advocacy representative.

The oversight group met every month. The CEO of Saolta Group, along with the Clinical Director of the Saolta Group's Women's and Children's Managed Clinical and Academic Network, submitted a progress report to the oversight group every month and attended meetings as requested to account for the progress in implementing the recommendations. The oversight group in turn submitted a progress report to the HSE's Chief Operations Office regularly. At the time of HIQA's review, the oversight group was in the process of winding up, and had submitted its final report to the

HSE's Chief Operations Officer — despite the fact that the six recommendations from the Price report had not been fully implemented. As a result, oversight of the implementation of the Price report recommendations was due to revert to being part of the established and formalised accountability and performance arrangements between the HSE and the Saolta Group.

4.1.11 Summary of findings related to the changes implemented to improve the governance of gynaecology services at Saolta Group level

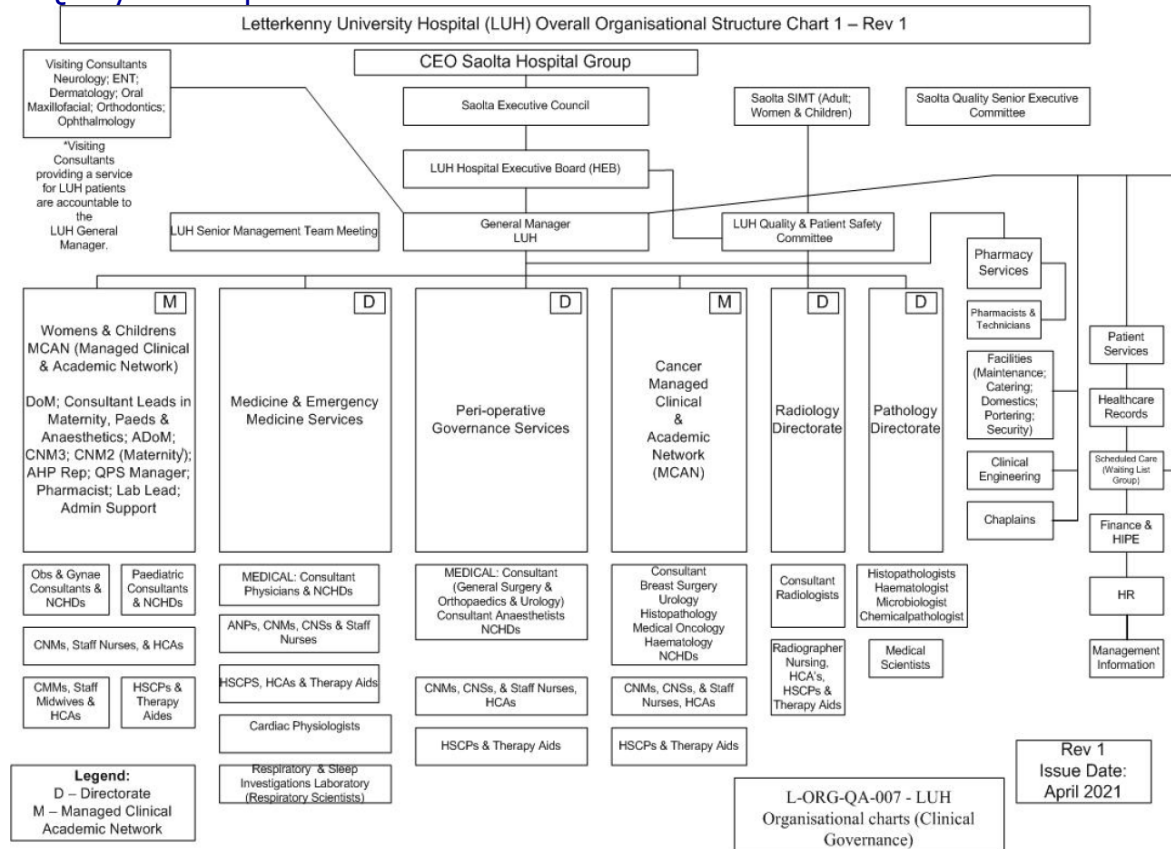
The Saolta Group had formalised corporate and clinical governance structures in place to oversee the quality and safety of women and children's services across the hospital group. The hospital group had introduced a revised governance structure to ensure a more integrated approach for the governance and delivery of women and children's services across Saolta Group, but at the time of HIQA's review these structures were new and in the process of establishing. The hospital group had developed key performance indicators to monitor, evaluate and compare the performance of gynaecology services delivered across the group, but was reliant on the HSE's National Women and Infants Health Programme to develop key performance indicators for the ambulatory gynaecology service. Following the Price report, the hospital group convened an implementation group with assigned responsibility to implement the report's recommendations. The Saolta Group had defined accountability and reporting arrangements with the HSE.

4.2 Corporate and clinical governance at Letterkenny University Hospital

During HIQA's review, the geographic location of Letterkenny University Hospital and the potential isolation that might arise as a result were consistently referred to in meetings with senior management from the hospital and Saolta Group. HIQA was provided with an assurance that the Saolta Group was striving to ensure further meaningful integration of the hospital into the hospital group. Structures within the revised accountability and performance framework (as outlined in section 4.1.5 above) and planned on-site visits to the hospital by members of Saolta Group's executive management team were all provided as evidence of measures to support Letterkenny University Hospital's further integration into the hospital group.

Letterkenny University Hospital had formalised corporate and clinical governance structures in place for gynaecology services delivered at the hospital. The hospital provided a diagram depicting the formalised clinical and corporate governance arrangements and lines of accountability within the hospital and upwards to the Saolta Group (see Figure 19).

Figure 19 Organisational structure at Letterkenny University Hospital provided to HIQA by the hospital



The General Manager at Letterkenny University Hospital had overall managerial responsibility and executive accountability for the operational management of the gynaecology services at the hospital. The General Manager was accountable to Saolta Group’s CEO. The General Manager presented formal reports on the hospital’s performance as part of the accountability and performance arrangements to the executive management team of Saolta Group every month.

Executive authority, accountability and responsibility for the delivery of maternity, gynaecology and children’s services at the hospital was assigned to Letterkenny University Hospital’s Women’s and Children’s Managed Clinical and Academic Network.

4.2.1 Women’s and Children’s Managed Clinical and Academic Network at Letterkenny University Hospital

The Women’s and Children’s Managed Clinical and Academic Network at Letterkenny University Hospital was led by an Associate Director who, at the time of HIQA’s review, was a consultant obstetrician and gynaecologist. The Associate Director was responsible for the clinical practice, standards of care and the quality and safety of gynaecology services at the hospital.

HIQA found that the terms of reference for the hospital's Women's and Children's Managed Clinical and Academic Network did not align with the purpose and function of the network as described to HIQA during meetings with senior management from the hospital and Saolta Group. The terms of reference (as submitted to HIQA and dated 2018) preceded the introduction of the Women's and Children's Managed Clinical and Academic Network in 2020. Terms of reference are essential in defining and setting the purpose, role, responsibilities, structures and processes of any committee or structure. Furthermore, evaluation of the performance and effectiveness of that structure is determined against its defined purpose and function as set out in terms of reference. Therefore, it is important that senior management at the hospital urgently review and develop an appropriate terms of reference for the hospital's Women's and Children's Managed Clinical and Academic Network that aligns with the revised purpose, objectives and reporting arrangements introduced following the Price report.

The Associate Director of the hospital's Women's and Children's Managed Clinical and Academic Network, together with the Director of Midwifery, were responsible for the day-to-day management of gynaecology services at the hospital. Both were members of the hospital executive board and both reported to the hospital's General Manager.

The Women's and Children's Managed Clinical and Academic Network at Letterkenny University Hospital had a dual reporting arrangement to both the hospital and the Saolta Group. At local hospital level, the Associate Director of the hospital's network reported to both the hospital's general manager and hospital executive board. At Saolta-Group level, the Associate Director of the hospital's network reported to the Clinical Director of the Saolta Group's Women's and Children's Managed Clinical and Academic Network. The Director of Midwifery at Letterkenny University Hospital also reported to both the general manager of the hospital and to Saolta's Chief Director of Midwifery on issues related to clinical practice, standards and nursing and midwifery resource planning.

4.2.2 Hospital executive board at Letterkenny University Hospital

The hospital executive board was the main governance committee at the hospital. This board had assigned responsibility for ensuring that services at the hospital were delivered within the clinical and corporate governance framework developed by the Saolta Group. Despite numerous requests by HIQA to the hospital, the terms of reference for the hospital executive board were not received by HIQA. Therefore, HIQA was unable to determine if the intended structure and functioning of the hospital executive board was appropriate to manage the assigned accountability and responsibility. However, minutes of meetings for 2019 and 2020 of the board

received and reviewed by HIQA showed that the terms of reference were being developed and that work on their development had started 12 months before HIQA's review.

Minutes of meetings of the hospital executive board also recorded that the board met every two weeks and was chaired by the General Manager. Membership comprised, amongst others:

- the Associate Director of the hospital's Women's and Children's Managed Clinical and Academic Network
- the Director of Midwifery
- clinical directors for the five clinical directorates*****
- the quality and patient safety manager.

Operational issues, clinical outcomes, service-user feedback, clinical incidents and quality improvement were standing agenda items for meetings of the hospital executive board. Notably, while minutes of meetings of the board indicated a focus on the quality and safety of services, in the documentary evidence received by HIQA there was little evidence that findings of the Price report or the work of the special measures team were being reviewed and or considered at meetings of the board. While meetings appeared to be well attended, actions arising from deliberations at these meetings were not recorded in any minutes of meetings received and reviewed by HIQA. Therefore, it was difficult for HIQA to identify how issues considered at meetings of the hospital executive board were addressed.

4.2.3 Quality and patient safety committee at the Letterkenny University Hospital

The hospital's quality and patient safety committee had overall responsibility and oversight of the quality and safety of services across all specialties at the hospital. This multidisciplinary committee was chaired by the Director of Nursing and was focused on developing, implementing and evaluating a comprehensive quality and safety programme throughout the hospital. The committee met every month to review the hospital's performance and quality and safety outcomes. In addition, the quality and patient safety department submitted a formal report to the committee at the end of every year. This report presented information on the performance of the gynaecology services, trend analysis and recommendations from that analysis.

***** The five clinical directorates established by the Saolta University Health Care Group were the Women's and Children's Managed Clinical and Academic Network, Perioperative Directorate, Medical Directorate, Radiology Directorate and Laboratory Directorate.

It was evident that this was a functioning committee — meetings were well attended and decisions and actions with defined timelines for implementation were documented. The committee reported to the general manager at the hospital and provided assurance on known risks to the hospital executive board. The committee submitted reports to the hospital executive board, clinical leads and heads of each department every three months and submitted a report to the quality and patient safety committee of the Saolta Group every month.

At the time of HIQA's review, the hospital had received approval to recruit and appoint one whole-time equivalent registered general nurse at clinical nurse manager grade 2 level to the quality and patient safety department. The recruitment campaign for this position was to begin in May 2021. This appointment was intended to supplement the pre-existing staff complement in the quality and patient safety department, and enhance clinical expertise in the department.

4.2.4 Management of risk at Letterkenny University Hospital

Effective risk management is essential to the safeguarding and avoidance of harm for women who use the gynaecology services. HIQA found that the hospital had mechanisms in place for staff to identify, assess and report risks related to gynaecology services and for identified risks to be managed. Overall, there was evidence that identified risks had been managed actively in the period immediately prior to the HIQA review, with some control measures being put in place to manage identified risks to the gynaecology service.

The hospital established a risk register committee in January 2021 in response to concerns in the Price report that previous risk management structures were not as effective as they should have been in managing both strategic and operational risks to the quality and safety of gynaecology services at the hospital. The risk register committee was chaired by the General Manager and its membership comprised the chairperson of the quality and patient safety committee, the quality and patient safety manager and the Associate Director of the hospital's Women's and Children's Managed Clinical and Academic Network. The committee met every two months and reported to the hospital's quality and patient safety committee. Identified risks were recorded on the hospital's risk register.

The hospital's risk register was updated after each meeting of the risk register committee and was approved by the hospital's quality and patient safety committee. Afterwards, the risk register was sent to the hospital executive board and to all medical consultants, service managers, heads of departments, clinical nurse managers and clinical midwife managers. Risks related to the gynaecology services that could not be managed at hospital level were escalated to the Saolta Group.

Documentation received by HIQA showed that there had been eight risks related to the gynaecology services recorded on the hospital's risk register. These included:

- Increasing waiting list numbers and the resultant impact on the delayed diagnosis and treatment of women referred to the hospital with post-menopausal bleeding.
- Recruitment and retention of appropriately skilled staff and consultant recruitment.
- Non-compliance with healthcare records national standards.
- Information technology and network infrastructure.

Risks had been assessed, analysed and risk-rated using the two-dimensional probability and impact risk matrix. Corrective actions and controls had been applied to manage identified risks.

The hospital had implemented some controls to militate against the risk associated with increasing waiting times for women referred to the hospital with post-menopausal bleeding. This had been assigned a high-risk rating. Corrective actions and controls had been implemented to militate against the risk. These included the triaging, tracking and prioritising of all women presenting to the hospital with post-menopausal bleeding. All woman diagnosed with cancer had been prioritised and referred to a gynae-oncology specialist at St James' Hospital, Dublin. There was evidence that waiting list times were being monitored closely and discussed at meetings of the hospital's Women's and Children's Managed Clinical and Academic Network and with senior management at the hospital and Saolta Group.

The hospital had been engaged in a continual recruitment campaign to address the risk associated with the difficulty in recruiting and retaining appropriately skilled staff and consultant recruitment. This risk had been assigned a high-risk rating. To control the risk, the hospital had increased the number of fixed-term locums and reduced the number of agency locum consultants, which had allowed the Saolta Group to directly recruit consultant posts.

The hospital's non-compliance with national standards for the management of healthcare records had also been identified as a risk. The risk had been assigned a high-risk rating. To militate against the risk, the hospital had reconvened the healthcare records committee to oversee the hospital's management of healthcare records and ensure compliance with national standards. Hospital management had also identified that additional investment is needed to increase staffing levels,

improve storage facilities and to introduce an electronic tracking system for all healthcare records.

4.2.5 Management of patient safety incidents at Letterkenny University Hospital

It was clear from documentation received by HIQA and from staff engagement during HIQA's review that the hospital had defined arrangements for identifying, managing, reducing and reporting patient safety incidents, serious incidents and serious reportable events. Patient safety incidents related to gynaecology services were being reviewed and discussed at monthly meetings of the hospital's quality and patient safety committee and the hospital's Women's and Children's Managed Clinical and Academic Network. The hospital executive board received a report every three months from the hospital's quality and patient safety committee, which contained information about the patient safety incidents that had occurred in the hospital over the three-month reporting period.

Staff who spoke with HIQA were aware of their responsibility to report patient safety incidents. They were clear about the process and system in place to report and manage any patient safety incidents that occur in the ambulatory gynaecology service and post-menopausal clinic. Incidents were reported on the hospital's quality management system and the National Incident Management System (NIMS). Nursing staff could clearly outline the process involved in reporting and reviewing incidents in line with the HSE's incident management framework.⁷¹

Documentary evidence received by HIQA showed that, in 2020, a total of 140 patient safety incidents relating to gynaecology services were reported in the hospital. Two of these incidents were related to the post-menopausal bleeding clinic. Overall for 2020, the rate of patient safety incidents reported by Letterkenny University Hospital to the National Incident Management System ranged between 18.40 and 31.20 per 1,000 bed days. When compared to other model 3 hospitals in the Saolta Group, this rate of reporting was similar or higher. For example, the rate of reporting was similar to Mayo University Hospital whose rate of reporting of patient safety incidents to the National Incident Management System for 2020 ranged between 16.00 and 36.60 per 1,000 bed days. It was higher than Sligo University Hospital whose rate of reporting of patient-safety incidents to the National Incident Management System for 2020 ranged between 11.10 and 14.80 per 1,000 bed days.⁷² Higher reporting rates of patient-safety incidents reflects a positive safety culture.⁷¹

4.2.6 Monitoring and evaluation of post-menopausal bleeding clinic at Letterkenny University Hospital

During the on-site inspection at Letterkenny University Hospital, HIQA was told that the hospital was developing a software dashboard containing key performance indicators to assist in the monitoring and reporting of performance of the gynaecology services. The dashboard was expected to be available for use by clinicians in August 2021. When in use, HIQA believes that the dashboard will be an important management tool in the measuring, monitoring and management of the performance of gynaecology services.

Following the publication of the Price report, the hospital, Saolta Group and national HSE had developed a set of key performance indicators for women presenting to hospital with post-menopausal bleeding, which the hospital was using to monitor and evaluate service performance (see Table 17).

Table 17 Key performance indicators monitored for the post-menopausal bleeding clinic at Letterkenny University Hospital

Key performance indicator	Monitored
Percentage of women referred for post-menopausal bleeding who require histology investigation and have investigation within 56 calendar days of referral.	Weekly
Percentage of all gynaecology-oncology patients who are referred to a tertiary service within one week of diagnosis.	Monthly
Percentage of adult women waiting 15 months for inpatient treatment.	Monthly
Percentage of women who have their procedure cancelled by the hospital within 24 hours of the date of the procedure.	Monthly
Percentage of women who positively evaluated their experience of the post-menopausal bleeding clinic.	Monthly

Key performance indicators on timelines set out in Table 17 were being collated, reviewed, tracked and trended by the hospital's scheduled care manager and patient and safety department on a weekly or monthly basis. Documentary evidence received by HIQA showed that the hospital was monitoring the first three key performance indicators set out in Table 17 above. Hospital management told HIQA that they intended to progress monitoring against the latter two key performance indicators when the business manager of the hospital's Women's and Children's Managed Clinical and Academic Network was in post.

The hospital also monitored hospital-specific indicators related to the 'referral to review' and 'review to histological investigation' timelines (see Table 18).

Table 18 Key performance indicators for 'referral to review' and 'review to histological investigations'

Key performance indicator	Monitored
Percentage of women seen at the post-menopausal bleeding clinic within 28 days of referral ('referral to review').	Weekly
Percentage of women where transvaginal scan and pipelle biopsy offered.	Weekly
Percentage of women where hysteroscopy was performed within 28 days of post-menopausal bleeding clinic appointment ('review to histological investigations').	Weekly

The 28-day timeline for 'referral to review' plus 28-days for 'review to histological investigations' when combined was the same as the 56-day 'referral to diagnosis' timeline — from appointment at the post-menopausal bleeding clinic to having a hysteroscopy — set by the Saolta Group.

In addition, Letterkenny University Hospital had endeavoured to maintain the national timelines for women presenting to the hospital with post-menopausal bleeding set by the HSE's National Women and Infants Health Programme in August 2020 following the Price report (see Table 19).

Table 19 National timelines for women presenting with the post-menopausal bleeding

Key performance indicator
Referral from general practitioner (GP) to be seen in outpatient/ambulatory gynaecology clinic — four weeks.
Seen in outpatient and or ambulatory gynaecology clinic to histological results — four weeks.
90% of referrals to be seen within four weeks of referral; receiving histological confirmation within an additional four-week period.
100% of women with post-menopausal bleeding are seen and receive histological confirmation within 12 weeks of referral.

The hospital had devised a clinical red flag list where compliance with key performance indicators for the post-menopausal bleeding clinic were being tracked and monitored by the scheduled care manager. This data had been reviewed at meetings of the hospital's quality and patient safety committee every month.

4.2.7 Clinical effectiveness and audit activity at Letterkenny University Hospital

Clinical audit supports and directs continual quality improvement and is an important process for services to understand, assure and ensure the quality and safety of the care they provide. HIQA found that despite evidence of some audit activity at the hospital, the Saolta Group implementation group and hospital did not have a clearly defined clinical or non-clinical audit plan for gynaecology services. In 2020, a small number of clinical audits related to gynaecology services at the hospital had been conducted by non-consultant hospital doctors. These had focused on:

- consent for hysteroscopy
- clinical history taking and or admission record template
- follow-up scan post-menopausal bleeding clinic completed transvaginally.

Two audits focusing on the quality of documentation had been planned for 2021.

Furthermore, HIQA found that Letterkenny University Hospital had not conducted a formal, structured audit to determine the level of compliance with procedures and timelines for the review and triage of referrals to the hospital's gynaecology services. This was an action in the 51-point implementation plan developed by the Saolta Group following the Price report. Hospital management told HIQA that the audit had not happened because staff from the hospital's patient and safety department, which was tasked with doing the audit, were deployment to the local HSE's COVID-19 vaccination clinic. Hospital management anticipated that the formal, structured audit would be conducted in July or August 2021. Meanwhile, the referral triage, pathway and treatment timelines were collated and reviewed every week at the operational gynaecology meeting and every month by the Saolta Group's implementation group.

The hospital should commit to developing a comprehensive audit plan to ensure regular monitoring level of compliance with procedures, process and level of adherence with set targets and to provide assurance of the quality and safety of gynaecology services.

4.2.8 Summary of findings related to the changes implemented to improve the governance of gynaecology services at Letterkenny University Hospital

Letterkenny University Hospital had formalised corporate and clinical governance arrangements in place. Revised structures were introduced at hospital level to ensure a more integrated approach for the delivery of women and children's services at the hospital. While there was evidence that the hospital did monitor performance of the gynaecology services, this was an area that required significant improvement.

4.3 Ineffectiveness of governance assurance structures and processes identified during HIQA's review

Despite the governance structures and processes in place at the Saolta Group and hospital level as outlined in this report, during the course of this review and in testing these arrangements, HIQA identified a failure in governance assurance mechanisms at hospital and Saolta Group levels.

As part of the methodology of the review, HIQA reviewed a sample of healthcare records of women who had attended the hospital's post-menopausal bleeding clinic in February 2021. HIQA selected 25 (56%) randomly selected healthcare records from a total of 45 for review. The aim was to assess compliance with the processes and timelines outlined in the hospital's standard operating procedure for the management of referrals to gynaecology outpatients. Almost two out of three (68%) of the healthcare records reviewed were new referrals, while approximately one in three (32%) were recalls to the post-menopausal bleeding clinic.

It was evident from the healthcare records reviewed that the processes set out in the standard operating procedure was not being followed in all the healthcare records reviewed. For example, some of the records did not have a date stamp as was the process set out in the standard operating procedure. Therefore, HIQA's review team relied on other information to determine when the referral was received by the hospital and if the timelines for triage, review and investigation (where needed) were within or outside set timelines. Furthermore, the standard operating procedure set out that all referrals should be triaged by a consultant within five days of referral. Of the referrals to the hospital's post-menopausal bleeding clinic, 16 of 25 (64%) had been triaged by the consultant obstetrician and gynaecologists within five days. Of the remaining nine (36%), the date of triage was not recorded in eight records, and therefore HIQA could not determine the date when they had been triaged and if there was or was not a delay in the triage process. HIQA did find that one case was outside the set timeline of five days for triage by the consultant obstetrician and gynaecologist.

The hospital and national HSE have set a timeline of 28 days for women to be reviewed at the post-menopausal bleeding clinic following referral to the clinic ('referral to review'). In four of the 25 healthcare records reviewed, the 28-day timeline had not been achieved. The hospital and Saolta Group have also set a timeline of 56 days for women referred to the post-menopausal bleeding clinic to have histological investigations performed, if clinically indicated. In a further four of the 25 healthcare records reviewed, the 56-day timeline had not been achieved. One of these four cases had also experienced a delay in the 'referral to review' timeline and is included in the referral-to-review delay figure identified above.

4.3.1 HIQA's escalation of concerns about failure to meet timelines for women presenting to Letterkenny University Hospital with post-menopausal bleeding

On 29 June 2021, HIQA sought clarification from the General Manager of the hospital and the CEO of the Saolta Group about the failure to achieve set timelines in the case of seven women discussed in section 4.3. On that date, HIQA also sought an update on the scheduling of clinic appointments and or histological investigations for each woman. HIQA received a response on 14 July 2021. It was evident from the hospital's response that it was aware of and had, through established formal governance structures, escalated the issue of delay in relation to six of the seven women to the Saolta Group. However one case, identified through HIQA's review, had not been picked up by the governance assurance structures and processes at hospital and Saolta Group levels.

Correspondence to HIQA from the CEO of Saolta Group stated that it was not aware of the case identified by HIQA of one woman where the timelines for 'referral to review' and subsequently 'referral to histological investigation' had both been missed. Furthermore, the CEO acknowledged in the correspondence that the failures in governance assurance structures and processes identified by HIQA had demonstrated a breakdown in the oversight of the quality and safety of services at Saolta Group and Letterkenny University Hospital levels.

While the sample of healthcare records reviewed was small, the failure to meet set timelines represented a 1 in 25 (4%) failure rate in the adherence to timelines for the review, testing and diagnosis of women referred to the hospital with post-menopausal bleeding. The woman affected had been waiting for a protracted time from initial referral to being reviewed at the post-menopausal bleeding clinic. Furthermore, this failure identified weaknesses, which was subsequently acknowledged by the CEO of the Saolta Group, in the governance structure and oversight arrangements at the hospital and at Saolta Group levels, and this was a concern for the HIQA review team. HIQA sought and was provided with confirmation from Saolta Group that the woman affected had been communicated with and was informed about the delay in arranging an appointment for review at the hospital's post-menopausal bleeding clinic.

4.3.1.1 Retrospective audits of healthcare records of women referred to Letterkenny University Hospital for investigation of post-menopausal bleeding

Subsequently and following HIQA's findings, the hospital group conducted two retrospective audits of healthcare records of women referred to the hospital's gynaecology services for investigation of post-menopausal bleeding. One audit focused on the healthcare records of women referred to the hospital's gynaecology services between May 2020 and April 2021. A second audit focused on the

healthcare records of women referred to the hospital's gynaecology services from January to mid-July 2021.

The first audit identified that of the 366 women referred with post-menopausal bleeding to the hospital's gynaecology services between May 2020 and April 2021, 99% were seen and reviewed within the 28-day 'referral to review' timeline. However five women (1%) had not been seen within the 28-day timeline. HIQA was informed that the hospital and Saolta Group were aware of four of the five cases where there was a delay in the 28-day 'referral to review' timeline. HIQA was further informed that the failure to meet the timelines in these four cases was a result of appointments being cancelled and other hospital-related issues, such as staffing shortages, day-to-day operational issues due to COVID-19 and what it termed 'administration errors' which had resulted in the women being given an appointment for a different clinic. However, the hospital and Saolta Group acknowledged that they were not aware of the one case, as identified by HIQA during the conduct of its review, where one woman experienced a delay in the 'referral to review' timeline.

It should be recognised that if benchmarked against performance in many similar services nationally, and noting the absence of key performance indicators relating to post-menopausal bleeding nationally until August 2020, a 99% adherence rate with the timelines set for the gynaecology services would likely compare favourably. Notwithstanding this overall level of performance, the failure to adhere to timelines in the case of five women was a significant concern to HIQA given the previous failings in the gynaecology services at Letterkenny University Hospital, and more importantly given that the enhanced governance arrangements at hospital and Saolta Group levels did not identify these failures.

The audit of healthcare records for May 2020 to April 2021 also identified that, along with the non-adherence to the 28-day 'referral to review' timeline, the 12-week (84-calendar-day) national standard for 'referral to histological results'⁴⁶ for women experiencing post-menopausal bleeding was also breached. Of the 366 women referred to the hospital, 114 (31%) women had been referred on for hysteroscopy. Twenty-one of the 114 women (18%) referred for hysteroscopy had received a diagnosis after the 12-week (84-calendar-day) national standard.

In the second audit of healthcare records conducted by the Saolta Group, 912 healthcare records of women newly referred to the general gynaecology outpatient department at Letterkenny University Hospital for the period of January to mid-July 2021 were reviewed. This audit confirmed that five cases (including the case (in February 2021) identified by HIQA during the conduct of its review) had not been seen and reviewed within the set 28-day timeline. Four of the five women had also experienced a delay in the 28-day 'review to histological investigation (diagnosis)'

timeline. HIQA was concerned that the failures in meeting set timelines experienced by these five women was not identified by the governance structures and oversight quality assurance mechanisms at hospital and Saolta Group levels. At the time of writing this report, all five women had been informed of the delay in timelines and all had been seen and reviewed in the hospital's post-menopausal bleeding clinic, ambulatory gynaecology service or a general gynaecology clinic.

Following the two audits, the Saolta Group committed to implementing the following corrective actions at Letterkenny University Hospital:

- A person was to be recruited and allocated to the post-menopausal bleeding clinic to provide administration support and to monitor referrals, waiting lists and identify potential risks of breaching key performance indicators.
- All incidents where appointment timelines set out in the key performance indicators were not being met were to be reported on the hospital's quality management system (Q-Pulse) and reviewed by Saolta Group's Women's and Children's Managed Clinical and Academic Network serious incident management team.
- The multidisciplinary team would undertake a review of a random sample of healthcare records of all women who attend the gynaecology services each month to ensure compliance with timelines and key performance indicators.
- All new referrals to the general gynaecology clinic at Letterkenny University Hospital will be seen by a consultant obstetrician and gynaecologist or non-consultant hospital doctor at registrar grade.
- The hospital's induction programme for incoming locum consultants will be strengthened with particular reference to patient pathways in respect of potential endometrial cancer cases and pathways or timelines for other clinically urgent referrals.

HIQA was concerned that the revised governance and oversight structures and processes introduced at hospital level following the Price report had failed to identify failures in all five cases described above. Furthermore, the potentially significant failure for any woman in this situation had not been identified by the oversight structures at Saolta Group level. Based on the evidence from this review, HIQA was not assured that the governance and oversight structures at the Saolta Group and hospital were effective enough to assure the quality and safety of gynaecology services at Letterkenny University Hospital.

4.3.2 Recording of clinical practice

In addition to the failure to meet the 'referral to review' and 'review to histological investigation' timelines, HIQA's review of healthcare records identified issues with the quality of the documentation and recording of clinical care. The accessibility of high-quality information is an essential requirement for effective clinical decision-making. Healthcare records facilitate and support clinicians in their decision-making. HIQA's review of healthcare records identified an issue with the process of clinical documentation at the hospital. Specifically, HIQA found practices that were not consistent with best practice on recording and documenting clinical care. In some of the healthcare records reviewed, the follow-up plan of care had not been documented in the body of the healthcare record. Instead, the plan of care was recorded directly on the histology report. While this report could be attached to the healthcare records, it was the opinion of HIQA's review team that this could easily be misplaced or dislodged. HIQA believes this represented an inherent risk that had the potential to impact on the availability of information to inform clinical decision-making. HIQA escalated its concern about this practice to the General Manager of the hospital verbally on 22 June 2021 and sought an update on the corrective actions implemented to manage the risk on 29 June 2021. In response to HIQA, the hospital provided assurance that this practice had been reviewed and discontinued, and a new record template had been introduced to ensure the follow-up plan of care would be recorded in the body of the woman's healthcare record.

4.3.3 Measures to improve governance arrangements at Letterkenny University Hospital

As indicated in chapter 2 of this report, over the past three years, the Saolta Group has implemented a number of substantial initiatives, interventions, and managerial supports aimed at strengthening governance structures and processes and the day-to-day operations of services, including gynaecology services, at Letterkenny University Hospital. Initiatives and managerial supports implemented in November 2018 for a planned period of six months, had been extended for more than 12 months to late 2019.

Following the Price report, additional managerial supports in the form of a special measures team was in place for nine months between July 2020 and April 2021. Notwithstanding these supports, based on the evidence collected during this review, HIQA was not assured that the governance structures and processes at the hospital and oversight arrangements at Saolta Group levels were sufficiently effective to assure and ensure the quality and safety of gynaecology services at Letterkenny University Hospital.

During the latter stages of HIQA's review, the Saolta Group and national HSE recognised and acknowledged HIQA's ongoing concerns regarding the weaknesses in governance structure and process at Letterkenny University Hospital. In response, the Saolta Group has committed to introducing additional external initiatives to support senior management and strengthen the governance structures and processes at the hospital. At the time of drafting this report, Saolta Group told HIQA that it had very recently commissioned an external independent team, with membership from outside of the Republic of Ireland, to review the management and governance of services at the hospital, make recommendations and support management at the hospital to address any issues. As HIQA's review was concluding, the terms of reference, timeline for commencement and completion and the aims and expected outcomes of the external independent intervention were being developed by Saolta Group. HIQA was told that these should be completed during the month of September 2021.

While the external independent intervention and other support initiatives are welcomed, HIQA notes that this is the third time over three years (since 2018) that Saolta Group has introduced measures aimed at improving the governance structures and processes at Letterkenny University Hospital. Therefore, it is imperative that the weaknesses in governance structures that remain at Letterkenny University Hospital — and which have the potential to negatively impact on the quality and safety of services, in HIQA's opinion — are addressed this time in a sufficient, effective and sustainable way by the Saolta Group.

It is essential that there is now a concerted effort on behalf of the Saolta Group to ensure that any supportive measures to be introduced at the hospital should be targeted in scope and have a defined, focused objective. These efforts should be measurable and focused on establishing effective governance structures and processes at Letterkenny University Hospital and quality assurance mechanisms at Saolta Group level. The resulting governance structures and processes should be sustained in the long term so that women who use and depend on the gynaecology services at the hospital can be confident about the quality and safety of those services. The Saolta Group's performance and success in achieving this objective should be monitored every month as part of the accountability and performance management review process between the hospital group and the HSE. If progress in achieving improvements in governance structures and processes at hospital level and quality assurance mechanisms at hospital group level is insufficient then the HSE should hold the Saolta Group to account.

Summary of key findings related to governance of gynaecology services at Letterkenny University Hospital

- Since the publication of the Price report, there was evidence that changes have been implemented with the intention of improving and strengthening the governance structures and processes to assure and ensure the safety and quality of gynaecology services at Letterkenny University Hospital.
- The General Manager at Letterkenny University Hospital has overall managerial responsibility and executive accountability for the operational management of the gynaecology services at the hospital.
- The documented terms of reference for the hospital's Women's and Children's Managed Clinical and Academic Network did not align with the purpose and function of the network.
- Despite several requests to the hospital, the terms of reference for the hospital executive board were not made available for review by HIQA.
- The hospital had arrangements in place for staff to report risks related to gynaecology services.
- The hospital had defined arrangements for the identification, management, reduction and reporting of patient safety incidents, serious incidents and serious reportable related to the gynaecology services.
- The hospital demonstrated a culture of reporting patient safety incidents related to gynaecology services at the hospital.
- The hospital monitored and evaluated the quality and safety of services provided in the post-menopausal bleeding clinic using specific defined key performance indicators.
- The Saolta Group or Letterkenny University Hospital did not have clearly defined key performance indicators to monitor and evaluate the ambulatory gynaecology service.
- The Saolta Group had recently introduced a revised accountability and performance framework across the hospital group. These arrangements were still being established and were in the early stages of implementation at the time of HIQA's review.
- The identified failures in governance assurance structures and processes at Saolta Group and Letterkenny University Hospital levels, as identified by HIQA during the course of its review, demonstrated a breakdown in the oversight of the quality and safety of gynaecology services at the hospital.
- The standard of clinical documentation found in the gynaecology healthcare record was an issue of concern escalated by HIQA's review team to hospital management.
- The Saolta Group needs to substantially strengthen its oversight arrangements to effectively manage the ongoing re-orientation of gynaecology services at Letterkenny University Hospital following the handover of responsibility from the

special measures team to local hospital management and the Saolta Group's Women's and Children's Managed Clinical and Academic Network.

- The Saolta Group has commissioned an external independent team to review where the main issues exist in relation to the management and governance of services at Letterkenny University Hospital, make recommendations and support management at the hospital to address these issues.

4.4 Compliance with the *National Standards for Safer Better Healthcare*

As part of the targeted assurance review, HIQA assessed compliance with 11 national standards from the *National Standards for Safer Better Healthcare*. Tables 20 and 21 presents HIQA's judgments on compliance with six of the 11 national standards related to leadership, governance and management, effective care and support and safe care and support.

Table 20 Compliance with the *National Standards for Safer Better Healthcare*

Capacity and capability dimension
Theme: Leadership Governance and Management
<p>Standard 5.2 Service providers have formalised governance arrangements for assuring the delivery of high-quality, safe and reliable healthcare.</p> <p>Key findings: At both Saolta Group and Letterkenny University Hospital levels there were significant weaknesses in the governance structures and processes, and the quality assurance mechanisms overseeing the gynaecology services at the hospital. The documented terms of reference for the Women's and Children's Managed Clinical and Academic Network at Letterkenny University Hospital did not align with its purpose and function. HIQA did not receive a formalised, documented terms of reference for the hospital executive board. HIQA identified a failure to meet internal 'referral to review' and 'referral to histological investigations (diagnosis)' timelines, which had not been previously identified through the hospital's governance structures and processes or the governance assurance mechanisms at Saolta Group level. The Saolta Group had stood down the special measures team before the changes to improve efficiencies within the gynaecology services at the hospital were fully implemented and or bedded into practice. The process of standing down the special measures team began in January 2021. In April 2021, there was a formal handover of any outstanding actions and plans that needed to be implemented. The business manager for the hospital's Women's and Children's Managed Clinical and Academic Network was, in collaboration with the Saolta Group's Women's and Children's Managed Clinical and Academic Network, assigned responsibility for progressing any outstanding actions and plans after the standing down of the special measures team. At the end of HIQA's review, the hospital group commissioned an external independent team to review</p>

where the main issues exist in relation to the management and governance of services at the hospital, make recommendations and support hospital management to address these issues. Previous initiatives and measures introduced since 2018 by the Saolta Group to strengthen and improve the governance structures and processes at the hospital have not resulted in long-term sustainable gains. The progress in achieving sustainable, effective improvements in the governance structures and processes at Letterkenny University Hospital and oversight quality assurance mechanisms at Saolta Group should be monitored as part of the hospital group's accountability and performance arrangements with the HSE.

Judgment: Partially compliant

Theme: Leadership Governance and Management

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.

Key findings: There was no comprehensive, structured approach to the auditing of compliance with key performance indicators in the gynaecology services. The hospital did not have a clearly defined clinical or non-clinical audit plan for gynaecology services. Two retrospective audits of healthcare records of women referred to the hospital for investigation of post-menopausal bleeding for the periods from May 2020 to April 2021 and January to mid-July 2021 were conducted on foot of the non-adherence to internal timelines set for 'referral to review' and 'referral to histological investigations (diagnosis)' identified by HIQA during the conduct of its review.

Judgment: Partially compliant

Table 21 Compliance with the *National Standards for Safer Better Healthcare*

Quality and safety dimension

Theme 2: Effective Care and Support

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

Key findings: The hospital's gynaecology services did not have a defined suite of key performance indicators for the ambulatory gynaecology services. Performance of the post-menopausal bleeding clinic was monitored against defined key performance indicators. HIQA identified a failure to adhere to set timelines for 'referral to review' and 'referral to histological investigations (diagnosis)' that had not been identified or flagged by the governance structures and processes at hospital or Saolta Group levels.

Judgment: Partially compliant

Quality and safety dimension

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.

Key findings: The hospital had arrangements in place to identify risks related to gynaecology services. HIQA identified an issue with the recording and documentation of care in the healthcare records of some women who had attended the hospital's post-menopausal bleeding clinic. There was limited evidence that quality improvement plans for gynaecology services were implemented.

Judgment: Partially compliant

Theme 3: Safe Care and Support

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.

Key findings: There was evidence that the hospital were implementing the Price report's recommendations, but was reliant on substantial external support and resourcing to do so.

Judgment: Substantially compliant

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

Key findings: The hospital had defined arrangements to identify, manage, reduce and report patient safety incidents related to gynaecology services. However, there was limited evidence demonstrating how feedback from these incidents have improved the gynaecology services at the hospital.

Judgment: Partially compliant

4.5 Conclusion

While Saolta Group and Letterkenny University Hospital had formalised corporate and clinical governance arrangements in place with defined reporting structures, the effectiveness of these arrangements at Saolta Group and hospital levels was an issue of concern for HIQA.

HIQA recognises the efforts to strengthen and enhance the governance structures through the establishment of the Women's and Children's Managed Clinical and Academic Network at Saolta Group and Letterkenny University Hospital and the introduction of a revised accountability and performance framework, following the

Price report. Allied to this, the risk register committees at Saolta Group and hospital levels ensured a more proactive approach to identifying and managing risks to prevent harm and ensure the quality and safety of gynaecology services. However, despite the changes made to enhance governance structures and processes at Letterkenny University Hospital and the Saolta Group, HIQA identified failures in the governance processes at the hospital and oversight assurance mechanisms at Saolta Group level. Consequently, HIQA was not assured of the effectiveness of the governance structures, processes and oversight arrangements in place at the hospital or Saolta Group levels at the time of conducting this review.

Effective governance cannot be measured through the existence of structures and processes alone. Structures and processes working effectively in an integrated way are essential for good governance and management of a service. The incorporated, integrated governance structures for women and children's services introduced across the Saolta Group were in the early stages of implementation at the time of this review. Notwithstanding this, it is now imperative that Saolta Group management implement effective measures to address the identified weaknesses in the governance structures and processes, and quality assurance mechanisms at Letterkenny University Hospital.

HIQA acknowledges the recent measures taken by the Saolta Group to support the management team at the hospital. HIQA notes that these measures come on the back of other similar prior external interventions. It is vital that any measures introduced now to improve governance and oversight processes are sufficient, effective and sustainable. If progress in achieving improvements in the governance structures and processes at hospital and governance assurance mechanisms at Saolta Group levels is insufficient then the HSE should hold the Saolta Group to account.

Chapter 5 Conclusion

Effective governance structures and processes, together with efficient and supported leadership and management, are a critical line of defence for the delivery of safe, high-quality and reliable healthcare services. This HIQA review found that there needs to be strong, effective corporate and clinical governance, leadership and management at Saolta Group and Letterkenny University Hospital in order to establish and sustain a culture of patient safety.

Initial concerns about the safety of the gynaecology services at Letterkenny University Hospital were first raised with HIQA in 2018. Since then, and in line with HIQA's current powers, HIQA has raised concerns at all levels of the HSE and has sought regular assurances around the ongoing quality and safety of gynaecology services at the hospital — from hospital management, senior management in the Saolta Group and senior management nationally in the HSE.

On foot of HIQA's engagement with the hospital group and the HSE, an external review into the totality of services for women presenting to the hospital with post-menopausal bleeding was commissioned by the Chief Clinical Director of the Saolta Group in 2019. The report of the external review (the Price report) identified significant scope for improving the governance and management arrangements of the gynaecology services at both hospital and Saolta Group level. The Price report made six recommendations to improve the quality and safety of gynaecology services at the hospital.

Following the publication of the Price report in August 2020, the hospital and Saolta Group committed to implementing all of its recommendations. The Saolta Group developed a 51-point implementation plan to improve the quality and safety of services for women presenting to the hospital with post-menopausal bleeding and an implementation group was established at Saolta Group level to implement the recommendations.

The pace of progress of implementing the Price report's recommendation and the level of success or otherwise were monitored at national HSE level by an oversight group convened under the sponsorship of the Office of the National Director of Acute Operations in July 2020.

In April 2021, HIQA commenced a review of the governance arrangements of the gynaecology services at Letterkenny University Hospital, nine months after the publication of the Price report. This review aimed to identify the progress made in implementing the Price report's six recommendations and to determine the

effectiveness, and sustainability of any changes introduced to improve the governance structures and processes at the hospital and Saolta Group levels.

Prior to and during HIQA's review, the hospital was managing the impact of the COVID-19 pandemic and later the cyberattack on the HSE's information and communication technology systems. HIQA acknowledges the level of change made across gynaecology services that required significant work from all in the hospital and at Saolta Group level despite these challenges. Allied to this, the hospital and clinical team were also delivering a busy maternity service at the hospital.

Substantial supports and resources, both financial and staffing, had been provided to the hospital and the Saolta Group to promote changes and efficiencies in the structure and process governing the gynaecology services at Letterkenny University Hospital and the successful implementation of the Price report's recommendations. The implementation process was supported by a special measures team with the assigned responsibility to achieve efficiencies, compliance with best practice clinical guidelines and the provision of safe and reliable services for women attending the hospital.

The hospital introduced a new ambulatory (outpatient) gynaecology model of care on 29 March 2021. While efforts to transition to this model of service are a positive development, at the time of HIQA's review, it was not fully established and was only working at 50% of its potential capacity. It was evident that the special measures team had an important role in leading and driving the changes to achieve efficiencies in the service. HIQA was told that the implementation group convened by Saolta Group would continue to oversee the implementation process and progress further actions so as to achieve full implementation of Price report's recommendations. However, when the special measures team was stood down in April 2021, HIQA was not assured that the necessary leadership was in place at Saolta Group level and Letterkenny University Hospital to continue to drive the necessary changes and efficiencies in order to ensure an effective, well-governed service. This was further confirmed by the commissioning of an external, independent intervention by the Saolta Group to review and make recommendations to improve governance and management at the hospital.

The hospital and Saolta Group received additional funding from the National Treatment Purchase Fund which had enabled the scheduling of additional general gynaecology clinics and post-menopausal bleeding clinics, and the outsourcing of procedures for investigating post-menopausal bleeding. Combined with regular clinical and administrative validation of waiting lists, these actions improved waiting times for women and facilitated the hospital to better manage their outpatient, day cases and inpatient gynaecology services waiting list numbers. While the decline in

gynaecology waiting list numbers at Letterkenny University Hospital is a positive development, it has only managed to align the hospital to the ever-increasing waiting list numbers for gynaecology services across the healthcare system.

Welcome changes had also been introduced at hospital level to increase efficiencies in the referral and triage process for women presenting with post-menopausal bleeding. These changes had improved the process and increased its transparency by enabling the tracking of referrals. Defined timelines and arrangements were in place to escalate referrals whenever timelines were not achieved. However, the process was not automated and as a result still involved multiple manual processes that were labour and time intensive. This raised questions around the sustainability of improvements realised in this important area.

The efficiencies realised in operating theatre use at the hospital have led to increased operating theatre capacity for gynaecological cases referred to Letterkenny University Hospital, which has the potential to facilitate the more timely diagnosis and intervention for women attending gynaecology services at the hospital.

5.1 Workforce planning

While Letterkenny University Hospital and the Saolta Group had received additional staffing to support the effective implementation and day-to-day operation of the ambulatory gynaecology service and post-menopausal bleeding clinic, the hospital continues to struggle to recruit and retain medical, nursing and administrative staff. This situation remains a risk to patient safety.

Difficulty in recruiting staff from all specialties and an ongoing reliance on agency staff has had significant financial implications for the hospital and affects the sustainability of services. At the time of writing this report, gynaecology services at Letterkenny University Hospital were being sustained through a reliance on locum and agency medical, nursing and administrative staff, which is both costly and unsustainable.

The HSE's National Clinical Programme for Obstetrics and Gynaecology in 2015 called for the shortfall in consultant obstetrician and gynaecologist posts to be addressed in order to meet the projected maternity and gynaecology service's needs. HIQA's review of maternity services in 2018–2019 found that, despite recruitment campaigns, maternity services experienced ongoing difficulty in recruiting for approved permanent consultant posts across obstetrics, anaesthesiology, neonatology and paediatrics.

At that time, 15% to 20% of approved permanent consultant posts in obstetrics, anaesthesiology, neonatology and paediatrics were unfilled. HIQA previously identified that in 2019 approximately 20% of approved permanent consultant obstetrician positions were unfilled across maternity services and 15% of the unfilled posts were filled by consultant obstetricians and gynaecologists employed on a temporary or locum contracts. The remaining 5% of posts had remained unfilled.

Over the past three years (2019–2021), the HSE’s National Women and Infant’s Health Programme approved 29 additional consultant obstetrician and gynaecologist posts across the health service. While welcome, this number remains significantly short of the 100 identified by the HSE’s National Clinical Programme for Obstetrics and Gynaecology. At the time of HIQA’s review, the HSE’s National Women and Infant’s Health Programme was due to start a workforce planning project to determine the specific number of consultant obstetrician and gynaecologists posts needed to meet service needs.

5.2 Governance of gynaecology services at Saolta Group and Letterkenny University Hospital

Governance structures had been revised at the Saolta Group and Letterkenny University Hospital levels following the Price report and changes implemented with the intention of:

- enhancing and strengthening the corporate and clinical governance arrangements
- ensuring effective management and leadership at the hospital, and better oversight by the senior management at the Saolta Group.

However, at the time of HIQA’s review, these changes were still relatively new, and were still in the introductory phase.

It was clear who had overall executive accountability for the quality and safety of the services delivered at Letterkenny University Hospital and there was integration of the corporate and clinical governance arrangements at the hospital. However, effective governance must be measured on whether structures and processes work effectively and in an integrated way.

The integrated governance structures for women and children’s services introduced across the Saolta Group and the revised accountability and performance framework has the potential to ensure that effective, formalised governance structures and processes for delivering high-quality, safe and reliable gynaecology services are established at Letterkenny University Hospital. At the time of HIQA’s review, these

revised governance and accountability arrangements were new and only becoming established. The revised structures had not been reviewed or evaluated by the hospital or hospital group, but the Saolta Group had planned to do so in October 2021.

Nonetheless, the weaknesses in the governance and oversight arrangements along with the inadequate formal, structured monitoring and evaluation of gynaecology services at hospital and Saolta Group levels did not provide HIQA with adequate assurance of their effectiveness in ensuring and promoting sustainable quality gynaecology services at Letterkenny University Hospital.

On foot of this report, and given HIQA's ongoing concerns about the governance structures more generally at Letterkenny University Hospital, the Saolta Group decided to appoint an external, independent team to review the main issues in the management and governance of services at the hospital and to make recommendations to address these issues. This is the third time since 2018 that supportive measures aimed at improving governance structures and processes at the hospital have been implemented by the Saolta Group. The new intervention was starting as HIQA's review was concluding.

In the interim, by way of addressing the breach of 'referral to review' and 'referral to histological investigation (diagnosis)' timelines that occurred in the case of five women, the Saolta Group committed to implementing the following corrective actions, which should provide additional confidence for women using the services at the hospital:

- The recruitment and allocation of a dedicated administrative support to the post-menopausal bleeding clinic.
- All incidents where appointment timelines set out in the key performance indicators are not met will be reported to the hospital's quality management system and for review by the hospital group.
- A review of a random sample of healthcare records of all women who attend the gynaecology services each month to ensure compliance with timelines and key performance indicators.
- All new referrals to the general gynaecology clinic at Letterkenny University Hospital will be seen by a consultant obstetrician and gynaecologist or non-consultant hospital doctor at registrar grade.
- The hospital's induction programme for incoming locum consultants will be strengthened with particular reference to patient pathways in respect of

potential endometrial cancer cases and pathways or timelines for other clinically urgent referrals.

Along with these corrective actions, Saolta Group committed to providing on-site managerial support to the hospital's senior management team. HIQA was assured the new proposed independent review, along with the on-site supports provided by the hospital group were appropriate to identify how the approach to the management and oversight of gynaecology services at the hospital can be improved and supported. However, it is now essential that there is a concerted effort both at hospital and Saolta Group levels to ensure that these measures are truly effective and sustained. If progress in achieving effective improvements in the governance structures and processes at hospital level and quality assurance mechanisms at Saolta-Group level is insufficient then the HSE should hold the Saolta Group to account.

5.3 National perspective

In concluding this review of gynaecology services at Letterkenny University Hospital, it is important to place any findings into context from a national perspective. As outlined at the outset of this report, gynaecology services nationally have experienced significant and worsening waiting times for women over the past number of years, which has been further compounded by the COVID-19 pandemic.

During the course of this review, HIQA became aware that the HSE had conducted a national review into the diagnosis timeline of endometrial cancer in 2020. At the time of writing this report, the HSE was finalising its findings. However, HIQA is aware that the preliminary analysis of findings suggest that, in the absence of defined best-practice standards for the timely diagnosis of endometrial cancer in women referred to services with potential symptoms, similar historic challenges with timely access to diagnosis may have occurred in other hospitals.

HIQA notes that the HSE has since prioritised the implementation of the ambulatory gynaecology model of care across healthcare services. Fifteen healthcare services across Ireland have been supported and funded to date to implement this new model of care, with a further five services to be funded in 2022.

The HSE has considered a number of initiatives aimed at shortening the time from referral to diagnosis for endometrial cancer at a system level by optimising the referral, investigation and management pathway for women presenting with post-menopausal bleeding. HIQA would support the introduction of these initiatives, which include:

- developing and implementing a suite of key performance indicators for the ambulatory gynaecology model of care that would be monitored by both the Saolta Group and the HSE
- progressing and completing the rollout of the ambulatory gynaecology model of care across the health service
- continuing to support gynaecology requirements and target investment to improve access to gynaecology services
- implementing a gynaecology referral form from primary to acute and specialised gynaecology pathways
- developing a national clinical guideline specifying the timelines for the investigation and management of post-menopausal bleeding
- increasing the capacity of healthcare services to learn from incidents of delayed diagnosis of gynaecology cancer
- supporting the training of obstetric and gynaecology teams to implement the ambulatory gynaecology model of care.

Furthermore, the interdependencies of gynaecology and maternity services — which typically share a common pool of stretched medical resources — cannot be ignored. Over the past five years, following the publication of *National Standards for Safer Better Maternity Services* and the National Maternity Strategy, the main focus of funding and resourcing has been on maternity services.

HIQA believes realistic resourcing of both maternity and gynaecology services is needed. There is a need for a concerted national plan to pull together all of the developments, recommendations and learning from this review and others to enhance gynaecology services nationally for the benefit of women who depend on these services.

5.4 Concluding remarks

Overall, HIQA found that Letterkenny University Hospital and the Saolta Group had been adequately resourced to implement the recommendations of the Price report and to improve the governance arrangements to assure and ensure the quality of gynaecology services at the hospital. With the support and guidance of the special measures team, changes had been introduced to strengthen governance arrangements, increase capacity and improve the quality, safety and reliability of gynaecology services at the hospital. Additional resourcing had enabled the scheduling of additional general gynaecology clinics that were provided by hospital

staff, their efforts resulted in a decrease in waiting times for women referred to the hospital's gynaecology services, which is commendable.

While there has been some improvements in the governance structures and processes to assure and ensure the quality of gynaecology services at Letterkenny University Hospital, HIQA's review identified the need for these improvements to be bedded into practice. Furthermore, as a priority, Saolta Group needs to ensure the overall sustainability of the hospital's governance arrangements.

Since 2018, various attempts to address governance issues at Letterkenny University Hospital have had a mixed record of success, and weaknesses in governance structures and processes at the hospital remain. It is now imperative that any recommendations and actions arising from the planned external, independent intervention and additional management supports are implemented.

Following this HIQA review, efforts to establish effective and sustainable governance structures and processes should be measurable and focused so that women who depend on the gynaecology services at Letterkenny University Hospital can be confident in and assured of the quality and safety of those services.

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Appendix 1: Methodology for HIQA's targeted assurance review

This section outlines the methodology used by HIQA 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*.

HIQA looked 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.

1.1 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.

The methodology applied during the conduct of the target assurance review comprised three elements – documentation, data and information requests, on-site inspection and interviews.

1.2 Documentation, data and information requests

In accordance with section 8(1)(c), HIQA issued formal documentation, data and information request to accountable persons in the HSE, Saolta University Health Care Group and Letterkenny University Hospital.

The review team obtained documentation, data and informed which covered areas such as the:

- corporate and clinical governance structure and management arrangements in place for the gynaecology services as national HSE, hospital group and hospital level
- activity and clinical-outcome data for the gynaecology services at Letterkenny University Hospital
- risk management systems including reported adverse incidents in relation to the gynaecology services at Letterkenny University Hospital
- arrangements for the dissemination and implementation of policies, procedures, guidelines and best available evidence relevant to gynaecology services
- workforce planning and staffing arrangements gynaecology services at Letterkenny University Hospital and hospital-group levels.

HIQA provided accountable persons with a timeframe of 10 working days for the return of documentation, data and information from the date that the requests were issued.

1.3 On-site inspection at Letterkenny University Hospital

The review team conducted an announced on-site inspection at Letterkenny University Hospital to obtain information about the governance and oversight arrangements and the systems and structures in place to support operational performance of the gynaecology services at the hospital. Authorised persons also collected evidence of compliance with the 11 national standards monitored during the review. Evidence of compliance was collected through inspection and observation of the clinical area, review of documents and data, and meetings with management and staff. Clinical areas inspected and observed included the:

- Outpatient Department
- Post-menopausal Bleeding Clinic
- Ambulatory Access Clinic
- Gynaecology Ward
- Theatre Department.

1.3.1. Public health precautions applied during on-site inspection

Authorised persons took all necessary precautions, in line with public health advice to reduce risks associated with COVID-19 during the on-site inspection element of the review. These will include:

- the observation of physical distancing at all times throughout the on-site 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.

Authorised persons were familiar with the most recent guidance and guidelines from the Health Service Executive and the Health Protection Surveillance Centre.

1.3.2 Healthcare record review

In accordance with section 73 of the Health Act (2007) (as amended), the review team selected and reviewed the healthcare records of 25 of women who received care from the gynaecology services at Letterkenny University Hospital. This review of healthcare records informed HIQA's broader judgments and findings in accordance with the terms of reference of the review.

1.4 Interviews

Individual interviews were conducted with relevant staff members from the hospital, Saolta University Health Care Group and national HSE. These interviews were conducted remotely using videoconferencing technology, on a date or dates after

the completion of the on-site inspection element of this review at Letterkenny University Hospital. These persons were:

- At HSE level – National Director of Acute Operations, the Clinical Director of the National Women and Infants Health Programme, Assistant National Director, Quality and Patient Safety Lead, Acute Operations and the Chair of the Letterkenny University Hospital Gynaecological Clinical Service Review: Implementation of Recommendation Oversight Group.
- At Saolta University Health Care Group level – the Group Chief Executive Officer, the Clinical Director of the Women’s and Children’s Managed Clinical and Academic Network, the Group Chief Director of Midwifery.
- At Letterkenny University Hospital level – the General Manager, the Associate Director of the Network — Women’s and Children’s Managed Clinical and Academic Network and the Director of Midwifery.

All individuals who were interviewed were provided with a minimum of 10 working days’ notification of interview. The interviews were used to:

- clarify issues that may have been identified during the Review Team’s review of documentation, data and information, and or on-site inspection at Letterkenny University Hospital
- gather information generally
- consider any further information that was provided inform the review findings.

1.5 Experiences of service users and service referrers

HIQA surveyed women who had attended the post-menopausal bleeding clinic at Letterkenny University Hospital during February 2021. General practitioners who referred women to the post-menopausal bleeding clinic over the 12 month period before the commencement of HIQA’s targeted assurance review.

1.6 Due process feedback

HIQA provided a copy of the confidential draft report of the review findings, on an individual basis or in a representative role, to relevant persons and senior managers in the HSE, Saolta University Health Care Group and Letterkenny University Hospital. These persons were invited to offer their feedback and commentary generally on any matters in the draft report. HIQA provided a timeframe of 15 working days for

the return of any feedback and comments from the date of issue of the draft report. Every comment received was carefully considered by HIQA prior to the publication of the review report.

1.7 Confidentiality

In line with current data protection legislation⁵ HIQA requested that unless specifically requested to do so, services did 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 authorised person for removal from the service did not contain data that identified individual patients.

1.8 National standards to be monitored during the review

The terms of reference of the review focused on 11 specific national standards within four of the seven themes of the National Standards for Safer Better Healthcare, 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.

1.9 Assessment-judgment framework

The review team used an assessment-judgment framework to guide them in assessing and judging compliance with the 11 specific national standards monitored during the targeted assurance review. The framework set out the lines of enquiry to be explored by authorised persons in order to assess compliance with the standards being monitored. When the evidence was gathered and reviewed, authorised persons made a judgment on the service's performance. The following judgment descriptors were used to describe compliance with the 11 national standards monitored as part of the targeted assurance review.

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>

Appendix 2: Maternity hospitals and units in six hospital groups

No.	Hospital Group	Maternity unit and hospital in each hospital group
1	Ireland East Hospital Group	The National Maternity Hospital, Dublin Regional Hospital Mullingar Wexford General Hospital St Luke's General Hospital, Kilkenny
2	Dublin Midland Hospital Group	Coombe Women & Infants University Hospital, Dublin Midland Regional Hospital, Portlaoise
3	Saolta University Health Care Group	University Hospital Galway Letterkenny University Hospital Sligo University Hospital Mayo University Hospital Portiuncula University Hospital
4	South/South West Hospital Group	Cork University Maternity Hospital University Hospital Waterford University Hospital Kerry South Tipperary General Hospital
5	Royal College of Surgeons in Ireland Hospital Group	The Rotunda Hospital, Dublin Our Lady of Lourdes Hospital, Drogheda Cavan & Monaghan Hospital
6	University of Limerick Hospitals Group	University Maternity Hospital Limerick

Appendix 3: National Standards for Safer Better Healthcare

The *National Standards for Safer Better Healthcare* 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-centred healthcare service. Themes five to eight of the national standards describe the capacity and capability factors necessary to deliver high-quality safe care. The dimensions of quality and safety comprise of four themes:

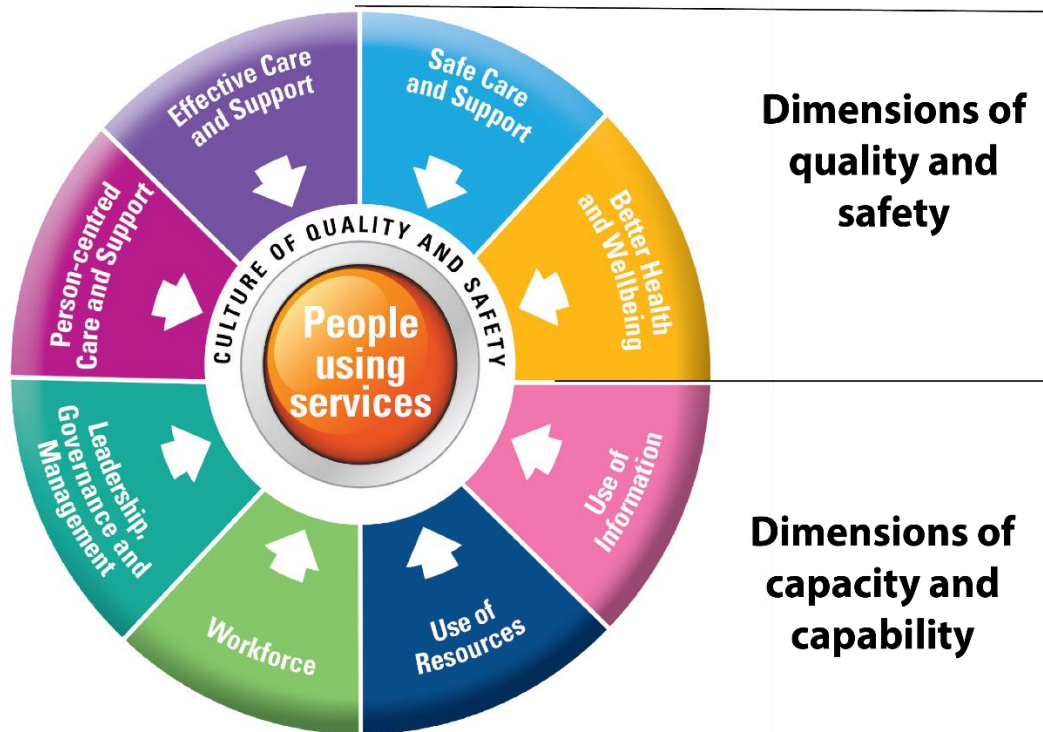
- Theme 1: Person-centred Care and Support
- Theme 2: Effective Care and Support
- Theme 3: Safe Care and Support
- Theme 4: Better Health and Wellbeing

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

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

The *National Standards for Safer Better Healthcare*³ set out the standards necessary for effective governance of a healthcare service (Theme 5). These standards define a well governed service as one that is clear about what it does, how it does it and is accountable to its stakeholders including the people who use health services.

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



Implementing evidence-based standards in healthcare settings, together with continual monitoring of compliance against these standards, is a well-recognised quality and safety improvement measure. Each service provider needs to assure themselves, people who use the service and the public that the services they provide is safe, high-quality care. This is measured through a service's level of compliance with national standards. HIQA, through its monitoring programmes, can further assure the public that service providers are implementing and meeting the national standards, and making any necessary quality and safety improvements required to safeguard people who use healthcare services.

To date, HIQA has monitored hospitals under section 8 of the Health Act 2007 (as amended) through a five thematic regulatory monitoring programmes:

- maternity services with a focus on obstetric emergencies
- medication safety
- nutrition and hydration
- prevention and control of healthcare associated infection (including reusable invasive medical devices)

- rehabilitation and community inpatient healthcare services.

HIQA's role and function in the regulation of healthcare services was extended in 2019 when it became the competent authority for the regulation of medical exposure to ionising radiation. The new regulations define the minimum safety requirements to protect people from the hazards associated with procedures such as X-rays and radiation therapy. The regulations apply to radiotherapy, nuclear medicine and dentistry facilities across the public and private sectors in the Republic of Ireland. This extension in HIQA's role and function across the healthcare domain is significant. The new legislation provides HIQA with enforcement powers when non-compliance with the regulations are identified and for the first time extends HIQA's remit into the private healthcare sector.

In addition to scheduled regulatory monitoring activity, HIQA receives information on healthcare services providers through a number of other means, including:

- statutory investigations and reviews
- receipt of solicited information
- receipt of unsolicited information.

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