Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

OVERVIEW REPORT

MONITORING AND REGULATION OF HEALTHCARE SERVICES IN 2020

August 2021

Safer Better Care

About the Health Information and Quality Authority (HIQA)

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

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

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

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A message from the Director of Regulation

Mary Dunnion, Director of Regulation, HIQA

Welcome to our overview report of the monitoring and regulation conducted by the Health Information and Quality Authority (HIQA) across healthcare services in Ireland in 2020. Our report details the approach taken by HIQA and summarises our findings across multiple monitoring programmes conducted throughout the year.

At the time of writing this report, the impact of COVID-19 on healthcare services in Ireland remains very significant. The third wave of the pandemic in Ireland placed unprecedented strain on the acute healthcare system. COVID-19 has also had an extreme impact among those who have fallen ill with the virus, families who have lost loved ones, the health and social care system, and indeed society at large.

In light of the pandemic, in 2020 HIQA focused on those services which appeared to have had higher levels of non-compliance with regulations or national standards — and therefore a higher degree of risk for patients and people using these services. This focus replaced our routine inspection schedule and involved a broader sample of services on the basis of potential risk.

In addition, we redesigned our inspection methodology against national standards on the prevention and control of healthcare-associated infections to place a greater focus on the management of the ongoing pandemic in inspected services.

During 2020, HIQA focused on a number of key areas of patient safety across healthcare services. These included:

- infection prevention and control in public acute hospitals and rehabilitation and community settings
- rehabilitation and community inpatient services — with a particular focus on governance and risk management, safe use of medicines and measures to ensure the prevention and control of healthcare-associated infections

- medication safety — with a particular focus on high-risk medications and high-risk situations in public acute hospitals
- and medical exposure to ionising radiation in public and private radiological facilities encompassing medical and dental X-ray services.

Implementing and monitoring compliance with national standards — and ensuring compliance with the medical ionising radiation regulations — helps to enable healthcare providers to sustainably safeguard people using services from potential harm and to continually improve the quality and safety of care and services. Our role is to promote continual, sustained quality improvement in healthcare services. However, our powers in relation to healthcare settings remain relatively limited. We do not have powers of enforcement in healthcare, other than when regulating medical exposures to ionising radiation, such as X-rays or radiation therapy safety.

However, where risk issues are identified, these are reported to either the Health Service Executive (HSE) or to the Department of Health. Proposed legal changes, as set out in the Patient Safety (Licensing) Bill and Patient Safety (Notifiable Patient Safety Incidents) Bill 2019, would see a major change and expansion to HIQA's role. This would not only lead to HIQA monitoring in private hospitals in the first instance, similar to our existing role in public acute hospitals, but would also be followed by formal regulation and enforcement powers in all healthcare services, both public and private.

This report aims to describe the journey that both HIQA and inspected services travelled during 2020 in order to improve levels of compliance against the national standards and regulations across key patient safety areas. During the year, we noted good levels of compliance across a number of services against the backdrop of a global pandemic. Nonetheless, this report identifies how insufficient resources, poor infrastructure and inadequate physical environments are in some instances, significantly preventing the effective implementation of national standards.

In recognising these inherent challenges, HIQA supports the implementation of the Sláintecare* reform plans for the healthcare service in Ireland, and the associated HSE structural reforms to create greater capacity across healthcare services. This has the potential to ease pressure on our acute hospital system. We also believe it will better enable an integrated model of care, where service users are treated at the lowest level of complexity that is safe, timely, efficient and as close to home as possible as set out in the Sláintecare plan.

* The Committee on the Future of Healthcare was established by Dáil Éireann in 2016 with the goal of achieving cross-party, political agreement on the future direction of the health service, and devising a 10-year plan for reform. Sláintecare sets out the intention to develop and adopt such a 10-year plan for health services to deliver the required changes. See here for more information.

COVID-19 will present significant challenges for the health service for many months to come. It is clear, however, that there is an absolute need to ensure that a high-performing, fit-for-purpose and properly resourced health service is in place to meet the healthcare needs of the population into the future. To help ensure such services are safe for patients and people using services, services must comply with nationally mandated standards and regulations. HIQA's experience, across both health and social care settings over the past 12 years, has demonstrated that monitoring and regulation have a positive influence on change. We aim to positively influence the delivery of safer, better healthcare and protect the health and wellbeing of patients who depend on the health system today and into the future.

To help achieve this goal of improved quality and safety of services, and in recognition of the challenges faced as a result of the ongoing pandemic, we are committed to working closely and openly with all stakeholders and interested parties who are contributing collectively to these national efforts. People using services, healthcare providers, healthcare professionals, policy-makers or other regulators all have a role to play in supporting compliance with standards and regulations and safer better care for all.

Finally, I would like to thank the patients, staff and providers in public hospitals for their continued engagement with HIQA and our work. We are aware of the challenging working environment in which care is delivered and in which patients receive care, especially during the most testing year we have faced. We appreciate your ongoing commitment to working with us to provide safe, high-quality care to all people who depend on these services.

Mary Dunnion

Director of Regulation

Health Information and Quality Authority

1. Introduction

This report presents an overview of HIQA's monitoring and regulatory activity conducted across healthcare services in 2020. It outlines inspection activity in public acute healthcare services and community and rehabilitation inpatient services to assess compliance with national standards. The report also outlines inspections and other statutory functions undertaken in line with HIQA's remit as the competent authority in Ireland with responsibility for regulating services providing medical exposure to ionising radiation.

Key findings are presented from HIQA's monitoring and regulation programmes in 2020, including examples of good practice and opportunities for improvement. HIQA aim to positively influence the delivery of safer, better healthcare and protect the health, wellbeing and dignity of people who use healthcare services today and into the future through effective monitoring and regulation.

In the context of the COVID-19 global pandemic, this report also details HIQA's involvement with collective national efforts in response to COVID-19 in healthcare services. It also outlines the ongoing challenges faced by these services as seen through HIQA's various healthcare monitoring programmes throughout 2020.

The report concludes with an overview of HIQA's future monitoring activity approach against the national standards.

The national standards that HIQA monitors in healthcare services include the:

- *National Standards for Safer Better Healthcare*
- *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*
- *National Standards for infection prevention and control in community services*
- *National Standards for Safer Better Maternity Services*
- *National Standards for the Conduct of Reviews of Patient Safety Incidents.*

2. Placing HIQA's monitoring activity in healthcare services into context

At the time of writing this report, Ireland, along with the rest of the world, continues to address the very significant challenges posed by the COVID-19 pandemic. The crisis has had a profound impact on our healthcare system and has likely permanently changed the way that healthcare will be delivered into the future.

Healthcare staff across all roles and services have shown continued resilience under unprecedented stress and pressure and have adapted quickly to work in different ways to keep people safe. Through its monitoring work, HIQA has observed the efforts and great lengths taken by those working within the healthcare system to address the challenges of the pandemic head on.

The most fundamental change was the need to scale up capacity across the health sector to deal with the surge of cases associated with COVID-19. Significant changes were required to meet the anticipated unprecedented surge and demand. These changes included postponing and or cancelling elective surgery[†], curtailing some treatments, procuring facilitates and beds in the private sector, and setting up additional health facilities to increase capacity, particularly critical care capacity, across the health sector.

While Ireland's hospital system has had some success in managing the additional burden of COVID-19, the pandemic has further exposed many of the long-standing and well-recognised issues within our healthcare system. The system has sought to grapple with it in the face of an ever-increasing and chronic demand for services. Such underlying challenges, which have been identified throughout HIQA's monitoring activity over the past number of years, include:

- capacity deficits
- long waiting lists
- overcrowding problems in hospitals
- poor infrastructure and physical environment
- over-reliance on a hospital-centric model of care.

[†] Elective surgery or elective procedure is surgery that is scheduled in advance because it does not involve a medical emergency.

The underlying challenges that the Irish healthcare system faces have been well documented in a number of HIQA publications,[1, 2, 3, 4, 5] as well as publications from other bodies and groups.[6, 7, 8]

HIQA's *Overview report of five years of monitoring in Irish public acute hospitals against the national standards: 2015-2019*,[2] published in 2020, highlighted how the focus on compliance with national standards has contributed to tangible improvements and change across public acute hospitals to ensure the delivery of effective and safer healthcare.

This has since been further enhanced by increased investment and dedicated resourcing by the Government and the HSE and better, more effective systems of oversight of performance in services, such as ongoing surveillance and audit. Collectively, this has contributed to improved quality and safety in many of these healthcare services, particularly in the context of the current global pandemic.

Notwithstanding this progress, HIQA's five-year overview report, published in 2020, identified how insufficient resources, poor infrastructure and physical environment, high bed-occupancy levels, and a lack of funding for new infrastructure are significantly inhibiting the implementation of national standards.

The challenges outlined above will continue to affect the country's options for responding to the pandemic and its aftermath. These challenges can also potentially impact on healthcare services' capacity and capability to meet national standards and regulations. If compliance with national standards is to be achieved nationally, then these challenges must be addressed.

At the time of writing this report, the impact of the COVID-19 crisis remains a significant challenge for people who use healthcare services and healthcare providers. Indeed, this impact has been additionally compounded more recently by the cyber-attack on the HSE's information technology systems. Responding to these two unprecendented challenges will require significant time, effort and resources for all those involved in leading and providing services over the coming months and years ahead.

The need for fundamental reform of and investment in the Irish healthcare service, has been further substantiated by the challenges that the pandemic has highlighted. Notably, HIQA continued to identify many of these challenges throughout 2020. The Sláintecare report outlines the need to re-orientate services away from the prevailing hospital-dominated model of care to a more integrated community-based model. HIQA fully supports this proposal for fundamental change.

The Irish healthcare system's ability to continue to manage COVID-19, alongside the resumption of non-COVID-19 healthcare services to pre-pandemic levels, will require considerable short, medium and long-term planning. While healthcare services have demonstrated the ability to respond to severe capacity constraints, more innovative planning, aligned with the vision of Sláintecare, is needed to continue to accommodate future potential COVID-19 surges, while trying to meet the ever-increasing demand for care.

As healthcare services deal with the fallout from the pandemic and as we learn to adapt and live with COVID-19, acute and community healthcare services need to finely balance the capacity to provide both COVID-19 and non-COVID-19 care. Ensuring that the needs of all people who use services are met, as well as the continued implementation of Sláintecare, aligned with the enactment of the Patient Safety (Notifiable Patient Safety Incidents) Bill[‡] and the Patient Safety (Licensing) Bill,[§] will provide a clear policy focus to promote standards of quality and safety across both the public and private healthcare systems arising from the experiences of the past 18 months.

[‡] The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 will cover a number of patient safety priorities, including mandatory open disclosure of serious, reportable patient safety incidents, the notification of reportable incidents to the regulator, the use of clinical audit to improve patient care and outcomes and the extension of HIQA's remit to private hospitals.

[§] The Patient Safety (Licensing) Bill proposes a mandatory licensing system for public and private hospitals and other providers of high-risk healthcare activities.

3. Overview of monitoring and regulation conducted by HIQA across healthcare services in 2020

This section outlines HIQA's inspection activity and collective findings obtained through HIQA's monitoring and regulatory programmes in 2020. More detailed findings from each inspection can be found in the individual inspection reports, which are published in www.hiqa.ie.

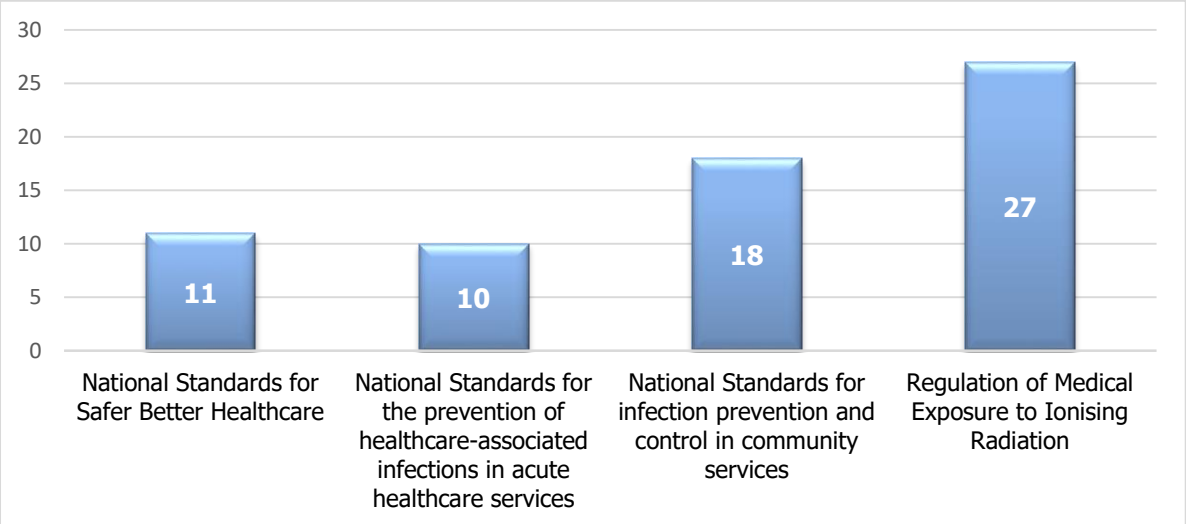
HIQA's role and remit in monitoring and regulating healthcare services is outlined in Appendix 1 of this report.

3.1 Inspection activity for 2020

In 2020, HIQA conducted 66 inspections for the purpose of monitoring compliance with the relevant national standards and regulations in healthcare settings (see Figure 1). Although routine monitoring inspections were carried out in the early part of 2020, with the onset of the global pandemic in March 2020, HIQA needed to refocus its efforts in response to the public health situation by adopting a risk-based approach to inspections in the context of the realities posed by the pandemic.

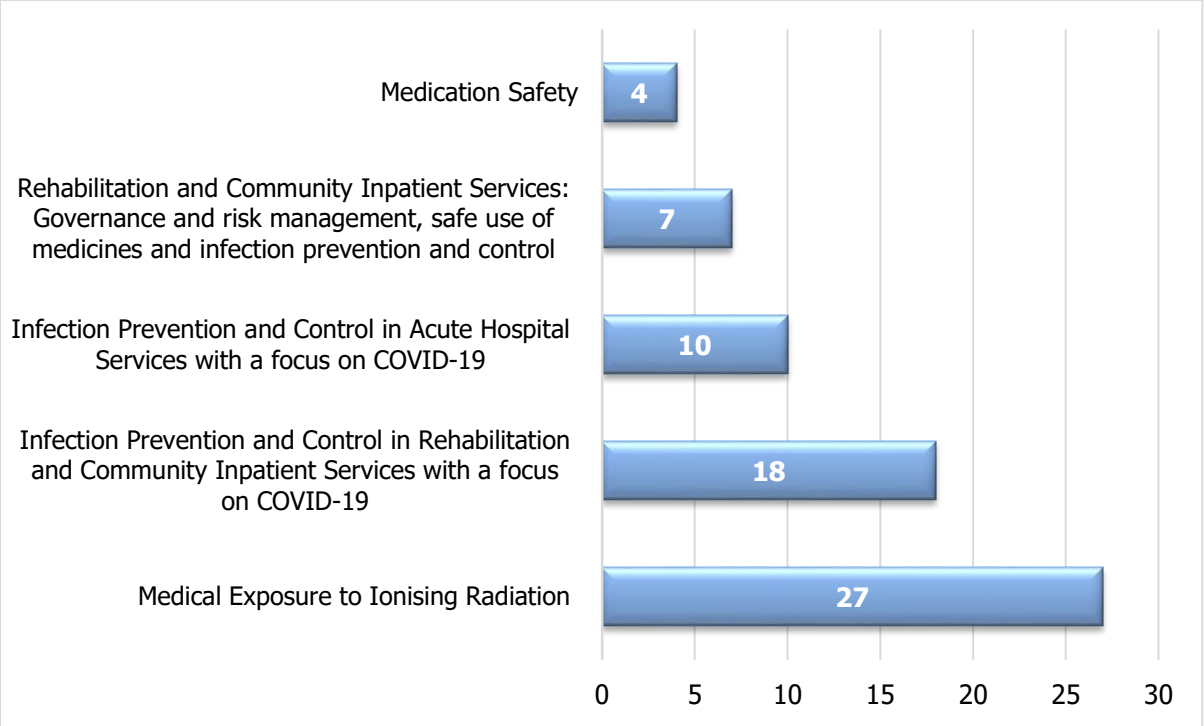
HIQA, therefore, focused on services where information suggested that there was a higher degree of risk of non-compliance with regulations or standards — in place of a routine inspection schedule — which would take a broader sample of services on the basis of potential risk. Furthermore, HIQA's inspection methodology against the national standards on the prevention and control of healthcare-associated infections was redesigned to place a greater focus on the standards relating to the governance and management of the ongoing pandemic in inspected services.

Figure 1. Inspections conducted by HIQA in 2020 against the relevant national standards and regulations



These inspections were conducted over a range of services as part of HIQA's thematic monitoring and regulation programmes (see Figure 2).

Figure 2. Type and number of inspections conducted by HIQA in 2020.



3.2 Overall findings from HIQA's monitoring activity in 2020 under section 8 of the Health Act 2007

Programme for the prevention and control of healthcare-associated infections

HIQA monitors infection prevention and control practice in hospitals against the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services* (2017), and in rehabilitation and community inpatient services against the *National Standards for infection prevention and control in community services* (2018).

In light of the global pandemic, HIQA applied a risk-based approach to monitoring against these national standards and ran two concurrent infection prevention and control inspection programmes in 2020, both with a particular focus on COVID-19, across both public acute hospitals and public rehabilitation and community inpatient healthcare services.

Such inspections took place during a period of great uncertainty arising from this novel coronavirus, when little was known about the virus at the onset of the pandemic. HIQA was conscious that rapidly emerging evidence relating to this virus led to frequently updated national guidance. This required healthcare workers to facilitate implementation of updated guidelines into everyday practice at an unprecedented pace. The efforts and energy required to train and update healthcare staff to adapt and enhance infection prevention and control practices and implement protective measures is acknowledged by HIQA.

In 2020, 28 healthcare services were inspected under HIQA's infection prevention and control monitoring programmes with a particular focus on COVID-19. Eighteen of these inspections were completed in rehabilitation and community inpatient services and 10 inspections were completed in public acute hospitals. An overview of findings from both monitoring programmes are detailed separately in the following section.

3.3 Monitoring against national standards in rehabilitation and community and inpatient healthcare services

HIQA's monitoring programme in rehabilitation and community inpatient healthcare services against the *National Standards for Safer Better Healthcare*, which began in 2019, continued into early 2020. In 2020 HIQA became responsible for monitoring 31 rehabilitation and community inpatient services, an increase of eight such services from the previous year.

These services typically provide step-down inpatient healthcare services for patients who have finished their acute episode of care in acute hospitals, or specialist rehabilitation care. In some instances that also provide short term "step-up" rehabilitation care for people who reside at home and who are frail and have complex care needs, in an effort to proactively prevent potential future admission to acute healthcare services. This programme focused on:

- governance and risk management structures
- measures to ensure the prevention and control of healthcare-associated inspections
- and the safe use of medicines.

A total of seven inspections had been completed as part of this programme in 2020 before HIQA's resources were reoriented towards a more targeted inspection of services arising from the COVID-19 pandemic. Findings in respect of these

inspections are outlined in section 3.5 of this report. The following section focuses on inspections which examined infection prevention and control practices in these services.

Infection prevention and control standards in rehabilitation and community inpatient services

Due to the pandemic, HIQA targeted its approach in rehabilitation and community inpatient services under a new focused inspection approach from July 2020 against the *National Standards for infection prevention and control in community services* (2018).

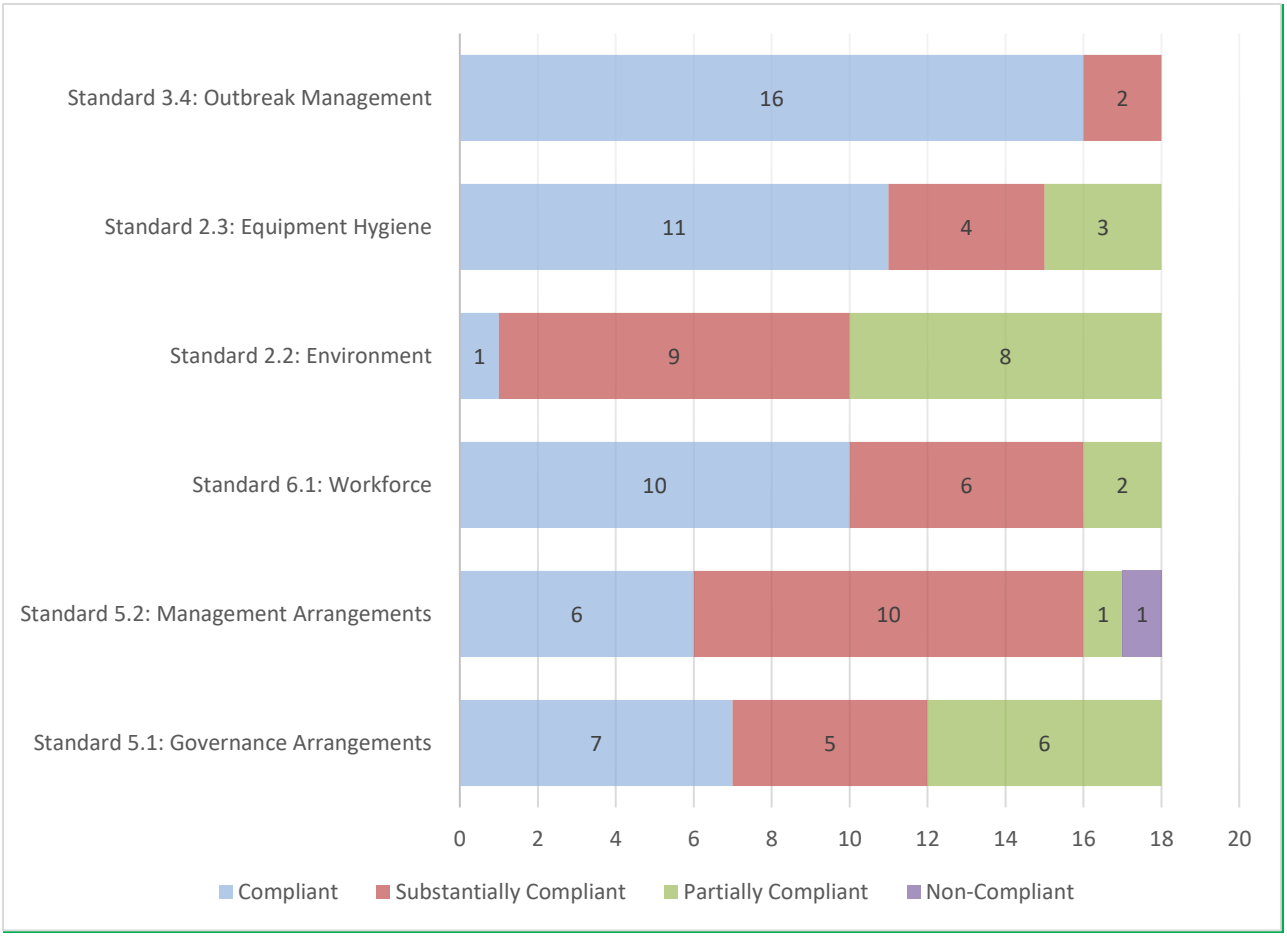
The refined approach particularly focused on the ongoing COVID-19 pandemic and its management in rehabilitation and community inpatient healthcare services. The programme monitored and assessed compliance against four key themes and six specific national standards (see Appendix 2). The standards selected provided a lens that looked at capacity and capability, and the systems and processes in place in each service to protect people using the service from the risks posed by the virus.

Eighteen on-site inspections of individual services were conducted under the new methodology between July and November 2020.

Key findings — overall level of compliance in rehabilitation and community inpatient services against the relevant national standards for infection prevention and control

Levels of compliance achieved against the relevant standards for the services inspected is outlined in Figure 3. Overall, most services inspected were found to be compliant or substantially compliant against the relevant national standards, which was a positive finding. However, there were higher levels of partial compliance in relation to standards on leadership, governance and management arrangements (Standard 5.1) and on environment and infrastructure (Standard 5.2).

Figure 3: Overall level of compliance in rehabilitation and community inpatient healthcare services against the relevant national standards for infection prevention and control in community services (2018)



Compliance findings for individual services are detailed in Appendix 3 of this report. The following section outlines key findings from these inspections which are presented under the themes of leadership, governance and management, workforce, effective care and support and safe care and support.

Findings on leadership, governance and management

National Standards for infection prevention and control in community services Theme 5: Leadership, Governance and Management
Standard 5.1 The service has clear governance arrangements in place to ensure the sustainable delivery of safe and effective infection prevention and control and antimicrobial stewardship.
Standard 5.2 There are clear management arrangements in place to ensure the delivery of safe and effective infection prevention and control and antimicrobial stewardship within the service.

Governance arrangements in rehabilitation and community inpatient services

Overall, the majority of the 18 rehabilitation and community services inspected in 2020 had defined leadership, governance and management arrangements with clear lines of accountability and responsibility for the infection prevention and control of healthcare-associated infections. However, HIQA found that four services did not, with governance arrangements found to be in need of further strengthening, and with improved oversight required from the respective community health organisations.

Risk and incident management in rehabilitation and community inpatient services

A key feature of managing risk in everyday practice is recognising the risks relating to the service and having the systems and processes in place to reduce the likelihood of those risks occurring or if they do to minimise their impact. HIQA found that services had systems in place for the management of risks that required escalation through their respective services' governance structures. However, HIQA identified that improvement was required with the documentation of risks in a number of services inspected. A number of risk registers were not managed, reviewed and escalated in line with national policy.[9]

All services stated that infection prevention and control incidents were reported to the National Incident Management System (NIMS).** While a small number of services were tracking and trending infection prevention and control incidents, improvement was required in the overall reporting and management of incidents. Furthermore, HIQA found that the culture of identifying and reporting infection prevention and control incidents needed to improve in some services. It is important that staff are knowledgeable about the types of infection prevention and control incidents that should be reported so that incidents can be better tracked and trended. Learning from incidents should be shared among staff and used to promote quality improvement in services.

A need to enhance antimicrobial stewardship activities in rehabilitation and community inpatient services

Half of the rehabilitation and community inpatient services inspected in 2020 needed to improve their antimicrobial stewardship†† activities. The need to improve structures to manage the risk of antimicrobial resistance across all care settings, including community settings, was a finding in HIQA's 2016 *'Report of the review of antimicrobial stewardship in public acute hospitals'.*[5] That particular HIQA report related to acute hospital services only, while the programme in 2020 was the first time HIQA looked at antimicrobial stewardship activities within community inpatient settings.

In recognition of this deficit, during our on-site activity in 2020, HIQA was informed that a number of community health organisations had recently appointed antimicrobial stewardship pharmacists. Building multidisciplinary infection prevention and control and antimicrobial stewardship teams within each organisation has been identified as integral to developing a sustainable, proactive and responsive community infection and prevention control workforce.[7] Given these new appointments, antimicrobial stewardship in rehabilitation and community inpatient healthcare services should begin to improve where required.

** The State Claims Agency's National Incident Management System is a risk management system that enables hospitals to report incidents in line with their statutory reporting obligations.

Antimicrobial stewardship: describes a system or collection of measures introduced into a healthcare setting which aim to improve the quality of antimicrobial usage across a patient population, to optimise outcomes, reduce adverse events, minimise the emergence of antimicrobial resistance and reduce treatment costs.

Monitoring, audit and quality assurance arrangements in rehabilitation and community inpatient services

Some services were conducting audits; for example, in the areas of environmental hygiene, equipment hygiene, sharps management, and linen and waste management. However, HIQA identified that there was scope for improvement in relation to monitoring and evaluation activity across a number of services. In some instances, these were either not in place or were not comprehensive. Without comprehensive environmental and equipment hygiene audits in place, services cannot have effective assurance of the hygiene within a service.

Coordination of care within and between services in rehabilitation and community inpatient services

Timely access to complete documentation regarding an inpatient stay can lead to improved quality of care after discharge. Patient discharge and transfer letters or forms in a small number of services did not contain information on patients' infection prevention and control status or their COVID-19 status. Information as to whether the patient had been tested for COVID-19 prior to discharge and the result was also not included. In line with national standards, all hospitals must communicate the patient's infection prevention and control status to the receiving service provider on discharge.

Policies, procedures and guidelines in rehabilitation and community inpatient services

National guidance recommends that patients are tested for COVID-19 either within three days before admission or within one day after admission.[10] Seventeen of the 18 services inspected were in compliance with this guidance. One service was not in compliance, and HIQA sought assurances immediately from this particular service following the inspection regarding arrangements in place to ensure compliance with the national guidance. This service provided written assurances to HIQA with a commitment that full compliance with national guidance would be implemented.

All services had infection prevention and control policies in place, including standard- and transmission-based precautions. However, policies in 7 of the 18 hospitals required updating or had not been approved by senior management. Final policies, procedures, protocols and guideline (PPPG) documents should be signed off by senior management and or the relevant governance process, confirming the document meets the standard required for a robust policy procedure and guideline.[11]

Findings on workforce

National Standards for infection prevention and control in community services **Theme 6: Workforce**
Standard 6.1 Service providers plan, organise and manage their workforce to meet the services' infection prevention and control needs.

Rehabilitation and community inpatient services — access to specialist staff with expertise in infection prevention and control

Effective workforce planning helps to ensure enough staff are available at the right time with the right skills and expertise to meet the service's infection prevention and control and antimicrobial stewardship needs.[12]

Rehabilitation and community inpatient healthcare services received infection prevention and control advice from a number of sources. Advice was provided by infection prevention and control staff from community health organisations, public health, acute hospitals and hospital groups. However, HIQA found that in some instances, this advice was not formalised and relied on the goodwill of particular infection prevention and control staff.

Five services were found to have either limited or no access to on-site advice. However, in each instance, telephone advice from infection prevention and control experts was available. It was reported in one service that out-of-hours access to senior management within the community health organisation was limited in the event of having to approve additional staff to cover unplanned absences. HIQA also found that staffing contingency plans in one service needed reviewing should an unexpected surge in cases of COVID-19 occur. National standards state that staffing levels, including infection prevention and control personnel, should be maintained at levels to safely meet the service's infection prevention and control needs and activities. This includes appropriate staffing levels for out-of-hours arrangements.

Rehabilitation and community inpatient services — infection prevention and control education

All staff should receive suitable and sufficient education and training in infection prevention and control practice and antimicrobial stewardship that is appropriate to their specific roles and responsibilities.[12]

While HIQA identified that the majority of services inspected had infection prevention and control training in place, a small number of services needed to improve uptake of mandatory infection prevention and control training and antimicrobial stewardship training. Furthermore, opportunities for improvement were identified in relation to induction and ongoing infection prevention and control training for cleaning staff. Staff need to be supported to attend induction training, and education and training updates to attain and maintain their competencies.

Findings on effective care and support

National Standards for infection prevention and control in community services **Theme 2: Effective Care and Support**
Standard 2.2 Care is provided in a clean and safe environment that minimises the risk of transmitting a healthcare-associated infection.
Standard 2.3 Equipment is decontaminated and maintained to minimise the risk of transmitting a healthcare-associated infection.

Infection prevention and control consists of the application of good care principles that are part of the routine delivery of effective care and support. This includes achieving and maintaining high standards of cleanliness within the environment and ensuring that all equipment is appropriately decontaminated. While the majority of services achieved good levels of compliance in relation to equipment hygiene (Standard 2.3), HIQA found that challenges relating to the overall environment and infrastructure had the potential to negatively impact on infection prevention and control measures within these services (Standard 2.2).

Physical infrastructure in rehabilitation and community inpatient services

At the start of the COVID-19 pandemic, a small number of services that HIQA subsequently inspected through this programme were renovated and upgraded. However, in many instances, the infrastructure of hospitals inspected through this programme was found to be poor. HIQA continued to identify deficiencies in hospital infrastructure which had the potential to negatively impact on infection prevention and control measures. HIQA noted that improvements were required in nearly all services inspected except for one. Specifically, very significant infrastructural challenges were identified in 12 hospitals. These included:

- insufficient numbers of single rooms to manage the ever-increasing number of patients requiring isolation for infection prevention and control reasons
- the physical environment inspected had not been maintained in line with the relevant national and international standards to reduce the risk of infection to patients and as such were not compliant with the *National Standards for infection prevention and control in community services.*
- The building fabric and infrastructure of some services presented ongoing challenges to their maintenance and upkeep. It is essential that infrastructure is maintained at a high standard to ensure the effectiveness of infection control practices and to prevent the transmission of infection.

It is recognised that addressing the ageing infrastructure in many of these services will take time and a significant amount of funding. However, pending new units being built or other units being upgraded, the risks to patients must be militated against to help ensure that the environment in which they are accommodated and cared for is as clean and safe as possible.

Environmental hygiene in rehabilitation and community inpatient services

HIQA found that rehabilitation and community inpatient healthcare services were generally clean at the time of each short-notice announced inspection, with a few exceptions. However, HIQA noted that the standard of cleaning and cleaning practices required improvement across some services. Findings in this regard included inconsistent and inadequate cleaning records, lack of a designated cleaners' room in some services, inappropriate storage of cleaning products and lack of appropriate hand hygiene facilities. In addition, HIQA found that the management and storage of laundered textiles and linens was not always in line with recommended practices.[10]

In general, the majority of services had signage in place indicating patients who required isolation precautions. However, doors to isolation rooms were observed to be open in a small number of services, which is not good practice. Overall, waste was managed in line with national guidelines. However, scope for improvement was noted around the inappropriate placement of clinical waste bins in two services. Appropriate placement of clinical waste bins should be based on a risk assessment to include correct segregation between clinical and non-clinical waste.

Patient equipment in rehabilitation and community inpatient services

Eleven services had systems and processes in place to ensure that equipment was decontaminated and maintained to minimise the risk of transmitting a healthcare-associated infection. A number of services had implemented a tagging system to identify if and when equipment was cleaned.

However, areas for improvement were identified across some services. These included ensuring frequently-used patient equipment is cleaned in line with national and evidenced-based guidelines and ensuring all patient equipment is detailed in equipment cleaning checklists.

Findings on safe care and support

National Standards for infection prevention and control in community services **Theme 3: Safe Care and Support**
Standard 3.4 Outbreaks of infection are identified, managed, controlled and documented in a timely and effective manner.

Outbreaks of infection, especially those due to common seasonal infectious agents, must be anticipated and planned for proactively. While it may not always be possible to prevent an outbreak, prompt and appropriate management can reduce the spread of infectious agents and limit the impact on the delivery of routine care and support.

HIQA found that all services were either compliant or substantially compliant with this standard (Standard 3.4), which was a positive finding in the context of an ongoing pandemic. Systems and processes in place for the management of outbreaks of COVID-19 included:

- services had identified a designated lead for managing COVID-19

- staff were trained to perform sampling for COVID-19
- patients were frequently monitored for symptoms of COVID-19. In one particular service, patients were monitored twice daily using a COVID-19 screening tool
- staff had access to occupational health resources if required
- outbreaks were reported to the regional department of public health in line with national guidance
- signage promoting physical distancing and infection prevention and control practices was evident.

Opportunities to further enhance measures to manage infectious outbreaks were identified across some services. For example, outbreak management plans were not always ratified by the appropriate governance structures. Furthermore, one service had not included definitive plans for the cohorting and zoning of patients likely to present with COVID-19. Moreover, minutes and documentation of meetings held with the regional public health departments were not recorded or were limited in nature, and such documentation and minutes required improvement in some services.

Rehabilitation and community inpatient services — summary of good practices identified through these inspections

Specific areas of good practice noted on inspections included the following:

- All but one of the services monitored through this programme were compliant with national guidance on testing patients on admission for COVID-19. All were compliant following HIQA's inspections.
- Sixteen hospitals out of the 18 hospitals inspected had systems and processes in place for the management of outbreaks of COVID-19.
- There had been a noticeable improvement in staff uptake of the influenza vaccine from the previous seasonal influenza vaccine year (2018/2019).
- Learning notices following a review of clinical incidents had been devised by one service and circulated across its community health organisation to promote wider learning around infection prevention and control.

- An infection prevention and control newsletter for patients and staff had been developed by one service. It included the latest hand hygiene results and information on COVID-19, including hand hygiene and cough etiquette.

Rehabilitation and community inpatient services — summary of key opportunities for improvement

Specific opportunities for improvement noted by HIQA throughout this monitoring programme related to the following:

- A number of risk registers were not managed, reviewed and escalated in line with national policy.
- Infrastructural challenges across many services posed an infection prevention and control risk. The number of single rooms was insufficient in many services to manage the ever-increasing number of patients requiring isolation for infection prevention and control reasons.
- The physical environment in a large number of services inspected had not been maintained in line with relevant national and international standards to reduce the risk of infection to patients. Inspectors observed ward-wide maintenance issues, such as poorly-maintained surfaces, finishes, flooring and some furnishings in patient rooms. These issues included windows, wall paintwork, woodwork and wood finishes. As such, the standard of maintenance observed did not facilitate effective cleaning.
- Across some services, improvements were required to address deficiencies in:
  - equipment hygiene and oversight of equipment hygiene
  - infection prevention and control monitoring and auditing programmes.
- Improvements were also required across some services in:
  - induction and ongoing infection prevention and control training for cleaning staff
  - the availability and uptake of antimicrobial stewardship training.

Overall summary of findings from infection prevention and control inspections in rehabilitation and community inpatient services

Infection prevention and control is an essential part of ensuring the safety and quality of care and support provided to people using services. Overall, this

monitoring programme found providers meeting many aspects of the standards, and a requirement for further improvement with respect to others. Specifically, HIQA notes that the underlying fabric and ageing infrastructure of some services continue to present ongoing challenges to their maintenance and services' ability to adhere to best practice and national standards.

HIQA is conscious that despite some enhancements by providers, infection prevention and control resourcing levels in community settings were found to continue to lag behind those of acute settings. As outlined in the HSE's National Service Plan 2021,[13] the HSE has stated that it believes that additional resources provided in 2021 will develop community infection, prevention and control teams. This will include additional investment in staff, eHealth, and education and training. HIQA welcomes such investment.

3.4 Monitoring against the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*

Background and context

In light of the ongoing COVID-19 pandemic, HIQA developed a further monitoring programme in 2020 to assess compliance against the *National standards for the prevention and control of healthcare-associated infections in acute healthcare services* during the duration of the pandemic. The refined inspection approach particularly focused on the ongoing COVID-19 pandemic and its management in public acute hospitals services.

The programme monitored and assessed compliance against four key themes and six specific national standards (see Appendix 4). The standards selected focused on governance, leadership and management, and the systems and processes in place in each service to protect people using the service from the risks posed by the new coronavirus called SARS-CoV-2 and the coronavirus disease that it causes (COVID-19). During these inspections, inspectors spoke with hospital managers, staff, representatives from infection prevention and control committees and patients. Inspectors also observed the clinical environment in a sample of clinical areas by visiting both COVID-19 and non-COVID-19 patient-care pathways that hospitals had put in place. In addition, inspectors conducted a walkthrough of the emergency department of the hospitals inspected.

HIQA commenced the first inspection under this programme in September 2020 following a period over the summer months when community-transmission levels of the virus had been relatively low. When this programme started, transmission levels had begun to rise and hospitals had resumed much of their normal scheduled care services. In those hospitals inspected between September and December 2020, providers, managers and staff frequently identified significant challenges with balancing routine scheduled and unscheduled care with rising confirmed and suspected COVID-19 cases.

Many of the COVID-19 mitigation measures that had been readily facilitated in hospitals during the first phase of the pandemic were not an option for some services during the second phase. This was due to the need to provide a greater level of services for patients who did not have COVID-19. This meant that clinical areas that had been allocated for COVID-19 care and isolation during the initial

phase had been returned to their original functions by the start of the second phase, and staff resources had also been redeployed back to their original roles.

HIQA carried out 10 inspections of acute hospitals under this particular programme, the first of which was a 'short-term announced inspection'. This means HIQA gave the service 48 hours' notice of the inspection. This was followed by a further nine inspections which were unannounced — with these services having been afforded more time than the first service inspected in order to familiarise themselves with the new inspection methodology which was published shortly before the first inspection.

Key findings: Overall level of compliance against the relevant national standards in acute hospitals

Levels of compliance achieved against the relevant standards for the services inspected is outlined in Figure 4. Overall, the majority of services inspected were compliant or substantially compliant against the relevant standards, with the exception of Standard 2.6 which relates to a hospital's physical environment. The layout of the infrastructure and maintenance of the physical environment in all hospitals inspected presented ongoing and significant challenges to best practice and compliance with national standards.

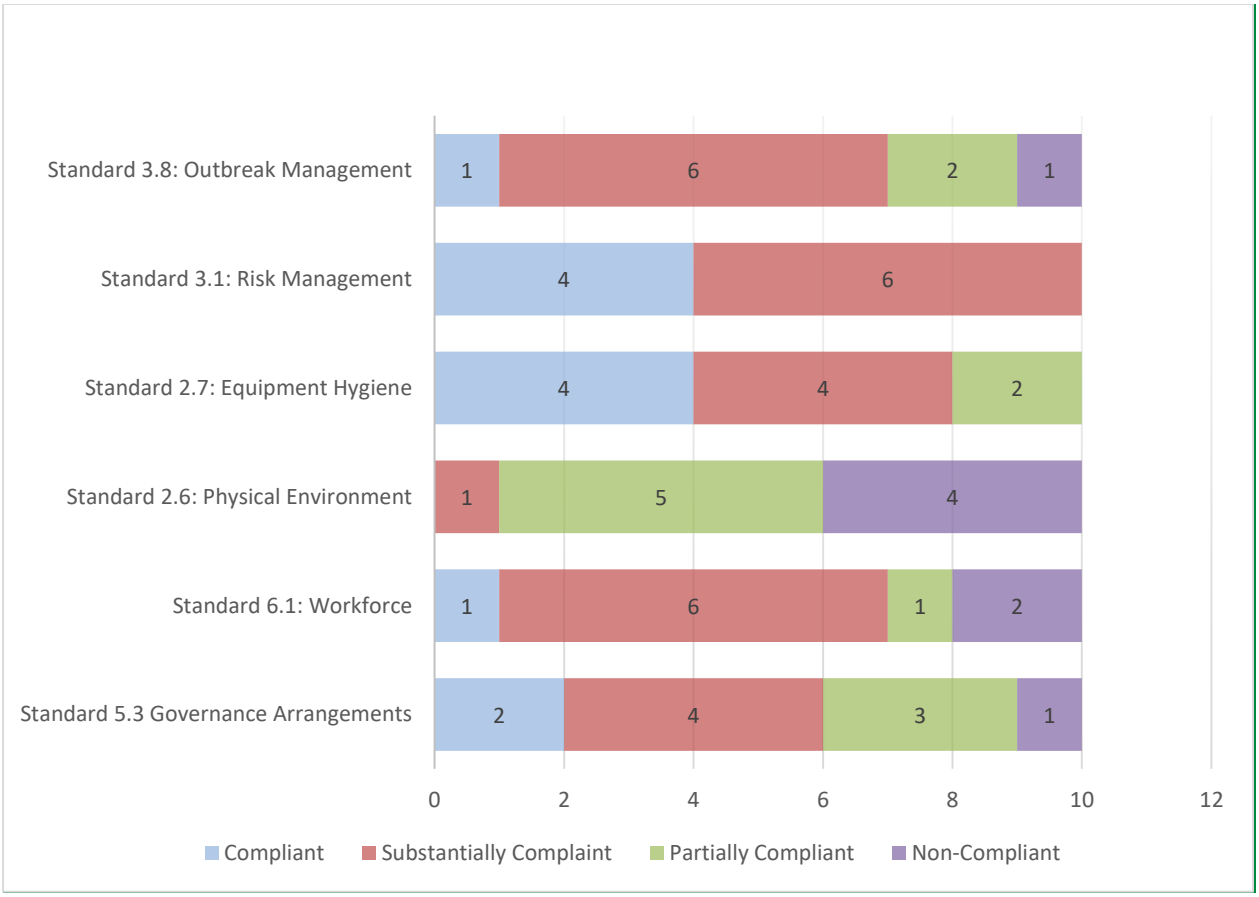
HIQA escalated risks identified in five out of the 10 hospitals inspected. These risks were either escalated locally to senior management at the hospital or at HSE hospital-group level as appropriate. These risks included:

- a lack of or inadequate on-site consultant microbiology within two hospitals
- inadequate screening or streaming of COVID-19 and non-COVID-19 patients in line with national guidance[14]
- insufficient controls in place in emergency departments to reduce the risk of transmission.

Additional risks escalated included insufficient COVID-19 preparedness within one hospital as demonstrated by the hospital's COVID-19 oversight group not meeting at a frequency that would have been originally planned or might have been expected, and having no up-to-date COVID-19 preparedness plan in place.

Opportunities for improvement were also identified within some hospitals in relation to Standard 5.3 (governance arrangements), Standard 3.8 (outbreak management) and Standard 6.1 (workforce).

Figure 4: Overall level of compliance against the relevant national standards for infection prevention and control in acute healthcare services



Compliance findings for individual hospitals are detailed in Appendix 5 of this report. The following section outlines key findings from these inspections, which are presented under the themes of leadership, governance and management, workforce, effective care and support, and safe care and support.

Findings on leadership, governance and management

National Standards for the prevention and control of healthcare-associated infections in acute healthcare services **Theme 5: Leadership, Governance and Management**
Standard 5.3 Service providers have formalised governance arrangements in place to ensure the delivery of safe and effective infection prevention and control across the service.

Leadership, governance and management — assurance in relation to infection prevention and control activities in public acute hospitals

Good governance and managerial support are crucial to support outbreak management, and it is vital that service providers have formalised governance arrangements in place to ensure the delivery of safe and effective infection prevention and control across services.

During the initial phase of the pandemic, there was strong evidence to show that there was appropriate governance, leadership and oversight of COVID-19 in each hospital. These arrangements were in addition to established infection prevention and control structures. Inspectors found that COVID-19 oversight was accomplished mainly through regular operational meetings — the frequency of which increased or decreased according to the level of risk posed by the pandemic. Staff discussions with inspectors across all hospitals indicated satisfaction with the arrangements put in place, and there was an acknowledgement of support provided to staff by hospital managers.

HIQA found that system-wide responses were most effective in services where there were well-planned governance and oversight arrangements, clear decision-making and escalation plans. However, not all services had these measures in place and for those services that did, sustaining this throughout the pandemic was often a challenge.

Seven hospitals had clear lines of accountability and responsibility in relation to governance and management arrangements for the prevention and control of healthcare-associated infection at the hospital. However, HIQA found four hospitals needed to improve the frequency and convening of oversight committee meetings which had responsibility for infection prevention and control programmes. It was identified that antimicrobial stewardship activities had been curtailed across two services, and relevant infection prevention and control committees had not been meeting as planned within two other services.

As a result, HIQA identified the need for stronger oversight and monitoring of compliance with infection prevention and control activities other than those directly related to COVID-19. The temporary suspension of infection prevention and control management structures needed to be balanced with additional governance measures put in place for COVID-19 oversight to ensure that other existing infection prevention and control challenges continued to be targeted.

Leadership, governance and management — monitoring, audit and quality assurance arrangements

In most hospitals, there were evidence that audit and monitoring of multiple elements of their infection prevention and control programmes were providing assurance of the effectiveness of their infection prevention and control systems and processes.

However, insufficient assurance of the monitoring of hospital-environment hygiene — specifically patient environment hygiene — was noted in one hospital, and further development and progression of antimicrobial stewardship programmes was required in three hospitals.

Leadership, governance and management — acute hospital overcrowding in the context of COVID-19

Overcrowding in hospitals has been shown to increase the risk of spreading infection[15] and is of particular concern in the context of the pandemic.

Overcrowding in two hospitals inspected in late 2020, including in their emergency departments, had been identified as an ongoing challenge for the hospitals and an area of concern for HIQA. A contributing factor for hospital overcrowding in one hospital was deemed to be the insufficient inpatient bed capacity at the hospital and in the wider geographical region. Significant efforts had, however, been employed to increase inpatient bed capacity to help alleviate overcrowding and in response to the COVID-19 pandemic.

Findings relating to overcrowding in the emergency department in the second hospital — in the context of not fully using contingency bed capacity that was available at another step-down service nearby — indicated a need to further review bed management oversight arrangements in the hospital and group.

Leadership, governance and management — on-site COVID-19 testing capacity in acute hospitals

Following one inspection, HIQA requested that the inspected hospital review its on-site testing capacity for COVID-19. This was because limited on-site testing capacity had resulted in the requirement to send one out of every two COVID-19 samples (50%) off site. HIQA escalated this matter to the hospital group in question. Following the inspection, HIQA received assurances from the hospital group's chief executive officer that the hospital would be provided with resources to meet the demand for its COVID-19 testing requirements.

Findings in relation to workforce

National Standards for the prevention and control of healthcare-associated infections in acute healthcare services **Theme 6: Workforce**
Standard 6.1 Service providers plan, organise and manage their workforce to meet the services' infection prevention and control needs.

Infection prevention and control specialist staffing in acute hospitals

HIQA found that many hospitals had acted to supplement their infection prevention and control staffing with the redeployment of staff during the first wave of the pandemic. In most cases, infection prevention and control teams had received additional resources.

In an example of good practice, HIQA found that one hospital regularly reviewed infection prevention and control staffing resources to ensure the levels required were appropriate to the services provided.

Access to occupational health department services for hospital staff was available on site in five of the 10 hospitals inspected. Staff in the remaining hospitals accessed this service through off-site regional bases. Of the 10 hospitals inspected, six hospitals reported that available occupational health services resources were inadequate to meet the additional needs of the hospitals during the ongoing COVID-19 pandemic. As a consequence, hospitals had to add their own resources to supplement occupational health resources.

In 2020, HIQA identified that the allocated level of on-site consultant microbiologist cover in two hospitals within a hospital group required review. This deficit had been highlighted in HIQA's desktop analysis of infection prevention control preparedness for COVID-19, which had been conducted at the request of National Public Health Emergency Team (NPHET) in April 2020.[1] This risk was escalated to the chief executive officer of the hospital group, and a response was received outlining the interim arrangements for consultant microbiologist cover and the time frame for the recruitment of consultants to approved posts.

Infection prevention and control training in acute hospitals

HIQA found that a significant amount of intensive infection prevention and control training was provided to ensure staff became familiar with and proficient in the use of personal protective equipment (PPE) and the application of infection prevention and control measures.

Notwithstanding these efforts, opportunities for improvement were identified across a small number of services in relation to infection prevention and control training. For example, the uptake of hand hygiene training and other aspects of infection prevention and control training needed to improve. This included training in relation to aspergillosis, Carbapenemase Producing Enterobacteriaceae (CPE) and basic infection prevention and control training. In addition, fit testing[‡‡] for FFP2 and FFP3 facemasks[§§] to avoid COVID-19 transmission among a number of staff disciplines required review in some hospitals.

Findings in relation to effective care and support

National Standards for the prevention and control of healthcare-associated infections in acute healthcare services **Theme 2: Effective care and support**
Standard 2.6 Healthcare is provided in a clean and safe physical environment that minimises the risk of transmitting a healthcare-associated infection.
Standard 2.7 Equipment is cleaned and maintained to minimise the risk of transmitting a healthcare-associated infection

Infection control challenges posed by the physical environment in acute hospitals

Maintenance of the physical environment and environmental hygiene are necessary to prevent cross-contamination of infection within hospitals.

[‡‡] Tight-fitting facemasks rely on having a good seal with the wearer's face. In order to be effective, the mask must fit tightly to the wearer's face, and fit testing should be undertaken by a trained professional.

[§§] FFP2 or FFP3 facemask is recommended for patients with respiratory symptoms or suspected or confirmed COVID-19 who require an aerosol generating procedure (for example intubation).

Overall, HIQA found that hospitals had made a lot of progress in relation to adapting their environments to minimise the risk of transmitting infection. However, the underlying ageing hospital infrastructure continues to negatively impact on the acute healthcare system's ability to make the changes needed.

Significant reconfiguration and renovations had been undertaken in hospital emergency departments to enable separate pathways for patients presenting with suspected and confirmed COVID-19 and non-COVID-19 conditions. However, most hospitals experienced difficulty in separating COVID-19 and non-COVID-19 patient-care pathways due to the layout of their buildings. In addition, the layout of the infrastructure and maintenance of the physical environment in all hospitals inspected presented ongoing and significant challenges to best practice and compliance with national standards. Issues noted in all 10 hospitals included:

- infrastructural and maintenance issues
- insufficient number of single en-suite rooms
- insufficient number of showering and toilet facilities
- lack of storage space for equipment
- insufficient number of and access to clinical hand-wash sinks, particularly in multi-occupancy rooms.

The movement of staff between facilities should be minimised to reduce the risk of infection transmission.[10] Staff crossover between COVID-19 and non-COVID-19 areas was an issue identified primarily as a consequence in many instances of limited resources. Many hospitals had received funding for additional posts but were waiting on national recruitment to progress filling the vacancies identified.

Equipment hygiene in acute hospitals

Within five hospitals, equipment in the areas inspected was clean and well maintained, with few exceptions. Designated patient equipment, such as monitoring equipment, was available, and patient equipment was observed to be stored appropriately. Equipment cleaning checklists were available and signed daily. Patient equipment audits were undertaken.

In four hospitals, improvement was required to ensure that patient equipment was adequately cleaned. Regular audit of equipment hygiene was not undertaken in one hospital.

Overall, HIQA found that systems were in place to ensure equipment hygiene was maintained to minimise the risk of transmitting a healthcare-associated infection

across the vast majority of hospitals inspected under the monitoring programme during 2020.

Findings on safe care and support

National Standards for the prevention and control of healthcare-associated infections in acute healthcare services **Theme: Safe care and support**
Standard 3.1 Service providers integrate risk management practices into daily work routine to improve the prevention and control of healthcare-associated infections.
Standard 3.8 Services have a system in place to manage and control infection outbreaks in a timely and effective manner.

Infection control risk management in acute hospitals

Four hospitals had systems in place for the proactive identification, assessment, mitigation, monitoring and reporting of infection risks in line with the service's risk management policy. Risk assessments relevant to the management of COVID-19 at the hospitals had been undertaken and had been recorded on the hospitals' risk registers. Infection prevention and control risks articulated to inspectors were consistent with risks documented on these risk registers.

Opportunities for improvement were identified across six hospitals in relation to risk management processes, such as the documentation of risks on a hospital's infection prevention and control risk register.

Healthcare-associated infection incident reporting in acute hospitals

All hospitals stated that incidents of healthcare-associated infection were reported on the National Incident Management System (NIMS), in line with national standards. Tracking and trending of incidents and the sharing of learning from incidents were undertaken in most hospitals, but not all. A need to improve such practice in two hospitals was highlighted by HIQA following these inspections.

Outbreak management in acute hospitals

Outbreak investigation is one of the key components of outbreak management that supports quality care and prevention of disease transmission. Four hospitals had not completed an outbreak report, contrary to best practice guidelines.[12] The completion of an outbreak report following an outbreak is an important step in the effective management of outbreaks, as it enables opportunities for learning. It is also important that learning identified is shared appropriately throughout the hospital.

While HIQA identified expected systems and processes in place to correctly manage outbreaks, HIQA also noted a difficulty in managing outbreaks of Carbapenemase-Producing *Enterobacteriaceae* (CPE) [***] and *Clostridiodes difficile*[†††] in one hospital. This highlighted a requirement to further enhance these measures in the context of the hospital's underlying infrastructure, occupancy rates and other factors, including those posed by the incidence of CPE colonisation in the hospital's catchment population.

COVID-19 preparedness in acute hospitals

Initial screening of patients for COVID-19 risk status when they arrived at the emergency department in one hospital was not being undertaken in the department at the time of the inspection, in keeping with relevant HSE national guidelines.[16] This was brought to the attention of hospital management to be addressed during the inspection, and assurances were provided to HIQA that this had been addressed after the inspection had concluded.

In one hospital, there was a lack of segregation of patients in the emergency department to ensure separate COVID-19 care pathways (for those at risk of COVID-19) and non-COVID-19 pathways (where COVID-19 was not clinically suspected). Additionally, there was a lack of adequate on-site COVID-19 testing in another hospital that was inspected. HIQA raised these risks with hospital management and the hospital group, and a response was submitted to HIQA outlining how these risks were being mitigated.

[***] Carbapenemase-Producing *Enterobacteriaceae* (CPE) are a family of bacteria which can cause infections that are difficult to treat. This is because they are resistant to most antimicrobials, including a class of antimicrobials called carbapenems, which have typically been used as a reliable last line treatment option for serious infection. Bloodstream infection with CPE has resulted in patient death in 50% of cases in some published studies internationally.

[†††] *Clostridiodes difficile* (C. difficile) is a spore forming bacterium that causes inflammation of the colon, with symptoms including watery diarrhoea, fever, appetite loss and nausea. It can spread to patients or contaminate surfaces through hand contact.

Prevention and control of healthcare-associated infections in acute healthcare services — summary of areas of good practice identified through inspection

Specific areas of good practice noted on inspections included the following:

- clarity around leadership and COVID-19 planning at site level
- availability of access arrangements to clinical and infection prevention and control expertise 24/7
- implementation of critical infection prevention and control measures — rapid setting apart and isolation of possible COVID-19 cases, and measures to protect staff from risk of COVID-19 (although adhering to physical distancing guidance was challenging to enforce)
- contingencies in place to plan essential services — catering, laundry, mortuary services and security
- the majority of clinical areas inspected were generally clean
- oversight of performance across clinical areas in relation to infection prevention and control was facilitated by ongoing monitoring and audit programmes in the majority of hospitals
- patient admission and discharge documentation in most hospitals incorporated an infection prevention and control risk-assessment in relation to multidrug-resistant organisms and COVID-19 status
- improvement in staff uptake of the influenza vaccine
- up-to-date policies, procedures and guidelines in place to inform staff
- introduction of a COVID-19 screening tool which was being completed twice daily on all patients and auditing of compliance with the tool in one hospital
- social distancing and COVID-19 senior management walk arounds with an accompanying action plan in one hospital
- procurement of PPE.

Prevention and control of healthcare-associated infections in acute healthcare services — further identified opportunities for improvement

HIQA noted specific opportunities for improvement across some services which included:

- deficiencies in hospital infrastructure — highlighted in previous HIQA inspections and which have the potential to hinder infection prevention and control measures — were again identified during these inspections. The number of single rooms was insufficient to manage the ever-increasing number of patients requiring isolation for infection prevention and control reasons and particularly during a pandemic
- the physical environment in a large number of hospitals inspected had not been maintained according to relevant national standards to reduce the risk of infection to patients and were not compliant with the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*
- additional resources were required to support the microbiology and infection prevention and control services in five hospitals
- progression of hospitals' antimicrobial stewardship programmes was required in three hospitals.

Overall summary of findings from infection prevention and control inspections in acute hospitals

During the initial phase of the pandemic, HIQA found that unprecedented efforts had been made by all hospitals to prepare for the anticipated surge in activity that might arise. The creation of additional bed capacity was achieved through temporarily suspending scheduled care. Other measures used included finalising and commissioning newly built units, providing modular units and pods and decanting and repurposing administration or outpatient facilities.

In some cases, these additions provided a significant boost to available isolation facilities and in most cases facilitated the implementation of parallel pathways for dividing patients into COVID-19 and non-COVID-19 care pathways. The use of pods and temporary structures provided additional waiting capacity and areas for staff breaks to help maintain physical distancing requirements. Some hospitals had more modern infrastructure which better supported the changes needed, while older

hospitals demonstrated remarkable resilience and creativity in rising to the challenges posed.

During 2020, HIQA found that the majority of hospitals inspected were substantially or fully compliant with most of the national standards assessed as part of HIQA's targeted approach to inspections. However, despite supplementary investment, others were not, which was of concern to HIQA in the context of a pandemic. Furthermore, HIQA escalated concerns in relation to risks identified in five out of the 10 inspections conducted in public acute hospitals.

HIQA also identified a degree of variation in performance between the 10 hospitals inspected. Scope for improvement was identified in a significant number of hospitals in relation to their infrastructure and the maintenance of environmental hygiene. Infrastructural deficiencies and maintenance issues continue to be found in HIQA's various infection prevention and control inspection programmes over many years. Public acute hospitals need to be better supported through the existing hospital-group structures and the HSE at national level to better address long-standing infrastructural deficiencies.

Findings from monitoring work in acute hospitals during 2020 show that providers, staff and managers in public acute hospitals responded well to the COVID-19 pandemic. Overall, HIQA found that those hospitals which achieved higher compliance levels against the standards had employed a collaborative and cohesive approach within their hospital to defend against the threats posed by COVID-19.

While this report outlines further scope for improvement across public healthcare services, it is clear that their unprecedented efforts, allied to the extra resources used to meet the national standards, have helped to organise and prioritise local infection prevention and control efforts in addressing the profound challenges presented by the ongoing pandemic.

3.5 Monitoring activity conducted by HIQA in 2020, prior to the onset of COVID-19

This next section outlines monitoring activity conducted by HIQA in 2020 prior to the onset of COVID-19. Areas of work progressed at the beginning of 2020 included:

- HIQA's monitoring activity against the *National Standards for Safer Better Healthcare* in rehabilitation and community inpatient settings[17], with a particular focus on:
  - governance and risk management
  - safe use of medicines
  - measures to ensure the prevention and control of healthcare-associated infections
- the conclusion of HIQA's separate 'thematic' medication safety monitoring programme[18], also conducted under the *National Standards for Safer Better Healthcare*.

In addition, HIQA also published its *Overview report of HIQA's monitoring programme against the National Standards for Safer Better Maternity Services, with a focus on obstetric emergencies*.[3]

National Standards for Safer Better Healthcare — rehabilitation and community inpatient services monitoring programme

HIQA continued its monitoring programme in rehabilitation and community inpatient healthcare services at the beginning of 2020. The programme, which began in 2019, monitored compliance with three national standards from the *National Standards for Safer Better Healthcare* (see Appendix 6).

A total of seven inspections were completed in early 2020 as part of this programme. The following section discusses the high-level findings from the published inspection reports under the themes of leadership, governance and management, person-centred care, and safe care and support.

National Standards for Safer Better Healthcare — high-level findings against the relevant national standards

Overall, the majority of rehabilitation and community inpatient services inspected were found to be either compliant or substantially compliant with the relevant

standards. Only two services were found to be partially compliant with one standard each (Standard 3.1 and 5.2). Notwithstanding this positive finding, areas identified for improvement related to infection prevention and control, which was often negatively impacted due to a lack of resources.

Findings on formalised governance structures

National Standards for Safer Better Healthcare **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.

The majority of services were found to have clear lines of accountability in relation to governance arrangements. Many of the services inspected had put several oversight committees in place to govern services.

HIQA found that services had systems in place to identify and manage risk. However, some services needed to improve capturing identified risks on their risk registers; for example, infrastructural risks. In addition, the culture of reporting clinical incidents required improvement across some services inspected.

Findings on identifying patients' needs and preferences to inform the planning, design and delivery of services.

National Standards for Safer Better Healthcare **Theme 1: Person-centred Care and Support**
Standard 1.1 The planning, design and delivery of services are informed by patients' identified needs and preferences.

HIQA found that all services inspected had systems in place to ensure that the planning, design and delivery of services were being informed by patients' identified needs and preferences. For example, patient information leaflets on a range of topics were available and accessible to patients in all services. Coordination of care within and between services took account of patients' needs and preferences.

Services had processes in place to seek feedback from patients and to inform improvements. The majority of patients who spoke with inspectors during the inspection were complimentary of the staff, the service provided and the care that they received.

Findings on protecting patients from harm

National Standards for Safer Better Healthcare **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.

National Standards for Safer Better Healthcare — prevention and control of healthcare-associated infections

Overall, HIQA found that services were committed to improving infection prevention and control practices and were endeavouring to implement the *National Standards for Safer Better Healthcare*;[19] however, this was often adversely affected by relatively limited resources.

Some services were found to have no dedicated infection prevention and control nurse at community level. The absence of adequate access to infection prevention and control nursing expertise impacted services' capacity and capability to deliver a wider infection prevention and control programme and services' access to on-site infection prevention and control advice.

The majority of services had clear management and formalised support arrangements in place to support infection prevention and control practices. However, improved oversight from infection prevention and control committees was required in relation to equipment and hygiene audits and clinical incidents.

HIQA found that the infrastructure in the majority of services was poor from an infection prevention and control perspective. The following areas required improvement:

- general maintenance and infrastructural deficiencies
- maintenance of equipment

- oversight of environmental and equipment hygiene
- storage of equipment.

National Standards for Safer Better Healthcare — safe use of medicines

The majority of services inspected had processes in place for the safe use of medicines, and medication practices were reviewed and monitored regularly. Inspectors found that ensuring the safe use of medicines was actively being progressed by a drugs and therapeutic committee within some services. However, one such committee within one service inspected had not been operational for a number of years, and this was highlighted to the service provider by HIQA following the inspection with a view to addressing this finding.

Areas of good practice were identified across some services. For example, some services had adopted a team-based clinical pharmacy service which ensured smoother transitions between and within services, leading to improvements in medication safety at the hospital and community interface.

Opportunities for improvement were identified across some services in relation to having intravenous medication administration guidelines available for staff at the point of preparation. In addition, services should maintain a high-risk medicine list to determine which medicines require special safeguards to reduce the risk of errors. Risk-reduction initiatives should be implemented and underpinned by policies, procedures and guidelines.

National Standards for Safer Better Healthcare — summary

Notwithstanding the small number of inspections carried out under this programme before the arrival of COVID-19, HIQA found good levels of compliance across the majority of services in relation to national standards associated with leadership, governance and management, and person-centred care and support. Furthermore, findings from this programme provided a valuable insight into effective infection prevention and control measures within these services which were used to inform HIQA's refined, targeted approach to inspection due to the COVID-19 pandemic.

3.6 Dedicated hospital medication safety programme under the National Standards for Safer Better Healthcare

Background and context

2020 represented the final year of HIQA's first dedicated thematic monitoring programme in the area of hospital medication safety. This thematic monitoring programme began in 2016 in recognition that patients receiving medications are exposed to potential harm as well as benefits, with medicine usage identified as the leading cause of injury and avoidable harm in healthcare settings.

Public acute hospitals were monitored against the *National Standards for Safer Better Healthcare*[19] to examine and positively influence the adoption and implementation of evidence-based practice in relation to medication safety.

During the programme between October 2016 and March 2020, HIQA conducted a total of 68 announced on-site medication safety inspections under this programme across public acute hospitals in Ireland. Forty-four inspections were carried out during the first phase of the programme and 24 inspections in the second and final phase (see Table 1).

Table 1. Medication safety inspections conducted by HIQA between 2016 and 2020.

Year	Type of inspection	Phase 1 or Phase 2	Number of inspections
2016–2018	Medication Safety Monitoring in Acute Hospitals 2016	Phase 1	44
2019–2020	Medication Safety Monitoring in Acute Hospitals 2019	Phase 2	24
Total			**68**

As this thematic medication safety monitoring programme concluded in 2020, the following section of this report reflects upon the key findings, reports and recommendations, and the opportunities for improvement outlined by HIQA throughout this monitoring programme.

The first phase of HIQA's medication safety programme focused on the systems and processes in place to support medication safety. In 2018, following the completion of

34 of the 44 first-phase medication safety inspections, HIQA published an overview of findings of the medication safety monitoring programme up to that point.[4] This report collated the findings from those 34 inspections and outlined areas of good practice seen on inspection. The overview report also set out 12 key recommendations to improve medication safety at hospital and national level (see Appendix 7).

HIQA revised the medication safety monitoring programme in January 2019. This final phase of the programme focused on the key areas for improving medication safety as highlighted in HIQA's 2018 report,[4] with an additional focus on high-risk medications[‡‡‡] and high-risk situations.[§§§] Twenty-four inspections were undertaken up to March 2020 using the updated methodology.

In 2020, HIQA published an overview report of five years of HIQA's monitoring in Irish public acute hospitals against national standards: 2015–2019.[2] This report highlighted the key overall findings from the medication safety monitoring programme and outlined opportunities for improvement (see Appendix 8). A brief summary of the overall findings of the medication safety monitoring programme is outlined below.

Medication safety 'thematic' programme under the National Standards for Safer Better Healthcare — summary of key findings and opportunities for improvement

Throughout the course of the monitoring programme, all services inspected were committed to supporting and progressing a medication safety agenda. The degree to which the medication safety agenda was progressed did, however, vary across hospitals.

Medication safety 'thematic' programme — findings on leadership, governance and management

As the monitoring programme progressed, HIQA found that all public acute hospitals inspected had formalised governance structures in place with clear accountability and responsibility arrangements to support medication safety. The majority of hospital had developed medication safety programmes to promote and direct improvement activity.

[‡‡‡] High-risk medications are those that have a higher risk of causing significant injury or harm, if misused or used in error.
[§§§] High-risk situation is a term used by the World Health Organization (WHO) to describe situations where there is an increased risk of error with medication use.

Hospitals with clearly defined and sufficiently resourced medication-safety programmes performed better.[¥] Good performance in this area was dependent on effective leadership with well-established governance structures, multidisciplinary team involvement, and investment in dedicated resources to enhance medication safety and clinical pharmacy services.

While a number of hospitals had medication safety plans in place, HIQA recommends that all hospitals should have clear strategic plans with short, medium and long-term goals to improve medication safety.

Medication safety 'thematic' programme — findings on risk management and incident reporting

All hospitals had systematic risk management processes in place to identify, manage and escalate risks to improve the quality, safety and reliability of healthcare services. In the majority of hospitals, the frequency in the reporting of medication safety incidents increased over the course of HIQA's monitoring activity. However, in a small number of hospitals, the reporting of incidents had declined. This decline was generally attributed to a reduction in clinical pharmacy resources in hospitals.

The majority of hospitals inspected tracked and trended medication safety incidents. Hospitals used the information from this process to target medication safety education sessions and for quality improvement initiatives in the safe use of medicines. Over the course of the inspections, HIQA identified better collaboration and sharing of learning within and across hospitals groups to improve medication safety.

Medication safety 'thematic' programme — findings on clinical pharmacy services and medicine reconciliation

Over the course of HIQA's work, many hospitals had allocated resources to clinical pharmacy services. However, all hospitals needed to progress the provision of clinical pharmacy services for all inpatient areas.

Disparities in approved pharmacy resources across the hospitals inspected remains, with some hospitals identifying difficulties in filling approved pharmacist posts during later inspections. A national plan should be prepared for developing comprehensive clinical pharmacy services. The plan should set out the desired model of care and the appropriate resources to ensure consistency across hospitals.

[¥] These hospitals were mostly the well-resourced model-4 and specialist hospitals located in Dublin.

The number of hospitals where clinical pharmacists were formally conducting medication reconciliation had increased. While the benefits of clinical pharmacists conducting medication reconciliation[****] and the impact on safe care are well documented,[20,21,22,23] the process is labour and resource intensive. HIQA believes hospitals should identify the most appropriate person and efficient way to conduct medication reconciliation. A national approach is needed across hospitals and within the HSE to advance medication reconciliation.

Medication safety 'thematic' programme — findings on formulary

Through use of technology or by collaboration between hospitals, the implementation of medicines formularies (approved and managed lists of preferred medicines)[††††24] had increased greatly over the course of HIQA's monitoring activity. The number of hospitals with defined governance arrangements in place for the review and approval of medicines for use in the hospital also improved.

However, not all hospitals had a medicines formulary in place. HIQA recommends that those hospitals should move towards the development of a defined formulary system. This work could be supported through collaboration with other hospitals and within hospital groups.

Medication safety 'thematic' programme — findings on monitoring and evaluation

All hospitals inspected had measured and evaluated performance in relation to medication safety through such means as audits, metrics, key performance indicators[‡‡‡‡] and findings from the National Inpatient Experience Survey.

While all hospitals used audit to measure and evaluate performance regarding medication safety, there was still opportunity for improvement in many hospitals to

[****] Medication reconciliation is a process of creating and maintaining the most accurate list possible of all medications a person is taking including drug name, dosage, frequency and route. This process identifies any discrepancies and ensures any changes are documented and communicated to complete an accurate medication list.

[††††] A formulary is a managed list of preferred medicines that have been approved by a hospital's drugs and therapeutics committee for use at the hospital. Use of a formulary ensures governance oversight of the introduction and ongoing use of medicines in practice at the hospital, and in doing so ensures an appropriate level of management control over medicines' use, in the interest of both patient safety and financial management.

[‡‡‡‡] Quality care metrics and key performance indicators are mechanisms to measure quality, and they provide an indication of the quality of care provided.

ensure the recommendations were implemented to achieve the required improvement.

Medication safety 'thematic' programme — findings on information for patients and clinical staff

All hospitals had systems in place to provide medication-related information to patients.[25, 26] Most hospitals had formalised systems in place for counselling patients who were starting on certain medications, such as anticoagulation. However, not all patient education was formalised. Hospitals should build patient education requirements into the medication management process to ensure patients and or care givers are given the appropriate medicines-related information.[4]

All hospitals had systems in place to provide medicines information for staff in order to support safe prescribing and administration of medicines. Much of this progress had been supported through sharing of information and collaboration between hospitals and hospital groups.

However, staff in some hospitals could not access medicines information at the point of use. This was often due to a lack of information technology infrastructure[§§§§] to support electronic medicines information. Access to the most up-to-date medicines information at point of use is essential for the provision of safe care. Hospitals, supported by hospital groups, need to progress the introduction of information technology infrastructures to improve medication safety.

Up-to-date policies, procedures and guidelines are essential for the delivery of evidenced-based care. While hospitals had implemented a wide range of medication-related policies, procedures and guidelines, at the time of the inspections, many of these documents required updating in line with national guidelines.[27]

Medication safety 'thematic' programme — findings on education and training

HIQA found that knowledge and awareness of medication safety had significantly increased among medical, nursing and midwifery staff. Structured, formal mandatory induction programmes were provided in all hospitals inspected, as were other learning methods to share information relating to medication safety.

Despite good practice seen by HIQA inspectors, staff attendance at continual programmes of education for medication safety was inconsistent and varied across

[§§§§] Information technology infrastructure: combination of hardware, software and network connectivity.

hospitals. HIQA has recommended that hospitals should ensure that professionals have the necessary competencies to deliver high-quality medication safety through structured targeted ongoing programmes of education, aligned with the hospital's medication safety programme.

Medication safety 'thematic' programme — findings on high-risk medications and high-risk situation

During the 2019–2020 medication safety inspections, HIQA reviewed the management of high-risk medications and management of medications in high-risk situations. Examples of good practice were observed in most, but not all hospitals.

All hospitals had identified high-risk medications in use and had implemented risk-reduction strategies using the hierarchy of effectiveness framework.[>28] Risk-reduction strategies of varying leverage[±] were implemented across hospitals to reduce the risks associated with high-risk medications and to improve medication safety in higher-risk situations.

While the use of these strategies in some hospitals was commendable, HIQA found that over half of the hospitals inspected needed to review and strengthen their risk-reduction strategies. Safety strategies and risk-reduction measures, including technology, system improvements, patient and staff education, and enhanced patient monitoring systems must be implemented.[29]

Hospitals also need to have effective assurance systems in place to ensure risk-reduction strategies are effectively and consistently implemented in practice across all clinical areas.

Strengthening these strategies will help reduce the risk of error and minimise unintentional harm from these high-risk medications and from administration of medicines in high-risk situations.

[>] The framework categorised strategies into person or system-based strategies and rated the level of risk-reduction strategies as low leverage and least effective strategies; medium leverage and moderately effective strategies; and high leverage and most effective strategies.

[±] High leverage risk-reduction strategies such as forcing functions, standardisation and simplification needs to be implemented alongside low leverage risk-reduction strategies, such as staff education, passive information and the use of reminders.

Medication safety 'thematic' programme — conclusion

Overall, the findings from HIQA's medication safety monitoring programme over the past number of years provided some assurance that public acute hospitals had the necessary structures, systems and processes in place to protect patients from unintentional harm associated with medication use.

For most services, these arrangements continued to improve as the HIQA programme advanced. Hospitals which performed better had:

- clearly defined and sufficiently resourced medication-safety programmes
- effective leadership
- multidisciplinary involvement
- oversight by and support from senior management
- adequate specialist supports
- good information and communication technology systems.

During this monitoring programme, HIQA observed numerous examples of good practice and medication safety initiatives driven by dedicated hospital staff who were committed to improving patient safety.

HIQA believes that the focus on medication safety throughout the monitoring programme has contributed to improvements in the quality and safety of medication safety across public acute hospitals. HIQA has seen sustainable improvements in governance structures within hospitals, with more awareness and emphasis on medication safety capability and capacity.

However, there are still opportunities for improvement as outlined in previous HIQA reports.[2, 4] A national approach and targeted investment is required to assist many hospitals to address gaps in services and achieve genuine systems improvements to enhance medication safety.

Many improvements could be achieved within existing resources if sufficient support is provided at local hospital, hospital group and HSE level to implement recommendations and best practice initiatives to address the reduction in medication-related harm.

As previously mentioned, this thematic medication safety monitoring programme has now concluded. However, medication safety will continue to be an area of focus in a

new inspection methodology that is currently under development. This is discussed in more detail under section 7 of this report.

As part of a broader assessment of services, HIQA will continue to monitor the systems and processes in place to support medication safety across public acute hospitals and rehabilitation and community inpatient healthcare services. There will also be a focus on the medications with the greatest potential for patient harm.

In doing this, HIQA hopes to support organisations to sustain the improvements achieved to date and to further drive improvements at local, group and national level. This aims to enhance the quality and safety of medicine use for patients receiving care in public acute hospitals and in rehabilitation and community inpatient healthcare services.

3.7 Monitoring against the *National Standards for Safer Better Maternity Services*

In February 2020, HIQA published its 'Overview report of HIQA's monitoring programme against the *National Standards for Safer Better Maternity Services,* with a focus on obstetric emergencies'.[3] The report set out the cumulative findings from the programme, which began in 2018.

The programme monitored compliance across the 19 maternity units and hospitals in Ireland against 21 specific standards from *the National Standards for Safer Better Maternity Services,*[30] with a focus on obstetric emergencies.

HIQA found high levels of compliance across maternity services, and findings provided assurance around the arrangements that have been in place to detect and respond to obstetric emergencies across the services.

Notwithstanding these positive findings, high levels of non-compliance were identified in two maternity units under the standards for leadership, governance and management, staffing, staff training and audit activity. Follow-up inspections conducted by HIQA in the two services provided assurance that many of the key issues and areas of non-compliance had been addressed, or were being addressed at the time of re-inspection or in the process of being resolved.

Key findings from the overall report included the following:

- the need to progress the formation of maternity-service networks to ensure equity in access to the same level of care
- the need to develop a comprehensive, time-bound and fully costed National Maternity Strategy[7] implementation plan, which spans the remaining time frame of the strategy
- the need to review and address the impact of infrastructural and design issues of many maternity units and hospitals for women and their babies
- the need for improvement in the uptake of training on the management of obstetric emergencies.

Having concluded this review, HIQA is now affording services time to implement these recommendations, and is maintaining a watching brief in relation to this. HIQA acknowledge that in doing so, required levels of funding to implement the National Maternity Strategy are needed to fully address the recommendations made.

4. Regulation of medical exposure to ionising radiation

Background and context

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019 (referred to in this chapter as the 'regulations') provide a framework for the regulation of medical exposure to ionising radiation in Ireland.

Since January 2019, HIQA has been the competent authority in Ireland with responsibility for inspecting and enforcing these regulations. As part of its regulatory function, HIQA is responsible for ensuring that public and private facilities^ in Ireland providing medical and dental radiological services to people◊ are compliant with the regulations.

HIQA's function in this area is exercised through monitoring and inspection. If non-compliances or potential risks to people using services are identified, then escalation and enforcement by HIQA may follow. HIQA is responsible for regulating a total of 1,671 medical radiological installations. A breakdown of these services is outlined in Figure 5.

Figure 5. Number of ionising radiation services regulated by HIQA.

^ A facility is a medical radiological installation which provides medical and dental radiological services.
◊ Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

The inspection programme to assess compliance with the regulations started in the latter part of 2019 with six inspections carried out in facilities providing medical exposure to ionising radiation. During 2020, HIQA conducted a further 27 inspections of public and private facilities including both medical and dental X-ray services. The list of the inspected facilities and the associated service provider[*****] with responsibility for the service is provided in Appendix 9 of this report.

Regulation of medical exposure to ionising radiation — impact of COVID-19

Although routine monitoring inspections were carried out in the early part of 2020, on-site inspections were deferred for a number of weeks in line with public health advice with the onset of the global pandemic in March 2020. However, services continued to be monitored remotely.

When on-site inspections resumed, a risk-based approach was used to prioritise services for inspection, and the inspection methodology was redesigned to reduce the time spent on site. The risk-based approach that was used when prioritising facilities considered the following information:

- an assessment of the radiation risk associated with different service types; for example, the size, scale and complexities of X-ray services provided at a major hospital as distinct from a small dental service
- solicited information[†††††] received, including statutory notifications and results of provider-led incident investigations into significant incidents
- an assessment of the results of regulatory self-assessment questionnaires completed by service providers
- unsolicited information[‡‡‡‡‡] received by HIQA.

This information, along with information supplied by the service provider in advance of the inspection, facilitated inspectors[§§§§§] to determine the focus required in each facility and identify the specific regulations and lines of enquiry (the questions to be asked) that were used when inspecting each site.

[*****] Service provider is the term used in this report to describe an undertaking under SI 256 of 2018 who is legally the entity with overall responsibility for the conduct of medical exposures.

[†††††] Solicited information is information the service provider is required to submit as part of its statutory obligations or requested by HIQA.

[‡‡‡‡‡] Unsolicited information is information that is not requested by HIQA but is received by HIQA from any member of the public.

[§§§§§] Inspector refers to an authorised person appointed by HIQA under Regulation 24 of SI 256 of 2018 for the purpose of ensuring compliance with the regulations.

Focus of inspections relating to medical exposure to ionising radiation

Of the 27 inspections conducted in 2020, five inspections were of dental facilities. These inspections were conducted in late 2020 following an online stakeholder engagement campaign with the dental sector. The facilities identified for inspection were prioritised on the findings of a self-assessment questionnaire that had been issued in 2019 to facilities providing cone beam computed tomography.******

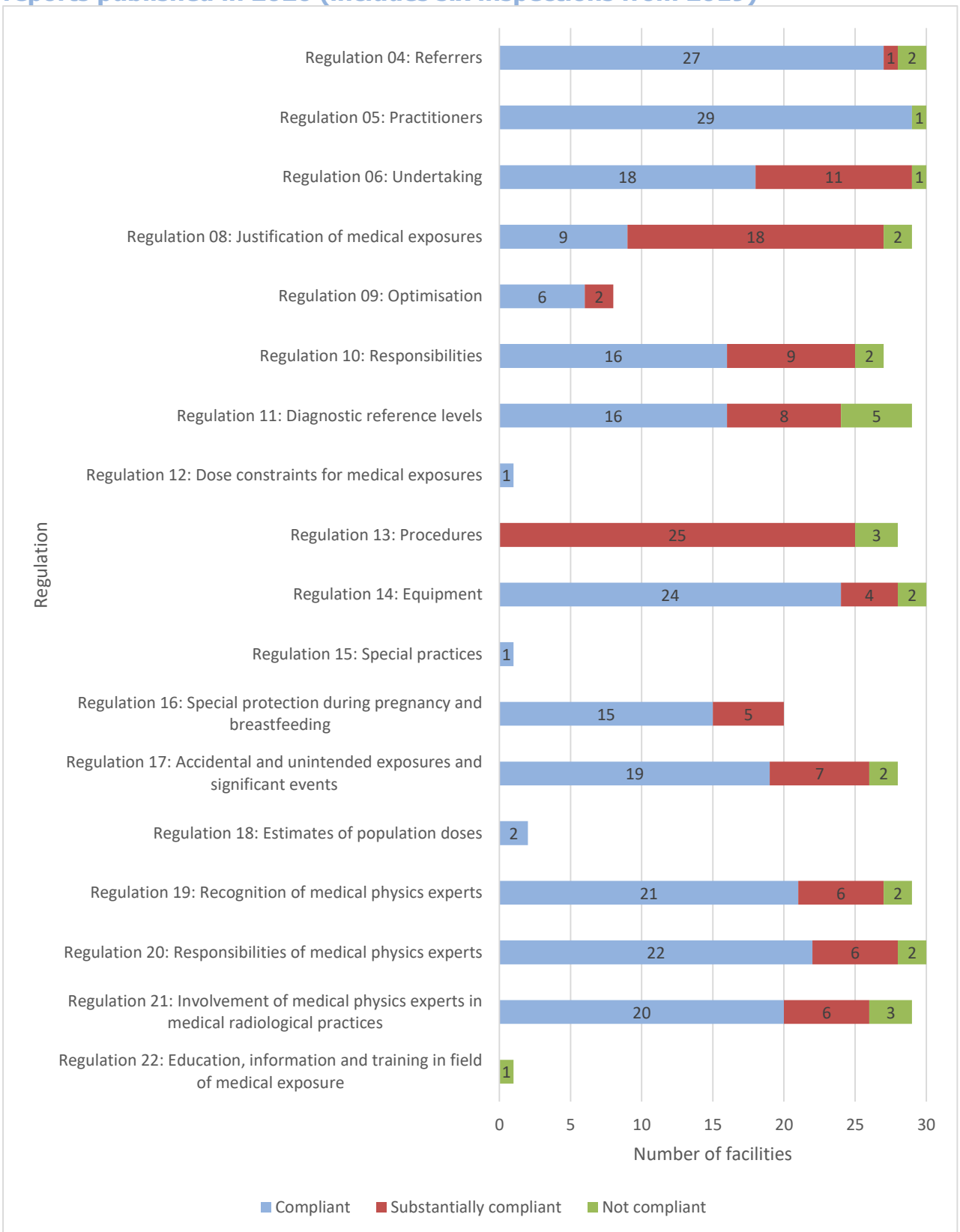
Information provided for stakeholders during the online campaign and further guidance documents for dental services are available on www.hiqa.ie.

Figure 6 on the following page shows levels of compliance against the regulations detailed in 31 inspection reports published in 2020 following 33 inspections (six inspections completed in 2019 and 27 completed in 2020). Two services which were each inspected twice had a single inspection report published in relation to those inspections.

A standard inspection may not assess all regulations. Instead, HIQA includes key lines of enquiry (questions) requiring review in relation to specific relevant regulations identified during the pre-on-site assessment. In Figure 6, it is worth noting that in the 31 inspections, Regulation 12, Regulation 15, Regulation 18 and Regulation 22 were only assessed in certain circumstances based on information reviewed in advance of the inspection or specific to the service that was to be assessed; for example, special practices in the case of a paediatric service.

****** Cone beam computed tomography is a technique for imaging the body in sections or slices using specialised computers and imaging equipment

Figure 6. Level of compliance found under each regulation from inspection reports published in 2020 (includes six inspections from 2019)



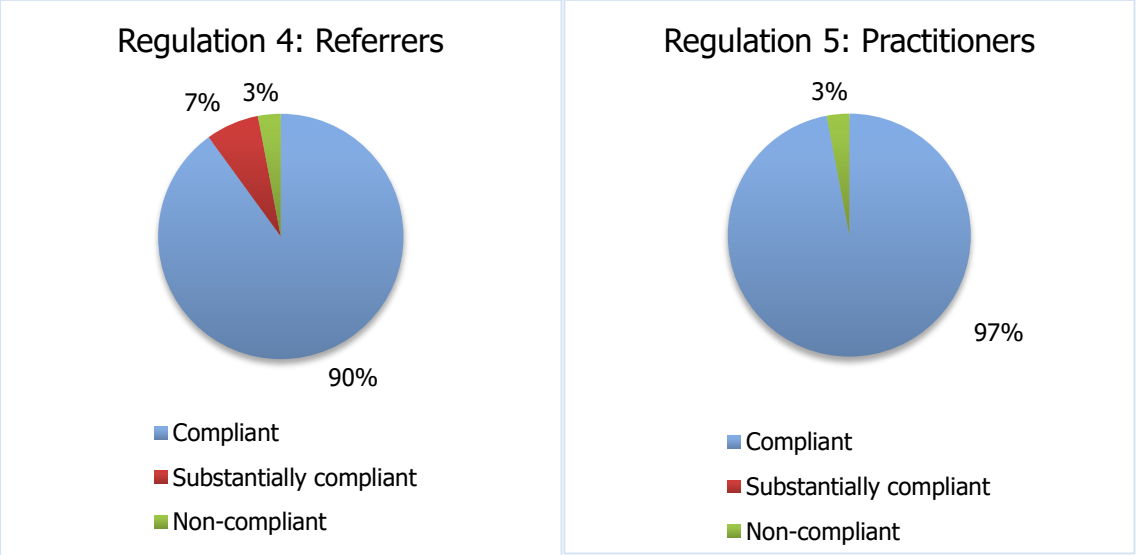
Key findings from inspections of medical exposure to ionising radiation

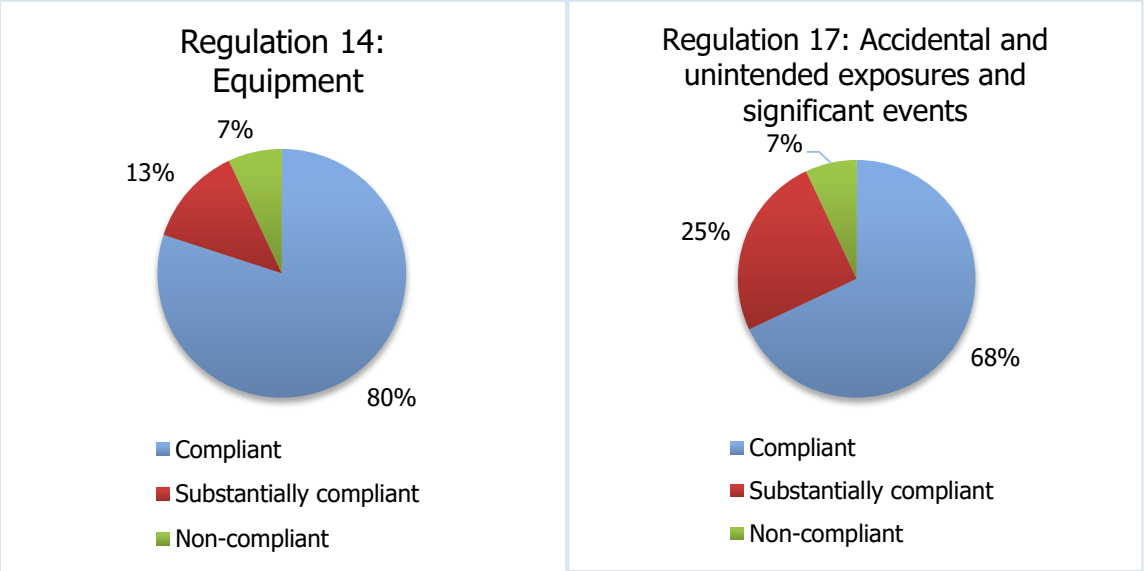
To date, as shown in Figure 7, high levels of compliance with Regulations 4 and 5 were found in the majority of facilities. This means that only appropriately trained and recognised healthcare professionals referred service users for medical exposures and these professionals took clinical responsibility for exposures.

Similarly, inspectors were assured that service providers in inspected services had the appropriate arrangements in place to ensure that radiological equipment was safe and fit for purpose, and that it had undergone the appropriate acceptance testing and performance testing.

The inspection findings also highlight that most facilities had reasonable measures in place to identify incidents involving or potentially involving accidental and unintended exposures to ionising radiation through structured incident-reporting mechanisms. For the majority of facilities, any identified events were managed, responded to and reported in a timely manner in line with national legislation, policy, guidelines and guidance.

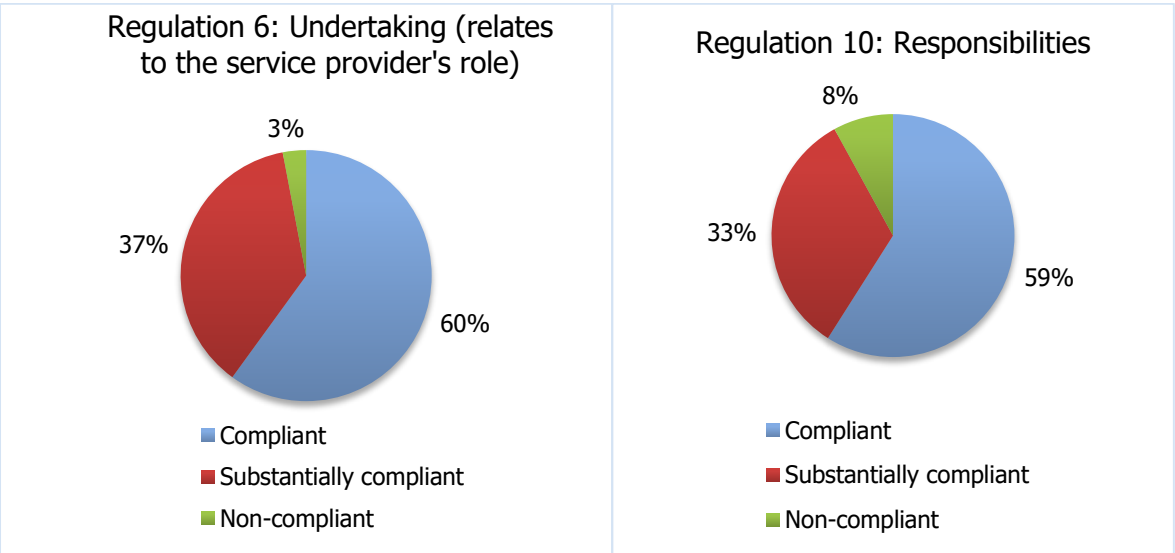
Figure 7. Regulations with good levels of compliance





However, in some larger facilities or in situations where a service provider had responsibility for a number of facilities, inspectors noted that specific reporting structures, and governance and management arrangements for medical exposures were not fully understood by some staff. Therefore, findings in relation to the regulations on roles, responsibilities and accountability were not as positive (see Figure 8).

Figure 8. Regulations with varied levels of compliance



For example, although the local reporting structures within the facility were well known in most facilities, HIQA was not assured that communication pathways were

in place with the service provider with overall responsibility. This could result in service providers not having full oversight of their facilities.

Further findings on governance of medical exposure to ionising radiation

To ensure that safe, effective and person-centred care is provided for service users undergoing medical exposures to ionising radiation, it is essential that service providers have clearly documented the allocation of responsibilities and that this information is communicated to, and known by, all staff.

The value of comprehensive oversight by service providers was seen in facilities where measures had been taken to continually improve the quality of their services. These measures included establishing and reviewing diagnostic reference levels[††††††] (DRLs) as a means of reducing radiation dose while maintaining the diagnostic outcome of the exposure. Similarly, some service providers had carefully selected equipment and had dedicated practical techniques and dose-tracking systems designed specifically for their patient cohort.

An example of good practice identified in larger facilities included the presence of a radiation safety committee which reviewed audits and measures in place for the safe delivery of ionising radiation. Similarly, some service providers held frequent multidisciplinary quality assurance and risk assessment meetings to consider the results of the performance testing on equipment and assess the quality assurance programmes that were in place. While these meetings are important, their main value is in ensuring that any identified issues are acted on and that appropriate changes are decided, implemented and re-evaluated. Having good oversight and management structures in place with identified lines of accountability will ensure recommendations from these types of committees are acted upon.

In some facilities, inspectors noted that the level of involvement of the medical physics expert[‡‡‡‡‡‡] (MPE) was not at the required level in line with the level of risk posed by some services. For example, in some instances, informal arrangements were in place without regard for the continuity of the service should the medical physics expert be unavailable. However, in contrast, other facilities had comprehensive service-level agreements in place which allowed for the sharing of medical physics expertise across a number of facilities under the responsibility of a

[††††††] Diagnostic reference levels are a benchmark of the typical dose levels for types of radiological procedures. They provide a benchmark to compare doses received by individuals having the same procedures in different rooms, facilities or organisations.

[‡‡‡‡‡‡] A medical physics expert is an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure to ionising radiation.

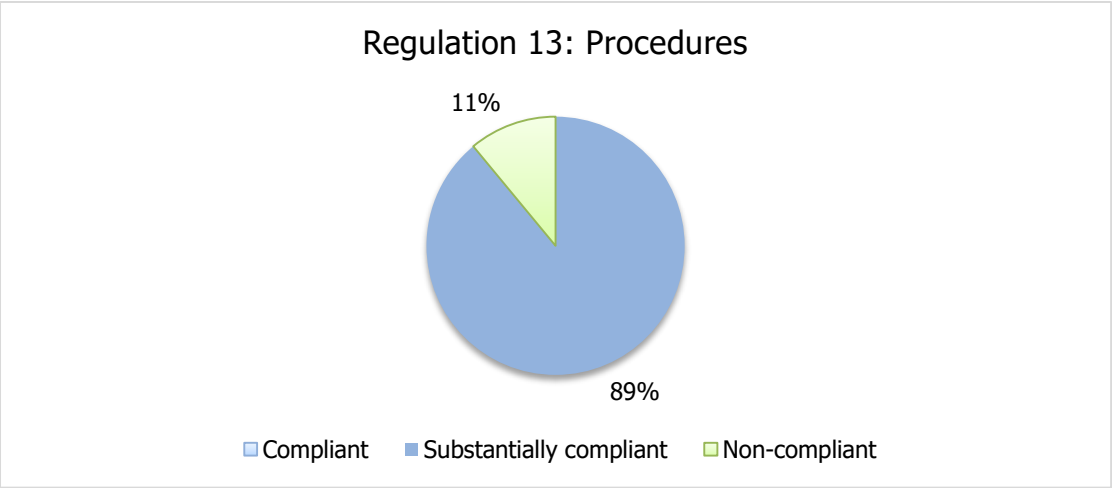
larger service provider. This finding demonstrates how formal arrangements and a clear allocation of responsibilities can support quality improvements in a service by sharing the available resources and expertise across a number of facilities.

As shown in Figure 9, no service provider was found to be fully compliant with Regulation 13 (procedures). This regulation, which included new requirements under the regulations, contains four sub-regulations which require service providers to have:

- written protocols in place
- information relating to the patients' exposure available in the patients' report
- referral guidelines in place
- had carried out clinical audits.

In most facilities, service providers, although compliant with a number of these sub-regulations, were unable to provide evidence that information relating to the exposure was available in patients' reports. As a consequence, most services were found to be substantially compliant with this regulation. At the time of preparing this overview report, HIQA was aware that many service providers were reviewing how this information can be incorporated into a patient's report and had engaged with HIQA on how to achieve compliance with this regulation.

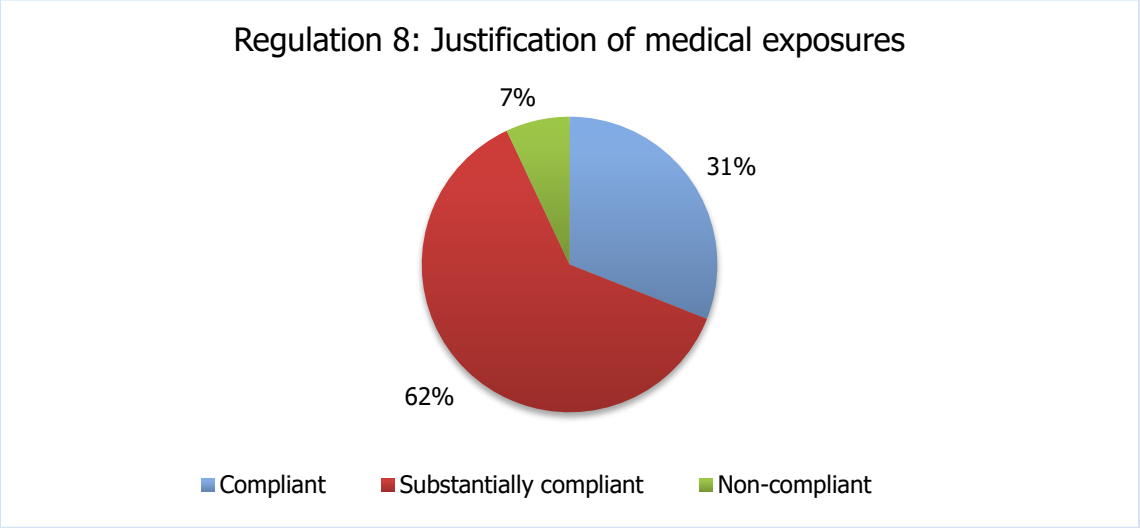
Figure 9. The level of compliance found for Regulation 13: Procedures



Finally, as shown in Figure 10 on the following page, findings in relation to the justification of medical exposures (Regulation 8) were mixed. Some service providers had not recorded that justification in advance of an exposure to medical ionising radiation had occurred. Therefore, there was an absence of evidence that

consideration was given as to whether the benefits outweighed the risks of all such exposures.

Figure 10. The level of compliance found for Regulation 8: Justification of medical exposures



Medical exposure to ionising radiation — summary of areas of good practice identified

Specific areas of good practice noted on inspections included the following:

- facilities with radiation safety committees with clear terms of reference and appropriate membership which met regularly, and which were able to discuss issues relating to radiation protection and advise the service provider appropriately
- many larger facilities had identified personnel, such as a radiation safety officer, with responsibly for promoting a positive culture of communication, learning and supporting staff in radiation safety
- a number of facilities had processes in place to establish, review and act on diagnostic reference levels, which enabled service providers to reduce the typical radiation doses delivered for particular procedures without compromising the image quality
- one facility had carefully selected equipment and had designed techniques and dose-tracking systems specifically to suit its paediatric population.

While nationally mandated clinical audit procedures are yet to be established by the Minister for Health, as intended in legislation, HIQA found good quality clinical audit processes were in place in many facilities, and evidence of the actions taken from the recommendations of these audits was also available.

Medical exposure to ionising radiation — summary of further opportunities for improvement identified

Although HIQA found that facilities were compliant with the majority of the regulations, HIQA noted specific opportunities for improvement in some facilities, which included the implementation of:

- comprehensive governance arrangements within larger facilities to ensure oversight of all areas that use ionising radiation
- clearer and more accountable processes to identify the practitioner responsible for justifying individual X-ray exposures
- systems or processes to accurately record the justification for certain medical radiological procedures.

In addition, it is essential that facilities and service providers:

- have sufficient medical physics involvement relevant to the size and scale of the service and appropriate involvement of key individuals, such as medical physics experts, to optimise radiation safety processes
- implement processes to ensure all documentation available to staff is up to date and out-of-date policies, procedures and guidelines are removed
- incorporate information related to the exposure of patients into the report of the procedure
- involve the appropriate personnel to fulfil comprehensive diagnostic reference level reviews and to maintain a proactive approach to equipment quality assurance.

Overall summary of findings from the first year of HIQA inspections in the area of medical exposures to ionising radiation

Overall, having commenced the first inspections in the latter part of 2019 and continuing a programme of inspection of medical radiological installations in 2020, HIQA found that inspected facilities were compliant with most regulations. This has provided HIQA with an overall assurance that service providers had the capacity and

capability to deliver safe and effective radiological services. In particular, HIQA noted that some service providers had used the self-assessment questionnaire issued by HIQA in 2019 as a gap analysis tool and had acted on the areas identified for improvement in the questionnaire. By using this self-assessment questionnaire as a quality improvement tool, service providers demonstrated that they had the initiative to address any potential regulatory issues in their facilities.

Having effective management arrangements that promote an open culture of patient safety among staff and that seeks feedback from service users help to improve practice. By having full oversight across all facilities, service providers should strive to constantly seek ways to go beyond the minimum requirements set out in these regulations in order to deliver a high quality and safe service for all service users. As the regulations set the minimum standards for the protection of service users when being exposed to medical ionising radiation, it is important that those service providers who are found to be compliant seek to build upon such findings to further enhance radiation safety for patients beyond the baseline minimum expected through regulation.

5. What people told us about services and how we engaged with stakeholders during 2020

As part of its monitoring and regulatory functions, HIQA receives information from a variety of sources. This information can be categorised into solicited[§§§§§§] and unsolicited information.[*******] In addition, as HIQA is the competent authority for service-user protection in relation to medical exposure to ionising radiation in Ireland, we are responsible for receiving statutory notifications of accidental and unintended exposures, in line with regulations.

The following section outlines the information received and used by HIQA when carrying out its roles and functions. It also outlines its engagement with various stakeholders and interested parties during 2020.

Unsolicited receipt of information (UROI)

During 2020, HIQA's Healthcare team received 293 pieces of unsolicited information from service users, relatives, employees and other members of the public. This was an increase of 5% compared to the 278 pieces of information received in 2019.

The main themes of the information received included the quality of care received; for example, admission, transfer and discharge processes, overcrowding (mainly in the emergency department), dignity and respect, food and nutrition, safeguarding, falls management, wound management, waiting times and medication management. In addition, a number of pieces of information received from service users, relatives and employees related to infection prevention and control measures, including use of and or availability of personal protective equipment (PPE) for staff, cleaning protocols, testing, social distancing and cleaning of areas within the hospital during the pandemic. Other themes included the management of complaints, records management, and the behaviour and attitudes of staff.

Five people contacted HIQA with compliments about the quality of the care they had received in a number of acute hospitals.

[§§§§§§] Solicited information is defined as information that the provider and or person in charge is required to submit as part of their statutory obligations, such as specified information, notifications or applications forms or information that inspectors request. It also means information requested from providers and submitted as part of monitoring or thematic reviews, such as self-assessment questionnaires.

[*******] Unsolicited information is defined as information which is not requested by HIQA but is received by HIQA from people, including the public or people who use services. This could be information that indicates a deviation from the regulations or national standards (information of concern) or compliments or general comments about a designated centre, service and or a provider.

Of the 293 pieces of information received, seven (2.4%) related to services that carry out medical exposure to ionising radiation.

All of the unsolicited information received was acknowledged, and assessed and risk-rated by an inspector with appropriate regulatory follow up carried out where necessary.

Request of information (ROI)

The healthcare team received a total of 20 requests for information (ROI). Eight of these related to queries on infection prevention and control and COVID-19.

Statutory notifications of accidental and unintended exposures

In line with regulations, all undertakings[†††††††] have a statutory obligation to ensure that appropriate arrangements are in place to notify HIQA of significant events[‡‡‡‡‡‡‡] within three working days from their discovery.

In 2020, HIQA reviewed and assessed 76 statutory notifications of significant events of accidental and unintended medical exposures and subsequent reports on the outcomes and mitigative actions. Furthermore, in September 2020, HIQA published the first *Overview report on significant events of medical exposure to ionising radiation 2019.*[31] That report presented an overview of the findings and lessons learnt from notifications received in 2019 with the aim of sharing the learning from these notifications and related provider-led incident investigations.

Findings from the significant-event report indicate that, overall, the use of radiation in medicine in Ireland is generally quite safe for patients. The report noted that radiation incidents reported to HIQA in 2019 involved relatively low radiation doses with limited risk to service users. The most common error reported in diagnostic imaging were failures in patient identification, resulting in incorrect patients receiving medical exposures. While this finding is in line with previously reported national and international data, it certainly highlights an area for improvement for undertakings. Refresher training for staff was the type of corrective measure frequently taken by undertakings to prevent further incidents. While updated training is an important corrective measure, it can be relatively ineffective in addressing complex issues. Undertakings should consider alternative corrective and risk-management strategies,

[†††††††] An undertaking is a person or body, who in the course of a trade, business or other undertaking (other than as an employee), carries out, or engages others to carry out, a medical radiological or the practical aspects of a medical radiological procedure.

[‡‡‡‡‡‡‡] Incidents involving medical exposures that are deemed to be above or below an acceptable threshold and have the potential to cause harm are called significant events.

such as simplifying or standardising procedures or the automation of processes to help prevent errors from reoccurring.

Stakeholder engagement

In spite of the obvious impact of COVID-19 on face-to-face meetings with stakeholders and other interested parties in 2020, engagement with services and organisations was progressed in a number of areas.

HIQA continued to work the Department of Health and with other stakeholders to prepare for the passing of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 into law. Such engagement was accompanied by a body of internal preparatory work, which included a review of our monitoring approach to national standards, which will be further discussed under section 7. Further engagement arising from this review, and in contemplation of this new legislation, is planned for later in 2021.

In regard to HIQA's medical ionising radiation regulatory role, key stakeholders, including the Health Service Executive Radiation Protection Office and representatives of the Dental Council, were met with regularly. A Memorandum of Understanding was also agreed with the Environmental Protection Agency and continued virtual engagement took place during 2020 with this agency about respective roles in different aspects of regulating ionising radiation.

In advance of commencing inspections in the dental sector in the area of radiation protection, HIQA hosted two webinars to provide information about its monitoring approach for the regulation of dental services providing medical exposure to ionising radiation. These webinars provided guidance for dental undertakings and other interested stakeholders relating to:

- a self-assessment questionnaire and how it was to be completed
- the format of HIQA's on-site inspections.

Almost 590 people attendees across the two sessions, posing over 190 questions during the live questions and answers session.

HIQA's Expert Advisory Group (EAG) for medical exposure to ionising radiation met virtually in September 2020. This meeting was to facilitate consultation on competent authority functions that HIQA is required to fulfil. Furthermore, HIQA continues to be represented at the Heads of European Radiological Competent Authority (HERCA) regulators' forum, which also met virtually in September 2020.

6. HIQA Healthcare team's involvement with national efforts in addressing COVID-19.

During 2020, in addition to our routine monitoring and regulatory work, the Healthcare team within HIQA also further assisted national efforts in addressing COVID-19 in a number of ways. This ranged from undertaking specific work at the request of the National Public Health Emergency Team (NPHET), assisting the HSE with contact tracing and working as part of HIQA's Infection Prevention and Control Hub set up to support social care services as they tackled COVID-19.

Desktop analysis of public acute hospital infection prevention and control preparedness for COVID-19

HIQA has a significant level of experience in inspecting hospitals against national standards for the prevention and control of healthcare-associated infection in acute hospitals. Therefore, in April 2020, NPHET requested that HIQA provide a desktop evaluation of infection prevention and control preparedness relating to COVID-19 in public acute hospitals. A resulting report was submitted to NPHET and published on the HIQA website.[1] The evaluation was informed through a self-assessment exercise conducted by hospital groups, and HIQA's own information gained through inspection activity over recent years.

In response to recommendations made by HIQA, a commitment to a significant investment in infection prevention and control capacity and capability in acute hospitals has been made by the Government. In particular, such investment relates to additional specialist staffing resources (hospital consultants, infection control nurses, surveillance scientists and pharmacists). It also includes extra capacity funding to improve information and communication technology (ICT) surveillance systems, as well as some minor improvements to infrastructure.

This commitment, supported by an increase in allocated funding in 2021, is welcomed by HIQA. HIQA believes such investment is necessary to support acute hospital services in their continued efforts to respond to both the COVID-19 pandemic and other underlying infection prevention and control threats that equally need to be addressed by services.

During the year, inspectors of healthcare services also assisted with HIQA's Infection Prevention and Control Hub which was set up to provide advice and support to social care services as they tackled COVID-19. They were also involved in contact tracing as part of collective national efforts in response to the initial wave of COVID-19.

Further details in relation to HIQA's involvement with national efforts in addressing COVID-19 can be found in HIQA's 2020 Annual Report, which can be viewed on www.hiqa.ie.

7. Future monitoring approach against the national standards

Taking the findings from previous monitoring activity programmes, HIQA is building on its prior body of work in promoting and advancing quality improvement in key areas of acute healthcare. To date, these areas have included governance, infection control, medication safety, nutrition and hydration, antimicrobial stewardship and maternity services. This experience is being used to develop a broader approach to monitoring against the *National Standards for Safer, Better Healthcare.*

The project has a number of primary goals including:

- developing for the first time a comprehensive monitoring approach plan to support a monitoring programme against specific standards as required under the *National Standards for Safer Better Healthcare*
- developing a broader inspection methodology which draws together elements of and learning from many of our pre-existing thematic programmes, allied to new areas of monitoring — to establish a 'core assessment' against the *National Standards for Safer, Better Healthcare*
- implementing methodologies, which would in time act to familiarise and support the development of a registration or licensing model for use in a wide range and size of acute healthcare services.

HIQA is currently progressing the project and developing a broader assessment approach to allow for the monitoring of compliance with standards. The new approach to inspection will assess compliance with a core set of standards from the *National Standards for Safer Better Healthcare,* reflecting key themes of person-centred care, effective care, safe care, leadership, governance and management, and workforce. An integral part of the approach will be capturing the voice of people using the service to determine if they receive person-centred, safe and effective care underpinned by HIQA's human rights-based approach to monitoring.

To date, the project team has developed a comprehensive 'Assessment-judgment framework for the *National Standards for Safer Better Healthcare'*. This is further supported by a detailed guidance document for service providers on the assessment-judgment framework. At the time of preparing this report, extensive engagement with service providers and the public is planned around these changes. It is intended to progress to piloting of these inspections over the coming months — subject to no

further unforeseen issues arising, including those that may be presented by the ongoing pandemic.

This monitoring approach is being designed so that it will be effective in promoting improvement across the wide range of healthcare services that HIQA monitors, as well as services that may monitored in the future.

8. Conclusion

The healthcare system in Ireland, and those that work within it, have experienced extreme pressure due to COVID-19. The pandemic has demonstrated the strategic need for the State to have a well-functioning, resilient and adequately resourced health service — which in essence is what the *National Standards for Safer Better Healthcare* aim to achieve. HIQA's role in monitoring these standards seeks to promote improvements in achieving safer, better healthcare for all.

During 2020, HIQA focused its resources on known areas of risk and worked to develop targeted approaches to inspections, with a particular focus on the management of COVID-19 across public acute hospitals, and rehabilitation and community inpatient services in response to the challenges being faced by service providers.

Despite the well-documented challenges that the Irish health service continues to work to address, HIQA continues to find examples of excellent care which meet and exceed the national standards, delivered by committed and highly capable people. Findings from HIQA's monitoring and regulatory activity throughout 2020 demonstrate how good governance and leadership is the first line of defence when providing safe, high-quality and reliable healthcare, particularly against the backdrop of a global pandemic. Effective leadership, governance and management are fundamental to the sustainable delivery of safe, effective care and support. The culture of a service is also crucial, and leaders at all levels can strengthen and encourage a culture where quality and safety are at the forefront.

Notwithstanding the progress achieved in relation to achieving compliance with standards and regulations as seen across our different monitoring programmes, variation and discrepancies across different settings and hospitals have continued. Some healthcare services continue to be proportionately less resourced than others. HIQA's monitoring activity has particularly identified this finding in the resourcing of infection prevention and control in community settings. Despite some improvement, infection prevention and control resourcing in these settings continues to lag behind the acute healthcare setting. It is essential that these environments are maintained at a high standard to ensure the effectiveness of infection control and decontamination practices and to prevent the transmission of infection, particularly in the context of COVID-19.

Alongside the recognition that COVID-19 has fundamentally changed so much in Ireland's healthcare system, it is important to recognise what has not changed. While an analysis of the collective findings from HIQA's monitoring programmes in

2020 identifies some improvement, recurring issues emerge year-on-year in the country's acute hospitals. These include overcrowding, capacity issues and workforce challenges, which continue to raise concerns. HIQA continues to highlight that the underlying fabric and ageing infrastructure of healthcare services will continue to present ongoing challenges to their maintenance and their ability to adhere to best practice and national standards.

Inconsistencies with compliance with the national standards could be addressed if service providers acted the opportunities for improvement identified in each HIQA inspection report. However, services need to be supported and resourced in their efforts to do so.

Before COVID-19 emerged, the structure of the public healthcare system was already at a crossroads. The Sláintecare reform plans, coupled with the potential impact of planned legislation, such as the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 and Patient Safety (Licensing) Bill, were (if fully implemented) already likely to result in significant changes to how healthcare is provided. However, the way in which services plan and deliver healthcare in Ireland must now be shaped by the experience of dealing with an international public health emergency. The learning from this experience must be integrated into healthcare policy and future delivery of services. In the interim, while awaiting the implementation of policy developments, the Irish health service will continue to face significant challenges.

Arising from this experience, a high-performing, fit-for-purpose and properly resourced health service — which complies with nationally mandated standards and regulations — must be in place to meet the totality of healthcare needs of the population now and into the future. To support this, HIQA will advance and implement a new monitoring programme against the *National Standards for Safer Better Healthcare* and implement methodologies that can be applied to all healthcare services and are responsive to existing healthcare challenges. HIQA also remains committed to supporting continual and sustainable improvement in services across those public and private healthcare and dental services providing medical exposure to ionising radiation to ensure patients are receiving a high-quality and safe standard of care.

2020 has been a challenging year, and the next number of years will be a time of transition for both healthcare services and for HIQA in adapting to these changes. HIQA commits to ensuring that these changes are fully communicated to providers, funders, and people using health services in an open and transparent way.

Building upon its experiences gained through its various monitoring and regulatory programmes as outlined in this report, HIQA will work with stakeholders and other interested parties to further advance the quality and safety of care for people who use healthcare services in Ireland.

9. Appendices

Appendix 1 — HIQA's remit and how it monitors and regulates healthcare services

Monitoring against national standards

HIQA's role in monitoring healthcare services is directed by its legislative remit, national standards and evidence of what interventions reduce risks for patients and promote safe, effective and quality care.

In the healthcare setting, HIQA's remit has until recently predominately extended to monitoring public hospital services against national standards under section 8(1)(c) of the Health Act 2007 (as amended). HIQA also has powers under section 9 of the Act to undertake a statutory investigation of a service or services.

The national standards that HIQA monitors in healthcare services include:

- *National Standards for Safer Better Healthcare* [19]
- *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services* [32]
- *National Standards for infection prevention and control in community services* [12]
- *National Standards for Safer Better Maternity Services* [30]
- *National Standards for the Conduct of Reviews of Patient Safety Incidents.*[¥, 33]

Figure 11 outlines the profile of those healthcare services that HIQA monitors under section 8 of the Health Act 2007 (as amended). This includes 49 public acute hospitals inclusive of 19 maternity units and or hospitals. These 49 public acute hospitals are organised across seven hospital groups, with each hospital group being led by a group chief executive officer.

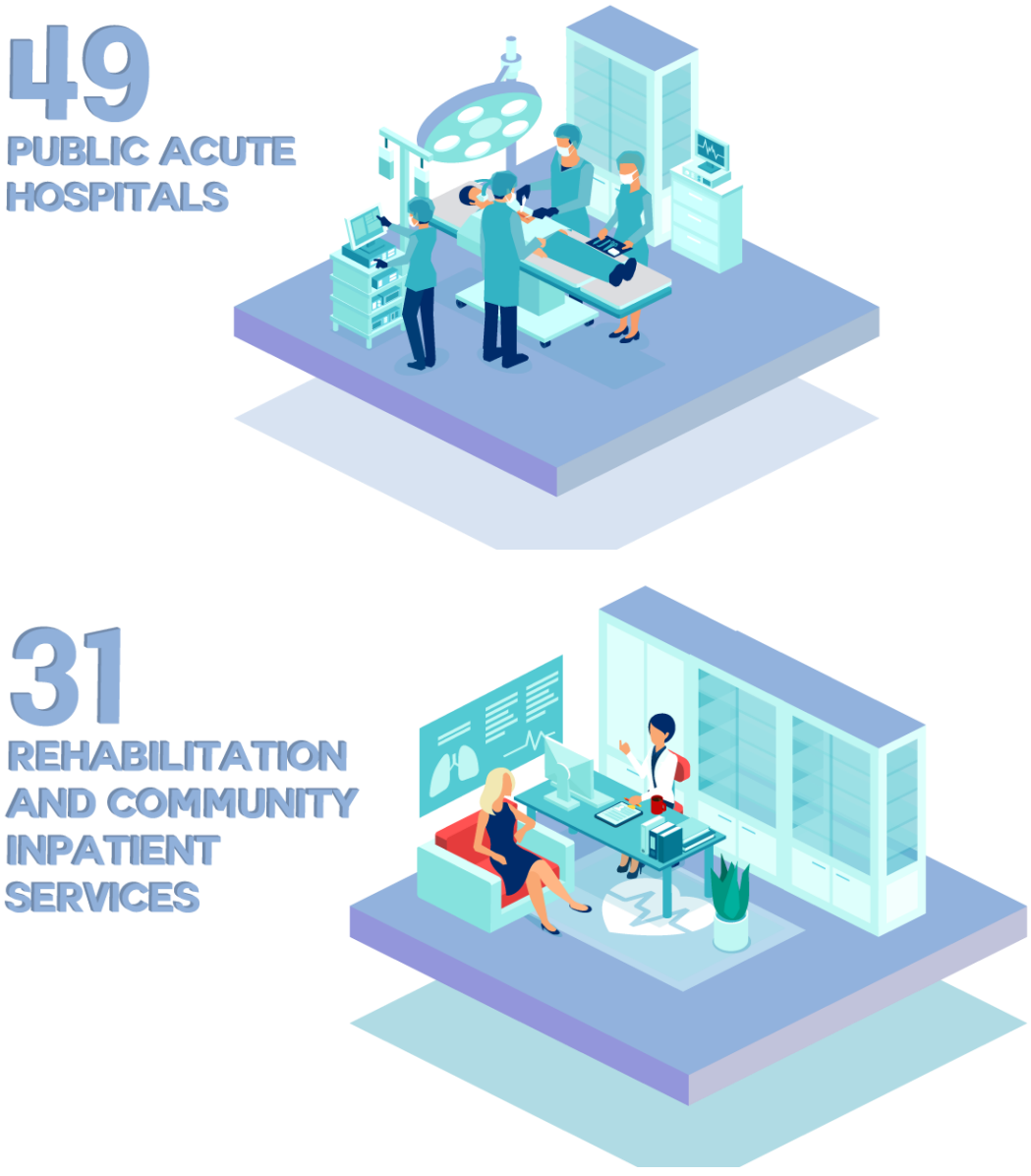
Community healthcare organisations support the provision of integrated care within community healthcare services[§§§§§§§] and between community and acute hospital

[¥] HIQA and the Mental Health Commission (MHC) jointly developed the *National Standards for the Conduct of Reviews of Patient Safety Incidents*.

[§§§§§§§] Services provided by the community healthcare organisations include primary care, older persons' services, palliative care, mental health services and services for people with disabilities.

services.******** In 2020, HIQA was responsible for monitoring 31 rehabilitation and community inpatient services. This was an increase of eight services from the previous year (n=23).

Figure 11. Healthcare services monitored under section 8 of the Health Act 2007 (as amended)



Regulations governing the use of medical exposure to ionising radiation

HIQA's role in healthcare was extended in 2019 in line with new legislation[††††††††] to include the regulation of medical exposure to ionising radiation.[‡‡‡‡‡‡‡‡] This extension to HIQA's role and function has been a significant move which has, for the first time, extended HIQA's remit into the private healthcare sector in Ireland. The legislation and accompanying regulations gives HIQA enforcement powers when regulating in this area to address issues of non-compliance.

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019 provide a framework for regulating medical exposure to ionising radiation in Ireland. These regulations define the minimum safety requirements to protect people from the hazards associated with procedures such as X-rays and radiation therapy.[34, 35] The regulations apply to diagnostic and interventional radiology, radiotherapy, nuclear medicine and dentistry facilities across the public and private sectors in the Republic of Ireland.

As part of its regulatory function, HIQA is responsible for ensuring that radiation protection of service users[§§§§§§§§] in public and private facilities[*********] in Ireland are compliant with the regulations through monitoring and inspection. If non-compliances or potential risk to service users is identified, escalation and enforcement action by HIQA may follow. At the time of writing, HIQA is responsible for regulating 1,671 facilities providing various medical radiological therapies and diagnostic services.

Monitoring and regulatory programmes

HIQA conducts thematic monitoring inspections against relevant national standards in public acute hospitals and operates a regulatory programme for medical exposure to ionising radiation across healthcare services.

[††††††††] European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

[‡‡‡‡‡‡‡‡] A medical exposure is an exposure of ionising radiation delivered to patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment. Medical exposures are intended to benefit an individual's own health. Additionally, comforters or carers and volunteers in medical or biomedical research can also receive medical exposures.

[§§§§§§§§] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

[*********] A facility is a medical radiological installation which provides medical and dental radiological services.

HIQA's healthcare monitoring and regulatory activity is informed by a number of different sources of information. Sources include solicited information, such as data requested from the Health Service Executive (HSE) or the National Care Experience Programme[†††††††††] or unsolicited information[‡‡‡‡‡‡‡‡‡] provided by the public about services (including people who use the service, relatives and staff members working in healthcare organisations). When required, HIQA engages with healthcare providers to seek assurances in relation to specific concerns and risks seen by HIQA or brought to its attention.

HIQA's monitoring and regulation of healthcare services is further informed by other publicly available key sources of information, such as healthcare review reports and national or international benchmarking data.

All the information gathered through our monitoring and regulation programmes informs HIQA's overall understanding of how services are performing.

Thematic monitoring programmes

During 2020, HIQA focused on three key areas of patient safety in public acute hospitals and rehabilitation and community inpatient services using what is termed 'thematic monitoring programmes'. These measure and report on a service's compliance against relevant national standards, with a view to improving these services. The monitoring programmes focused on the following key areas:

- infection prevention and control in public acute hospitals[36] and rehabilitation and community settings, with a particular focus on COVID-19[37]
- rehabilitation and community inpatient services with a particular focus on governance and risk management, safe use of medicines and measures to ensure the prevention and control of healthcare-associated infections[17]
- medication safety with a particular focus on high-risk medications and high-risk situations.[13]

[†††††††††††††††] The National Care Experience Programme is a joint initiative from HIQA, the HSE and the Department of Health. It asks people about their experiences of care in order to improve the quality of health and social care services in Ireland. This initiative provides vital information to HIQA's Healthcare Team and is used as part of its monitoring programmes (see https://yourexperience.ie/ for more information).

[‡‡‡‡‡‡‡‡‡] Feedback is received by HIQA's dedicated Concerns Team, which provides advice and guidance as required. All information provided to HIQA is treated with confidence and in line with our privacy policy, which is available on the HIQA website, www.hiqa.ie.

Programme of regulating medical exposure to ionising radiation

As the competent authority in Ireland with responsibility for inspecting against and enforcing the regulations, HIQA advanced a programme of inspection in 2020 to assess compliance with the relevant regulations.[34, 35] The programme inspected public and private radiological facilities encompassing medical and dental X-ray services.

Each thematic and regulatory programme was developed by HIQA, and the methodology and approach for each of these programmes was supported by international research, national guidelines and best practice.

Each programme has its own assessment and judgment framework (to guide inspectors with checking compliance and to allow providers to self-assess their own service) and lines of enquiry§§§§§§§§§ that sets out how services are monitored against standards and regulations and what is expected of services. Further guidance on each programme is available on the HIQA website, www.hiqa.ie.

Inspection process

Inspections are either announced or unannounced and are conducted over one to two days depending on the size of the service. In light of COVID-19 and associated public health advice, measures were put in place to limit the time spent on site by inspectors. Furthermore, remote interviews with key staff through videoconferencing was introduced in some circumstances to reduce where possible on-site interaction with staff. Inspections involved extensive review of information before and after the on-site part of the inspection and a feedback process with the service once a draft report has been issued.

Publication of inspection reports

Inspection reports are published following each on-site inspection. These reports detail what inspectors found at the time of the inspection. The reports detail areas of compliance and or non-compliance with national standards and regulations, areas of good practice and high-quality care, and opportunities for improvements.

Where issues of high risk and or non-compliance are identified, inspectors will seek assurances from the health service provider, which is ultimately responsible for the quality and safety of the service it provides, and or hospital group and the HSE as required. In the context of medical exposure to ionising radiation, enforcement

§§§§§§§§§ Lines of enquiry are the key questions or prompts that inspectors use to help inform their inspection, assessment or investigation.

procedures can be followed up if non-compliances or potential risks to services users are identified. All inspection reports are published on the HIQA website, www.hiqa.ie.

Planned legislative changes impacting on HIQA's future role and function

The Health Act 2007, as currently amended, defines HIQA's role in the healthcare setting as that of monitoring against national standards in public hospitals. In addition, the Health Act 2007 also gives HIQA the power to conduct statutory investigations. At present, HIQA does not currently have the legal remit to enforce compliance with national standards. HIQA's enforcement powers for healthcare services are limited to the area of medical ionising radiation. Furthermore, HIQA currently does not have a remit in the monitoring of private services. However, HIQA's role and function in the monitoring of healthcare services would be significantly expanded with the enactment of two distinct pieces of draft legislation. These are as follows:

- **Patient Safety (Notifiable Patient Safety Incidents) Bill 2019**

This Bill, when enacted into law, would provide for the mandatory open disclosure of serious reportable patient safety incidents to those who have been harmed by them. The Bill also contains provisions to support the conduct of clinical audit in the health service. The proposed legislation would expand HIQA's role and function in a number of ways. The new Bill would require notification of patient safety incidents to HIQA as required and other relevant regulators, which would contribute to national patient safety learning and improvement. The Bill would also extend HIQA's monitoring remit in healthcare into the private sector and provides for a number of amendments to definitions and sections in the Health Act 2007, including a 'prescribed private health service' and a new definition of 'private hospital'. The Bill would also enable HIQA to carry out an investigation in both public and private hospitals where it believes there is a serious risk to the health or welfare of a person receiving services in that health service.

- **Patient Safety (Licensing) Bill**

This Bill sets out the legislative framework for the introduction of a mandatory system of licensing for public and private hospitals and other providers of high-risk healthcare services. The Patient Safety (Licensing) Bill would assign HIQA with responsibility for the following areas:

(i) the licensing of public and private healthcare services

(ii) the monitoring of performance of licensed services against standards and regulations and

(iii) enforcement powers to address non-compliance or risk to the health and safety of patients.

Enactment of these key pieces of legislation would include the imminent expansion of HIQA's current powers into the private healthcare sector, with increased awareness of mandatory notifiable patient safety incidents through notification under the Patient Safety (Notifiable Patient Safety Incidents) Bill, and in time healthcare licensing under the Patient Safety (Licensing) Bill.

Appendix 2 — Themes and standards assessed in rehabilitation and community inpatient services as part of HIQA's monitoring programme in 2020 against the *National Standards for infection prevention and control in community services* with a focus on COVID-19

Theme 5: Leadership, Governance and Management
Standard 5.1 The service has clear governance arrangements in place to ensure the sustainable delivery of safe and effective infection prevention and control and antimicrobial stewardship.
Standard 5.2 There are clear management arrangements in place to ensure the delivery of safe and effective infection prevention and control and antimicrobial stewardship within the service.
Theme 6: Workforce
Standard 6.1 Service providers plan, organise and manage their workforce to meet the services' infection prevention and control needs.
Theme 2: Effective Care and Support
Standard 2.2 Care is provided in a clean and safe environment that minimises the risk of transmitting a healthcare-associated infection.
Standard 2.3 Equipment is decontaminated and maintained to minimise the risk of transmitting a healthcare-associated infection.
Theme 3: Safe Care and Support
Standard 3.4 Outbreaks of infection are identified, managed, controlled and documented in a timely and effective manner.

Appendix 3 — Findings of 18 infection prevention and control risk-based inspections during the pandemic in 2020. Rehabilitation and community inpatient healthcare services: levels of compliance

Compliant (C) Substantially Compliant (SC) Partially Compliant (PC) Non-compliant (NC)

Standard No.	Standard	Gorey District Hospital	Royal Hospital Donnybrook	Lisdarn Transitional Care Unit	St Theresa's Hospital, Clogheen	Fermoy Welfare Home	Castlecomer District Hospital	Rivermeade Unit, St Patrick's Hospital, Carrick on Shannon	St Patrick's Hospital, Cashel	St Ita's Hospital, Newcastlewest
5.1	The service has clear governance arrangements in place to ensure the sustainable delivery of safe and effective infection prevention and control and antimicrobial stewardship.	SC	SC	PC	SC	SC	C	C	PC	C
5.2	There are clear management arrangements in place to ensure the delivery of safe and effective infection prevention and control and antimicrobial stewardship within the service.	SC	C	SC	C	PC	SC	SC	SC	SC
6.1	Service providers plan, organise and manage their workforce to meet the services' infection prevention and control needs.	SC	SC	C	SC	C	C	C	C	C
2.2	Care is provided in a clean and safe environment that minimises the risk of transmitting a healthcare-associated infection.	SC	SC	SC	PC	PC	PC	PC	PC	C
2.3	Equipment is decontaminated and maintained to minimise the risk of transmitting a healthcare-associated infection.	SC	C	SC	C	C	C	PC	C	C
3.4	Outbreaks of infection are identified, managed, controlled and documented in a timely and effective manner.	C	C	C	C	C	C	C	C	C

Appendix 3 (continued) — Findings of 18 infection prevention and control risk-based inspections during the pandemic in 2020. Rehabilitation and community inpatient healthcare services: levels of compliance

Compliant (C) Substantially Compliant (SC) Partially Compliant (PC) Non-compliant (NC)

Standard No.	Standard	Belmullet Community Hospital	St. Joseph's Community Hospital, Ennis	Clifden District Hospital	Grove House, Cork	Swinford District Hospital	Peamount Healthcare: Rehabilitation Services	St. Patrick's Hospital, Waterford	Carlow District Hospital	St. Camillus's Hospital, Limerick
5.1	The service has clear governance arrangements in place to ensure the sustainable delivery of safe and effective infection prevention and control and antimicrobial stewardship	PC	C	SC	PC	PC	C	PC	C	C
5.2	There are clear management arrangements in place to ensure the delivery of safe and effective infection prevention and control and antimicrobial stewardship within the service	NC	C	SC	SC	SC	C	SC	C	C
6.1	Service providers plan, organise and manage their workforce to meet the services' infection prevention and control needs.	SC	C	C	SC	PC	C	SC	C	PC
2.2	Care is provided in a clean and safe environment that minimises the risk of transmitting a healthcare-associated infection	PC	SC	PC	SC	SC	SC	SC	SC	PC
2.3	Equipment is decontaminated and maintained to minimise the risk of transmitting a healthcare-associated infection	PC	C	C	C	PC	C	SC	C	SC
3.4	Outbreaks of infection are identified, managed, controlled and documented in a timely and effective manner.	SC	C	C	C	SC	C	C	C	C

Appendix 4 — Themes and standards assessed in 2020 as part of HIQA's monitoring programme against the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*, with a focus on COVID-19

Theme 5: Leadership, Governance and Management
Standard 5.3 Service providers have formalised governance arrangements in place to ensure the delivery of safe and effective infection prevention and control across the service.
Theme 6: Workforce
Standard 6.1 Service providers plan, organise and manage their workforce to meet the services' infection prevention and control needs.
Theme: Effective Care and Support
Standard 2.6 Healthcare is provided in a clean and safe physical environment that minimises the risk of transmitting a healthcare-associated infection.
Standard 2.7 Equipment is cleaned and maintained to minimise the risk of transmitting a healthcare–associated infection
Theme 2: Safe Care and Support
Standard 3.1 Service providers integrate risk management practices into daily work routine to improve the prevention and control of healthcare-associated infections.
Standard 3.8 Services have a system in place to manage and control infection outbreaks in a timely and effective manner.

Appendix 5 — Infection prevention and control risk-based inspections during the pandemic in 2020. Compliance findings for 10 public acute hospitals

Compliant (C) Substantially Compliant (SC) Partially Compliant (PC) Non-compliant (NC)

Standard No.	Standard	University Hospital Waterford	Mayo University Hospital	Naas General Hospital	Letterkenny University Hospital	University Hospital Limerick	South Tipperary General Hospital	Midland Regional Hospital Mullingar	Wexford General Hospital	University Hospital Kerry	Tallaght University Hospital
5.3	Service providers have formalised governance arrangements in place to ensure the delivery of safe and effective infection prevention and control across the service.	SC	SC	NC	SC	C	PC	C	PC	SC	PC
6.1	Service providers plan, organise and manage their workforce to meet the services' infection prevention and control needs.	C	SC	SC	PC	SC	NC	SC	SC	NC	SC
2.6	Healthcare is provided in a clean and safe physical environment that minimises the risk of transmitting a healthcare-associated infection.	SC	NC	NC	PC	PC	PC	PC	NC	PC	NC
2.7	Equipment is cleaned and maintained to minimise the risk of transmitting a healthcare-associated infection.	C	C	C	PC	SC	C	SC	SC	SC	PC
3.1	Service providers integrate risk management practices into daily work routine to improve the prevention and control of healthcare-associated infections.	SC	C	SC	SC	C	SC	C	SC	C	SC
3.8	Services have a system in place to manage and control infection outbreaks in a timely and effective manner.	C	SC	NC	SC	PC	SC	SC	SC	SC	PC

Appendix 6 — *National Standards for Safer Better Healthcare* monitored by HIQA in rehabilitation and community inpatient healthcare services from 2019 to early 2020

Theme 5: 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.
Theme 1: Person-Centred Care and Support
Standard 1.1 The planning, design and delivery of services are informed by service users' identified needs and preferences.
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.

Appendix 7 — Key recommendations from HIQA's 2018 overview report on its medication safety monitoring programme in public acute hospitals

	Recommendations focused on improving medication safety at a national level
1.	At a national level, efforts to enhance learning from medication incidents and quality improvement initiatives should be put in place. This should include reviewing research in relation to medication safety, both nationally and internationally, to proactively address medication-related risks.
2.	Centralised arrangements should be put in place to ensure good practices that HIQA has reported through these series of inspections are shared.
3.	A national plan for the development of comprehensive clinical pharmacy services that sets out the desired model of care, and the appropriate resources to ensure consistency across hospitals should be developed.
4.	Develop a national approach to advance medication reconciliation to include defining responsibility for medication reconciliation and using electronic solutions to reduce time spent by clinical staff on medication reconciliation.
5.	Utilise information technologies such as ePrescribing, smart pump technology and decision support tools to reduce medication incidents and risks. At a national level, hospital groups should work together to commence the implementation of electronic solutions to improve medication safety.
	Recommendations focused on improving medication safety in hospitals
6.	Hospitals must have formalised governance structures with clear accountability and responsibility arrangements to support medication safety. This includes a functioning Drugs and Therapeutic Committee with clear terms of reference and membership to provide assurance that medication management systems are safe.
7.	The Drugs and Therapeutics Committee should have a clear strategic plan for improving medication safety outlining short-, medium- and long-term goals, with a supporting time-bound medication safety programme or plan.

8.	Hospitals should have a defined formulary process to outline medicines that are approved for use in the hospital, and provide information and standard guidance on the use of these medicines.
9.	Hospitals should build patient education requirements into the medication management process, based on services provided and their patient population, to ensure patients and or care givers are given the appropriate medicines-related information.
10.	Hospitals should provide clinical staff with easily accessible information and or policies, procedures, guidelines and or protocols to guide the safe use of medicines at the point of prescribing, preparation and administration.
11.	Hospitals should support a culture of reporting medication related incidents and near misses among all healthcare professionals. Data from medication incidents should be routinely analysed to identify trends or patterns in relation to risk and identify areas that require targeted improvement.
12.	Hospitals must ensure healthcare professionals have the necessary competencies to deliver high-quality medication safety through induction and ongoing training. This should include a structured, targeted programme of education for medication safety aligned with the hospitals' medication safety strategy.

Appendix 8 — Recommendations from the 2020 HIQA overview report in relation to medication safety in public acute hospitals

HIQA made a total of eight recommendations to be acted on at hospital-group level and or nationally by the HSE.

Theme	Opportunity for improvement
Leadership, governance and management	All hospitals must have a functioning drugs and therapeutic committee. These must have clear terms of reference, with appropriate membership and adequate attendance at meetings by all members to provide assurance on the safety of medication management systems. Hospitals should develop a medication safety strategy to clearly articulate the short-, medium-and long-term operational goals for medication safety.
Workforce	A national plan should be prepared for developing comprehensive clinical pharmacy services. The plan should set out the desired model of care and the appropriate resources to ensure consistency across hospitals.
Education and training	Hospitals must ensure healthcare professionals have the necessary competencies to deliver high-quality medication safety through induction and ongoing training. This should include a structured, targeted programme of education for medication safety aligned with each hospital's medication safety strategy.
Clinical pharmacy services	Hospitals should progress the provision of a clinical pharmacy service for all inpatients, and examine how best to allocate the resources currently available.
Medication reconciliation	Hospitals should work towards developing or expanding the medication reconciliation service for patients on admission to and discharge from hospital. A national approach is needed to advance medication reconciliation.
Defined formulary system	All hospitals should move towards developing a defined formulary system and provide information and guidance on the use of these medications. This work could be supported through collaboration with other hospitals within the hospital groups.
Procedural sedation	Opportunities for improvement were identified in relation to procedural sedation, in the following areas: ▪ oversight arrangements ▪ standardisation of practice across the hospital ▪ the requirements for training and supporting policies in line with international best practice and guidance.
Monitoring and evaluation	All hospitals should expand systematic monitoring arrangements through the use of additional metrics and performance indicators to monitor the effectiveness of medication safety processes. This is especially the case in relation to high-risk medications. The information gathered should be used to improve services, and the learning gained should be shared throughout the hospital, hospital group and, where relevant, with external organisations.

Appendix 9 — Facilities (n=33) that were inspected in 2019 and 2020 as part of HIQA's medical ionising radiation function

The service provider (the undertaking) with overall responsibility for these facilities is also listed.

Facility	Service provider (undertaking)
Year of inspection — 2019	
Beacon Hospital	Beacon Hospital Sandyford Limited
Blackrock Clinic	Blackrock Clinic
Clontarf Chiropractic	Owgar Ltd
Mercy University Hospital	Mercy University Hospital
Naas General Hospital	Health Service Executive
Our Lady of Lourdes Hospital, Drogheda	Health Service Executive
Year of inspection — 2020	
*3Dental (Dublin)	3Dental
Affidea Cork	Affidea Diagnostics Ireland Ltd
Aut Even Hospital LTD	Aut Even Hospital LTD
Bon Secours Diagnostic	Alliance Medical Diagnostic Imaging Ltd
Children's Health Ireland at Crumlin	Children's Health Ireland
*Clontarf Chiropractic	Owgar Ltd
Connolly Hospital	Health Service Executive
Cork University Hospital	Health Service Executive
Global Diagnostics (Navan)	Global Diagnostics Ireland
Gracefield Dental	Dr Jerome P Sullivan
Kilcreene Regional Orthopaedic Hospital, Kilkenny	Health Service Executive
Limerick Clinic	Galway Clinic Doughiska Ltd
Mallow General Hospital	Health Service Executive
Mater Misericordiae University Hospital	Mater Misericordiae University Hospital
Merlin Park Imaging Centre	Alliance Medical Diagnostic Imaging Ltd
Midland Regional Hospital Portlaoise	Health Service Executive
Nenagh Regional Hospital	Health Service Executive
Northbrook Clinic	Northbrook Healthcare Services Limited
Portiuncula University Hospital	Health Service Executive
Rdent	Dr Mamoon Rashid
Sligo University Hospital	Health Service Executive
Smiles Dental Wexford	Xeon Dental Services Limited
South Tipperary General Hospital	Health Service Executive
St Columcille's Hospital	Health Service Executive
St Vincent's Private Hospital	St Vincent's Private Hospital
Tallaght University Hospital	Tallaght University Hospital
University Hospital Limerick	Health Service Executive

*The findings of these inspections have not been included in the data presented in this review as the associated reports were not completed at the time of collating data for this review

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