Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulation of Health and Social Care Services

Overview report of five years of HIQA monitoring in Irish public acute hospitals against national standards: 2015–2019

August 2020

Safer Better Care

Overview report of five years of HIQA's monitoring in Irish public acute hospitals against national standards: 2015–2019

Health Information and Quality Authority

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 and Youth Affairs, 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

Welcome to our overview report, which outlines the work that the Health Information and Quality Authority (HIQA) has conducted in monitoring how publicly funded acute hospitals in Ireland have been working to meet selected national standards over the five years between 2015 and 2019.

As I write this message, Ireland and indeed the world, continues to grapple with the severe challenges posed by the COVID-19 pandemic. We truly are in unprecedented times. The virus has had a profound impact amongst those who have experienced it, the families that have lost loved ones, the health and social care system and indeed society at large.

Adhering to nationally mandated standards is a key aspect of ensuring that the health system has the required underlying capacity and capability needed to address these demands. Over the past decade and more, HIQA, on behalf of the State, has set national health and social care standards. In the healthcare setting, HIQA has monitored compliance in public acute hospitals against the *National Standards for Safer Better Healthcare*. Such standards aim to ensure consistent and high-quality care across the hospital system.

Quality improvement efforts by hospitals to meet these standards often takes significant time and sometimes, but not always requires, financial investment. In healthcare, HIQA has a mostly monitoring role rather than regulatory role. This means we inspect and publish our findings. We do not have powers of enforcement in healthcare, other than when regulating medical exposures to ionising radiation, such as X-ray or radiation therapy safety. However, where risk issues are identified, these are reported to either the HSE or to the Department of Health.

Despite these regulatory limitations, HIQA's monitoring work can and does act as a catalyst for significant improvement in our healthcare services. One such example

relates to the extensive body of work that HIQA have engaged in over many years in the area of infection prevention and control and antimicrobial stewardship, as outlined in Chapter 4 of this report. Since 2015, a continued focus on this area by HIQA has seen a steady improvement within the acute hospital system's long-term ability to sustainably address this area of risk.

There is still further scope for improvement in many hospitals. Nonetheless, their efforts and the resources used to meet the national standards have helped to organise local infection prevention and control efforts, when faced with the current pandemic. They have also helped to ensure that necessary expertise in the areas of antimicrobial stewardship (such as the prudent use of antibiotics) have been present in each acute hospital, albeit at limited levels in some cases.

Furthermore, HIQA's role in promoting standards and high-quality care for patients needs to run alongside the work of other similar bodies, State agencies, healthcare providers and the professionals that work in those settings. Indeed the role of a systems regulator, such as HIQA, acts as a third line of defence for the public. The professionalism and the practice of staff on the ground and the local governance arrangements and structures that each hospital uses to oversee such practice, act as earlier barriers to potential harm for patients.

The following report has taken a five-year view of the thematic monitoring work HIQA has done in Ireland's public acute hospitals, as it is over such a time frame that the impact of this work and the reciprocal actions that it incentivises can be best observed. Over this time period, HIQA has prioritised the focus of a relatively limited inspectorate staffing complement in this area towards a number of key patient safety risks. These have included:

- infection prevention and control and antimicrobial stewardship
- medication safety
- patient nutrition and hydration, and
- maternity services.

More recently, HIQA has also expanded its focus to explore the application of selected key national standards in Ireland's rehabilitation and community inpatient healthcare services. Furthermore, and in accordance with European legislation, HIQA has assumed responsibilities for the regulation of medical exposures to ionising radiation such as X-rays and radiation therapy.

This report aims to describe the journey that both HIQA, and those that have been inspected under these programmes, have covered over the past five years to

improve levels of compliance against the national standards in these key patient safety areas. The report also outlines key remaining areas of care where ongoing improvement to better protect patients continue to be required. Before COVID-19 emerged, the structure of the public healthcare system was already at a crossroads about its future direction. The Sláintecare reform plans, allied to the potential impact of planned legislation such as the Patient Safety (Notifiable Incidents) and Patient Safety (Licensing) Bill, were already likely to result in significant changes to how healthcare is provided, if fully implemented.

Proposed legal changes will also see a major change and expansion to HIQA's role. This will not only lead to HIQA monitoring in private hospitals in the first instance, similar to our existing role in public acute hospitals, but will also be followed by formal regulation and enforcement powers in all healthcare services, both public and private.

COVID-19 looks set to present significant challenges for the health service for many months if not years 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 which complies with nationally mandated standards is in place to meet the totality of healthcare needs of the population into the future.

We will apply our experiences and expertise to seek to advance patient quality and safety at a time of considerable challenge for the Irish healthcare system. In doing so, we commit to working closely and openly with all other contributors to these national efforts, whether they are people using services, healthcare providers, professionals, policy makers or other regulators.

Mary Dunnion
Director of Regulation
Health Information and Quality Authority

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Chapter 1. Introduction

1.0 Introduction to this report

This report reviews HIQA's monitoring activity in healthcare services in Ireland over the past five years. It describes HIQA's function in setting national standards for public hospitals and other services funded and provided by the Health Service Executive (HSE) and monitoring compliance with those standards. It describes the four defined monitoring programmes completed over the five years in Ireland's public acute hospitals, in the areas of infection prevention and control, medication safety, maternity services, and nutrition and hydration.

This overview report presents key findings, examples of good practice and opportunities for improvement identified during HIQA's monitoring activity. It also describes the two new monitoring programmes which started in 2019 in the areas of rehabilitation and community inpatient healthcare services, and medical exposure to ionising radiation.

1.1 Healthcare services monitored by HIQA

Over the past five years, HIQA's work in public acute hospitals, and more recently certain services delivered in non-acute rehabilitation and community hospitals, occurred within the context of these services continuing to plan for and implement reform and restructuring programmes across the healthcare sector. These changes are aligned with key policies set out by the Department of Health, key among them being Sláintecare,[1] the National Trauma Strategy[2] and the National Maternity Strategy.[3,4]

The vision of the health system set out in these policies, especially in Sláintecare will, if realised, have a significant impact on the future design and provision of healthcare services across Ireland. Sláintecare aims to create a universal, single-tier health system with patients accessing treatment on the basis of need and with services and care being predominantly provided in the community.

Other events also impacted on the planning and provision of healthcare services over the last five years. Key among them being the Carbapenemase Producing Enterobacteriaceae (CPE) public health emergency,[5*] involving an emerging 'superbug' in Irish hospitals which is highly resistant to treatment. We believe our work in this regard has helped secure increased investment and expansion of health

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[*] Ireland's National Action Plan on Antimicrobial Resistance (2017-2020), was jointly published in October 2017 by the Department of Health and the Department of Agriculture, Food & the Marine.

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service capacity, to improve antimicrobial use, stewardship and infection prevention and control practices.

More recently, and similar to healthcare systems worldwide, the COVID-19 pandemic has presented unprecedented challenges for healthcare services in Ireland. The most fundamental of these has been the need to repurpose and scale up capacity to manage the surge of COVID-19 cases in Ireland between March and April 2020.

Planned reforms such as those envisaged within will take time, but it is noteworthy in acknowledging this need for reform as envisaged by Sláintecare, that clinical outcome-measures, such as mortality rates related to respiratory and heart conditions, in Ireland often compare positively to other European countries.[6]

In addition, service users who responded to the 2018 National Patient Experience Survey and the 2019 National Inpatient Experience Survey were generally satisfied with the care provided in the public acute hospitals. The majority (80%) of respondents reported good or very good experiences of the services provided.[7] As healthcare services continue to be reformed and restructured, the focus must remain on the quality and safety of services provided. HIQA, in the performance of its role and function, can significantly contribute to this.

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Chapter 2. How we monitor and regulate healthcare and maternity services

2.0 HIQA's role and function – monitoring against national standards and regulations

Since being established in 2007, HIQA has regulated and monitored certain health and social care services across Ireland. HIQA's current healthcare functions are set out in Section 8 (1)(b) and (c) of the Health Act 2007 (as amended).[8] HIQA sets national standards and monitors compliance with those standards in healthcare services provided or funded by the Health Service Executive (HSE), such as small and large hospitals.

In 2019, HIQA began regulating medical exposure to ionising radiation across public and private healthcare and dental services. Prior to this, HIQA did not have a legal remit to regulate or monitor healthcare services in the private sector or dental services. Through monitoring and regulation, HIQA assists health and social care providers to promote quality improvement in order to help ensure the provision of safe, quality services.

In keeping with Section 8(1)(b) of the Health Act 2007 (as amended) (referred to in this report as 'the Act'), HIQA sets standards on the safety and quality for services provided by HSE or a service provider in line with the Health Acts 1947 to 2007, Child Care Acts 1991 and 2001, the Children Act 2001 and nursing home services as defined in Section 2 of the Health (Nursing Homes) Act 1990.

Under Section 8(1)(c) of the Act, HIQA monitors compliance with national standards, and advises the Minister for Health and the HSE about the level of compliance of service providers with these standards. The monitoring of compliance with national standards is completed by authorised persons, under Section 70(1)(a) of the Act. While standards set by HIQA are not statutory, they are approved by the Minister of Health and services are expected to meet them.

HIQA standards do not apply to mental healthcare services, and HIQA does not monitor or regulate mental healthcare services (these services are regulated by the Mental Health Commission). Furthermore, HIQA's remit does not include the regulation of individual healthcare staff, such as doctors, nurses and other health and social care professionals. These professionals are regulated through their relevant professional regulators.

2.1   Regulations governing the use of medical exposure to ionising radiation

On foot of new legislation,[†] HIQA's role in healthcare was extended in 2019 to include the regulation of medical exposure to ionising radiation.[‡] The new regulations define the minimum safety requirements to protect people from the hazards associated with procedures such as X-rays and radiation therapy.[9,10] They apply to radiotherapy, nuclear medicine and dentistry facilities across the public and private sectors in the Republic of Ireland.

This extension to HIQA's role and function was significant. Up to then, HIQA's role in healthcare was to set and monitor compliance against national standards across public healthcare services provided or funded by the HSE, but HIQA did not have enforcement powers to address issues of non-compliance in healthcare nor did it have a remit in the private healthcare sector or dental sector.

The new legislation gave HIQA enforcement powers when regulating in this area, and for the first time extended its remit into the private sector.

2.2   Monitoring of healthcare services to improve quality and safety

It is well recognised that the setting, implementation and the continuous monitoring of compliance with national standards improves the quality and safety of care.[11,12,13] National standards set public, provider and professional expectations and enable services to improve the quality of care provided, and to safeguard people using their services. Table 1 on the following page details the national standards developed and published on HIQA's website: www.hiqa.ie.

[†] 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.

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Table 1. National Standards published by HIQA relevant to health and community services

National Standards published by HIQA relevant to health and community services	
2009	*National Standards for the Prevention and Control of Healthcare-Associated Infections*[14]
2012	*National Standards for Safer Better Healthcare*[15]
2016	*National Standards for Safer Better Maternity Services*[16]
2017	*National Standards for the Prevention and Control of Healthcare-Associated Infections in Acute Hospital Services*[17]
2017	*National Standards for the Conduct of Reviews of Patient Safety Incidents*[18]
2018	*National Standards for Infection Prevention and Control in Community Services*[19]

2.3 Thematic monitoring programmes conducted in the last five years

In the five years from 2015 to 2019, HIQA's monitoring activity was prioritised on the basis of internationally recognised areas of patient safety risk. HIQA's monitoring activity focused on four thematic areas (see Figure 1).

Figure 1. HIQA's thematic monitoring programmes completed 2015-2019
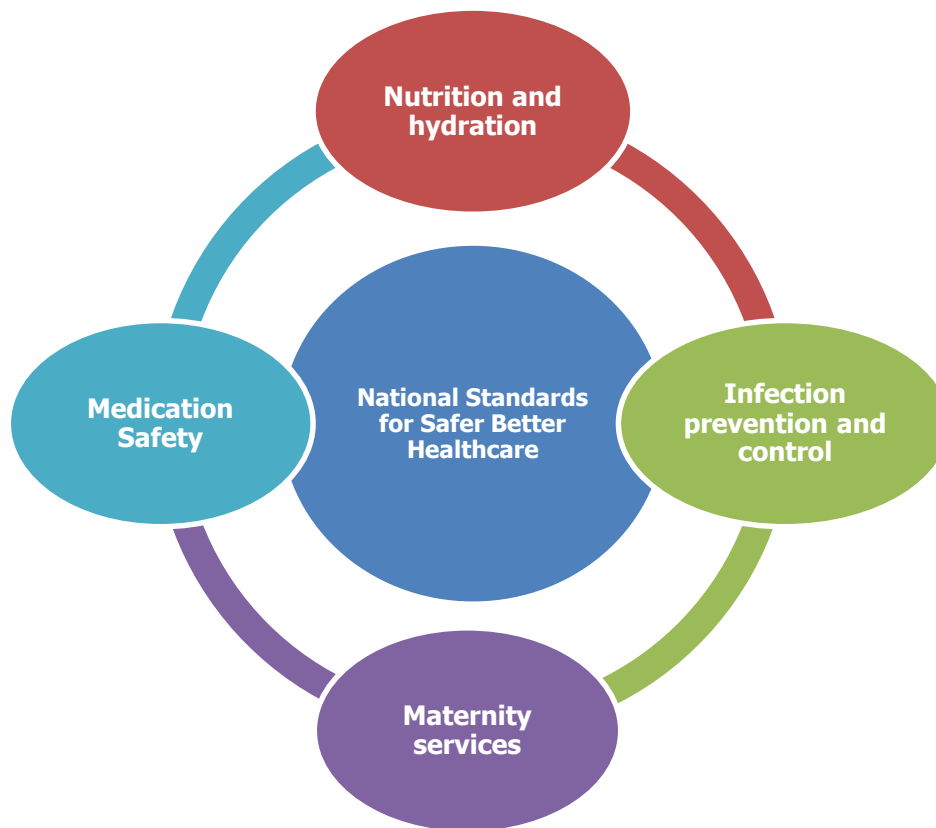
Of these thematic areas, both infection prevention and control and medication safety are well recognised as major causes of unintentional adverse harm to patients.[20,21] In late 2019, HIQA started two additional programmes of monitoring in the areas of rehabilitation and community inpatient healthcare services and medical exposure to ionising radiation in public and private healthcare and dental services.

2.3.1 Engaging with interested parties

Engagement with providers, funders of services and other interested parties was an important element of HIQA's monitoring and regulation activity over the last five years. HIQA listens to and meets with interested parties through focus groups, setting up advisory groups and expert groups, and meeting or consulting with patients with experience of healthcare services. The views and feedback of people using services were and are essential in helping to inform, develop and prepare HIQA's monitoring programmes for healthcare services.

The methodology used for each programme was informed by international research, national guidelines and best practice.[22,23,24,25,26,27,28,29,30] Each programme had specific

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lines of enquiry§ setting out how inspectors monitored healthcare services against the relevant national standards and what was expected of services. Each monitoring programme had its own assessment and judgment framework that guided inspectors when determining compliance with national standards.

Service providers also used the assessment and judgment framework to self-assess their services' compliance with national standards. Overall, findings from the monitoring programmes provided a degree of assurance that hospitals were implementing nationally mandated standards and were making the necessary quality and safety improvements to safeguard patients. Further information on the methodology used in each programme can be found in the guidance documents developed for each of them, which are available on HIQA's website, www.hiqa.ie.

2.3.2   The inspection process

Each monitoring programme included on-site inspections in the services. Through this process, inspectors assessed the governance arrangements, capacity and capability and structures and processes in place to ensure the provision of safe, high-quality care. Announced or unannounced on-site inspections were conducted over a one- or two-day period with a team of inspectors. Before and after the on-site inspections, inspectors also reviewed information that was submitted by healthcare providers.

Announced inspections

Healthcare providers were provided with two weeks' advance notice of a planned announced inspection. The aim was to ensure that key personnel were available to meet with inspectors. Providers were required to submit certain information and documentation to HIQA, such as the minutes of relevant meetings, so that inspectors could review these before the on-site inspection.

Unannounced inspections

In these inspections, healthcare providers were not given advance notice, formally or informally, of a planned inspection of the service. The inspectors arrived at the service on the day of inspection and an on-site inspection was conducted. Relevant information and documentation was reviewed after the on-site inspection had been carried out.

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

2.3.3   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, 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, who are ultimately responsible for the quality and safety of the service they provide, and or hospital group and the HSE as required. All inspection reports are published on the HIQA website, www.hiqa.ie.

2.4   Planned legislative changes impacting on the regulation of health services

HIQA's role and function in the monitoring of healthcare services would be significantly expanded[31] with the enactment of two distinct pieces of draft legislation, the Patient Safety (Notifiable Incidents) Bill, and the Patient Safety (Licensing) Bill.

2.4.1   Patient Safety (Notifiable Incidents) Bill

In July 2018, the previous government approved a general scheme of a Patient Safety (Notifiable Incidents) Bill, which was then referred to the Oireachtas Health Committee for consideration. If enacted into law, the Bill would provide for the mandatory open disclosure of serious reportable patient safety incidents to those who have been harmed by them. The Bill would also provide for these reportable incidents to be notified to HIQA and would extend HIQA's monitoring remit in healthcare into the private sector.

2.4.2   Patient Safety (Licensing) Bill

Changes to how healthcare in Ireland is regulated have also been proposed in the Patient Safety (Licensing) Bill, which would also see a significant change in HIQA's role and function. The 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. Currently, HIQA monitors compliance with nationally mandated standards under defined programmes across the 49 public acute hospitals and 23 public rehabilitation and community inpatient healthcare services.

The Patient Safety (Licensing) Bill would assign HIQA with responsibility for (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. The Bill was approved by the previous government in 2017 and was referred to the Oireachtas

Joint Committee on Health in 2018. In the interim, HIQA continues to prepare for the possible extension to its role and function as proposed in both bills.

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Chapter 3. Profile of healthcare services monitored and regulated in the last five years

3.0   Introduction

The Department of Health is the government department that is responsible for the delivery of health and social care services in Ireland. The Department develops policy, provides governance and performance oversight for the health service, and promotes government policies on health and social care. Operationally, the Health Service Executive (HSE) is responsible for managing and delivering health and social care services in Ireland. The HSE is accountable to a governing board, which was re-established[**] in June 2019 following earlier reforms and now comprises 11 members. The Board of the HSE is accountable to the Minister of Health. A description of how healthcare services in Ireland are set out in Ireland is outlined in the following sections.

Hospital services

Healthcare services in Ireland are categorised as acute and non-acute care services. Acute healthcare services are provided across 49 public acute and 19 private hospitals. The 49 public acute hospitals are organised across seven hospital groups (see Appendix 1) and they provide a range of acute services.[††] Each hospital group is led by a Group Chief Executive Officer who is accountable for the performance of their hospital group and reports to the HSE's National Director of Acute Operations.

Other healthcare services

Non-acute HSE services are provided through nine community healthcare organisations (CHOs) (see Appendix 2). These community healthcare organisations support the provision of integrated care within community healthcare services and between community and acute hospital services.[‡‡] Each community healthcare organisation is led by a Chief Officer who reports to the four national HSE directors that are assigned responsibility for social care, primary care, health and wellbeing, and mental health.

In 2019, HIQA began a programme of monitoring across 23 rehabilitation and community inpatient healthcare services. Five of these services were under the

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[**] The previous HSE board was abolished in 2011 under reforms introduced by the then Minister for Health.

[††] These services include inpatient services, outpatient services, maternity services, urgent and emergency care and 11 local injury units in Ireland. These local injury units treat individuals with minor injuries such as broken bones, dislocations, sprains, strains, scalds and minor burns that are unlikely to need admission to hospital.

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

governance of an acute hospital, with the remaining 18 being either stand-alone voluntary services,[§§] or under the governance of a local community healthcare organisation.

Monitoring against national standards

Over the last five years, HIQA has monitored compliance with the following national standards under its thematic monitoring programmes across the acute and, more recently, non-acute healthcare sectors:

- *National Standards for Safer Better Healthcare* across the 49 acute healthcare services under the themes of:
  — nutrition and hydration
  — medication safety
- *National Standards for the Prevention and Control of Healthcare-Associated infections in Acute Hospital Settings* across the 49 acute healthcare services under the theme of infection prevention and control
- *National Standards for Safer Better Maternity Services* across the 19 maternity hospitals and units
- *National Standards for Safer Better Healthcare* across five of the 23 rehabilitation and community inpatient healthcare services.

HIQA inspection activity in healthcare

Up to the end of March 2020, HIQA had completed 265 on-site inspections under the different thematic monitoring programmes since 2015. Table 2 on the following page details the breakdown of the total number of on-site inspections completed in the five years from 2015 to 2019 in each thematic monitoring programme.

These inspections involve weeks of preparation, with teams of inspectors spending one or more days on site in hospitals. Follow-up may continue for some time after the on-site inspection. The infection prevention and control inspections are classified as a single programme with two distinct areas of focus, infection prevention and control and reprocessing reusable medical devices. Furthermore, in 2015 and 2016 HIQA also conducted a programme of national monitoring in the area of antimicrobial stewardship, which included inspections in a sample of hospitals, allied to interview with persons with relevant national responsibilities within the HSE.

[§§] Voluntary services refer to services that are independently owned and governed, not-for-profit organisations that operates in line with its mandate. The Health Service Executive fund voluntary organisations that provide health and social care services on its behalf. These arrangements are defined in sections 38 and 39 of the Health Act 2004 (as amended).

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Table 2. Number of thematic inspections conducted by HIQA, 2015–2019

Thematic monitoring programme	Nationals standards	Number of on-site inspections conducted
Nutrition and hydration	*National Standards for Safer Better Healthcare (2012)*	13
Infection prevention and control	*National Standards for the Prevention and Control of Healthcare-Associated Infections (2009) and National Standards for the Prevention and Control of Healthcare-Associated Infections in Acute Hospital Services (2017)*	161
Medication safety	*National Standards for Safer Better Healthcare (2012)*	64
Maternity services	*National Standards for Safer Better Maternity Services (2016)*	22
Rehabilitation and community inpatient healthcare services	*National Standards for Safer Better Healthcare (2012)*	5

3.1 Profile of regulated services providing medical exposure to ionising radiation

In January 2019, HIQA became the 'Competent Authority' in Ireland with responsibility for regulating practices related to medical exposure to ionising radiation. From that date, the responsible person or body (other than an employee),[***] who carries out or who engages others to carry out any procedure giving rise to such exposure,[†††] must comply with specific statutory responsibilities set out in the regulations for protecting patients in such cases. HIQA designed a programme of monitoring and began monitoring activity in this area in late 2019.

All service providers conducting medical radiological procedures were required to declare themselves to HIQA. By the end of 2019, a total of 1,128 responsible persons or bodies (termed 'undertakings') with responsibility for 1,660 facilities (such

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[***] In the regulations '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 procedure or the practical aspects of a medical radiological procedure' is defined as an undertaking.

[†††] This includes radiodiagnostic, radiotherapeutic, interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes.

as hospitals and dental practices) where such procedures were conducted[‡‡‡] had declared to HIQA. Table 3 details the number of medical radiological procedures by type declared. In future, new service providers will also be required to declare to HIQA one month before starting medical radiological procedures.

Table 3. Number of active medical radiological installations by type declared to HIQA

Type of installation	Total declared facilities
General radiography[§§§] only (including DXA)[****]	61
Radiology services (including interventional radiology, computed tomography and so on but excluding radiotherapy)	87
Radiotherapy	12
General dental radiography only	1,443
Dental radiography, including complex computed tomography	57
Total types of medical radiological installations	**1,660**

The key findings from the four defined monitoring programmes in the area of infection prevention and control, medication safety, maternity services and nutrition and hydration are set out in the following chapters.

[‡‡‡] In the regulations, the facilities where medical radiological procedures are carried out are referred to as medical radiological installations.

[§§§] Radiography or radiographs are often referred to as X-rays. These are two-dimensional images obtained to identify disease or injury.

[****] DXA or DEXA means Dual-energy X-ray absorptiometry which is a type of medical exposure used to assess bone density in patients where low bone density or osteoporosis is suspected.

Chapter 4. Infection prevention and control monitoring programme

4.0   Introduction

Preventing and controlling healthcare-associated infections can be a significant challenge for healthcare systems, but as the COVID-19 pandemic has demonstrated, it is of critical importance that hospitals effectively address this challenge. Effective structures, processes and systems to manage potential risk from the environment and activities within hospitals can prevent a substantial proportion of healthcare-associated infections.

Healthcare-associated infections have a significant effect on patients and their families, causing distress and anxiety, serious illness, long-term disability and in some instances death. The cost associated with these infections can significantly impact on services. Over the past number of years, there has been a concerted effort to build and scale up infection prevention and control capacity and capability across the 49 public acute hospitals in Ireland. This has been informed and aided by:

- the publication and mandating by the Minister for Health of national standards in the area of infection prevention and control

- monitoring compliance with those standards by HIQA

- publication of findings from the monitoring programmes

- improved resourcing of services.

HIQA has monitored compliance against the *National Standards for the Prevention and Control of Healthcare-Associated Infections in Acute Hospital Services* over many years. These standards promote improved practice in the area of infection prevention and control, and in the best usage of antimicrobial agents (such as antibiotics) through antimicrobial stewardship. In the five-year period under review, HIQA's monitoring programme focused on specific areas, including antimicrobial stewardship (see Appendix 3).[32]

Over the course of HIQA's work, the infection prevention and control capacity and capability in these hospitals has in general been enhanced, which HIQA believes has resulted in a baseline level of resourcing and expertise that, in general, has enabled them to be more responsive in preventing and controlling infection. Nonetheless, despite this, variation and discrepancies across different settings and hospitals have persisted. Some hospitals continue to be less resourced than others and the resourcing of infection prevention and control in community settings have, despite some recent enhancements, continued to lag behind the acute healthcare setting.

By way of context, the following section presents a brief description of the
chronology of HIQA's programme of monitoring in infection prevention and control
from 2015 to the present day. The composite findings from the monitoring activity
are presented after this section. These findings provided some assurance of services'
capacity and capability to deliver safe, effective and sustainable infection prevention
control practices across the public acute hospital sector.

4.1 Background and context

In the five-year period under review, HIQA has completed 161 unannounced on-site
inspections dealing with infection prevention and control across the 49 public acute
hospitals. HIQA's approach to monitoring has evolved year on year, with
modifications made to the programme in response to findings from the inspection
process, feedback from service providers, engagement with interested parties,
changes and challenges faced within the health service, best available evidence and
revised national standards.

Summary of 2015 activity

In 2015, HIQA's Healthcare Team focused on monitoring compliance with 12
national standards for the prevention and control of healthcare-associated infections.
The programme focused on four key areas, as follows:

- the use of hand hygiene practices

- the hospital environment

- the effective use of infection prevention care bundles[††††] to reduce infection
  related to invasive medical devices, and

- the use of antibiotics through effective antimicrobial stewardship.

The findings were a reference point for each service's capacity and capability to
deliver a safe and effective regime of infection prevention and control. HIQA's
monitoring activity in 2015 identified high risks concerning the effective cleaning,
decontamination and reprocessing of reusable invasive medical devices.[‡‡‡‡] Where
such devices are not effectively decontaminated, the risk of transmission of infection
between patients was significantly increased.[33,34,35] This informed the direction and

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[††††] Care bundles are a set of evidence-based actions that when applied consistently to specific activities during
routine patient care have been shown to improve patient safety.

[‡‡‡‡] A reusable invasive medical device is an object which is used for diagnostic or therapeutic purposes and
which penetrates or breaks the skin or a body cavity.

focus of HIQA's subsequent monitoring activity in the area of infection prevention and control.

Summary of 2016 activity

During 2016, HIQA continued to monitor compliance with the *National Standards for the Prevention and Control of Healthcare-Associated Infections*. This work focused on the physical environment and facilities, hand hygiene and invasive medical device-related infections. HIQA also separately reviewed antimicrobial stewardship across public acute hospitals, with a report on its findings being published in 2016.[36] Resistance to antimicrobials is a major global healthcare challenge and represents an existential threat to healthcare provision as currently provided.[37]

This review examined how resistance to antimicrobials and other related risks were being managed across the public acute hospitals and at national HSE level, including governance arrangements within hospitals and the level of investment and resourcing of hospitals. The review identified the following core findings:

- The national approach to leadership, governance and management of this key patient safety threat was unclear and ill-defined within the HSE. This hindered national coordination, oversight and planning efforts.

- Best practice in managing and using antimicrobials varied across the country.

- Larger academic teaching hospitals performed better than smaller hospitals.

- Several hospitals (mid-sized, model 3 hospitals[§§§§]) required further investment and or sharing of resources across their respective hospital groups; to implement sustainable measures such as an antimicrobial stewardship programme.

- A number of smaller hospitals (model 2 hospitals[*****]) had no antimicrobial stewardship programmes in place. These hospitals required significant investment and or resourcing to implement such a programme.

- The provision of antimicrobial stewardship and infection prevention and control in non-acute settings required significant enhancement and integration within existing services.

[§§§§] Model 3 hospitals have 24/7 Emergency Departments, acute surgery, acute medicine and critical care. Model 4 hospitals have all of the aforementioned services plus specialist, supra-regional care.
[*****] Model 2 hospitals provide some acute medical care in-patient and out-patient care for differentiated, low-risk medical patients, who are not likely to require full resuscitation.

- The level of screening for multi-drug resistant organisms across hospitals was not in line with national guidelines.[38]

Despite these findings, HIQA was assured that antimicrobial stewardship across hospitals was being monitored. Systems were in place to monitor antimicrobial prescribing, and to compare Ireland's antimicrobial resistance rates for serious infections with other European countries. The risk of resistance to antimicrobials is as much of a threat today as it was five years ago and this existential risk prevails across the healthcare setting.[36] Curtailment of the emergence and spread of multi-drug resistant organisms is possible, through the implementation of good infection prevention and control practices and prudent and effective use of effective antimicrobial agents.

Summary of 2017 activity

In 2017, HIQA published the revised *National Standards for the Prevention and Control of Healthcare-Associated Infections in Acute Healthcare Services*. In this revised version, the number of standards increased from 12 to 29 and specific standards were strengthened, including those relating to communication with patients, local, regional and national governance structures and workforce training. HIQA's programme of monitoring was revised to take account of the revised standards.

The monitoring activity during 2017 specifically focused on the systems to detect, prevent, and manage multi-drug resistant micro-organisms. Late in 2017, on foot of concerns raised by HIQA regarding the increasing rates of antimicrobial resistance and Carbapenemase Producing Enterobacteriaceae (CPE) in Irish public acute hospitals, the Minister for Health declared CPE to be a national public health emergency. Measures implemented in response included the activation of a public health emergency plan and the convening of a national public health emergency team.

HIQA believed this response to be proportionate and necessary to fully address an increasing incidence of CPE. The CPE emergency saw enhanced investment and resourcing of infection prevention and control measures across public acute hospitals. More significantly, national leadership and the governance of infection prevention and control across the healthcare sector improved, and this was aided by the establishment and implementation of a national Antimicrobial Resistance and Infection Control (AMRIC) team.[†††††]

[†††††] The national Antimicrobial Resistance and Infection Control team was established by the HSE in May 2017 in response to the CPE public health emergency. It focuses on the control of healthcare-associated infections and antimicrobial resistance across all services in healthcare.

Activity in 2018 and 2019

In the following two years (2018-19), HIQA continued to monitor compliance with national standards in the area of infection prevention and control. The monitoring activity focused specifically on (1) the structures, processes and systems in place to detect, prevent and respond to multi-drug resistant bacteria, (2) compliance with national guidance around screening for colonisation with CPE[39] and (3) the approach taken by hospitals to reduce the risk of infections related to reusable invasive medical devices.

4.2 Key findings from the infection prevention and control monitoring programme

HIQA's work in the area of infection prevention and control provided assurance that the majority of hospitals and hospital groups had the necessary structures, systems and processes to prevent, control and manage an outbreak of CPE. Over the course of HIQA's monitoring programme, improvements in both the overarching governance and the degree of implementation of national standards across hospitals increased. The essential elements needed for the prevention and control of infection were enhanced in the majority of hospitals. However, some inherent weaknesses, mainly related to capacity and capability, were identified in a small number of hospitals. The key findings of HIQA's monitoring activity are presented below.

4.2.1 Capacity and capability findings

A hospital's capacity and capability to deliver safe and effective infection prevention and control practices across its services depends on the hospital having the appropriate complement of specialised staff in place who work as a team, and effective governance and leadership from senior management. Other essential elements include a support framework which comprises sufficient laboratory facilities, information and communication technology, surveillance processes and adequate clinical pharmacy resources.

Governance, leadership and management

The national standards set out baseline standards for the governance and management of infection prevention and control, including antimicrobial stewardship, in the health and social care system in Ireland. Over the five-year review period, monitoring compliance against these national standards provided an insight into the governance in place, including multidisciplinary and interdepartmental cooperation and coordination, across public acute hospitals.

The majority of hospitals inspected by HIQA had appropriate governance and management arrangements in place for the prevention and control of healthcare-associated infections. In most cases, there were clear lines of accountability and responsibility. However, a small number of hospitals did not have appropriate governance arrangements in place. HIQA escalated its concerns in this regard to hospital management, the hospital group and the national HSE, as required.

Assurances provided by these parties to HIQA after the inspection process indicated that deficiencies in governance arrangements were being addressed. These corrective measures, however, needed to be sustained for sufficient governance of infection prevention and control to be realised across hospitals. HIQA found that the practice of cooperation and collaboration in the area of infection prevention and control was less well developed at hospital group level.

Hospitals that had successfully implemented an infection prevention and control programme were compliant with the national standards, but HIQA found variation in the level of compliance across hospitals. Key elements of an effective infection prevention and control programme included:

- the provision of advice and expertise
- conduct of clinical interventions
- surveillance[‡‡‡‡‡] activities appropriate to the level of risk in the service
- effective quality improvements to address risk in a timely and effective way.

At national HSE level, leadership and governance in relation to antimicrobial resistance and CPE was strengthened with the establishment of the national Antimicrobial Resistance and Infection Control (AMRIC) team.

Workforce, specialist workforce and staff training

Over the past two decades, there has been a significant scaling up in the appointment of specialised staff[§§§§§] to implement antimicrobial stewardship and infection prevention and control measures across the 49 public acute hospitals. This scaling up happened mainly in response to the CPE emergency and more recently to the COVID-19 public health emergency. Specialist staff in some hospital groups

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[‡‡‡‡‡] The ongoing systematic collection, collation, analysis and interpretation of data; and the sharing of information to those who need to know in order that action may be taken.
[§§§§§] Specialist infection treatment, prevention and control staffing includes Medical Microbiology Consultants and NCHDs, Infectious Diseases Consultants and NCHDs, Infection Prevention and Control Nurses, Surveillance Scientists and Antimicrobial Pharmacists. It is acknowledged that efforts in hospitals extends beyond this cohort of specialist staff, however, for comparative purposes a focus on these staff has been prioritised.

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increased by as much as 30%[******] and 40%.[††††††] However, the level of investment varied across hospitals. Specialised staffing levels in some hospitals remained static over the five years in response to ever increasing demands.[‡‡‡‡‡‡]

Microbiology services

All hospitals inspected had a microbiology service in place to support the prevention and control of healthcare-associated infections. This was a welcome finding and meant patients were being provided with an essential level of protection against such infections. However, while all hospitals had 24/7 access to a medical microbiologist and or infectious diseases expertise, for advice on treatment or infection control, the number of both specialties varied across hospitals.[§§§§§§]

Many smaller hospitals relied on limited consultant microbiology resources. In 2019, in over one in three hospitals, a sole microbiologist was employed (with no complementary infectious diseases service), while in other hospitals the microbiologists worked on a sessional basis.[*******] Such a situation placed these services, for patients and staff, in a potentially precarious position, for example, should post-holders become ill or go on leave.

While the sharing of resources and expertise is commendable, especially across hospital groups, the practicality and sustainability of having one microbiologist providing a 24/7 service in smaller hospitals requires urgent review by hospital groups and the national HSE.

Reusable invasive medical devices

In relation to reusable invasive medical devices, a decontamination lead or coordinator was assigned in some but not all hospitals inspected. During the inspections, all hospitals had assigned an authorised engineer for decontamination who provided oversight and subject matter expertise. This was a welcome finding for patients, and demonstrated the deployment of appropriate expertise. Support was also provided to hospitals by three HSE national leads in the area of decontamination. However, dedicated operatives were not always engaged in the

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[******] Saolta Health Care Group.
[††††††] The RCSI Hospital Group.
[‡‡‡‡‡‡] The University of Limerick Hospital Group.
[§§§§§§] Tullamore, Mullingar, Letterkenny, Naas, Ballinasloe (Portiuncula), Wexford and Kerry.
[*******] A sessional worker is defined as a person not employed under a contract of employment. He/she is paid for undertaking work or a service on the basis of an agreed range of hours to be worked. This is within a specified period, or on an ad-hoc arrangement to meet varying need.

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reprocessing of some invasive devices, such as ear, nose and throat (ENT) endoscopes[±] in satellite decontamination facilities.[#] This was a worrying finding.

The availability of support and expertise from such experts, both inside and outside the organisation, is important to promote and protect the quality and safety of services. Services need sufficient internal expertise in such a specialist area to comply with national standards and for recommended practices to be achieved.

Education and training

Since HIQA's monitoring programme for infection prevention and control began, there has been a concerted effort in hospitals to improve education and training in infection prevention and control, and standard transmission-based precautions, especially hand hygiene. Such education and training was mandatory in many hospitals and was included in structured, formalised staff induction programmes. Staff were also required to attend refresher training regularly. These were encouraging findings and provided assurance to HIQA that key skills and knowledge in infection prevention and control practices were being promoted amongst staff.

Academic training for staff working in centralised decontamination facilities was progressed in line with HSE recommendations. Staff working in satellite decontamination facilities were required to complete an e-learning module in decontamination on the HSELand platform and or the manufacturers' specific training. These were welcome findings, and demonstrated an awareness of the need for reflection on skills and practice, with patients ultimately benefiting.

Hand hygiene

There was evidence seen over the five-year period of a concentrated focus to improve hand hygiene culture and compliance across all hospitals. While a welcome finding, it is critically important that all hospitals continue to achieve high levels of performance in hand hygiene and to ensure compliance with national standards. This is particularly crucial given the gravity of the threat posed to healthcare services by antimicrobial resistance, and more recently COVID-19.

Risk management structures

Hospitals had systems in place to identify and manage risks in relation to the prevention and control of healthcare-associated infections and decontamination facilities. There was evidence of risks identified in clinical areas being addressed at

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[±] An endoscope is an illuminated instrument used to look deep into the body and are used in procedures called an endoscopy.

[#] Decontamination facilities refers to the physical infrastructure where decontamination of reusable medical devices is provided.

local, directorate and or senior management level, as required. High risks were
escalated in line with HSE policy to the hospital group and or HSE.[40] Staff are to be
commended for their efforts to promote a culture of safety.

4.2.2   Quality and safety findings

While there was evidence of committed hospital staff striving to ensure the safety of
patients, compliance with national standards within the dimensions of quality and
safety varied greatly across the 49 public acute hospitals. A number of factors
hindered the full implementation of effective infection prevention and control
practices and the level of compliance with national standards. These factors
included:

- a lack of clarity about the requirements for routine assessment and
  screening for multi-drug resistant organisms, such as CPE

- an absence of dedicated software to aid surveillance of infections in most
  hospitals

- inconsistent application of transmission-based precautions in some
  hospitals

- inappropriate design and insufficient maintenance of infrastructure and the
  physical environment in hospitals

- the sometimes unsystematic implementation of surgical-site infection
  surveillance in some hospitals.

Carbapenemase Producing Enterobacteriaceae (CPE) screening

A worrying finding over the five-year period was the inconsistency in the
implementation of the HSE's national CPE screening guideline across hospitals. For
example, in 2018, over half of the hospitals inspected were not fully compliant with
the HSE's guideline. This meant that proactive infection control strategies were not
implemented in a timely manner to prevent CPE outbreaks. CPE is an extremely
difficult healthcare-associated infection to treat, as it is resistant to many antibiotics.

At the time, HIQA escalated its concerns to the HSE about the shortfalls in CPE
screening and adherence with the HSE's national guideline. As the monitoring
activity continued over 2018 and 2019, HIQA noted a steady improvement in the
level of compliance with screening guidelines in most hospitals. While full compliance
with the screening guidelines was not achieved in all hospitals (often due to reported
laboratory resourcing constraints), the overall number of individuals screened in
most hospitals increased, to include most if not all at-risk groups.

This trend was also captured in the national CPE surveillance screening data, published by the HSE, which showed a steady increase from around 10,000 CPE screens per month in early 2018, to around 26,000 per month in the latter months of 2019 (see Figure 2). As such screening is a vital tool in protecting and managing patients, this was a welcome development. However, given the pressures on hospitals from COVID-19, CPE screening needs to be sustained into the future.

Figure 2. Total number of CPE screenings in public acute hospitals per month between November 2018 and November 2019 and total number of positive screens over this time period.
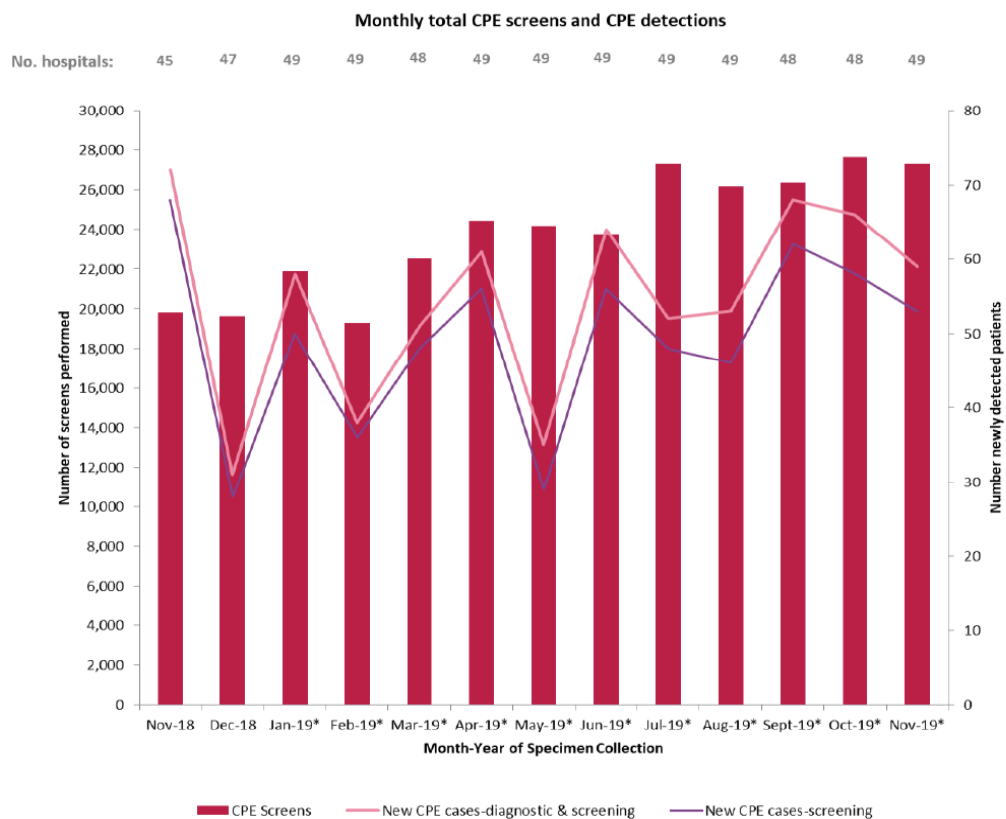
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Infrastructure and the physical environment in hospitals

The infrastructure and physical environment in many Irish hospitals did not always support the implementation of best practice on infection prevention and control or minimise the risk of transmission of healthcare-associated infections. The layout of the infrastructure and maintenance of the physical environment presented ongoing and significant challenges to best practice and compliance with national standards. Nonetheless, HIQA believes an acceptable standard of basic cleanliness and maintenance is both essential and attainable by all hospitals. Key challenges

identified with the physical environment and infrastructure during HIQA's monitoring activity that limited services' compliance with national standards included:

- potential high occupancy rates across hospitals, especially in critical care

- insufficient spacing between beds to prevent cross-contamination, with large multi-occupancy nightingale-style wards[†††††††] still accounting for a sizable proportion of beds in many hospitals

- insufficient number of and access to clinical hand-wash sinks, particularly in multi-occupancy rooms

- deficiencies in environmental and equipment hygiene

- lack of oversight of environmental and equipment hygiene practices to ensure they were in line with national and evidence-based guidelines

- deficits in hospital infrastructure — in most hospitals, the number of single rooms were insufficient to manage the ever-increasing number of individuals requiring isolation for infection prevention and control reasons

- the physical environment — in a large number of hospitals the physical environment was not maintained according to national and international standards.

In addition, the design and infrastructure of satellite decontamination facilities for decontamination and reprocessing of ENT endoscopes did not fully meet HSE standards and recommended practices. These findings were of significant concern to inspectors. As healthcare services navigate the COVID-19 pandemic, it is essential that the physical environment in hospitals is maintained to a high standard to support infection control and decontamination practices and to prevent the transmission of infection among patients.

Monitoring and evaluation

Throughout its monitoring activity, HIQA found that most hospitals monitored and evaluated the effectiveness of infection prevention and control practices and antimicrobial stewardship. This approach is essential for the safety and quality of services. Performance updates were reported through established infection prevention and control governance structures. In many hospitals, oversight of

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[†††††††] A nightingale ward is a type of hospital ward, which contains one large room without subdivisions for patient occupancy.

performance was enabled by ongoing microbiological surveillance, and monitoring and audit programmes.

HIQA also found that automated validated systems for high-level disinfection of semi-invasive ultrasound probes were in use in some satellite decontamination facilities. Despite such positive findings, some hospitals were more advanced than others in their oversight of the effectiveness of infection prevention and control practices and antimicrobial stewardship.

Manual or electronic track-and-trace systems relating to equipment decontamination were in place in all but one facility. HIQA believes such track-and-trace systems are an essential component for patient safety. In the event of an incident or infection, these systems allow hospitals to retrospectively find out which patients have been treated with particular instruments at any given point in time.

In this particular facility without either a manual or electronic track-and-trace system in place, HIQA raised its concerns with hospital managers. The rollout of the HSE's national electronic track-and-trace systems for surgical instrument and endoscope reprocessing in central decontamination facilities was progressing across hospitals during 2019.

The escalation of high risks related to infection prevention and control practice

High risks related to infection prevention and control practice identified during the monitoring activity were escalated to the hospital group and or national HSE. Between 2015 and 2019, HIQA escalated 21 such high risks. The majority of these risks (17) related to deficiencies in screening for CPE and non-compliance with the HSE's national guideline on CPE.

While risk often emerged as a result of a lack of dedicated specific resourcing, in some hospitals, there were fundamental weaknesses in their infection prevention and control programmes. These included infrastructural challenges, structural deficiencies in the governance and managerial oversight of both environmental and equipment hygiene and diagnostics in microbiology laboratories, and insufficient resourcing of decontamination services.

Overall, HIQA's work in the area of infection prevention and control identified some progress in the expansion of capacity and capability in this field across the 49 public acute hospitals over the five-year period. Allied to this, in more recent years, HIQA saw better national leadership structures around these practices across the healthcare sector, compared to findings seen in HIQA's national review of antimicrobial stewardship practices in 2015.

Many hospitals had appropriate structures, systems and processes to detect, prevent, and manage multi-drug resistant organisms. However, some hospitals needed to further enhance and develop antimicrobial stewardship programmes, screening and microbiological testing, specialist staffing, and infection prevention and control practices. Opportunities to improve infection prevention and control are further considered in the conclusion chapter of this overview report.

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Chapter 5. Medication safety monitoring programme

5.0   Introduction

The safe use of medicines is recognised nationally and internationally as a key area for improvement across all healthcare settings.[41,42,43,44,45,46] As advances in medical treatment progress, so too does the availability and use of medicines in preventing and treating disease. With this comes an increased risk of adverse events related to medication use. In 2017, the World Health Organization (WHO) set the goal for healthcare services to reduce avoidable harm associated with medication errors by 50% over a five-year period.[47] This, it suggested, could be achieved by focusing on three priorities:

- improving medication safety at transitions of care[¥]

- reducing the risk in high-risk situations[»]

- reducing the level of inappropriate polypharmacy.[◊]

Initiatives such as medication safety programmes minimise the likelihood of harm associated with the use of medications and maximise the benefits for patients. These programmes support a culture of safety, where safety is promoted, supported and led by senior management, and where systems that prevent and or hinder the risk of medication-related incidents are implemented.[48] Recognising the risk associated with medication use, HIQA started to monitor medication safety across public acute hospitals in 2016. The monitoring programme was devised to monitor compliance with the *National Standards for Safer Better Healthcare*. It focused on the systems and processes to support safe medication practice.

5.1   Background and context

Up to the end of March 2020, HIQA had completed 68 announced on-site medication safety inspections, across public acute hospitals (see Table 4 on the following page).

[¥] The WHO defines transitions in care as the various points where a patient moves to, or returns from, a particular physical location or makes contact with a healthcare professional for the purposes of receiving healthcare. This includes transitions between home, hospital, residential care settings and consultations with different healthcare providers in outpatient facilities. See the WHO's *Transitions of Care: Technical Series on Safer Primary Care* (2016), available online from: https://apps.who.int.
[»] High-risk situation is a term used by the WHO to describe situations where there is an increased risk of error with medication use.
[◊] Polypharmacy is the use of many medications together, commonly five or more.

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Table 4. Medication safety inspections conducted by HIQA in 2016-2020.

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**

Forty-four announced on-site inspections were conducted during the first phase of the monitoring programme. This phase of the programme focused on:

- governance of medication safety

- medication safety support structures and processes

- person-centred care

- policies, procedures and guidelines and information to support medication safety

- risk management and incident reporting

- evaluation and audit of medication safety

- training and education.

During this phase, HIQA issued high-risk letters to six hospitals. The risks identified in these hospitals included:

- limited clinical pharmacy services

- a lack of locally developed or adapted information to guide clinical staff in the safe use of medications, such as a hospital formulary (a list of approved medicines with guidance for their use by clinical staff) and intravenous medication monographs

- disparities and limitations in the implementation of quality improvements for medication safety

- inadequate storage of medications that required refrigeration

- risks associated with uncontrolled access to a treatment room in a clinical area where medications were stored.

In January 2018, HIQA published an overview report setting out the cumulative
findings from 34 of the 44 on-site inspections completed in the first phase of the
monitoring programme.[49] This report identified areas of good practice and set out a
number of key recommendations to improve medication safety at a local and
national level (see Appendix 4), which included, the need:

- to improve collaboration and the sharing of expertise across hospital groups
  to ensure that good practice is spread across the health services

- to develop a national plan outlining direction for improving medication safety
  across the healthcare sector

- for targeted investment in clinical pharmacy services and information and
  communications technology.

During the second phase of the monitoring programme (2019 to 2020), 24
announced on-site inspections were completed across public acute hospitals with a
focus on high-risk medications and high-risk situations. The WHO define high-risk
medications as those that have a higher risk of causing significant injury or harm, if
misused or used in error.[50] The type of high-risk medications used in hospitals vary
according to the type of services and care and treatment provided within hospitals.

While errors with high-risk medications are not necessarily more common than with
other medications, the consequences associated with such errors can be more
devastating for the patients concerned.[51] Therefore, to reduce the risk of errors,
healthcare providers should identify high-risk medications and high-risk situations
specific to their services and employ risk-reduction strategies.[52,53]^ Key findings from
the monitoring programme are described in the following section.

5.2 Key findings from the medication safety monitoring programme

5.2.1 Capacity and capability findings

The majority of hospitals inspected had the capacity and capability to support the
provision of safe, effective, high-quality medication practices. This was a welcome
finding, and it demonstrated that patient safety was being prioritised on a
sustainable and structured basis. Hospitals that were compliant with relevant
national standards had:

- prioritised medication safety

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^ Risk- reduction strategies: a term used to describe different ways of dealing with risks. Strategies include risk
avoidance, transfer, elimination, sharing and reducing risk to an acceptable level.

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- effective medication safety programmes in place

- well established governance structures for medication safety, supported by senior hospital management

- effective leadership from clinical pharmacists.

Leadership, governance and management

The majority of hospitals inspected had formalised governance structures in place with clear accountability and responsibility arrangements to support medication safety. Over the course of HIQA's work, the number of hospitals that had a drugs and therapeutics committee — a key component of medicine safety in hospitals — with oversight of medication safety at their hospitals increased from 62% to 95%.

While most drugs and therapeutics committees were functioning in line with their terms of reference, one out of five committees had difficulty in getting representatives from the required specialities to attend committee meetings. Hospitals must prioritise representation from the required specialities on these committees in order for the effective governance of medication safety to be achieved.

The governance and oversight of medication safety was severely impacted in one hospital by unexpected reductions in pharmacy resources. HIQA escalated its concerns in this regard to hospital management because, notwithstanding resource issues, hospitals should have sufficient contingency arrangements in place to ensure the appropriate and proportional governance and oversight of medication safety.

Medication safety strategy, programme or plan

All services inspected over the course of the monitoring programme were committed to supporting and progressing a medication safety agenda. This was a welcome and encouraging finding. In some hospitals, in keeping with good practice, this was aligned to the hospital's overall corporate strategy.[54,55]

Nonetheless, the degree to which hospitals progressed the medication safety agenda varied. Hospitals with a clearly defined and sufficiently resourced medication-safety programme performed better.[¥] Good performance in this area was contingent on effective leadership, multidisciplinary involvement, oversight by and support from senior management, adequate specialist supports and information and communication technology.

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

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Workforce

The implementation of a medication safety programme across hospitals depended on available and adequate levels of specialist supports. HIQA found a disparity in approved pharmacy resources across the hospitals inspected. Hospitals experienced difficulty in filling approved pharmacist posts. One hospital was extremely hampered because five whole-time equivalent (WTE) approved pharmacist positions were unfilled. Such findings severely impacted on a hospital's ability to protect patients from potential medicine related errors. However, despite the difficulties with filling approved posts and disparities in approved resources, some hospitals managed to prioritise medication safety. These hospitals had committed to allocating limited resources to clinical or team-based pharmacy services in order to support medication safety.

Education and training

Similar to the infection prevention and control monitoring programme, over the last five years, there is evidence that the knowledge and awareness of medication safety has significantly increased among medical, nursing and midwifery staff. This finding, combined with other strategies, effectively strengthens medication safety.[56] Structured, formal mandatory induction programmes for medical, nursing and midwifery staff were provided in all hospitals inspected.

Different learning methods were used to share information relating to medication safety, including classroom teaching, an e-learning module on the HSELand platform[*] and practical assessment of medication procedures. Figure 3 provides examples of education and training content included in structured induction programmes for nurses across 30 public acute hospitals.

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[*] The HSE's e-learning and development service.

Figure 3. Medication safety education and training content included in structured induction programmes in 30 public acute hospitals.
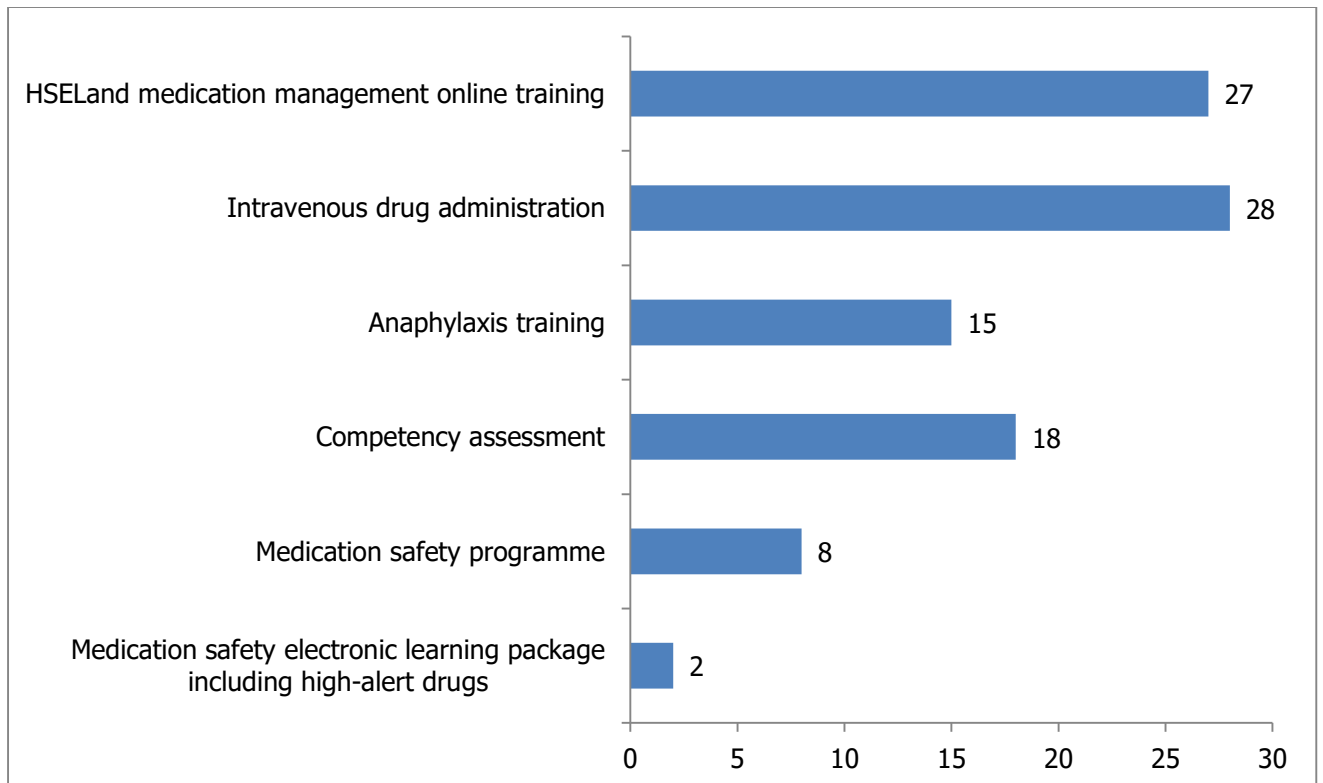
Examples of good practice relating to staff education and training that were noted in the area of medication safety included the following:

- In some hospitals, a bespoke medication record e-learning programme on the HSELand platform was developed. Medical and nursing staff were provided with protected time to access and review the programme.

- Many hospitals used a variety of methods to keep medical, nursing and midwifery staff up to date and informed on issues relating to medication safety, such as learning notices, pharmacy memos, medication safety newsletters and bulletins.

- In some hospitals medication safety awareness and the sharing of learning from medication related incidents was shared using the internal staff communication process.

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Despite good practice seen by HIQA inspectors, staff attendance at continual programmes of education for medication safety was inconsistent and varied across hospitals. Consequently, in 2018, HIQA recommended that hospitals should, in line with national standards, introduce structured education on medication safety for relevant staff to support the development and maintenance of competence in the safe use of medicines.

However, on-site inspections completed in 2019 demonstrated that this recommendation was not actioned by most hospitals. Given the critical risk to patients from medication errors, this lack of progress on providing a rolling targeted programme of education in this area was disappointing. All hospitals must begin to address this significant deficiency. HIQA, in the absence of enforcement powers, will in the interim continue to advocate for such initiatives.

Risk management structures

All hospitals had systematic risk management arrangements and escalation processes in place to manage identified risks and improve the quality, safety and reliability of healthcare services. Hospitals had corporate risk registers, which were reviewed by their executive management teams. Risks that could not be managed at hospital level were escalated to the hospital group and or the HSE. The systematic identification, evaluation and management of risk is important for the achievement of high-quality, safe and reliable services, and to reduce risk and unintentional harm to patients.

5.2.2   Quality and safety findings

Health services had structures and processes in place to support the provision of safe medication use, which are outlined in the following sections.

Clinical pharmacy services

The role and use of a clinical pharmacy service to prevent adverse drug events and reduce the risk of harm to patients is well documented.[57,58,59,60,61,62] Clinical pharmacists working on site in hospitals provide the following services:

- prescription monitoring
- prescribing advice
- optimising therapeutic use of medicines
- adverse drug reaction detection and prevention
- patient counselling
- inter-professional education about medicines.

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They may also be involved in some or all of the following activities:

- medication history taking
- medication reconciliation
- specialist clinics
- clinical audit
- protocol and or guideline development.

Ireland does not have a national strategy or national standards specifying the provision of clinical pharmacy services in public acute hospitals.[63] Across the hospitals inspected, HIQA found that there were disparities in the provision and resourcing of a comprehensive clinical pharmacy services. While the number of hospitals providing a clinical pharmacy service, on a full-time basis or in a limited capacity, increased over the course of the monitoring programme, this service was not available in six hospitals.

This was a troubling finding, and indeed four of these six hospitals only provided a medication dispensing service.[#] The lack of progress in providing a full clinical pharmacy service in all services remains a concern to HIQA, especially in the context of the size and complexity of services in some of the hospitals concerned. The inclusion of on-site clinical pharmacists in hospital clinical teams is essential to the safe and effective use of medicines in hospitals and to prevent the potential harm associated with medication use.

Medication reconciliation

Over the course of HIQA's work, the number of hospitals that formally conducted medication reconciliation[«] at the point of a patient's admission to hospital increased. This process facilitated the identification of discrepancies in medication prescriptions and ensured that changes to prescriptions were accurately communicated to the multidisciplinary team.[64,65,66] A small number of hospitals conducted medication reconciliation on discharge from hospital, albeit in a limited capacity. Medication reconciliation was conducted predominantly by clinical pharmacists.

[#] Dispensing involves the preparation, packaging, labelling, record keeping, and transfer of a prescription medication to a patient or an intermediary (such as a nurse or doctor), who is responsible for administration of the medication.

[«] 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.

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While the benefits of clinical pharmacists conducting medication reconciliation and the impact on safe care are well documented,[64,65,66,67] the process is labour and resource intensive. In the context of competing demands on resources and inspection findings in this area, HIQA believes hospitals should identify the most appropriate person and efficient way to conduct medication reconciliation.[67,68]

Clinical incidents related to medication reconciliation can be minimised by using information and communication technology.[69,70] Only a small number of hospitals inspected used technology to support medication reconciliation and promote the safe use of medicines. Examples of such technology included:

- Electronic Health Records

- National health identifier infrastructure

- ePrescribing systems

- Telehealthcare[¥] — relating to chronic diseases

- development of patient summary records

- online access to Health Information

- National Patient Portal.[^]

Formulary

Over the course of the monitoring programme, the governance process related to the evaluation and approval of medications for use in hospitals,[71] significantly increased. All hospitals had implemented a formal process to consider, evaluate and approve requests to use new medications in their hospital. The number of hospitals using a medicines formulary[‡‡‡‡‡‡‡] increased greatly over the course of HIQA's monitoring activity.

There was variation in the type of formulary used in hospitals. Some hospital groups had developed a formulary that was used by all hospitals within the hospital group. Some hospitals had adopted a formulary that was used by other hospitals, usually the larger tertiary referral hospital, within their group. Other hospitals were

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[¥] Telehealthcare: involves the distribution of health-related services and information via electronic information and telecommunication technologies.

[^] A National Patient Portal: allows the patient to view their medical data, submit statements of intention, appoint representative(s), and act on behalf of the persons.

[‡‡‡‡‡‡‡] A formulary is a managed list of preferred medicines that have been approved by the 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.

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customising and implementing web-based products such as the FormularyComplete eBNF (British National Formulary). The effective use of formularies improves access to affordable care and to an improved quality of life.

Higher-risk situations associated with increased risk of medication error

During 2019, HIQA inspected higher-risk clinical areas where the risk of medication error was greater. These included operating theatre departments and non-theatre areas, such as the interventional radiology department, where procedural sedation was used. These clinical areas represented areas with a high patient turnover and in areas where a diverse range of high-risk medications were used.[72] Examples of good practice were observed in most hospitals, but not all. Hospitals that standardised and rationalised medication use, that used prefilled syringes wherever possible, and that used colour-coded syringe labels to minimise the risk of error or misidentification had greater levels of compliance with relevant national standards.

Risk-reduction strategies to reduce the risk of error and minimise harm

To reduce the risk of error and minimise harm from medication use, hospitals developed and implemented risk reduction strategies using the hierarchy of effectiveness framework.[73]> Risk reduction strategies of varying leverage± were implemented across hospitals to reduce risks in higher-risk situations and when using high-risk medications to improve medication safety.

Examples of risk-reduction strategies implemented by hospitals to counteract the risks associated with high-risk medications and higher-risk situations included:

- High-strength heparins were not stocked on general wards.

- Concentrated potassium chloride ampoules were not routinely stocked on general wards. Intravenous potassium was supplied in pre-mixed potassium chloride solutions, which were stored securely and segregated from other intravenous fluids.

- The medication record had a specific colour-coded section for the prescribing of all anticoagulants, to support reducing the risk of duplicate anticoagulant prescriptions.

> 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.

- International standardised colour-coded labels were used for drawn-up medications.

- Oral methotrexate was not stocked in clinical areas. Only one strength of methotrexate tablets was stocked in a hospital and dispensed as a patient-specific single dose.

- Insulin pens in use in the hospital were for single-patient-use only.

- Prefilled syringes were used when available.

- A high-risk medications list was maintained.

- A sound-alike look-alike drugs (salads) list was used.

While the use of these strategies in some hospitals was commendable, HIQA identified that 60% of the hospitals inspected needed to review and strengthen their risk reduction strategies. Strengthening these strategies will help reduce the risk of error and minimise unintentional harm from medicines.

Clinical incident reporting

All hospitals inspected had established systems for reporting medication errors and near misses. This facilitated the identification of risk and opportunities for improvement.[74] High incident-reporting rates are generally associated nationally and internationally with a strong patient safety culture.[75] Hospitals with high rates of clinical incident reporting does not necessarily imply particular problems in those services, but better reporting cultures.

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. Most hospitals categorised medication safety incidents using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Medication Error Index.[76]

HIQA believes the reporting of incidents is of little value unless the data collected is analysed to identify trends or patterns in relation to risk and the resulting recommendations for improvement are shared with staff. 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.

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Quality improvement initiatives were generally implemented across hospitals in response to medication safety incidents and while this is a necessary and important endeavour, this approach is reactive. A more proactive, responsive approach is needed to reduce the risk of harm to patients.[77] Some examples of quality improvements initiatives implemented to enhance the safe use of medicines included the (1) redesign of medication prescription and administration records to include a specific coloured section to enhance anticoagulant prescribing and (2) introduction of:

- direct oral anticoagulants (DOAC) stickers

- antimicrobial guide

- analgesia prescribing and administration card

- education and learning quality improvement initiatives

- a 'good catch system' initiative where staff were encouraged and supported to report near-miss incidents.

Information for patients and clinical staff

All hospitals had systems in place to provide medication-related information to patients.[78,79] Medication-related education was provided by relevant professionals, such as doctors, nurses, midwives, clinical nurse specialists, clinical midwife specialists and advanced nurse practitioners in different specialties. Pharmacists and doctors provided counselling to patients who were starting on anticoagulants. While information was available in all hospitals, in the opinion of inspectors, the quality and quantity of information leaflets varied across hospitals.

All hospitals had multiple systems in place to support the safe use of medicines and to provide staff with relevant up-to-date and accurate information when prescribing and administering medications. All hospitals had access to intravenous monographs, but because of issues with wireless networking technology connectivity, some hospitals could not access intravenous monographs at point of use. Access to the most up-to-date intravenous monographs at point of use is essential for the provision of evidence-based care.

Policies, procedures and guidelines

The HSE[80] and the National Clinical Effectiveness Committee (NCEC)[81] recommend that policies, procedures and guidelines are reviewed and updated every three years. All hospitals had implemented a wide range of medication-related policies, procedures and guidelines. However, in the majority of hospitals inspected, these policies, procedures and guidelines required updating in line with HSE and NCEC

policy. Up-to-date policies, procedures and guidelines are essential for the delivery of evidenced-based care.

Monitoring and evaluation

All hospitals inspected measured and evaluated performance in relation to medication safety. This was a welcome finding and an essential process in improving healthcare services. Performance was measured and evaluated through a number of means, including incident reporting, risk assessments, nursing and midwifery quality care metrics, key performance indicators,§§§§§§§ clinical audits and findings from the National Inpatient Experience Survey.

While all hospitals used audit to measure and evaluate performance regarding medication safety, over half of the hospitals inspected had not developed time-bound action plans to implement recommendations arising from completed audits. This finding represented a lost learning opportunity in these services. This shortfall in the audit cycle must be addressed by hospitals in order for meaningful improvements in services to occur.

National Inpatient Experience Survey

The National Inpatient Experience Survey[*] provides service users with the opportunity to provide feedback on their experiences of services and the care they received in the 49 public acute hospitals in Ireland. The survey, contains two questions relating to medication use and possible side effects.[********] Seventeen of the 20 public acute hospitals inspected in 2019 were included in the survey (which was originally called the National Patient Experience Survey).

Twelve of the 17 hospitals used findings from the survey to target identified areas for improvement in their hospitals. Nine of the 17 hospitals had revised and improved information about the safe use of medicines and possible side effects of medications. Six hospitals had devised a discharge leaflet detailing where advice on changes to medication could be sought. Six hospitals were progressing with implementing the 'Know, Check, Ask' campaign, which encouraged patients to keep an up-to-date record of their medications.

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

[*] The National Inpatient Experience Survey is a nationwide survey which asks people for feedback about their stay in hospital. The survey is a partnership between HIQA, the Health Service Executive (HSE) and the Department of Health.

******** Question 44 asked service users if members of staff explained the purpose of new medicines in an understandable way. Question 45 asked service users if, prior to discharge from hospital, a member of staff informed them about the possible side effects of medicine to be monitored for when at home.

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Overall, the findings from HIQA's medication safety monitoring programme over the past number of years provides some assurance that public acute hospitals had the capacity and capability, and structures and processes essential to protecting patients from unintentional harm associated with medication use. Some hospitals have demonstrated a commitment to improve their approach to medication safety.

Notwithstanding this, there are opportunities for improvement, which are described further in Chapter 9 of this overview report. These opportunities need to be urgently addressed in order to ensure that a culture of medication safety is promoted and established across all healthcare services. While targeted investment will be needed to assist many services in their efforts to improve medication safety, many improvements can be achieved within existing resources, if sufficient support is provided at local hospital, hospital group and HSE level.

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Chapter 6. Maternity services monitoring programme

6.0   Introduction

Each year, over 60,000 babies are born in Ireland. For most women, pregnancy and birth are safe and result in a successful outcome. For a minority of women, even those considered to be at low-risk of developing complications, circumstances can change dramatically prior to and during labour and childbirth. These can place both the woman and baby at risk.[82]

Maternity services and clinical staff must be responsive to the needs of all women, from those who have a straightforward pregnancy to those who experience complications or an obstetric emergency and are in need of extra support. This includes being able to communicate effectively with colleagues, and staff having the necessary experience and competence to provide appropriate clinical support and or a clinical intervention whenever it is necessary.[83,84] Reviews into failings in maternity care conducted in Ireland and other countries over the last number of years have revealed significant service failings.[85,86,87,88]

In 2018, HIQA began a programme that monitored compliance across the 19 maternity units and hospitals in Ireland with specific standards from the *National Standards for Safer Better Maternity Services*, with a focus on obstetric emergencies. The monitoring programme concluded in February 2020, with the publication of an overview report which set out the cumulative findings.[89] The overview report and individual inspection reports for the 19 maternity units and hospitals are available on HIQA's website: www.hiqa.ie.

6.1   Background and context

The National Standards for Safer Better Maternity Services were approved by the Minister for Health and published in December 2016. Earlier that year, the Minister for Health launched the *National Maternity Strategy: Creating a Better Future Together: 2016–2026*. This strategy sets out a significant programme of restructuring and reform of maternity and neonatal services in Ireland over a 10-year period. The strategy, together with national standards, promote improvements in the quality and safety of maternity care and services.

HIQA's monitoring work in maternity services was specifically designed to assess the level of compliance with 21 specific national standards from the *National Standards for Safer Better Maternity Services*. In monitoring compliance with these national standards at individual maternity unit or hospital level, HIQA focused on:

- leadership, governance and management arrangements

- the capacity and capability to identify women at risk of developing complications and to provide, or arrange, for their care to be provided in a more appropriate clinical setting
- the resources available to detect and respond to obstetric emergencies

- the numbers of clinical staff, supported with specialised regular training, to care for women and their newborn babies during obstetric or neonatal emergencies.

6.2 Key findings from the monitoring programme against the *National Standards for Safer Better Maternity Services*, with a focus on obstetric emergencies

Overall, HIQA found high levels of compliance across maternity services with the 21 national standards assessed during this monitoring programme. The majority of maternity units and hospitals had arrangements in place to identify women at higher risk of complications and to ensure their care was provided in the most appropriate setting. All maternity units and hospitals had arrangements in place to respond to obstetric and neonatal emergencies 24/7.

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 at the time of re-inspection, in the process of being resolved.

6.2.1 Implementation of the National Maternity Strategy

The National Maternity Strategy, if realised, would result in significant restructuring and reform of maternity and neonatal services over a 10-year implementation period. While progress had been achieved in the implementation of some important elements of the strategy, HIQA was concerned about the overall level of progress and pace in implementing the strategy.

Oversight of the implementation of the National Maternity Strategy was assigned to the HSE's National Women and Infants Health Programme. However, HIQA found

that there was ambiguity surrounding the role and function of this entity within the HSE. This ambiguity, combined with a lack of clarity around the governance and accountability arrangements and the non-assignment of budgetary control, hindered progress in implementing the strategy.

HIQA considered this a significant risk to the ongoing and effective implementation of the strategy and of national standards. Over the course of the monitoring programme, the HSE reviewed and amended governance and accountability arrangements for the National Women and Infants Health Programme. While HIQA welcomed these strengthened governance and accountability arrangements, it believes that the implementation of the National Maternity Strategy must be progressed without further delay. To support this goal, the HSE should immediately develop a comprehensive, time-bound and fully costed implementation plan, spanning the remaining time frame of the strategy.

6.2.2 Capacity and capability findings

Across the 19 maternity services, HIQA monitored compliance against seven specific national standards under the theme of leadership, governance and management; and three specific national standards under the theme of workforce.

Leadership, governance and management at maternity unit, hospital and network level

Strong and effective leadership, governance and management arrangements are essential to create and sustain the goal of providing safe and high-quality maternity services. HIQA found that leadership, governance and management arrangements at an individual maternity unit or hospital level were, in general, well defined. The governance arrangements acknowledged the interdependencies between organisational arrangements and clinical practice and integrated these to achieve safe and effective maternity services.

At hospital group level, none of the groups had succeeded in fully establishing a maternity network under a single governance framework, as recommended in the National Maternity Strategy. It is crucially important for the sustainability of a consistently safe and high-quality service for women and their babies that these networks (involving a mixture of large and small hospitals and units) advance beyond their current early states of formation. HIQA believes this requires effective national coordination at a senior level.

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Workforce

To be effective, maternity services need sufficient staff at the right time, with the right skills and competencies, diversity and flexibility to deliver safe and high-quality care. Maternity services were very reliant on front-line medical staff working onerous rosters and midwifery staff working overtime to maintain service levels, which raised significant questions around the long-term sustainability and safety of services.

Medical staffing

Maternity services experienced difficulty in recruiting for approved permanent consultant positions across the specialties of obstetrics, anaesthesiology, neonatology and paediatrics. During the monitoring programme, 15% to 20% of approved permanent consultant positions across the specialties were unfilled. Maternity units that experienced the greatest difficulties with recruiting and retaining consultant medical staff, often operated with onerous and unsustainable on-call rosters of less than one in every five nights. Furthermore, the level of on-site anaesthetic cover available out of hours in five of the co-located maternity units was contrary to the national standards and national guidelines. Difficulty in recruiting medical staff significantly impacts on the sustainability and delivery of high-quality, safe and reliable services.

Non-consultant hospital doctors not on a recognised training scheme

Many smaller maternity units relied heavily on the work and commitment of non-consultant hospital doctors, all of whom were registered medical professionals, who were not on a recognised training scheme. These doctors were often in post for a number of years providing a vital service and a degree of workforce stability over that time. Reliance on the contribution of these doctors to provide 24/7 maternity services in many parts of the country, in the absence of a formalised training and career pathway, was found to be a potentially precarious situation for service continuity.

HIQA believes this issue needs to be more comprehensively addressed by the HSE and medical training bodies. HIQA recommended that the HSE review current workforce arrangements in each maternity unit or hospital to determine the required levels of staff and skill-mix needed for the provision of safe, high-quality maternity care.

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Midwifery and nursing workforce arrangements

Maternity services implemented a number of measures to manage midwifery staffing shortages and to keep maternity services safe. These included a reliance on staff to work overtime, internal rotation and redeployment of midwives and employment of agency staff. HIQA was concerned that the national shortage of midwives impacted on services' abilities to provide safe, high-quality care and potentially impeded progress in the implementation of the National Maternity Strategy.

Training and education of multidisciplinary teams

All maternity services provided a multidisciplinary training programme in obstetric emergencies for obstetricians, midwives and anaesthesiologists. Additionally, multidisciplinary skills and drills in relation to obstetric emergencies were provided in all maternity units and hospitals, but the frequency of these sessions was not consistent across maternity services. Training on cardiotocography interpretation (fetal heart rate monitoring) and neonatal resuscitation was also provided in all maternity units and hospitals. However, the level of attendance at training programmes, and the levels of recording of attendance where training occurred, was inconsistent across maternity services.

HIQA identified the need for greater standardisation of multidisciplinary training related to obstetric emergencies and cardiotocography interpretation across the maternity services. A standardised approach to such training would provide consistency in the detection and management of obstetric emergencies and cardiotocography interpretation across the services. This is particularly important in an environment where clinical staff rotate between maternity units and hospitals. HIQA also identified that better systems be implemented at local and national HSE level to record staff attendance at mandatory training sessions.

Monitoring and evaluation of quality and safety by maternity services

HIQA was assured by the evidence seen during its monitoring work that maternity services were proactively engaged in the ongoing monitoring and evaluation of maternity services. The majority of maternity services inspected had worked towards improving the quality and safety of maternity care. Maternity services used a range of measures to benchmark their performance against other maternity services, nationally and internationally. These included the routine monitoring of (1) outcomes for women and babies, (2) serious reportable incidents, (3) clinical incident reviews, (4) risk assessments compliments and complaints, (5) clinical audits and (6) women's experiences. All maternity units and hospitals audited the services and care provided.

Risk management structures and reporting of clinical incidents

All maternity services had systems and arrangements in place to identify and
manage risks, and there was oversight of identified risks by senior management
teams. Risks that could not be managed at local level were escalated to hospital-
group level. Services also had established systems in place to report and manage
clinical incidents. However, levels of reporting of clinical incidents varied considerably
across maternity services.

6.2.3 Quality and safety findings

HIQA's monitoring programme looked at compliance with 11 specific national
standards within the dimensions of safety and quality. HIQA specifically sought to
find out how maternity services:

- identified pregnant women at greater risk of developing complications

- planned and delivered care to meet the initial and ongoing assessed needs of
  women and their babies

- detected and responded to obstetric and neonatal emergencies

- identified, managed and escalated risks within maternity services

- reported patient safety incidents and ensured shared learning.

Maternity services had a number of the necessary systems, structures and processes
in place to ensure the provision of safe, quality care for women and babies who
experience an obstetric emergency.

Care pathways for women and newborns

The National Maternity Strategy identified three care pathways[90], supported, assisted
and specialised, to be implemented over the lifetime of the strategy. While HIQA
found some progress had been made across maternity services to provide a
supported care pathway and to facilitate choice for women with normal-risk
pregnancies, the progress made generally predated the National Maternity Strategy.
HIQA recommended in 2020 that the HSE and maternity services progress the
implementation of the supported care pathway for women with a normal risk
pregnancy to ensure greater availability across maternity services, without delay.

All maternity units had established pathways for the assessment, management and
admission of pregnant or postnatal women presenting for scheduled and

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unscheduled care. An anaesthetic pre-assessment clinic[††††††††] was available in most maternity services. All services had arrangements in place to transfer women and newborns to tertiary hospitals (these are larger hospitals offering a wider range of services) for specialised treatment, if required. However, in five of the hospital groups, these arrangements were not formalised. Formalisation of arrangements and the implementation of mandatory transfer and acceptance protocols should ensure that, when required, women and newborns are transferred to the most appropriate setting within and outside their hospital group in a timely and efficient manner.

Communication

HIQA believes that multidisciplinary team working, grounded in good communication, is essential for the delivery of safer, better healthcare. All maternity services had emergency multidisciplinary response teams and established protocols and procedures in place 24/7 to provide an immediate response to obstetric and neonatal emergencies.

Clinical handover was practised in all maternity units and hospitals; however, the national guideline guiding this practice was not implemented in full in all maternity services during the programme review. In some maternity units and hospitals, senior medical staff in the medical specialties of obstetrics, anaesthetics, neonatology or paediatrics did not always attend clinical handover. Effective multidisciplinary handover and team working are essential for effective, safe, high-quality care. It is essential that all specialties involved in the care of women and babies share information so that potential clinical concerns are identified and improve the safety of care.

Some maternity units and hospitals had implemented safety huddles or pauses.[‡‡‡‡‡‡‡‡] These safety huddles or pauses helped foster and create a culture of safety, increased safety awareness and improved communication among healthcare professionals.[91]

Physical environment and infrastructure challenges

Across the majority of maternity services, HIQA found significant levels of non-compliance with the national standard relating to the services' physical environment

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[††††††††] A pre-assessment anaesthetic clinic is a service whereby women with risk factors for anaesthesia or women who might have difficulties are reviewed by the duty anaesthesiologist and a plan of care is developed that is appropriate for the women. Such clinics review women presenting with a high-risk of obstetric complications. Body mass index (BMI) greater than 40kg.m-2 at first antenatal booking appointment, history of previous difficulties with, or complications of, regional or general anaesthesia and or significant medical conditions.

[‡‡‡‡‡‡‡‡] Safety huddles held by the multidisciplinary team improve communication, situational awareness and care for women and babies among all team members.

and infrastructure (National Standard 2.7). In most services, the physical environment did not align with modern international design requirements and standards for modern maternity and neonatal services.[92,93]

Findings in relation to infrastructure and the physical environment varied considerably across the 19 maternity services. HIQA found that the majority of maternity services were providing care in an inadequate, outdated and ageing infrastructure. Key issues identified with the physical environment and infrastructure included:

- assessment areas did not always have a suitable, designated space for the clinical assessment of pregnant or postnatal women
- clinical areas were not conducive to promoting dignity and privacy for women during assessment and examination
- inadequate en-suite toilets and showers, contrary to those recommended in guidelines for modern maternity services
- limited storage space resulting in essential equipment being stored inappropriately
- limited numbers of birthing rooms in large and medium-sized maternity services to meet the demand required
- multi-occupancy rooms had limited space — especially when accommodating baby cots — which potentially increased the risk of cross infection.

Deficiencies in the physical environment and infrastructural challenges impacted negatively on a woman's comfort, dignity and privacy and increased the potential risk of cross infection for women and newborns. Furthermore, cramped, overcrowded and cluttered environments could potentially impede the timely attendance to woman and newborns during an emergency.

HIQA acknowledges that addressing the ageing physical infrastructure across many maternity services will take time and a significant amount of funding. HIQA also recognises that some maternity services do not have the resources or capacity to expand the size of accommodation and facilities within their current physical space. However, if compliance with national standards is to be achieved, significant investment is needed to improve the current infrastructure and physical environment of most of Ireland's maternity services.

Implementation of evidence-based practice

HIQA found that maternity services had implemented the National Clinical Effectiveness Committee's (NCEC's) clinical practice guidelines relating to the Irish Maternity Early Warning System and Sepsis Management. Services had also

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implemented the HSE's clinical practice guidelines relating to obstetric emergencies.[94,95,96,97] However, the NCEC's clinical practice guidelines on communication (clinical handover) in maternity services had not been implemented fully in all maternity services. Furthermore, a number of HSE clinical practice guidelines relating to obstetric emergencies were out of date and needed to be revised and updated in line with HSE policy.[98]

Sharing of learning to improve safety and quality of maternity care

At individual maternity unit and hospital level, there were arrangements in place for the sharing of learning and implementation of recommendations of reviews of clinical incidents. However, there was little evidence to suggest that the sharing of learning occurred across maternity services. Sharing of learning is essential to reducing the risk of reoccurrence of preventable clinical incidents that may cause harm to women and newborns. Maternity services should improve the sharing of learning from reviews of reported clinical incidents at a local and national level.

Quality improvement programmes

While all maternity services inspected were undertaking quality improvement work only a small number of maternity units and hospitals had a structured and resourced quality improvement programme in place. Examples of quality improvement initiatives identified during the monitoring programme included the following:

- Ten out of the 19 maternity services had a dedicated operating theatre located in or adjacent to the labour ward. The remaining nine had implemented measures to facilitate the safe and timely transfer of woman to the operating theatre so that obstetric surgery was conducted within the internationally recognised time frames for different levels of caesarean section.[§§§§§§§§]
- All maternity services had arrangements in place for the transfer of women at high risk of complications and babies requiring complex neonatal care.
- Small and medium-sized maternity units co-located with an acute general hospital had access to critical care and consultant specialist services on site
- Fourteen maternity services provided fetal ultrasound services at intervals as set out in the national standards. There were plans in place in the remaining five maternity services to ensure access in 2020 to fetal ultrasound at the intervals outlined in the national standards.

[§§§§§§§§] The Royal College of Obstetricians and Gynaecologists has adopted a four-step classification system for determining the urgency and timing of caesarean section. The College recommends a delivery within 30 and 75 minutes for urgent and emergency caesarean section. A delivery within 30 minutes is recommended whenever there is an immediate threat to the life of the woman or baby.

In general, findings from HIQA's monitoring programme into maternity services provided assurance around the current arrangements in place to detect and respond to obstetric emergencies across the services. Overall, there were high levels of compliance with those national standards monitored against in the 19 maternity services.

However, HIQA made a number of recommendations to be acted on at hospital group level and or nationally by the HSE. These actions must be acted on in a timely manner in order to support the delivery of safe care to women and their babies. These actions are discussed in greater detail in the overview report for the maternity service monitoring programme, which was published in early 2020 and which can be downloaded from www.hiqa.ie.

Chapter 7. Nutrition and hydration monitoring programme

7.0   Introduction

Malnutrition is a serious condition occurring when there are insufficient nutrients in a person's diet to meet the demands of their body. If undetected and untreated, the condition will impact on an individual's growth, physical health, mood, behaviour and many of the person's bodily functions. In 2009, the Department of Health and Children published guidance[99] on how nutritional care and support for individuals admitted to hospital could be improved. The guideline was updated in 2018 on foot of findings from HIQA's nutrition and hydration monitoring programme.

When HIQA conducted the monitoring programme in nutrition and hydration during 2015, the cost of caring for individuals with malnutrition was estimated to be €1.4 billion, representing 10% of the total healthcare costs in Ireland at that time.[100] Approximately 33% of individuals admitted to an acute hospital in 2015 were at risk of malnutrition.[100] In 2015, it was estimated that 145,000 people in Ireland were either malnourished or at risk of malnutrition.

7.1   Background and context

HIQA's monitoring programme into nutrition and hydration was completed over two phases. During phase one, 42 public acute hospitals (maternity and children's hospitals were not included) submitted a self-assessment questionnaire,********* which provided HIQA with baseline information on the structures and processes in each hospital to assess, monitor and evaluate the nutritional and hydration needs of patients. During phase two, unannounced on-site inspections were conducted in 13 of the 42 public acute hospitals.

The cumulative findings from HIQA's monitoring programme were published in a detailed overview report, which is available on HIQA's website.[101] A selection of key findings from HIQA's work in this area across the 42 public acute hospitals in 2015 are presented in the following section. HIQA believes these findings remain relevant and provide an opportunity to share learning about this important aspect of care.

********* The hospitals were asked to submit (i) an organisational chart setting out the lines of communication between staff directly involved in nutrition and hydration care, teams, committees and management within the hospital, (ii) a copy of the formal documented processes (such as an algorithm, pathway, standard operating procedure and guidelines) for responding to the results of nutritional screening.

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7.2 Key findings from the nutrition and hydration monitoring programme

The structures and processes in place to assess, determine, manage and evaluate patients' nutritional and hydration needs varied across the 42 public acute hospitals. Many hospitals demonstrated a genuine commitment and enthusiasm to promoting and leading improvements in nutrition and hydration for patients. While shortcomings were identified in the area of monitoring and evaluation, over the course of the monitoring programme, there was evidence of improvement in this area of care across most public acute hospitals.

7.2.1 Capacity and capability findings

The following section describes the healthcare services' capacity and capability to provide sufficient nutrition and hydration relative to individual patient's needs.

Leadership, governance and management

The majority of hospitals had clear accountability arrangements and formalised governance arrangements to oversee the delivery of high-quality, safe and reliable care in relation to nutrition and hyrdation. In all hospitals, the responsibility and oversight of the standard of nutrition and hydration was assigned to a specific committee — the nutrition and hydration steering committee. These committees oversaw the implementation of relevant national guidelines, the food-service system, nutritional risk screening and audit activity in their hospitals.

HIQA found that nutrition and hydration was not systematically monitored or evaluated across the 42 public acute hospitals, which impacted on the services' ability to continually improve. Despite this finding, a number of hospitals used the data collected monthly, as part of the national nursing and midwifery quality care-metrics system,[††††††††††] to inform their performance in the area of nutrition and hydration.

Workforce

The majority of hospitals inspected had a dietetic service. In most hospitals, speech and language therapists were accessible during core working hours (Monday to Friday, 9am to 5pm) for individuals who experienced difficulty in swallowing and eating. Some of these hospitals, had a system in place to access a speech and language therapist at weekends too. This ensured that individual patients were not fasting unnecessarily for prolonged periods.

[††††††††††] Process performance quality indicators which provide a framework for how fundamental nursing care can be measured.

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Education and training

In the majority of hospitals, eduction and training on nutrition and hydration was included in structured, mandatory staff induction programmes for nursing, medical and auxillary staff. Nurses and healthcare assistants received training and education on texture-modified diets and thickened fluids for individuals with swallowing difficulties.

However, there was evidence that training on nutrition for staff at healthcare assistant grade was inconsistent and informal. The structure and frequency of additional training and education sessions provided for healthcare staff also varied across hopsitals. At the time, HIQA recommeded that a more structured and formal approach to education and training was needed across hospitals for service providers, to be assured that their workforce had the competencies required to deliver high-quality, safe and reliable care.
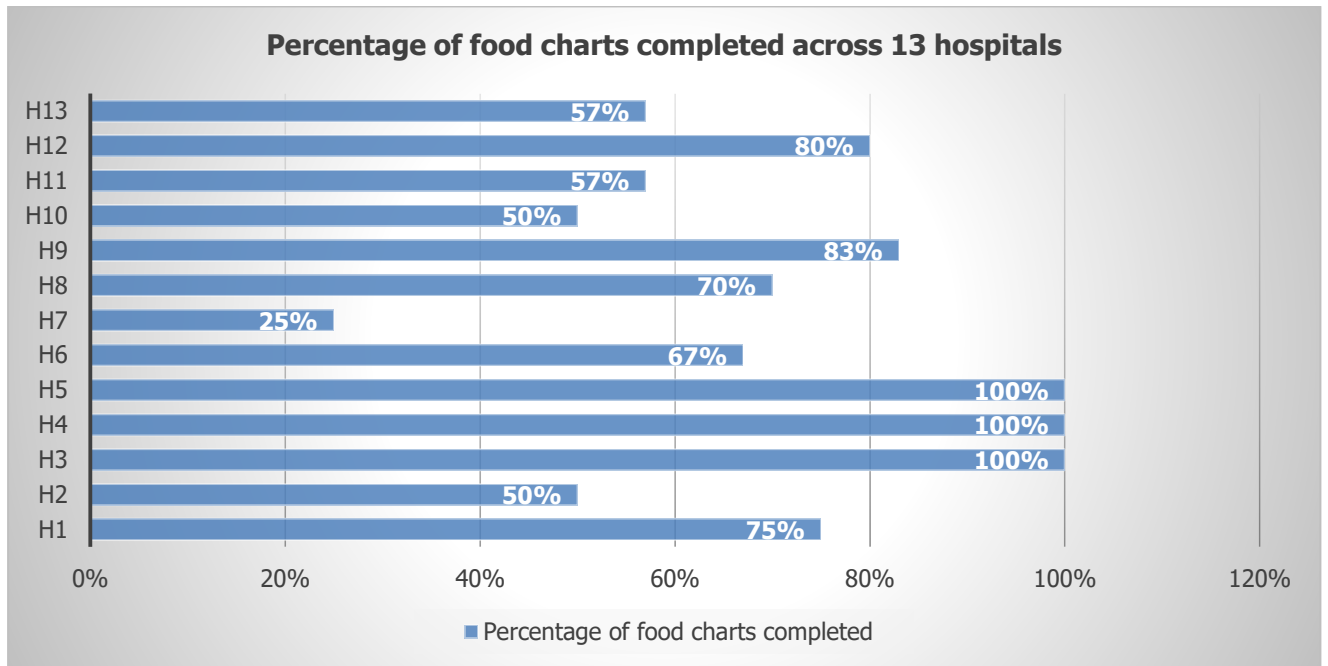
Use of resources

HIQA's monitoring progamme found that equipment used when screening for risk of malnutrition was not available in all clinical areas in hospitals and not all equipment was calibrated on an annual basis or in line with the manufacturer's guidance. Access to the right equipment is essential for the adequate assessment of patients at risk of malnutrition, this includes assess to weighing scales, chair scales (for more frail and dependent patients), stadiometers and measuring tapes.

Use of information

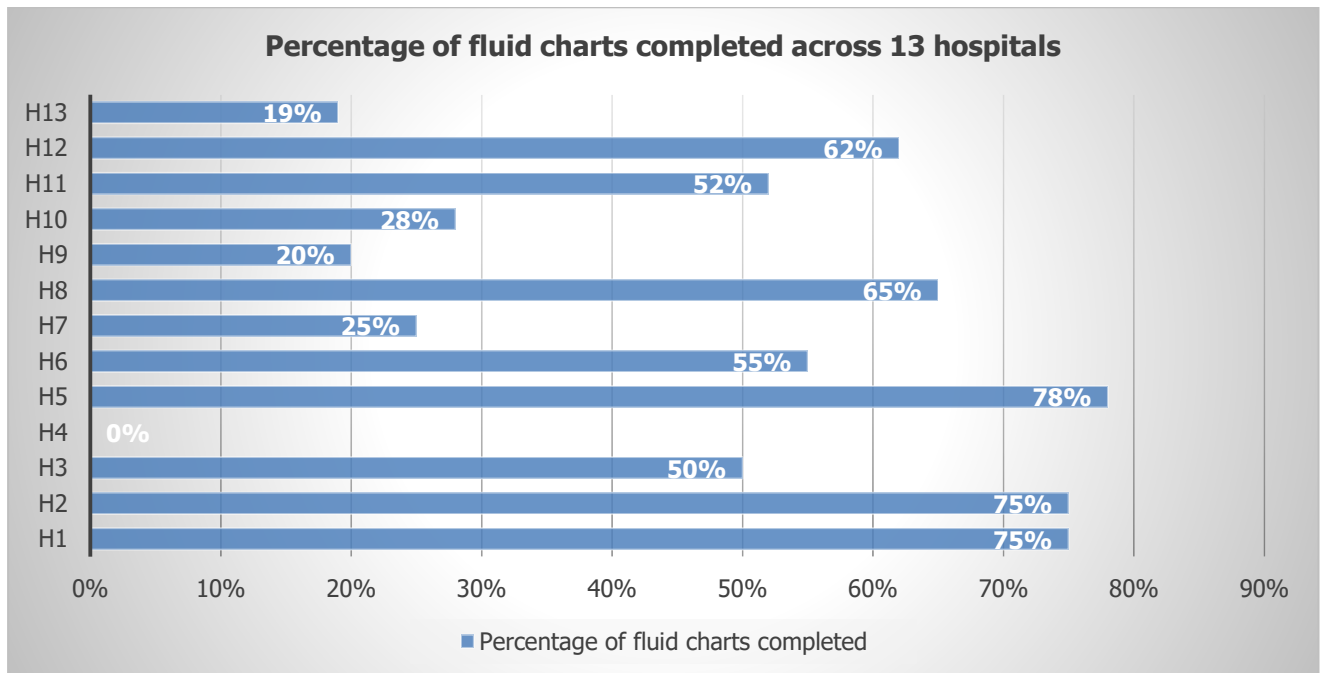Most hospitals inspected used food intake charts and fluid intake and output charts to monitor an individual's food and fluid intake. However, the use and the quality of recording content in these charts varied across hospitals. Consequently, clinicians may not have had all the necessary information about an individual's nutrition and hydration status when making decisions about clinical treatment.

Figure 4. Percentage of food charts completed across 13 hospitals inspected

Percentage of food charts completed across 13 hospitals

Hospital	Percentage
H13	57%
H12	80%
H11	57%
H10	50%
H9	83%
H8	70%
H7	25%
H6	67%
H5	100%
H4	100%
H3	100%
H2	50%
H1	75%

■ Percentage of food charts completed

Figure 5. Percentage of fluid charts completed across 13 hospitals inspected

Percentage of fluid charts completed across 13 hospitals

Hospital	Percentage
H13	19%
H12	62%
H11	52%
H10	28%
H9	20%
H8	65%
H7	25%
H6	55%
H5	78%
H4	0%
H3	50%
H2	75%
H1	75%

■ Percentage of fluid charts completed

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7.2.2   Quality and safety findings

The following section describes the structures and processes in place to ensure the provision of high-quality, safe and reliable care in the area of nutrition and hydration.

Screening for risk of malnutrition

In 2015, half of the 42 public acute hospitals screened patients for risk of malnutrition. The percentage of screening in nine of these hospitals varied from 25% to 82% (see Figure 6).

Figure 6. Percentage of patients screened for risk of malnutrition in nine hospitals
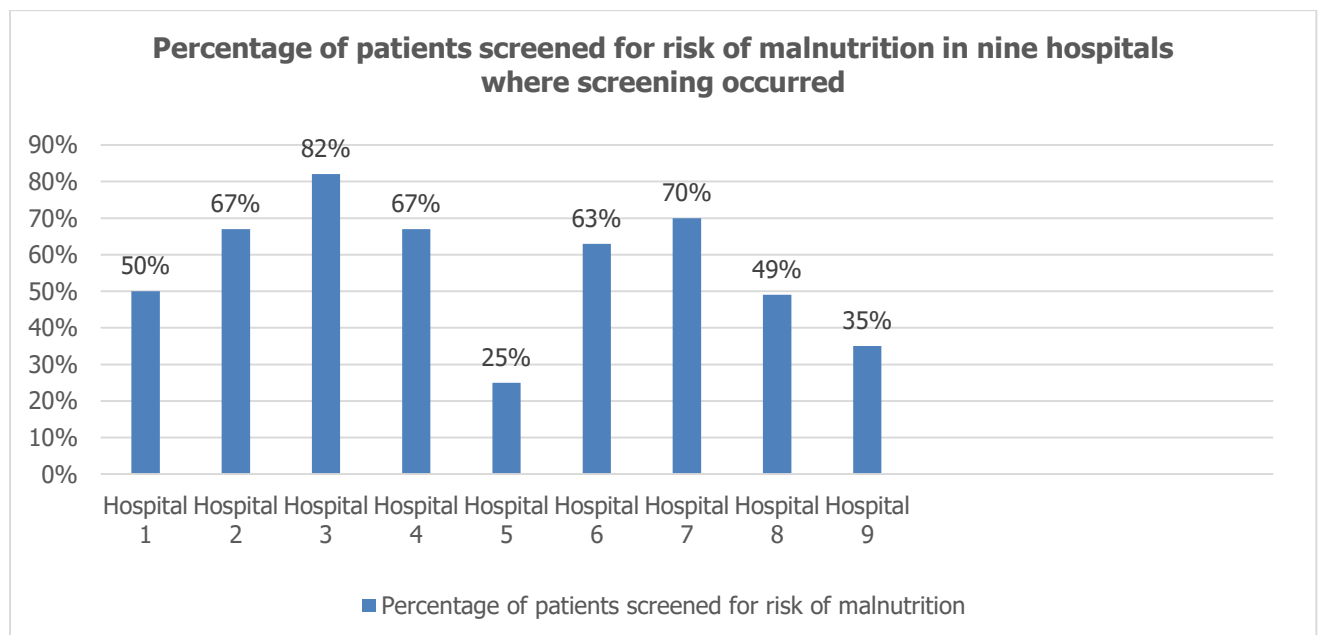
Person-centred care

During the review, there was evidence that patients received advice on nutrition and hydration from dietitians, speech and language therapists, medical and nursing staff, when required. All hospitals provided three main meals per day. However, mealtimes varied across hospitals, and mealtimes were not organised around patients and did not support a person-centred approach to care. More significantly, most hospitals were not adhering to best practice of having four or more hours between the end of one main meal and the beginning of the next.

Furthermore, at the time of inspection, different ethnic, religious and cultural backgrounds were not always catered for when providing meals. All hospitals had

systems in place to identify patients who needed assistance with eating and drinking. Nonetheless, in most hospitals inspected, drinking water was not replenished at regular intervals. Water was replenished when water jugs were empty or on request. In half of the emergency departments inspected, patients who had mobility difficulties were unable to access drinking water.

Infection prevention and control

In a small number of hospitals, multitask attendants had both cleaning and catering duties and were performing these duties interchangeably on the same shift. Cleaning duties included the cleaning of bathrooms, toilets and sluice rooms. This practice increased the risk of transmition of a healthcare-associated infection and other transmissible infections.

Policies, procedures and guidelines

Over half of the hospitals inspected did not have a policy on meal fasting prior to surgery. This meant that, in these hospitals, the practice of fasting prior to surgery or diagnostic investigations may not have been in line with best available evidence or guidance.

Monitoring and evaluation

Across hospitals, HIQA found a shortage in audit activity which impeded the service's ability to monitor and evaluate performance and implement quality improvements in the area of nutrition and hydration. Few hospitals had a structured audit programme that monitored the quality of nutrition and hydration care they provided. In most hospitals inspected, there was no coherent approach to identifying what should be audited and how findings from completed audits could be shared.

Clinical incident reporting

Across hospitals, there was significant under-reporting of nutrition and hydration related clinical incidents. While a small number of hospitals had reported incidents in a timely manner, a significant number of hospitals had not reported any patient safety incidents related to nutrition and hydration.

Quality improvement programme

Notwithstanding the limited audit activity and the under-reporting of patient safety
incidents in most hospitals, the majority of hospitals had developed quality
improvement programmes or initiatives to promote good nutrition and hydration
practices. These included:

- protected mealtimes
- coloured trays to identify patients requiring assistance with their meals
- coloured picture menus
- monitoring missed meals
- patient information booklets
- communication boards using symbols to communicate dietary needs.

Patients' experiences of care related to nutrition and hydration

One of the most positive findings from the 2015 review was that hospitals used
feedback from patients to identify areas for improvement. Hospitals obtained
feedback from patients using a number of forums; verbal feedback, survey and or a
patient partnership forum. In the hospitals inspected, patients who spoke with
inspectors were either satisfied or very satisfied with their nutrition and hydration
care.

These collective findings from HIQA's monitoring programme into nutrition and
hydration informed the development and content of the national guideline on
nutrition and hydration which was published by the HSE in 2018 and which puts
greater emphasis on more systematic screening for malnutrition.[102] Opportunities for
improvement were identified during the monitoring activity and are discussed in
greater detail in Chapter 9 of this overview report.

While the monitoring programme took place five years ago, HIQA believes the
findings remain relevant today. HIQA has included a selection of the findings in this
five-year overview report to promote some of the overall learning from it. It is hoped
that hospitals will examine or revisit the detailed overview report in order to identify
and share examples of good practice seen and perhaps reflect on potential
opportunities to improve care in this crucial area.

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Chapter 8. HIQA's new programmes of monitoring and regulation

8.0   Introduction

In 2019, HIQA started two new programmes of monitoring and regulation. These were:

- monitoring compliance against selected national standards in rehabilitation and community inpatient healthcare services
- regulation of medical exposure to ionising radiation in public and private healthcare and dental services.

8.1   Monitoring of rehabilitation and community inpatient healthcare services

In 2018, there were 23 hospitals and facilities, equating to 1,129 beds (see Figure 7) funded, and in some cases, managed by the HSE that provided rehabilitation or community inpatient healthcare services. These services are not registered designated centres, such as nursing homes, and, therefore, are not regulated by the Chief Inspector of Social Services within the Regulation Directorate in HIQA.

They are also not acute hospital services, yet they provide an important tier of often very specialised inpatient healthcare to the communities that they serve. Five of these services were under the governance of the local public acute hospital. The remaining 18 were either stand-alone voluntary services, or were HSE operated, under the governance of the local community health organisation.

Figure 7. Types of care provided in the 1,129 beds in the rehabilitation and community inpatient healthcare services
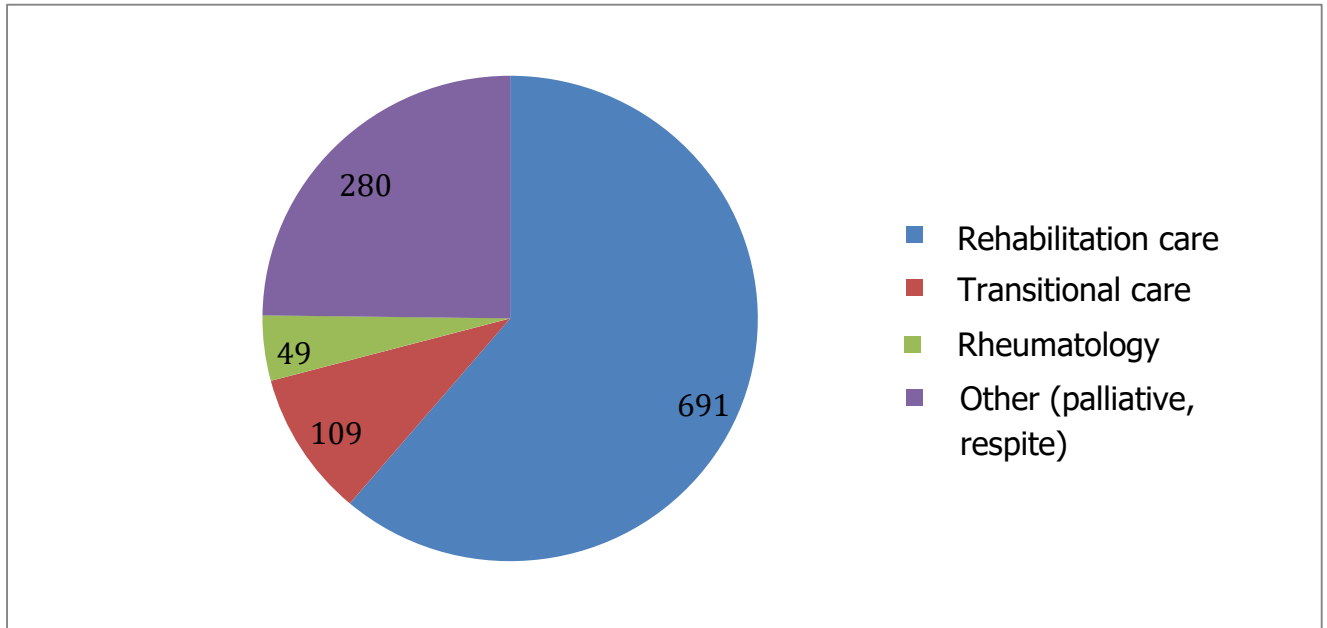
HIQA started monitoring rehabilitation and community inpatient healthcare services in October 2019. The monitoring programme focused on monitoring compliance with three national standards from the *National Standards for Safer Better Healthcare* (see Table 5).

Table 5. National Standards monitored in HIQA's rehabilitation and community inpatient healthcare services monitoring programme

Dimension	Theme	National Standard
Capacity and Capability	Leadership, Governance and Management	Standard 5.2: Service providers have formalised governance arrangements for assuring the delivery of high quality, safe and reliable healthcare.
Quality and Safety	Person-centred Care and Support	Standard 1.1: The planning, design and delivery of services are informed by patients' identified needs and preferences.
Quality and Safety	Safe Care and Support	Standard 3.1: Service providers protect patients from the risk of harm associated with the design and delivery of healthcare services.

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Five unannounced on-site inspections, were completed across the rehabilitation and community inpatient healthcare services. These inspections focused on the governance and risk management structures and process in place in each service, specifically the structures and process to ensure the prevention and control of healthcare-associated infections and the safe use of medicines. Patients' views and experiences were also obtained during the inspection process.

As the monitoring programme only began in late 2019, it is too early to present detailed findings from the monitoring activity or to draw conclusions on service providers' capacity and capability to provide safe, high-quality, reliable healthcare services. Notwithstanding this, preliminary findings from services inspected to date identified that the following structures and processes were in place to enable the delivery of safe, high-quality care:

- a defined governance and management arrangement — but not all had integrated corporate and clinical governance
- regular formal management meetings and quality and safety committees with accountability and reporting structures at hospital and or community health organisation level
- risk management and incident reporting structures and processes with oversight by senior management teams
- proactive and systematic identification of the needs and preferences of patients
- pre-admission processes ensuring that patients' needs and preferences were considered when planning, designing and coordinating care within and between services
- a formalised structure and process to obtain feedback from patients with information from this process informing the continual improvement of services for patients
- a complaints process with a designated person assigned to the role of complaints officer
- good ownership and oversight of environmental and equipment hygiene in the majority of hospitals inspected
- active progression of a medication safety agenda and on-site pharmacy facilities
- access to medication information sources, for example, the British National Formulary
- staff training and education in relation to infection prevention and control and medication safety.

HIQA found that those services that had been inspected so far through this programme were committed to improving infection prevention and control practices and were endeavouring to fully implement the *National Standards for Infection Prevention and Control in Community Services*.[19]

Nonetheless, during the monitoring activity, opportunities for improvement were identified in the areas of infection prevention and control and the safe use of medicines. These included the need for greater oversight of the proactive, monitoring and evaluation of infection prevention and control processes in some hospitals. If this lack of oversight was to continue, HIQA believes it could impact on the provision of safe services and care in those hospitals.

In addition, other opportunities for improvement included:

- services having greater access to specialist staffing and expertise in the area of infection prevention and control
- the need to have a standardised and consistent approach to infection prevention and control in place
- the need to revise and update infection prevention and control policies procedures and guidelines
- better and improved management and oversight of environmental hygiene in some services
- the need to establish a structure and process for medication reconciliation on admission, transfer of care and or discharge.

The preliminary findings presented here, especially those in relation to infection prevention and control, are important when considered in the context of the COVID-19 pandemic. Despite some resourcing in this sector, infection prevention and control measures in the community healthcare setting trail behind the acute setting.[103]

Infrastructural challenges and issues around access to specialist infection prevention and control expertise need to be addressed if compliance with national standards is to be achieved. Furthermore, there is a need to ensure that those services who have relied on infection prevention and control expertise and supports from the acute hospital sector, continue to be supported given the pressures on these acute services from COVID-19.

8.2   Monitoring of medical exposure to ionising radiation

The role of ionising radiation in medical diagnosis and treatments is well established. Nonetheless, exposure to such radiation can also damage healthy cells in the body and, therefore the benefits of its use need to be carefully weighed against the potential risk of harm for patients. Regulations in the area of medical exposure to ionising radiation aim to protect patients against these risks. Medical exposure occurs when an individual receives ionising radiation as part of their diagnosis or treatment. This can include a simple dental X-ray, a more complex CT or CAT scan and radiotherapy that an individual may receive as part of their cancer treatment.

In 2007, the International Commission on Radiological Protection recommended that exposure to ionising radiation be regulated. This recommendation was incorporated in the EU Council Basic Safety Standards (BSS) Directive of 2013 and was adopted into Irish legislation in January 2019. With the enactment of this legislation, HIQA became the competent authority in Ireland with responsibility for the regulation of medical exposure to ionising radiation.

During the development and preparation phase of the monitoring programme, HIQA engaged in an extensive process of engagement with many interested parties involved in regulating ionising radiation at national and international level. HIQA also published several guidance documents for healthcare and dental service providers, both public and private. These included:

- An assessment-judgment framework for assessment of compliance[104]
- Guidance on the assessment of compliance.[105]
- Guidance on inspection of services providing medical exposure to ionising radiation.[106]
- Guidance for undertakings[‡‡‡‡‡‡‡‡‡] on reporting accidental or unintended exposures.[107]

In early 2020, HIQA also published the following guidance documents for healthcare and dental services in the public and private sector:

- Guidance on Dose Constraints in Medical Exposures to Ionising Radiation.[108]
- Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation.[109]

[‡‡‡‡‡‡‡‡‡] In the regulations, '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 procedure or the practical aspects of a medical radiological procedure' is defined as an undertaking.

- Guidance on Criteria for the Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy.[110]

In addition, at the time of writing this overview report, HIQA was progressing the following initiatives in fulfilment of its regulatory functions relating to the medical exposure of ionising radiation:

- the establishment of national diagnostic reference level (DRLs)
- the setting up of dose constraints for carers, comforters and volunteers participating in research involving medical exposure
- the adoption of criteria for acceptability of equipment.

HIQA's regulatory monitoring programme in the medical exposure of ionising radiation commenced in late 2019. HIQA issued 230 self-assessment questionnaires to hospitals and other healthcare facilities where medical exposure to ionising radiation occurred, and to dental facilities where cone beam computed tomography§§§§§§§§§ was used. The information received from this process informed the roll out of the on-site inspections. To date, HIQA has completed a series of on-site inspections, and the first series of 10 inspection reports from these inspections were recently published and are available to read on HIQA's website, www.hiqa.ie.

Further publication of findings from this new area of regulation in healthcare will follow in due course, including a report outlining findings from the reporting of notifications of serious reportable events to HIQA. All of this work aims to share learning and therefore promote collective improvement across services, in an effort to enhance patient safety in this important area into the future.

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§§§§§§§§§ Cone beam computed tomography is a special type of x-ray equipment used when regular dental or facial x-rays are not sufficient, producing three dimensional (3-D) images of teeth, soft tissues, nerve pathways and bone in a single scan.

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Chapter 9. Overall conclusions

Internationally, it is well recognised that developing and implementing standards in healthcare and monitoring compliance with them, help support incremental improvements in such services.[10,11,12] This approach helps to promote safe, high-quality and reliable healthcare services.[10,11,12]

HIQA believes implementing and monitoring compliance with national standards — and ensuring compliance with regulations in the area of medical ionising radiation — help to enable healthcare providers to sustainably safeguard patients from potential harm and to continually improve their quality of care and service provided.

In setting and monitoring compliance with nationally mandated standards and enforcing medical ionising radiation regulations across healthcare and dental services, HIQA aims to promote learning. Where necessary, it will intervene where it has the power to do so to protect patients and enhance services.

Over the last five years, HIQA completed over 260 on-site inspections as part of the four defined monitoring programmes in the areas of nutrition and hydration, infection prevention and control, medication safety and maternity services. Findings from each inspection are published on HIQA's website. Each report set out the service's level of compliance and or non-compliance with national standards, areas of good practice and areas where improvements were needed.

In addition, HIQA published three overview reports, following extensive reviews in the areas of infection prevention and control, medication safety and maternity services. Furthermore, HIQA also carried out a comprehensive programme of national monitoring in the area of antimicrobial stewardship, with findings also published. Publishing these reports promotes public scrutiny and encourages compliance in the absence of enforcement powers to compel healthcare services to address areas of non-compliance with nationally mandated standards.

Observed improvement across the healthcare sector

Service providers are responsible for the safety and quality of the service they provide and for demonstrating compliance with national standards. Findings from HIQA's monitoring activity demonstrate how good governance, underpinned by an ethos of professionalism, is the first line of defence when providing safe, high-quality and reliable healthcare. 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.

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Through monitoring performance, services can be assured that the care and services they provide are of a consistently high quality and that the likelihood of potential variations in care across services is minimised. By fulfilling its statutory role, HIQA believes it helps services to promote quality improvement for patients by maintaining services' focus on compliance with national standards. With the cooperation and assistance of providers, HIQA's monitoring activity to date in public acute healthcare services has provided a level of assurance about the:

- quality and safety of those particular services which HIQA has monitored
- accountability arrangements for delivering good care in those services
- use of best available evidence in those services to ensure up-to-date, effective and consistent care for patients
- monitoring, evaluation and benchmarking of such services across the country
- identification and management of risk and opportunities to improve.[103,111]

Over the last five years, HIQA believes 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, combined with increased investment and dedicated resourcing by the HSE and better, more effective systems of oversight of performance in services, such as ongoing surveillance and audit, has contributed to improved quality and safety of these healthcare services.

Over the five-year period, HIQA has seen sustainable improvements in governance structures at hospital level. In addition, we believe overall healthcare governance structures have improved, resulting in a more connected and integrated approach at local, regional and national healthcare levels. The most notable improvements in services monitored by HIQA have occurred in the areas of infection prevention and control and medication safety. Improvements seen in the area of infection prevention and control included:

- strengthened governance and leadership structures at hospital level
- strengthened leadership and governance structures at national level
- better coordination of infection prevention and control at national HSE level, aided by setting up and implementing a national Antimicrobial Resistance and Infection Control (AMRIC) team
- significant scaling up in the appointment of specialised staff to implement antimicrobial stewardship and infection prevention and control measures
- greater coordination and management of multi-drug resistant organisms in hospitals
- increased screening for multi-drug resistant organisms, such as CPE, when patients are admitted to hospital

- greater oversight of performance, enabled by ongoing microbiological surveillance and monitoring and audit programmes
- a more concentrated focus and embedded approach to improve hand hygiene in hospitals through continual education and training
- better oversight and monitoring of environmental and equipment hygiene in many hospitals.[103]

Similarly, improvements observed in the area of medication safety included:

- heightened awareness and a greater level of emphasis and investment in medication safety capability and expertise in those hospitals that did not perform well in the first phase of the programme
- more consistent applications of best practice in terms of governance
- greater clarity on what needs to happen from a national planning perspective to advance the safe use of medicines
- better collaboration and sharing of learning within and across hospitals groups to improve medication safety.

Efforts to strengthen governance and accountability arrangements at a national level were also seen in maternity services in late 2019. Such changes will be important to achieve the vision and models of care set out in the National Maternity Strategy. However, as HIQA's monitoring activity into maternity services concluded in February 2020, it is too early to identify the impact that changes made to national governance within the HSE in this area might realise.

Opportunities for improvement across the healthcare sector

Notwithstanding the sustained improvements seen in the different monitoring programmes, HIQA also found that the level of compliance with national standards across public acute hospitals varied greatly. Some hospitals had governance and clinical structures and processes in place, in line with international best practice and national standards while other hospitals lagged behind. The quality of care provided across public acute hospitals was, therefore, inconsistent, which is at odds with the standardised approach promoted within the *National Standards for Safer Better Healthcare*.

Furthermore, HIQA 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. If compliance with national standards is to be achieved nationally, then these challenges must be addressed. HIQA believes inconsistencies with compliance with the national standards can begin to be addressed by acting on the opportunities for improvement, which are identified in each inspection report. Services need to be

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supported and resourced in their efforts to do so. Opportunities from each
monitoring programme are summarised in Tables 6, 7 and 8.

**Table 6. Opportunities for improvement identified during the HIQA
infection prevention and control monitoring programme**

Dimensions are the two overarching aspects of care in the national standards. They are: capacity and capability; and quality and safety. Themes describe each element of care.		
Dimension	**Theme**	**Opportunities for improvement**
Capacity and Capability	Workforce	- There is a need to fully identify and address deficiencies in specialist staffing levels, including a need to ensure the sustainability of 24/7 microbiology services where only one microbiologist is employed. - Dedicated staff should be engaged in the reprocessing of reusable ear, nose and throat (ENT) endoscopes in satellite decontamination facilities.
	Education and training	- All hospitals need to achieve and sustain the national target for hand hygiene. - A rolling programme of education and training needs to continue, and a regular review of staff competencies needs to be progressed to include personnel involved in the decontamination of reusable equipment outside of normal hours. - Policies, procedures and guidelines on decontaminating and reprocessing reusable equipment need to be updated in some facilities and should be reviewed in line with national guidelines.
Quality and Safety	Hospital infrastructure	- The underlying nature, design and maintenance of the infrastructure of some hospitals present ongoing and significant challenges to best practice and compliance with national standards. Significant investment is needed to address these challenges. - There is a need to centralise equipment decontamination activity and rationalise the number of satellite decontamination facilities in some hospitals.

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	Information and communication technology (ICT) infrastructure	▪ The implementation of dedicated software to aid surveillance of infections in most hospitals needs to be progressed. ▪ Implementation of validated automated decontamination systems and electronic tracking and tracing systems for reusable equipment needs to be progressed at some hospitals.
Quality and Safety	Environmental hygiene and equipment	▪ Good maintenance of the physical environment and environmental hygiene are necessary to prevent cross contamination of infection within hospitals. Despite the infrastructural challenges in older hospital infrastructures, an acceptable standard of basic cleanliness and maintenance is both essential and achievable. ▪ Cleaning specifications and hygiene auditing regimes should be in line with national recommendations for higher-risk functional areas, such as equipment decontamination facilities.
	Monitoring and evaluation	▪ All hospitals need to embed ongoing microbiological surveillance, monitoring and audit programmes and oversight of services in relation to infection prevention and control systems. ▪ Regular review, audit, feedback and quality improvement cycles should be implemented in relation to decontamination and reprocessing services.
	Decontamination and reprocessing equipment	▪ Investment is needed to replace ageing equipment. ▪ Align the decontamination and reprocessing of ENT endoscopes with HSE standards and recommended practices.

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Table 7. Opportunities for improvement identified during the HIQA medication safety monitoring programme

Dimensions are the two overarching aspects of care in the national standards. They are: capacity and capability; and quality and safety. Themes describe each element of care.		
Dimension	**Theme**	**Opportunities for improvement**
Capacity and Capability	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.
Quality and Safety	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.

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	Procedural sedation	Opportunities for improvement were identified in relation to procedural sedation, in the following areas: ▪ oversight arrangements[112,113] ▪ 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.

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Table 8. Opportunities for improvement identified during the HIQA nutrition and hydration monitoring programme

Dimensions are the two overarching aspects of care in the national standards. They are: capacity and capability; and quality and safety. Themes describe each element of care.		
Dimension	**Theme**	**Opportunities for Improvement**
Capacity and Capability	Leadership, governance and management	▪ Hospitals should have a nutrition and hydration steering committee in place.
Quality and Safety	Screening	▪ Patients should be screened for the risk of malnutrition on admission.
	Monitoring and evaluation	▪ Hospitals must audit compliance with all aspects of patients' nutritional care. ▪ Hospitals should engage with patients about food variety and choice in order to improve patients' experience of hospital meals.

Moving forward

HIQA's monitoring activity from 2015 until 2019 occurred during an ever increasing demand for healthcare services, increasing expectations of people using the services and a number of well-documented challenges for the healthcare system. The planned reform and restructuring of health services was under way across the healthcare sector in 2019 as HIQA continued to monitor compliance with national standards.

Compliance with patient safety regulations and nationally mandated standards is more essential now than ever before. As this report outlines, setting healthcare standards and independent monitoring by HIQA against these standards can contribute to improvements for patients. It is also an important safety mechanism which, along with providers improving services for patients in parallel, is vital to ensuring providers can sustainably deliver safe care over the long term.

At the time of preparing this overview report, HIQA does not have enforcement powers as part of its healthcare monitoring remit, with the exception of regulations governing medical exposure to ionising radiation, such as X-ray and radiation therapy safety. However, plans to introduce the regulation of healthcare, somewhat

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similar to the regulation of nursing homes and residential centres for people with disabilities in Ireland, as proposed in the Patient Safety (Licensing) Bill, would begin to address this regulatory shortfall.

Under the proposed framework, HIQA would become responsible for regulating healthcare services and would have enforcement powers to address issues of non-compliance. Such enforcement powers would strengthen HIQA's role in promoting compliance with national standards and quality improvement. HIQA believes such regulation is needed now more than ever as health services adapt to the requirement to provide both COVID-19 care, and other ever increasing demands associated with non-COVID-19 care.

Working with providers and funders of care, HIQA will continue to support continual and sustainable improvement in services, across public and private healthcare and dental services providing medical exposure to ionising radiation services. Furthermore, it is critically important to continue to progress the goals of the Patient Safety (Notifications) Bill, as a stepping stone towards an eventual licensing regime. In particular, such legislation would enable HIQA to monitor private healthcare services. Building upon our experiences over the past five years as outlined in this report, HIQA looks forward to working with interested parties in this regard, as such changes are advanced in the best interest of enhancing the quality and safety of patient care into the future.

Appendices

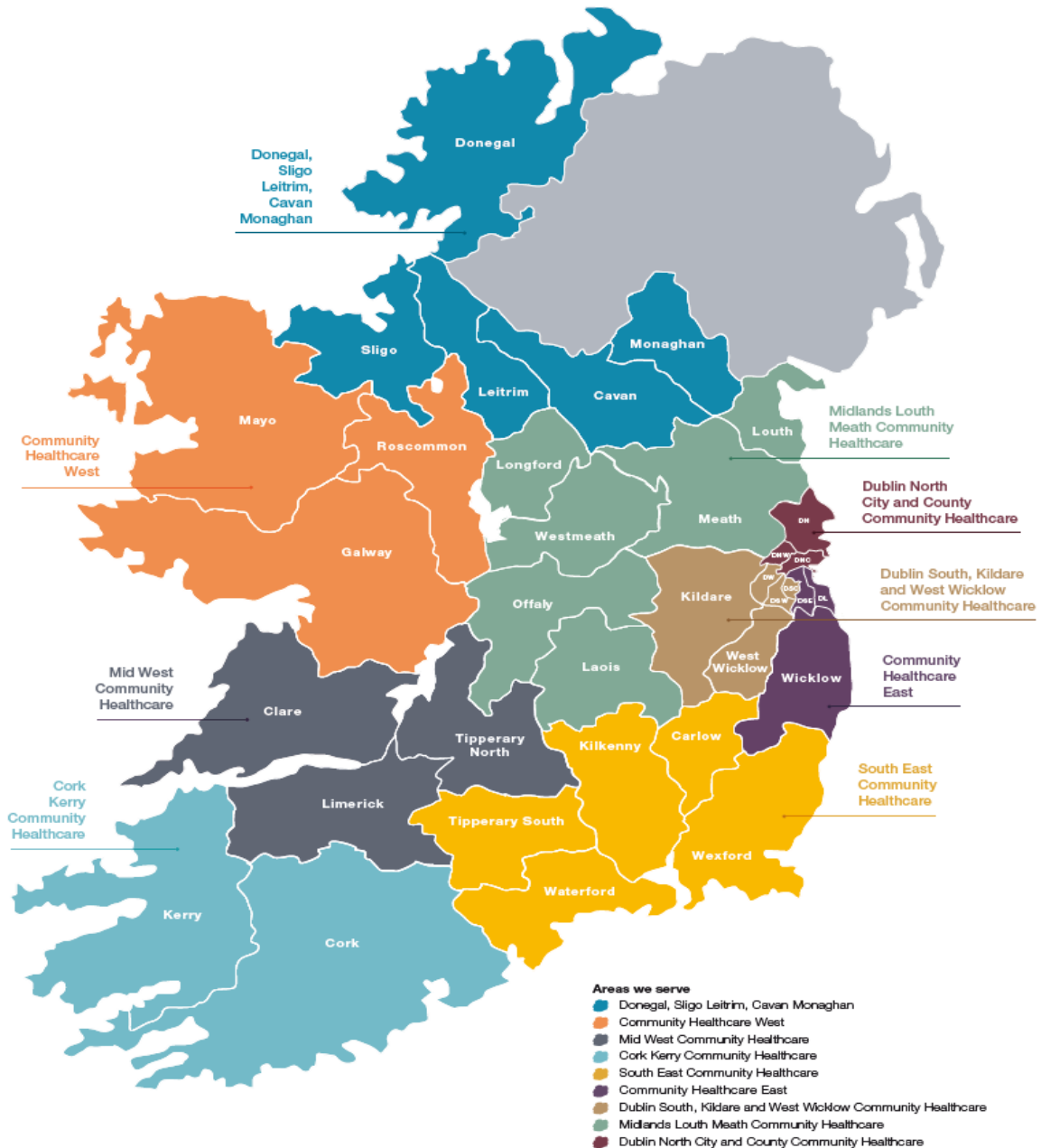## Appendix 1— Seven hospital groups in the Republic of Ireland
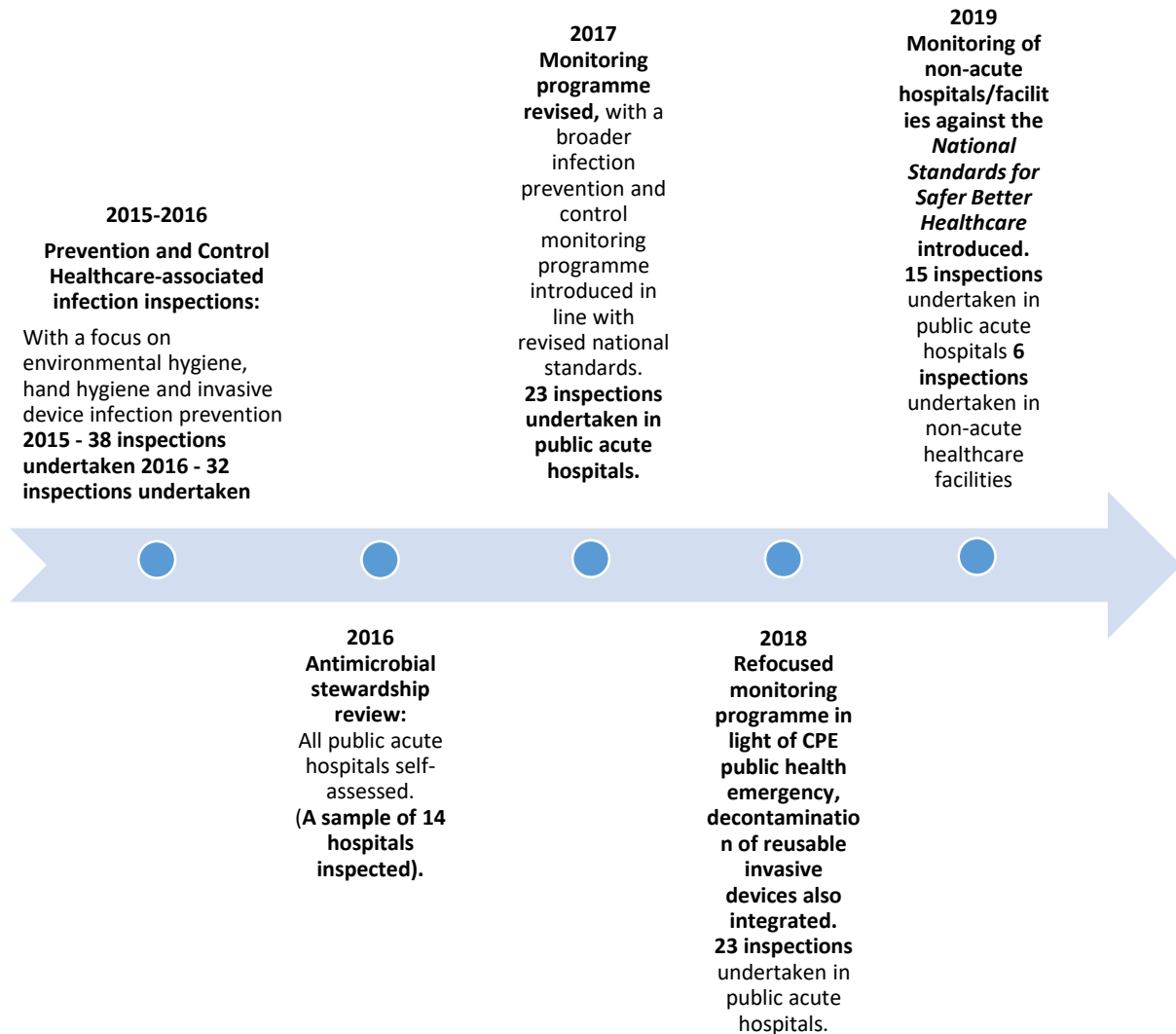

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Appendix 2 — Location of nine community healthcare organisations

Nine Community Healthcare Organisations…

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Appendix 3 — HIQA infection prevention and control monitoring and inspection programmes 2015-2019

2015-2016

Prevention and Control Healthcare-associated infection inspections:

With a focus on environmental hygiene, hand hygiene and invasive device infection prevention **2015 - 38 inspections undertaken 2016 - 32 inspections undertaken**

2017
Monitoring programme revised, with a broader infection prevention and control monitoring programme introduced in line with revised national standards. **23 inspections undertaken in public acute hospitals.**

2019
Monitoring of non-acute hospitals/facilities against the *National Standards for Safer Better Healthcare* introduced. 15 inspections undertaken in public acute hospitals **6 inspections** undertaken in non-acute healthcare facilities

2016
Antimicrobial stewardship review:
All public acute hospitals self-assessed.
(A sample of 14 hospitals inspected).

2018
Refocused monitoring programme in light of CPE public health emergency, decontamination of reusable invasive devices also integrated. 23 inspections undertaken in public acute hospitals.

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Appendix 4 — Recommendations from the HIQA overview report 2016–2017 medication safety monitoring programme in public acute hospitals

National recommendations focused on improving medication safety
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.
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.

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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.

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