Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Annual Report 2021

Safer Better Care

Safer Better Care

HIQA is an independent authority that exists to improve health and social care services for the people of Ireland.

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Foreword from the Chairman

Professor Pat O'Mahony
Chairman

I am pleased to introduce HIQA's 2021 Annual Report. This report outlines HIQA's achievements as we fulfilled the last year of our 2019–2021 Corporate Plan.

2021 was a busy year as the challenges of COVID-19 continued, and we worked to drive improvements across health and social care as set out in our remit under the Health Act 2007 (as amended).

The year also heralded a time of change in the organisation. Our Executive Management Team saw a change in Chief Inspector of Social Services and a new position of Director of Healthcare Regulation appointed. I would like to thank our former CEO Phelim Quinn and Chief Inspector Mary Dunnion for their contribution to the organisation, and also to health and social care services throughout their entire careers. On behalf of HIQA, I wish them a very happy retirement.

Throughout the year, we continued to provide evidence synthesis and advice to the National Public Health Emergency Team (NPHET) on behalf of the Minister for Health, and inform Ireland's public health response to the COVID-19 pandemic. In 2021, we also commenced the provision of evidence synthesis and evidence-based advice to support the National Screening Advisory Committee on behalf of the Minister. This is a new area of work for HIQA and one we will continue to deliver on in the coming years.

As the regulator, we continued to monitor the safety and quality of health and social care services, responding to risk, particularly the risk of infection in services. We liaised with the Health Service Executive (HSE) to provide support to the services that needed it, and we engaged with service providers, residents and relatives on issues that mattered to them. We also highlighted the inadequacies of the current regulations, and the need for regulations in other areas to better protect the people using health and social care services.

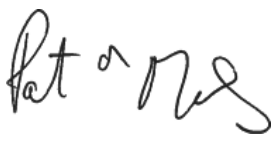
In 2021, we also commenced work in new areas, such as homecare. During the year, we conducted research on the homecare sector in Ireland, identifying the need for reform and the introduction of regulation in the area to safeguard the people availing of services. We also commenced the development of new national standards for homecare services. The standards will aim to promote progressive quality improvements in homecare services and give a shared voice to the expectations of the public, people using services, service providers and staff.

Events in 2021 further highlighted the need for developments in our health information policies, systems and legislation. The cyberattack on the HSE's systems highlighted the need to reform the health information system in Ireland, in line with the priorities set out under Sláintecare. During the year, we highlighted how reform is needed in the key areas of legislation, a national strategy, and leadership and governance.

We also continue to work with our partners in the Department of Health and HSE to implement the National Care Experience Programme. Last year, we ran the National Inpatient Experience Survey, marking the first time patients were asked about the impact of COVID-19 on their experiences in Irish hospitals. We will publish details of this patient feedback during 2022.

Looking forward, we will continue our advice on the need for reforms in the health and social care regulations and health information system. We will continue progress in the implementation of recommendations of the COVID-19 Nursing Home Expert Panel. We will also prepare to take on new responsibilities and commitments as set out in the Programme for Government and elsewhere, including provisions for the onward development of the Patient Safety Bill, the regulation of homecare services, as well as the inspection of direct provision centres.

I would like to thank all our staff for their hard work and commitment in 2021, and for carrying out our work in line with HIQA's missions and values. Finally, I would also like to thank the members of the Board for the advice and direction that they provided. We will ensure that HIQA continues to make a positive contribution to the quality and safety of Ireland's health and social care services.



Prof Pat O'Mahony
Chairperson

Message from the CEO

Angela Fitzgerald
Chief Executive Officer

Welcome to HIQA's 2021 Annual Report.

I am delighted to have joined HIQA as Chief Executive at an unprecedented time when we are building on our work and achievements of 2021 and the preceding years to improve the safety and quality of care in Ireland's health and social care services.

I take up this role at a time of great change in the organisation following two years of the COVID-19 pandemic, an expanding remit and organisational restructuring. I am looking forward to working with the highly committed team in HIQA in shaping and driving change so that we can support further improvements in the quality and safety of health and social care services.

The initiatives and projects outlined in this report were led by former Chief Executive, Phelim Quinn, who retired at the end of 2021, having served the organisation in that role for seven years, and having previously been HIQA's Chief Inspector of Social Services and Director of Regulation. The report is testament to his excellent leadership and significant expertise in regulation and quality improvement.

Over the years, I had the pleasure of working with Phelim to progress numerous patient safety and quality matters, including the National Care Experience Programme. Under his leadership, a focus on safeguarding and human rights was brought to the fore in HIQA, including in national standards, guidance and how services are regulated.

Over the past number of years, HIQA has also contributed to improving public health through membership of NPHET and the provision of evidence synthesis, and continued to further reforms in the health information landscape. HIQA's achievements and progress in these areas during 2021 are outlined throughout this report.

I would like to thank the Board, Executive Management Team and staff of HIQA for all their work in 2021. I look forward to working with them to progress this work and deliver on our vision for care in Ireland under our current remit, and as our role expands into new areas of work and responsibility.

Angela Fitzgerald
Chief Executive Officer

1 About HIQA

1.1 Introduction

The Health Information and Quality Authority (HIQA) is the independent authority established in 2007 to drive high-quality and safe care for people using health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

This Annual Report outlines the work of HIQA from 1 January to 31 December 2021, in keeping with the statutory requirements of the Health Act 2007, and includes HIQA's arrangements for implementing and maintaining adherence to the Code of Governance for public bodies. It also includes the Report of the Chief Inspector of Social Services and the Annual Governance and Compliance Report, as required by the Health Act 2007, and our annual financial statements.

1.2 Our mandate and activities

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

- **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.

The statutory functions that provide the basis for HIQA's work are outlined in the Health Act 2007, the Child Care Acts 1991 and 2001 (as amended), the Children Act 2001, the Education for Persons with Special Educational Needs Act 2004, and the Disability Act 2005.

2 Governance and management

2.1 Our Board

The Board is the governing body of HIQA and was first established on 15 May 2007. The Board is responsible for the appropriate governance of HIQA, ensuring effective systems of internal control, statutory and operational compliance and risk management. These provide the essential elements of effective corporate governance and compliance.

Membership of the Board is made up of a Chairperson and 11 non-executive directors who have been appointed by the Minister for Health. The Board members have specific experience and expertise in matters connected with HIQA's functions, and come from a range of health and social care professions and industries.

The members of the Board during 2021 included:

Prof Pat O'Mahony
Chairperson

Chief Executive of Clinical Research Development Ireland. Former Chairman of the Management Board of the European Medicines Agency. Former Deputy Secretary General and Head of Governance and Performance at the Department of Health. Former Chief Executive of the Health Products Regulatory Authority.

Bernadette Costello

Former Director, Internal Audit and Risk Management at NUI, Galway. Member of the Board of Irish Management Institute, Oberstown Children Detention Campus and Galway and Roscommon Education and Training. Former board member of the National Treatment Purchase Fund. Chartered Director and Chartered Accountant.

Dr Jim Kiely

Former Vice Chair of the Board of Tallaght University Hospital and member of the Commencement, Transition and Integration Committee for the National Children's Hospital. Former Chief Medical Officer in the Department of Health.

Dr Paula Kilbane

Former CEO of Eastern Health and Social Services Board in Northern Ireland and Director of Public Health of the Southern Health Board Northern Ireland. Currently a director of a number of boards in the private, public and charitable sectors.

Tony McNamara

Insight Management Consultancy. Former CEO of Cork University Hospital. Served on various national advisory and consultancy bodies for the Department of Health. Former board member of Irish Blood Transfusion Board, Road Safety Authority and Health Insurance Authority.

Lynsey Perdisatt

Senior HR professional having worked in both the private and public sector, with significant experience in employee relations, industrial relations and change management.

Prof Michael Rigby

Extensive experience in health service development and delivery, and in research into health policy and management in UK and Ireland. Member of the Roster of Experts appointed to support WHO Digital Health Technical Advisory Group.

Caroline Spillane

Director General of Engineers Ireland. Former CEO of the Medical Council of Ireland. Former Assistant National Director with the HSE and CEO of the Crisis Pregnancy Agency.

Martin Higgins

Chair of Food Safety Authority of Ireland Board. Former CEO of safefood. Previously served on boards of the Irish Medicines Board, the health and social care professionals regulator CORU, and the Nursing and Midwifery Board of Ireland.

Martin O'Halloran

Former CEO of the Health and Safety Authority, and former chairman of the Board of the Institute for Public Administration and the Association of Chief Executives.

Marion Meany

30 years' experience working in health services. Former HSE Assistant National Director for Disability Strategy and Planning.

Dr Daniel McConnell

Consulting Partner in Deloitte UK, with significant experience in digital and data transformation. Board Member of the South Eastern Regional College and Fellow of the Chartered Institute of Public Finance & Accountancy.

2.2 Board meetings

Under the Health Act 2007 the Board is required to meet six times annually. In total, HIQA's Board met 10 times during 2021 to progress various significant matters (see Chapter 5 for more detail on our Board's activities in 2021).

2.3 Board committees

Four Board committees support the activities of the Board in governing HIQA:

- **Regulation Committee** oversees the effectiveness, governance, compliance and controls around the delivery of HIQA's regulatory functions.
- **Audit, Risk and Governance Committee** supports the Board in relation to its responsibilities for issues of risk, control and governance and associated assurance. The Audit, Risk and Governance Committee is independent from the financial management of the organisation. In particular, the committee ensures that the internal control systems, including audit activities, are monitored actively and independently. The committee reports to the Board after each meeting, and formally in writing annually.
- **Standards, Information, Research and Technology Committee** oversees the governance arrangements, including compliance and controls, for the functions of standards development, health information and health technology assessment functions.
- **Resources Oversight Committee** monitors the resource requirements of HIQA to ensure that they are aligned with HIQA's corporate strategy, including oversight of resource related risks. In addition, it oversees organisational needs and managerial performance.

2.4 Executive Management Team

HIQA's organisational structure reflects the core functions and activities of Regulation, Health Technology Assessment and Health Information and Standards, together with the support services that enable us to achieve our corporate objectives: the Chief Executive's Office, Operations, Information Division and Communications and Stakeholder Engagement. The organisation is led by the Executive Management Team which is supported by other senior managers who are responsible for our business functions.

The membership of HIQA's Executive Management Team at 31 December 2021 comprised:

Phelim Quinn

CEO

Dr Máirín Ryan

Director of Health Technology Assessment and Deputy Chief Executive

Carol Grogan

*Chief Inspector of Social Services^*

Sean Egan

*Director of Healthcare Regulation**

Rachel Flynn

Director of Health Information and Standards

Sean Angland

Acting Chief Operations Officer

Bala Krishnan

Chief Information Officer

Mary Dunnion

*Director of Regulation and Chief Inspector of Social Services***

^Appointed in September 2021
*Appointed in October 2021
**Retired in September 2021

2.5 Corporate governance

HIQA's Board is responsible for internal controls and annually reviewing the effectiveness of these controls, including financial, operational and compliance controls, and risk management.

To deliver on this responsibility, the Audit, Risk and Governance Committee takes an active role in coordinating the assurances derived from various sources, such as:

- internal audit work
- audit by the Comptroller and Auditor General
- risk management
- review of financial controls
- review of financial statements.

In addition:

- The Executive Management Team provides an annual assurance statement to the Board which sets out the controls covering the totality of HIQA's functions.
- Regular corporate performance reports are provided to the Board, including corporate risks.
- The Chief Executive provides a report at each meeting of the Board.
- The four Board committees report to the Board.

Compliance with the Code of Practice for the Governance of State Bodies

HIQA has a Code of Governance, Code of Business Conduct and related governance policies and procedures to ensure its compliance with the revised Code of Practice for the Governance of State Bodies.

HIQA was recertified for the SWiFT 3000 Governance Standard from the National Standards Authority of Ireland. A detailed Annual Governance and Compliance report is included with the annual financial statements for 2021.

3 Strategic objectives

3.1 Mission statement, vision and values

Mission statement

Our vision

SAFER SERVICES
We work to protect and safeguard service users

BETTER CARE
We work to improve the quality of health and social care services

BETTER DECISIONS
We provide advice, evidence and information to inform local and national decisions about services

INDEPENDENT ASSESSMENT
We provide a reliable source of information for the public and our stakeholders

Our values

HIQA is driven by its values, which reflect the essence of the legislation that defines our remit.

HIQA's values	*In practice, this means we will:*
PUTTING PEOPLE FIRST	Put the needs, voices, rights and protection of people who use health and social care services at the centre of our work.
BEING FAIR AND OBJECTIVE	Be fair and objective in our dealings with people and organisations.
BEING OPEN AND ACCOUNTABLE	Communicate the nature and outcomes of our work and accept full responsibility for our actions.
STRIVING FOR EXCELLENCE	Continually improve the quality of our work and use the best available evidence.
WORKING TOGETHER	Listen to and work with those funding, planning, providing and using health and social care services.

3.2 Strategic objectives

HIQA's Corporate Plan 2019–2021 sets out the framework and strategic objectives that enable us to meet existing and new obligations. This plan outlines the direction and focus of the organisation for the period, and sets out our strategic objectives, as follows:

These commitments, included within the Corporate Plan, are met through objectives set out in our annual business plan. Read our 2021 business plan on www.hiqa.ie. Progress in achieving these objectives is summarised in the next chapter.

2021 in numbers

1,863

inspections of health and social care services

113

COVID-19 evidence synthesis reviews or advice published

1,638

concerns received about health and social care services

46,029

modules completed in our human rights-based approach e-learning course

16,170

people took our e-learning module on **infection prevention and control**

9,962

people took our e-learning module on **adult safeguarding**

36

academic publications in relation to our work

182

responses to our scoping consultation on new **National Standards for Homecare and Support Services**

4 Key activities

Our Business Plan 2021 set out an ambitious agenda to fulfil our strategic objectives in our Corporate Plan 2019–2021. This chapter sets out how HIQA has met these objectives, while also fulfilling our vision.

4.1 Regulation and monitoring of health and social care services

HIQA was established to drive high-quality and safe care for people using Ireland's health and social care services.

The Chief Inspector of Social Services oversees the registration and regulation of designated centres for adults and children: nursing homes, disability services and special care units. Furthermore, we inspect and monitor children's social services.

HIQA also has a remit to monitor compliance with national standards in public acute and community healthcare services. Furthermore, we regulate medical exposures to ionising radiation by both public and private providers.

As our remit continues to grow in these areas, in quarter 4 of 2021, we commenced work to split our Regulation Directorate into two fields – regulation of social care and regulation of healthcare. A new Chief Inspector of Social Services was appointed, Carol Grogan, as well as a Director of Healthcare Regulation, Sean Egan.

We also receive, analyse and risk-assess information from a range of sources. This includes notifications from providers relating to specific events, as set out in the regulations, as well as residents, people who use services, relatives, staff, advocates or third parties submitting information. All this information is used to inform our assessment of compliance and risk within services, and further inform our monitoring and inspection programme.

Our regulatory judgments are published thereby assuring transparency and that service users, their relatives, public representatives, service providers and the relevant government departments are aware of the levels of compliance with mandated regulations and standards, areas of good practice and the level of risk across services.

In addition, HIQA may undertake an investigation as to the safety, quality and standards of the services described in section 8(1) (b) of the Health Act if HIQA believes, on reasonable grounds, that there is a serious risk to the health or welfare of persons using those services. The Minister may also require HIQA to undertake an investigation in accordance with Section 9 of the Act.

4.1.1 Regulation of nursing homes

2021 was another difficult year for nursing homes. At the beginning of the year, COVID-19 continued to present a significant risk to the care and welfare of residents in nursing homes. As public health measures across the wider community took effect, the number of cases in nursing homes also reduced. The national vaccination programme saw the majority of residents and staff opting to avail of vaccination.

COVID-19 has been widespread in the lives of nursing home residents. During this time, a large number of nursing homes residents and staff contracted COVID-19 and, sadly, a number of residents died. Residents told inspectors of the loss they felt at the passing of many of their companions, both in the nursing home and in the wider community. They also described the impact of restrictions on their day-to-day lives, such as intermittent requirements to isolate within their home, and severely limited visits from family and friends. Residents frequently speak very highly of the care they have received, crediting the efforts of staff to keep them safe.

From the onset of this pandemic, the Chief Inspector has maintained regular contact with nursing home providers, monitoring and supporting their ability to manage an outbreak. We have shared learning from one nursing home to another, directed providers to additional supports and, where necessary, escalated issues that providers and managers reported to us to the HSE, such as the need for access to personal protective equipment (PPE), serial testing and centre-specific infection prevention and control or public health advice, access to funding, and in some cases, requests for replacement staff on an interim basis.

As detailed in this report, 516 nursing homes reported at least one confirmed COVID-19 case among staff or residents in 2021. The constant focus on prevention and then, if necessary, escalating to the recognition, management and containment of an outbreak has become a normal part of the day-to-day management of a nursing home. However, this 'new normal' does not mitigate the stress and anxiety experienced by residents, families, providers and their staff.

Throughout the pandemic, inspections of nursing homes identified the following key issues of concern:

- contingency plans that may not be commensurate with the pandemic
- a lack of resilience in respect of staffing, and the governance and management systems in place in some nursing homes
- infection prevention and control knowledge and competence that were not adequate.

The combination of these issues impacted the ability of some nursing homes to recognise and respond to an outbreak of COVID-19. For example, nursing homes that operate with only one nurse on duty for significant periods of time were unable to mitigate the risk of COVID-19 by creating staff and resident pods and thereby lessen the impact of COVID-19 once it entered their centre. Equally, staffing models that are largely based on one nurse had a significantly smaller nursing workforce impacting the ability of a provider to respond with agility to contain and manage an outbreak of COVID-19.

During the year, inspectors worked to ensure that residents' human rights with regard to access to visitors were being upheld and that providers were not enforcing restrictions well in excess of public health advice.

2021 saw a continuation of collaborative efforts among the wider health and social care community, including the Department of Health, national HSE structures, HSE crisis management teams, local public health officials, and gerontology and medical teams from the acute services. Relationships that were established at the onset of the crisis in 2020 have grown and strengthened over the last 12 months.

Registration

At the end of 2021, there were 567 registered designated centres for older people (nursing homes) in Ireland, with 31,842 registered beds.

Table 1 - Number of registered beds per county 2021

Dublin	**8450**	Wexford	**1052**	Offaly	**491**
Cork	**3566**	Kerry	**1024**	Cavan	**484**
Galway	**1886**	Donegal	**975**	Sligo	**426**
Kildare	**1627**	Clare	**908**	Monaghan	**417**
Limerick	**1283**	Waterford	**816**	Carlow	**408**
Tipperary	**1222**	Kilkenny	**713**	Laois	**339**
Wicklow	**1104**	Roscommon	**691**	Longford	**288**
Mayo	**1096**	Westmeath	**627**	Leitrim	**248**
Meath	**1083**	Louth	**618**		

The 2021 figures represent a reduction of six in the total number of nursing homes since the end of 2020. Since 2019, the number of nursing homes has reduced by 18 (3%). Over the same time period, the number of beds has remained fairly static with an overall minor reduction of 126 (0.4%).

Table 2 - The number of centres and beds over the last three years

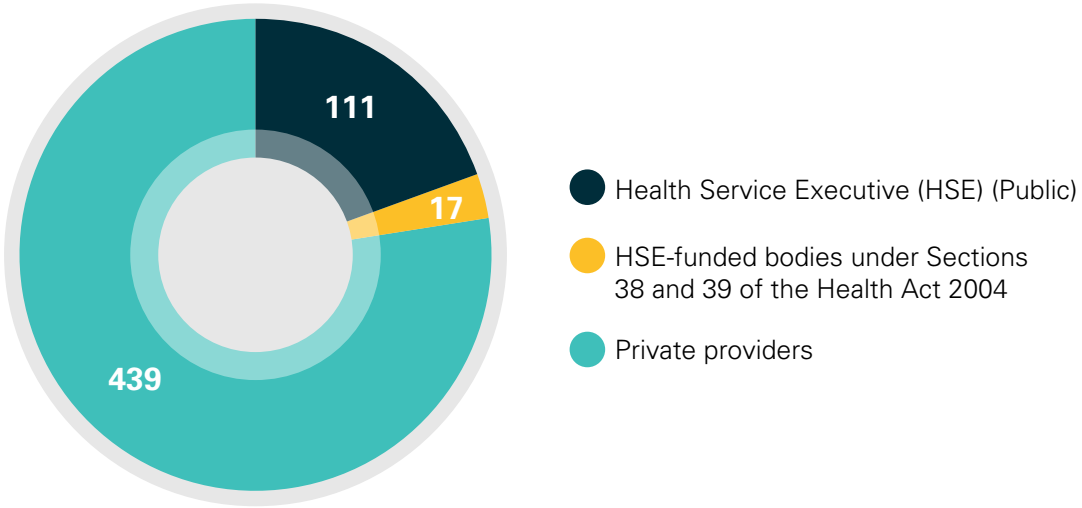
Year	Number of centres	Number of beds
2019	585	31,968
2020	573	32,091
2021	567	31,842

Nursing homes may be owned and operated by a number of legal entities, including:

- the HSE
- HSE-funded bodies under sections 38 and 39 of the Health Act 2004
- private providers.

The vast majority (77%) of nursing homes are owned and operated by private providers.

Figure 1 - The profile of ownership of nursing homes at the end of 2021



The percentage of nursing homes per provider type is not equal to the percentage of registered beds per provider type. For example, 77% of nursing homes are now operated by private providers; however, this accounts for 80% of registered beds available in the sector. Table 3 sets out the profile of ownership of nursing homes at the end of 2021. Table 4 sets out how the profile of ownership of centres and beds has changed somewhat in the last three years.

Table 3 - The profile of ownership of nursing homes at the end of 2021

Provider type	Number of centres	Number of beds
Health Service Executive (HSE) (Public)	111	5,322
HSE-funded bodies under Sections 38 and 39 of the Health Act 2004	17	946
Private providers	439	25,574
Total	**567**	**31,842**

Table 4 - The profile of ownership of centres and beds has changed somewhat in the last three years

	2019		2020		2021	
Provider type	**No. of centres**	**No. of beds**	**No. of centres**	**No. of beds**	**No. of centres**	**No. of beds**
Health Service Executive (HSE) (Public)	122 (21%)	5,864 (18%)	113 (20%)	5,596 (17%)	111 (20%)	5,322 (17%)
HSE-funded bodies under Sections 38 and 39 of the Health Act 2004	20 (3%)	1,123 (4%)	17 (3%)	978 (3%)	17 (3%)	946 (3%)
Private providers	443 (76%)	24,981 (78%)	443 (77%)	25,517 (80%)	439 (77%)	25,574 (80%)
Total	**585**	**31,968**	**573**	**32,091**	**567**	**31,842**

Bed capacity

In 2021, new nursing home beds became available through the registration of three new nursing homes and extensions in 16 existing nursing homes. New nursing homes provided 253 new beds, while extensions to existing nursing homes accounted for a further 172 beds.

The number of registered beds also changed due to the closure of nursing homes or a reduction in the number of beds in a nursing home. In 2021:

- 62 centres reduced capacity resulting in a decrease of 474 beds
- Nine centres closed which resulted in a decrease of 200 beds
  - five centres closed voluntarily
  - four centres were closed under Section 51 of the Health Act 2007.

Following the commencement of regulation of nursing homes in 2009, a time frame of December 2015 was put in place for all providers to ensure that the physical environment of their nursing home complied with Regulation 17 and Schedule 6 of the Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) Regulations 2013. In November 2015, the Minister for Health extended this time frame to 2022.

Specific provisions pertinent to the premises of a nursing home contained in Statutory Instrument (SI) 293 include:

1. On and from 1 January 2022, a bedroom in a designated centre, which was carrying on the business of a designated centre on or before July 2009 or a part of a designated centre where such business was carried on before that date shall have:

    a. an area of not less than 7.4 m^2 of floor space, which area shall include the space occupied by a bed, a chair and personal storage space, for each resident of that bedroom

    b. no bedroom shall have more than four residents other than a high-dependency room, which shall not have more than six residents

    c. adequate sitting and recreational space other than a resident's private accommodation and, on and from 1 January 2022, dining facilities for all residents which can cater to the number of residents concerned but not necessarily for all residents at the same sitting

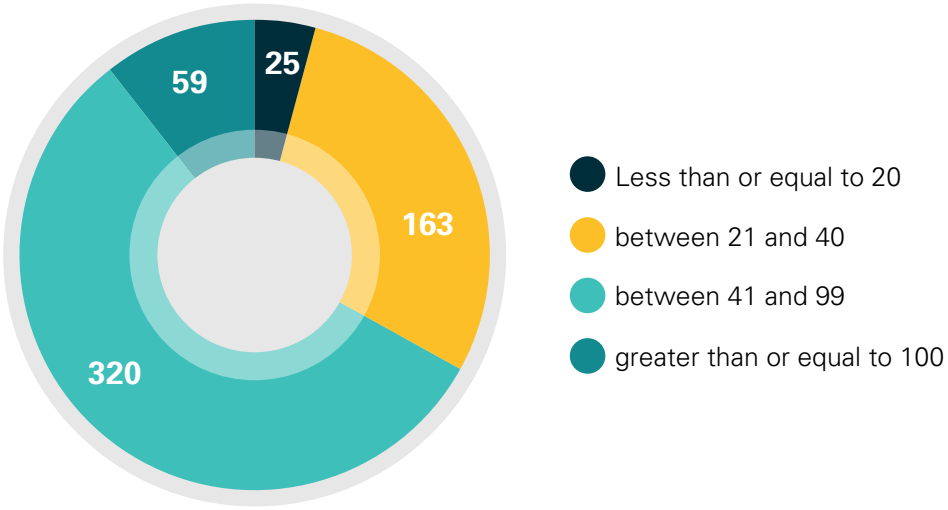
    d. toilets, including toilets which are easily accessible by, and in close proximity to, but not necessarily en-suite with the bedrooms of every eight residents.

The Chief Inspector is committed to ensuring that the quality of life, privacy and dignity of residents are not adversely impacted by the premises that they are living in. Since the enactment of SI 293 in 2016, there has been ongoing engagement between the Chief Inspector and registered providers of nursing homes in relation to this issue. Many current[1] providers who were aware that their premises would not be compliant with the revised regulations have taken significant action to address the identified issues and have either renovated or extended their premises, or reduced the occupancy and reconfigured their centre, actions which are reflected in the current numbers of nursing homes and registered beds.

At the end of 2021, 10% of nursing homes had 100 or more beds.

1 Some centres, where the financial model underpinning the nursing home did not support the level of investment required to achieve compliance, closed.

Figure 2 - Designated centres for older people by bed size, as of 31 December 2021



Inspections

In 2021, we carried out 555 inspections of 456 nursing homes. A single inspection may be carried out by one or more inspectors over one or more days. Factors that are considered in allocating resources to inspections include available information, the extent of an outbreak (if applicable) and the size of the centre and the history of regulatory compliance in the centre. In 2021, the 555 inspections of nursing homes equated to 948 inspection days.

Any inspection of a nursing home will be reflected in the publication of a report of the inspection with a few minor exceptions[2]. In 2021, 499 inspection reports were published with the remaining reports[3] progressing through the system.

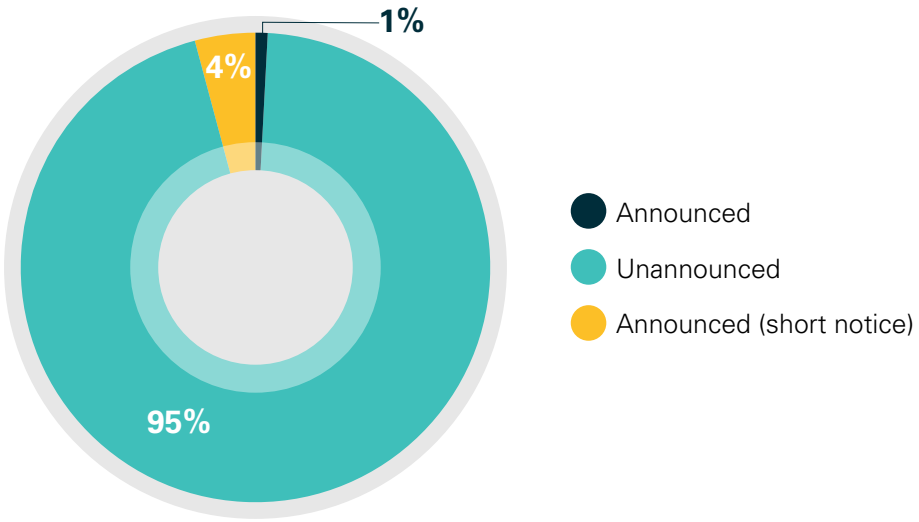
Since the onset of the pandemic, unannounced inspections of nursing homes have become the norm with 95% of all inspections of nursing homes in 2021 unannounced. Of the remaining 5% of inspections, 4% were short-notice announced[4] and the remaining 1% were announced. As the purpose of an announced inspection is to afford relatives of residents living in nursing homes the opportunity to be present during an inspection, the benefit of these inspections could not be realised as many nursing homes inspected in 2021 were in the middle of outbreak of COVID-19.

2 A report may not be published if the centre is unregistered and the inspection was for the purpose of registering it, or if the inspection was to inform an application to vary a condition of registration and did not include a review of any other issues.

3 Two reports which are subject to judicial review proceedings cannot be published at this time.

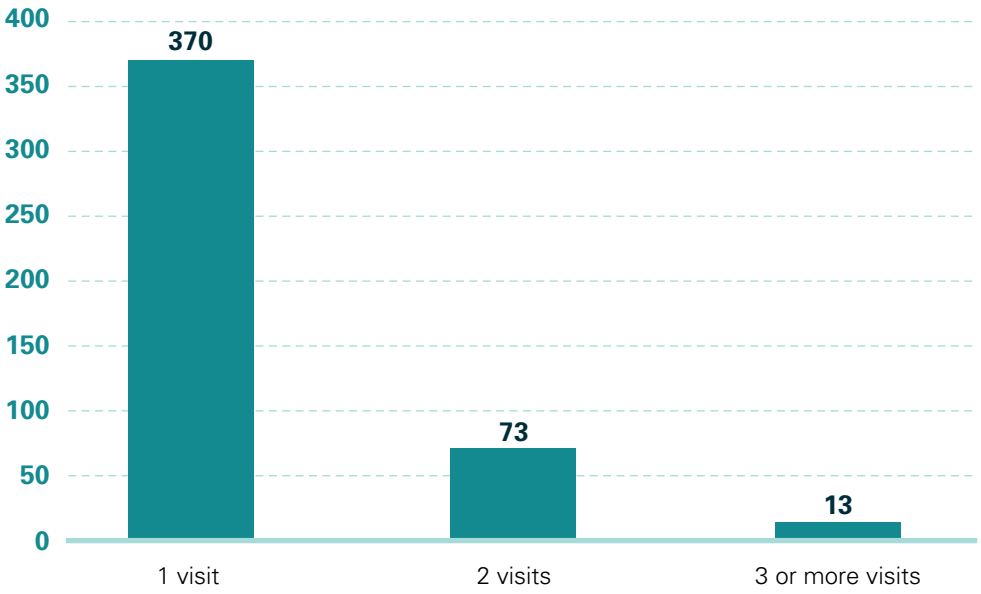
4 Short-notice announced inspections give the provider a maximum of 48-hours' notice prior to inspection.

Figure 3 - Percentage of announced, short-notice announced and unannounced inspections of nursing homes carried out in 2021



The vast majority of nursing homes inspected in 2021 received two or less inspections during the year. However, concerns about the care and welfare of residents in a small number of nursing homes led to more than two inspections. During 2021, 13 nursing homes required three or more inspections; 2.8% of all nursing homes inspected over the year.

Figure 4 - Number of inspections per centre in 2021



Receipt of information

HIQA and the Chief Inspector receive two different types of information about nursing homes:

- unsolicited information
- solicited information in the form of notifications.

Unsolicited information

Members of the public or others who have a concern about the care provided to residents in a nursing home may contact HIQA. All items of unsolicited information received are reviewed and risk rated and, where appropriate[5], the information received is used to inform our regulation of individual nursing homes.

During 2021, we received 1,024 pieces of unsolicited information relating to nursing homes, a 16% reduction on the number received in the previous 12 months.

Table 5 - Sources of unsolicited information in 2021

Source of unsolicited information	Numbers received in 2021
Residents of a nursing home	34
Relatives of residents	556
Employees of a nursing home	183
Others	251

The types of unsolicited information we received included concerns relating to the quality of care (including personal care, social care, healthcare, nutrition and hydration, care planning, falls management, and medicines management), safeguarding, residents' rights, governance and management, communication, staffing and workforce, infection prevention and control measures, general welfare and development, complaints handling, visiting and personal possessions.

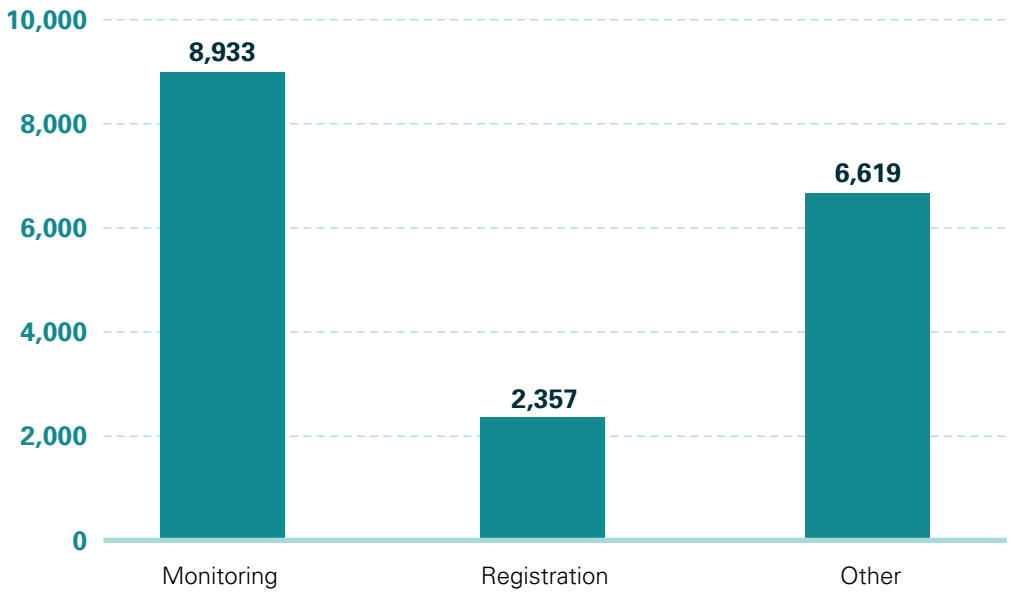
Eleven pieces of unsolicited information received were complimentary about a specific nursing home. Nine of these were from relatives, one from a resident and one from another person. These highlighted how residents' rights were upheld, and one also complimented the premises. Nine of the 11 compliments received also noted the good governance and management arrangements in place in the centre, and two of these also referenced staffing as being satisfactory.

5 While under the Health Act 2007 HIQA has no regulatory remit to investigate or manage an individual complaint, the Chief Inspector reviews the information received to establish if it indicates a risk to the safety, effectiveness, and management of the service and the day-to-day care residents receive.

Solicited information - notifications

Providers or persons in charge are required to submit notifications of significant events that occur in a centre within three days, and to notify the Chief Inspector of other specific matters in the centre on a quarterly basis. These notifications are risk assessed and inform our regulatory actions. During 2021, we received 17,909 notifications, slightly less than the number received the previous year[6].

Figure 5 - Regulatory notifications received from nursing homes in 2021



Notifications of COVID-19 in nursing homes

Nursing home providers are required to notify the Chief Inspector of any outbreak of infectious disease in a centre. In the context of COVID-19, providers are required to notify the Chief Inspector when one or more residents or staff members is suspected or confirmed to have COVID-19.

Since March 2020, COVID-19 has had a huge impact on nursing homes with only 53 nursing homes not reporting a confirmed case of COVID-19.

In 2021, 516 nursing homes submitted notifications to the Chief Inspector indicating that they had a confirmed case of COVID-19 among residents or staff. In addition, a further 13 nursing homes reported having one or more suspected cases, which subsequently transpired not to be COVID-19.

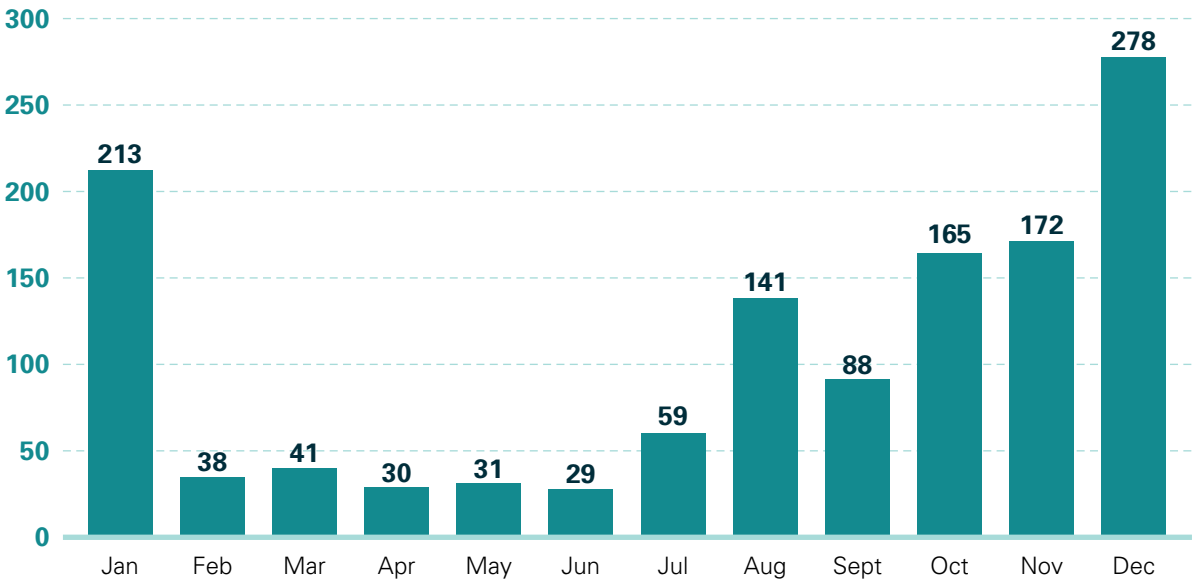
6 In 2020, the Chief Inspector received 18,475 notifications.

Three hundred and nineteen nursing homes submitted notifications to the Chief Inspector indicating that they had a confirmed case of COVID-19 among residents or staff on more than two occasions in 2021:

- 91% of nursing homes reported at least one case of confirmed COVID-19 (residents or staff).
- 9% of nursing homes reported no cases of confirmed COVID-19.
  - 7% have reported no cases of confirmed or suspected COVID-19 (residents or staff).
  - 2% of nursing homes had reported a case of suspected COVID-19 (residents or staff) which subsequently turned out not to be COVID-19.

The percentage of centres notifying the Chief Inspector of a confirmed case of COVID-19 among residents or staff were the same across all provider types. 91% of privately owned nursing homes (401) and 90% of statutory[7] operated or funded centres (115) have reported at least one confirmed case of COVID-19 among residents or staff members.

Figure 6 - Number of notifications received from in 2021 reporting a resident or staff member with confirmed COVID-19



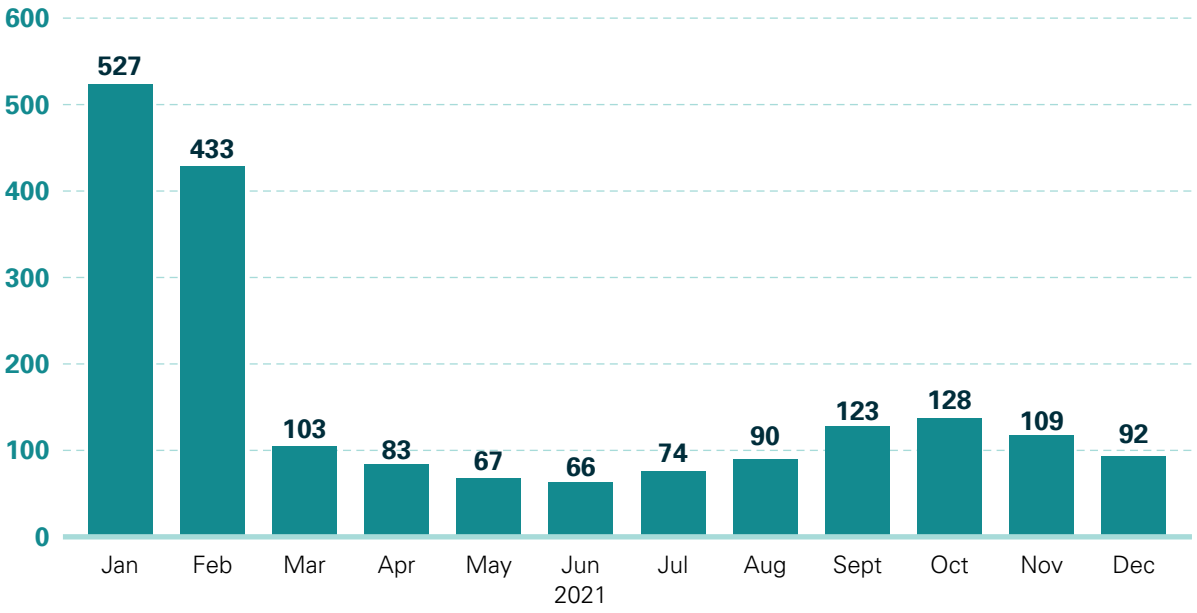
In addition to notifying the Chief Inspector of confirmed or suspected outbreaks of COVID-19, nursing home providers are required to inform the Chief Inspector about unexpected deaths. These notifications relate to all unexpected deaths and are not specifically COVID-19-related deaths.

7 This includes HSE-run centres and centres operated under Section 38 and Section 39 of the Health Act 2007.

The Health Protection Surveillance Centre (HPSC) provides information on verified COVID-19 related deaths. However, at the onset of the pandemic, the Chief Inspector issued a regulatory notice requiring that the death of a resident associated with COVID-19 infection, either suspected or confirmed, should be treated as an unexpected death and notified as such to the Chief Inspector.

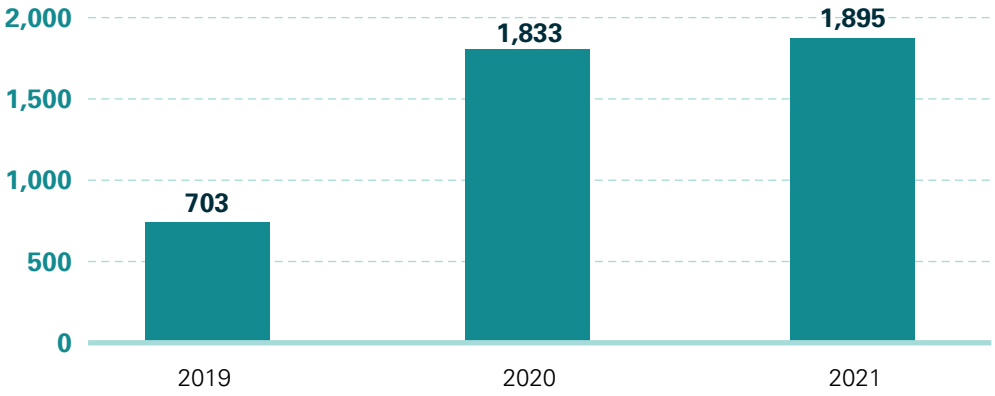
In 2021, the Chief Inspector was notified of 1,895 unexpected deaths[8] among residents in nursing homes.

Figure 7 - Notifications of an unexpected deaths received between January and December 2021



The number received in 2021 was similar to 2020 and significantly higher than 2019, before the onset of the COVID-19 pandemic.

Figure 8 - Notifications of an unexpected deaths 2019-2021



8 This number includes all unexpected deaths in all nursing homes and not just unexpected deaths among residents with COVID-19.

4.1.2 Regulation of designated centres for people with disabilities

Introduction

COVID-19 continued to be a dominant feature in the provision of services to people with disabilities in Ireland during 2021. The pandemic challenged providers to manage the risk of infection in centres, while also challenging them to ensure that the rights of people with disabilities were upheld and promoted during difficult times.

Overall, while there were unfortunately some exceptions, inspectors found that providers were effective in managing the risk of infection in designated centres. As in 2020, there was a significantly lower rate of infection in centres for people with disabilities than there was in other health and social care settings.

The implementation of public health measures and the vaccination programme also made an impact and inspectors noted that, generally, people with disabilities living in designated centres had similar restrictions on their day-to-day life as the wider population. This meant that, during the year, there was a reduction in the restrictions that people experienced in 2020 which led to improvements in everyday life for many residents. Often, residents were able to again meet in person with their families and friends, return to their day services and could participate in community-based activities of their choice.

Through announced and unannounced inspections in 2021, inspectors were able to provide assurances about the quality of service and support for people with disabilities in designated centres. However, inspectors also found that a cohort of centres did not have adequate infection prevention and control measures in place. In these situations, providers were required to implement actions to improve the management of risk in their centres.

In addition, inspectors found that providers had reduced or ceased on-site oversight arrangements for some centres during the pandemic. This meant that there was a reduced or an absence of on-site audit or management presence in these centres, and inspectors identified a deterioration in the quality of service to some residents. In such cases, providers were not only required to address the non-compliances, but to also review their management and accountability arrangements for the centres.

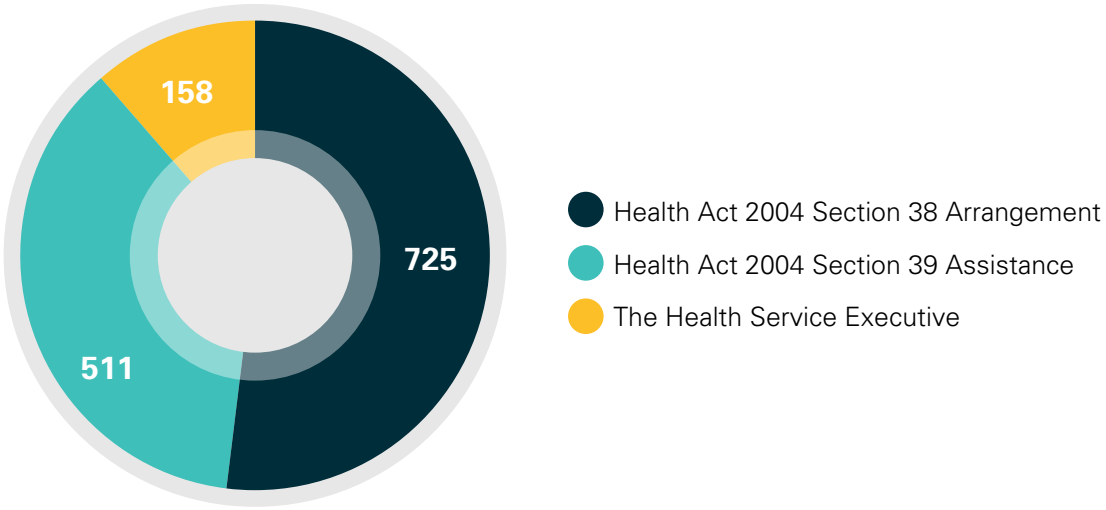
In our overview reports for 2019 and 2020, the Chief Inspector continued to identify that people with disabilities who live in congregated settings are at increased risk of poor quality standard of care and support. We support the national policy to transition people from congregated settings to more appropriate, community-based living arrangements. During 2021, there was an overall reduction of 422 in the number of residential places in congregated settings.

Again in 2021, there were incidents where the living arrangements for some residents broke down and it was unsafe for them to continue living in their current homes. These are emergency situations where there are no alternative, safe options for the residents. To ensure the safety of residents, providers have opened and operated unregistered centres, which is an offence under the Health Act 2007 (as amended). There were four such incidents in 2021. Since 2017, the Chief Inspector has been engaging with the Department of Health to support the development of provisions in the Health Act 2007 that address this gap in the legislation and which allows for the temporary registration of centres when residents are in crisis.

Registration

As of 31 December 2021, there were 1,401 registered centres providing residential services to adults and children with disabilities, a net increase of 61 registered centres since 31 December 2020. While the vast majority of these designated centres provide services to adults, 37 of them provide services to a mix of adults and children, the majority of which are respite centres that accommodate children and adults at different times. There are 94 centres specifically for children with a disability.

Figure 9 - Number of registered designated centres for people with disabilities (by provider type) at 31 December 2021[9]



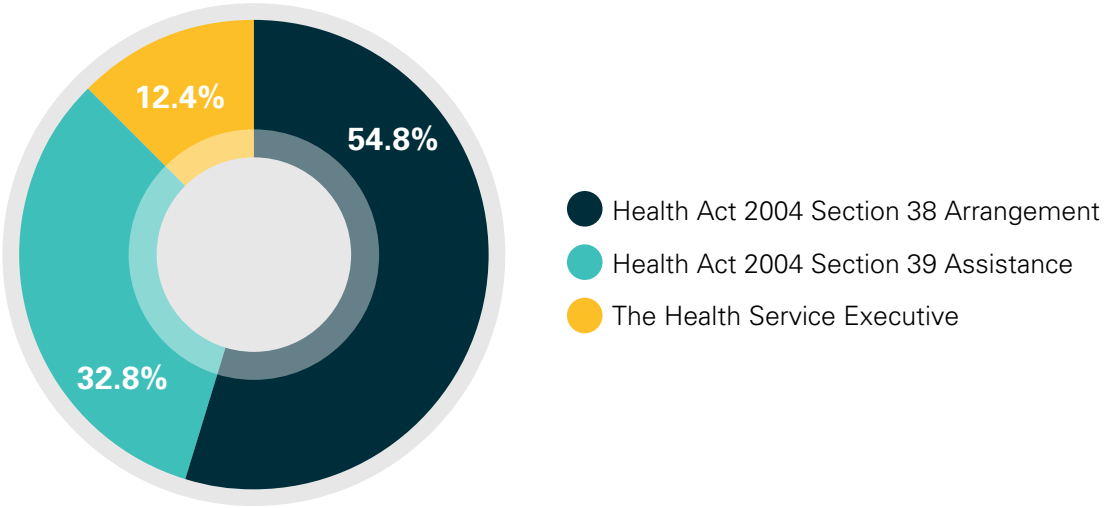
9 Section 38 of the Health Act 2004 states that the HSE can have an arrangement with a person to provide a health or personal social service on behalf of the HSE. Section 39 of the Health Act 2004 states that the HSE can provide assistance to any person or body providing a similar service to the HSE.

The 1,401 designated centres for people with disabilities provided 9,039 residential places, a decrease of 127 residential places compared to 2020. Most of these decreases were as a result of providers no longer requiring additional residential places that they had registered during 2020 as part of their COVID-19 precautions.

Of the total residential places, 8,424 were for adults, 233 were a mix of adult or children's places, and 382 were children's places. These included both long-term residential and short-term respite placements.

The HSE directly provided 1,114 (12.3%) of these residential places, with 4,940 places (54.7%) provided through a Section 38 HSE funding arrangement, and 2,985 places (32%) provided through Section 39 assistance by the HSE to providers.

Figure 10 - Percentage of places provided for people with a disability based on funding arrangement of the designated centre at 31 December 2021



Designated centres can comprise more than one building, and each of these buildings may be dispersed within a community setting, co-located in a town or housing estate, a standalone building or a cluster of buildings located together on a campus.

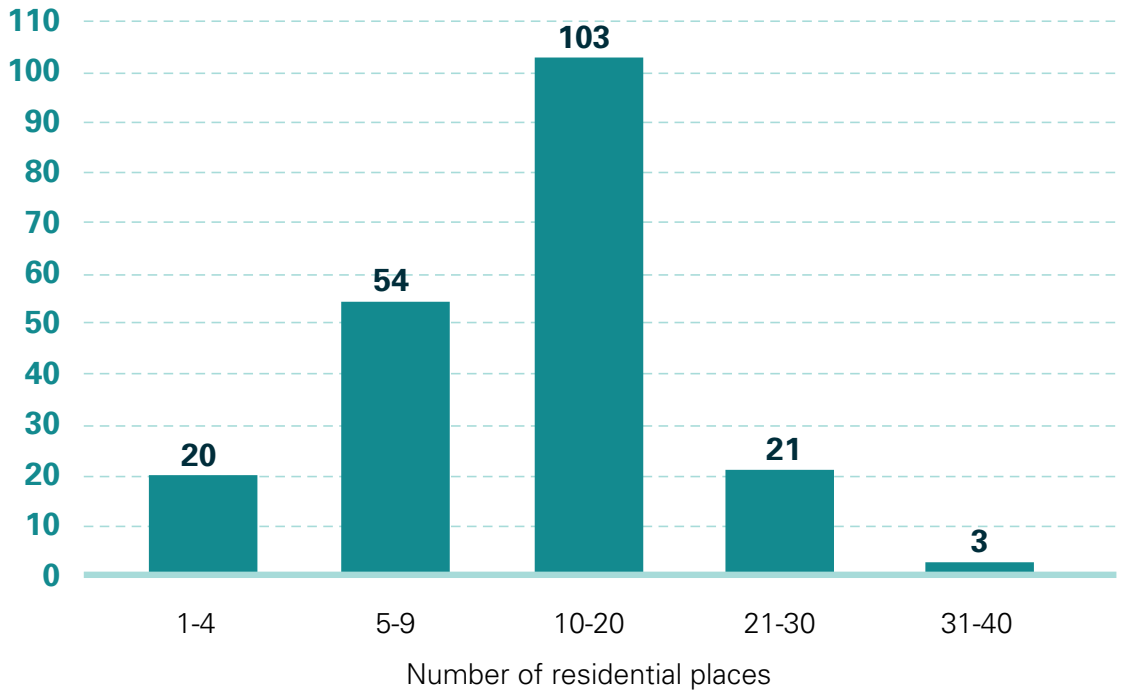
The national policy on congregated settings defines a congregated setting as follows:

> *"Congregated settings are where 10 or more people with a disability live together in a single living unit or are placed in accommodation that is campus based. In most cases, people are grouped together and often live isolated lives away from the community, family and friends. Many experience institutional living conditions where they lack basic privacy and dignity[10]."*

While there continues to be a decline in the number of residential places in congregated settings, in line with the HSE's national policy, they are still home to many residents. Of the 9,039 residential places registered at the end of 2021, 27% or 2,419 places continued to be located in congregated settings. This is a reduction of 422 on the number of registered places in 2020.

Of these, 1,893 residential places were located on 55 campus-based settings. These campuses are usually sub-divided into a number of designated centres. In addition, 526 residential places were located within 41 designated centres which were registered as standalone congregated settings for 10 or more people.

Figure 11 - Bed numbers in registered congregated settings for people with a disability as of 31 December 2021



10 Health Service Executive. Time to move on from congregated settings - A strategy for community inclusion. Dublin, Health Service Executive; 2011.

Inspection activity and regulatory response to COVID-19

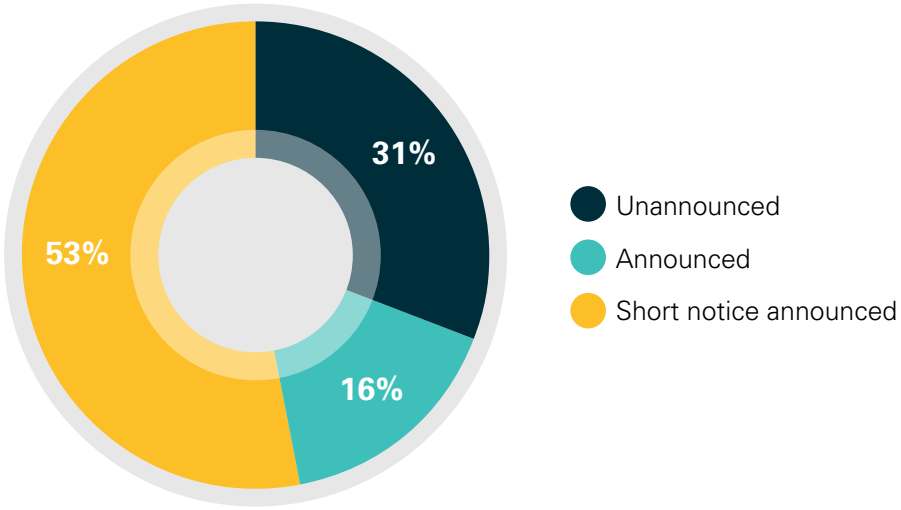
During 2021, we completed 1,220 inspections of centres for people with disabilities. Inspections consisted of routine monitoring inspections and risk-based inspections, where there were indications of a potential risk to the safety of residents.

In response to the ongoing public health emergency, we continued to closely monitor infection prevention and control measures while on inspection. Overall, Regulation 27: Protection against Infection was monitored in 1,048 inspections. In 77% of those inspections, providers had good infection control measures in place and were compliant with regulatory requirements. In the other centres, the main areas of non-compliance were in relation to staff training, general infection prevention and control measures, infection control care plans, and policies, procedures, practices and guidelines. In these centres, inspectors required providers to improve their overall infection prevention and control arrangements.

To support good practice and monitor how providers have adopted procedures consistent with the national standards, we developed and commenced an inspection programme focusing specifically on Regulation 27: Protection against infection. In November 2021, we commenced a series of 19 pilot inspections focusing on infection prevention and control across a broad spectrum of designated centres for people with disabilities. This inspection programme will be extended during 2022.

Inspections can be announced, unannounced or short notice announced and may take place at any time of day or night. Of the 1,220 inspections completed in 2021, 16% were announced, 53% were short notice announced with the remaining 31% unannounced.

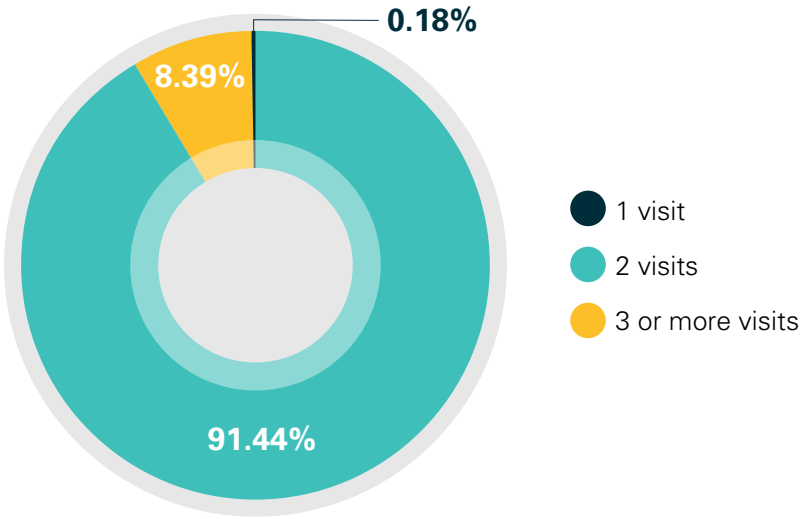
Figure 12 - Percentage of announced and unannounced inspections of designated centres for people with disabilities carried out in 2021



The majority of centres (1,025) visited in 2021 received one inspection. This indicates that they had a good level of compliance and that, where there were non-compliances, the provider responded appropriately. However, 94 centres required two inspections to monitor compliance, while two centres required three or more follow-up inspections. In these two centres, there were significant concerns in relation to the quality of life for residents which required increased monitoring by inspectors.

The seriousness of the concerns in two centres, one operated by Camphill Communities of Ireland and the other operated by Stepping Stones Residential Care Ltd, led to a decision by the Chief Inspector to cancel their registrations. The Stepping Stones Reidential Care Ltd centre ceased to operate as a designated centre while the Camphill Communities of Ireland centre was taken over and operated by the HSE under Section 64 of the Health Act 2007 until a new provider was registered. Follow-up inspections of that centre found that the HSE was ensuring residents' safety throughout the transition period.

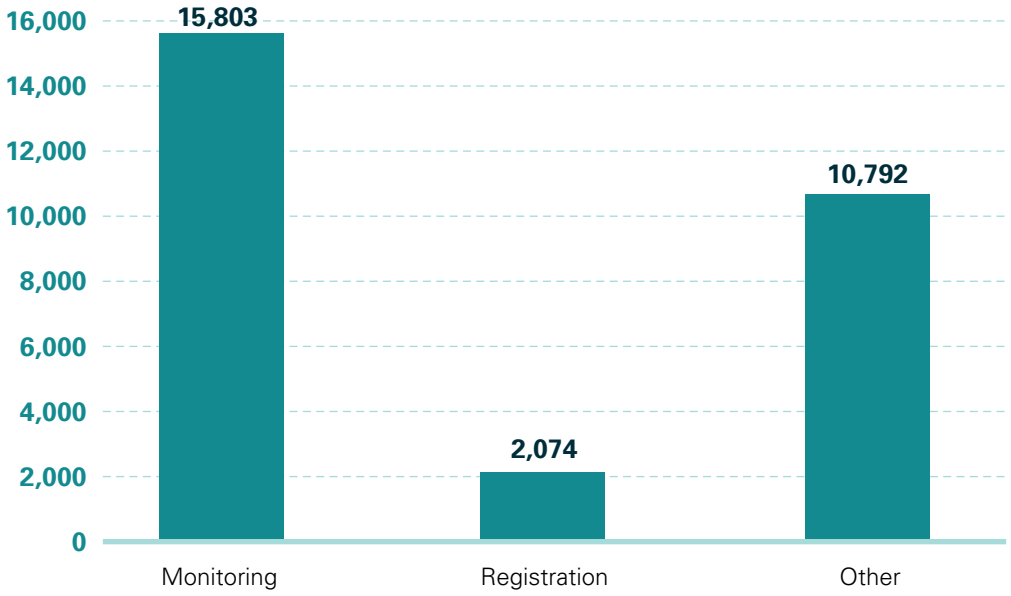
Figure 13 - Percentage of inspection visits per centre inspected in 2021



Receipt of information

Providers or persons in charge are required to submit notifications of significant events that occur in a centre within three days, and to notify the Chief Inspector of other specific matters in the centre on a quarterly and six-monthly basis. These notifications are risk assessed and inform our regulatory actions. During 2021, we received 28,669 notifications relating to services for people with disabilities.

Figure 14 - Regulatory notifications received from services for people with disabilities in 2021

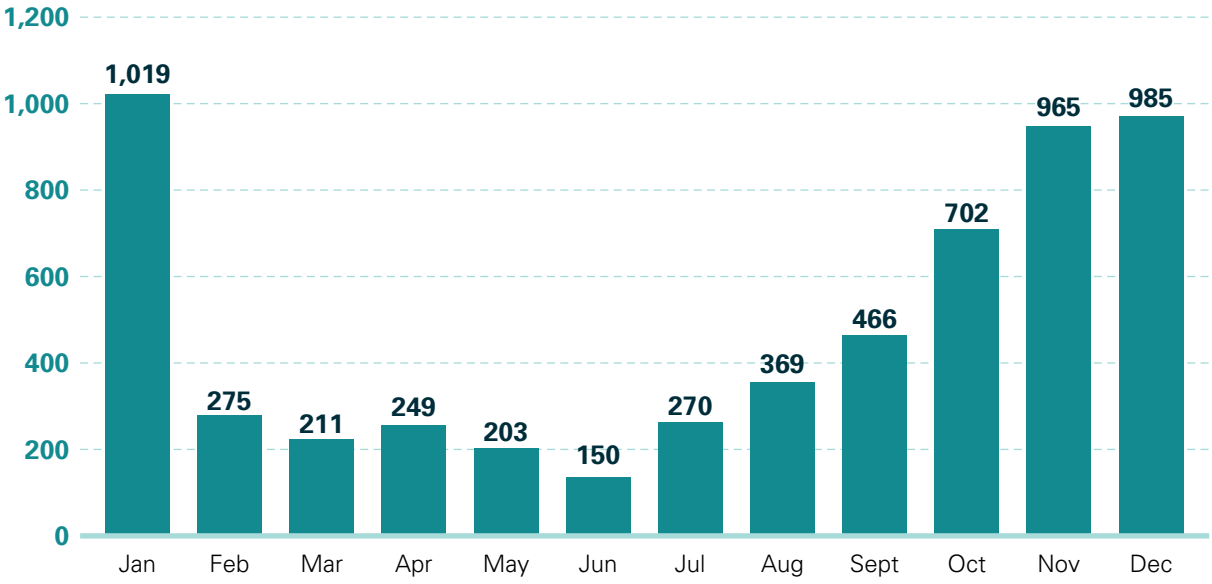


We also receive concerns about services from members of the public and other sources. This information is used to support our inspection programme. In 2021, we received 234 concerns about disability services.

Notifications of COVID-19 in centres for people with disabilities

Registered providers are required to notify the Chief Inspector of any outbreak of infectious disease in a centre. In the context of COVID-19, the Chief Inspector requires providers to submit notifications when one or more resident or staff member is suspected or confirmed to have COVID-19.

Figure 15 - Number of notifications received in 2021 reporting a resident or staff member with suspected or confirmed COVID-19

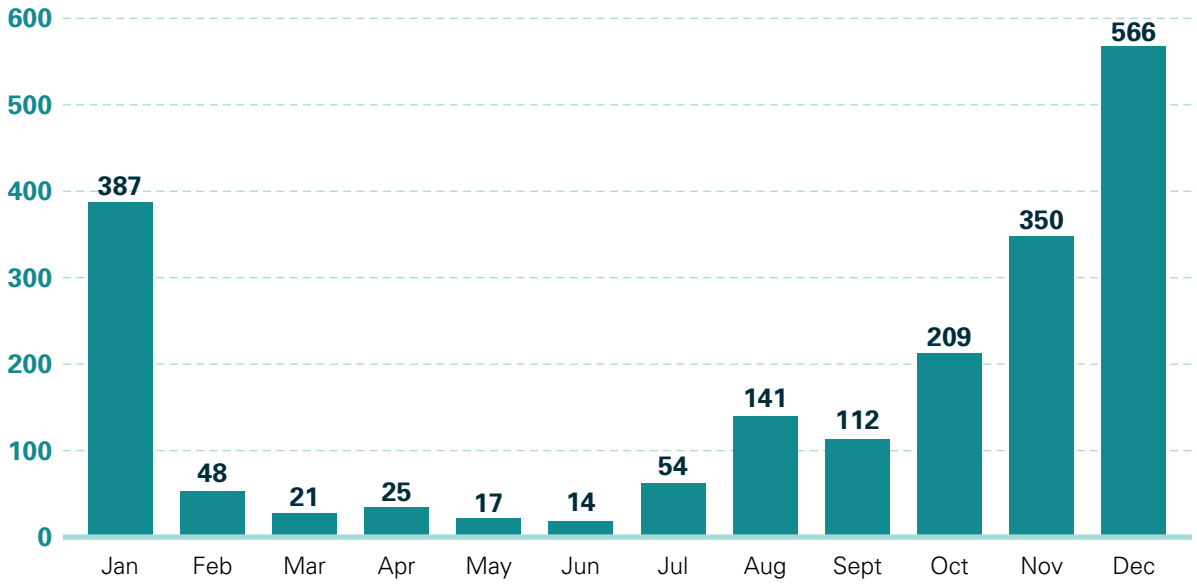


In 2021, 5,864 notifications were received where centres had suspected or confirmed cases of COVID-19. The highest number of notifications was received in January 2021, coinciding with the third wave of the public health emergency.

When a notification of COVID-19 is received by the Chief Inspector, it is reviewed, risk rated and closed where no outbreak is detected or when the outbreak at the centre is over, in line with public health advice. Of the 5,864 notifications received where centres had suspected or confirmed cases of COVID-19, 33% of these notifications had reported at least one or more resident or staff member with confirmed COVID-19.

Of the 1,401 registered designated centres for people with a disability, 1,305 centres submitted a COVID-19 related notification in 2021. Of these centres, 87% had at least one confirmed resident or staff case. In 2021, 271 centres reported no outbreak of COVID-19. Figure 16 provides information on confirmed COVID-19 infections.

Figure 16 - Number of notifications received in 2021 reporting a resident or staff member with confirmed COVID-19



In addition to notifying the Chief Inspector of confirmed or suspected incidences of COVID-19 infection, registered providers are required to inform the Chief Inspector about unexpected deaths in their centres. These notifications relate to all unexpected deaths and are not specifically COVID-19-related deaths. The Health Protection Surveillance Centre (HPSC) provides information on verified COVID-19 related deaths.

The number of unexpected deaths in 2021 showed a decrease on the number in 2020. However, the number remains higher than the number of unexpected deaths reported prior to the pandemic in 2019.

Figure 17 - Notifications of an unexpected death 2019-2021

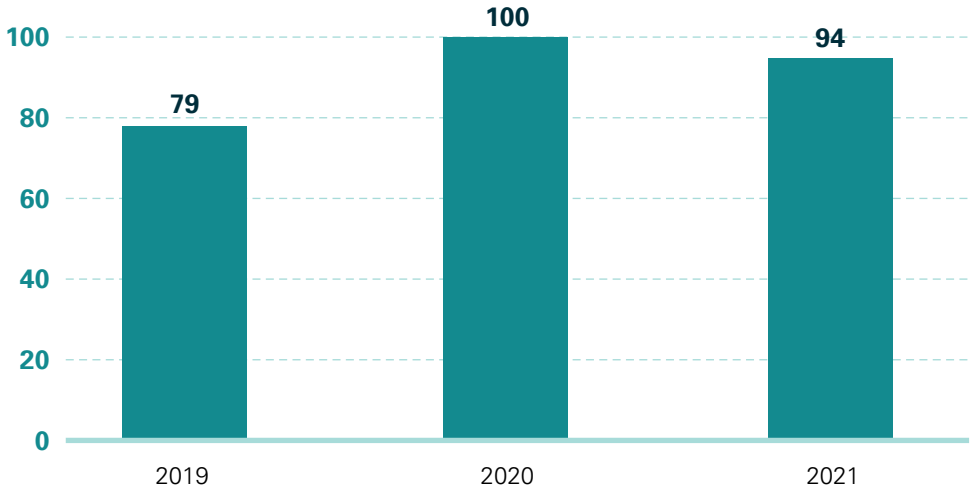
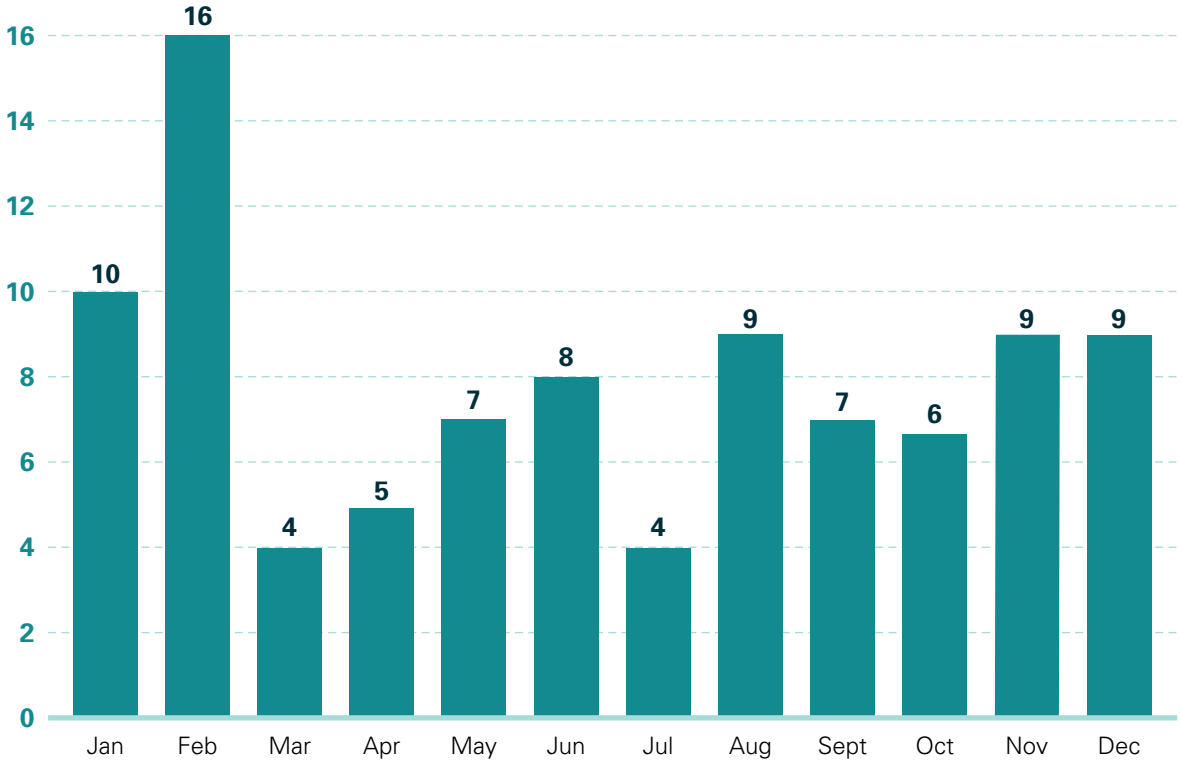


Figure 18 - Notifications of an unexpected death received between January and December 2021



Stakeholder engagement

In addition to meeting residents as part of the inspection process, we continued to meet with residents' groups to listen to their experiences living in registered designated centres. In 2021, we met with 22 resident groups across the country virtually via video conferencing. Topics discussed included their rights, choice, home, their experience of inspection and the impact of COVID-19 on their lives. Residents told us about their experiences living in a congregated or campus-based setting with many other people and what it was like moving into housing in the community.

On 3 December 2021, to mark International Day of People with Disabilities, we shared a video outlining these experiences in residents' own words. When asked what a home meant to them, residents told us they were happy when they had their own space and did not share homes with a lot of people. Some residents we spoke with had lived in congregated settings for a long time and told us of their delight at being able to decorate their bedroom in their new home. We will use the feedback from these meetings to enhance the inspection process for residents.

In 2021, we also continued our engagement with the four provider representative bodies of disability services; the National Federation of Voluntary Service Providers, Disability Federation of Ireland, National Disability Services Association and the HSE in their role as service providers. This forum met on nine occasions during 2021, supporting effective and ongoing channels of communication between the regulator and providers. These meetings have proven to be a valuable opportunity for providers of services to update HIQA on any emerging issues and for HIQA to provide regular updates on regulatory matters.

Conclusion

During 2021, we continued to engage with providers, residents, the HSE and with the Department of Health about services for people with disabilities. Our monitoring and inspection programme focused on ensuring effective infection prevention and control measures to protect residents from the risk of infection, while also focusing on ensuring a human rights-based approach to the provision of residential services for people with disabilities.

In 2022, we will continue with this programme of work, and will also continue to engage constructively with the Department of Health and with the Department of Children, Equality, Disability, Integration and Youth which is due to take responsibility for the disability sector in 2022.

4.1.3 Regulation and monitoring of children's social care services in Ireland

We monitor and inspect a range of services provided to children by statutory and non-statutory providers. These services include:

- children's residential centres (statutory)
- foster care (statutory and non-statutory)
- special care units (statutory designated centres)
- Oberstown Children Detention Campus
- child protection and welfare services (statutory).

Each service has its own statutory framework that gives HIQA the authority to monitor and inspect the service, using standards and or regulations which set out what is expected from the service.

Overall in 2021, inspections of children's services found improved levels of compliance against national standards and regulations and the majority of children were positive about their experience of services.

The experience and impact of COVID-19 on children's residential and secure care services was different from that of 2020. The information we gathered throughout the year showed that while the number of outbreaks remained low compared to other social care settings, there was an increase on the previous year.

Just over 5% of statutory children's residential centres, one special care unit and Oberstown Children Detention Campus experienced an outbreak of the virus in 2021. In addition, some services experienced high levels of staff absences as a result of being suspected cases and the need to isolate. Despite these challenges, we found that these services had effective contingencies in place which meant there was no or limited disruption to service delivery and continued good quality care to children.

The impact of COVID-19 on children and their families varied over the course of the year, and reflected the changing restrictions in place at any given time. For example, alternative ways to maintain access between children and their families were explored and utilised when visits to centres were curtailed. This included remote contact using various technologies. While some children were satisfied with this approach, others were not, and missed direct contact with their family and friends. Planning for children is an inclusive and consultative process, and again, we found that there was good use of technology when remote meetings were required to ensure plans for children progressed. However, children and parents said that while they were happy that these meetings went ahead, the remote approach was challenging in what was an already difficult circumstance for them, and they welcomed the return of face-to-face planning meetings.

Good quality accurate information is essential to making informed decisions in relation to children's safety and welfare. 2021 was a particularly challenging year for the Child and Family Agency (Tusla) in this regard. In May 2021, these systems were significantly compromised by a cyberattack on the HSE's information system, which is shared with Tusla. This was unprecedented, and severely impacted the service's ability to access key data on children at that time. From our inspections, it is clear that the service has responded appropriately in implementing the necessary changes to its system.

Access to sufficient resources in terms of staffing and suitable placements for children presented a challenge to Tusla during 2021. Despite ongoing recruitment drives and retention initiatives, staff vacancies remained a constant. These vacancies required Tusla to prioritise its allocation of available staff, and a national approach was taken to ensure children at most risk received a social work service. In addition, Tusla put systems in place to manage growing waitlists, which was more effective in some service areas than others. Several initiatives were taken to mitigate the risks associated with reduced staffing levels, including utilising social care staff to complete tasks traditionally completed by social workers. In addition, staff from a wide range of disciplines were recruited into services to ensure the needs of children were met. However, staff vacancies impacted directly on service delivery for some children in care and child protection services. As a result, many children did not have an allocated social worker to assess their needs or they experienced multiple changes in social workers over short periods of time.

It is essential that children in care have access to the right placement with appropriate supports to support their development and promote their safety and rights. Over the last year, inspections have illustrated that Tusla has had difficulty in ensuring there were sufficient and appropriate placements to meet the needs of some children, particularly those with complex needs. As a direct result of a lack of appropriate placements, there were delays in taking some children at risk into state care. Other children experienced delays in moving to long-term foster care placements or residential or specialist placements. HIQA escalated these service challenges to Tusla. Tusla provided assurances on individual cases and says it is committed to developing and implementing a new strategy in relation to residential care.

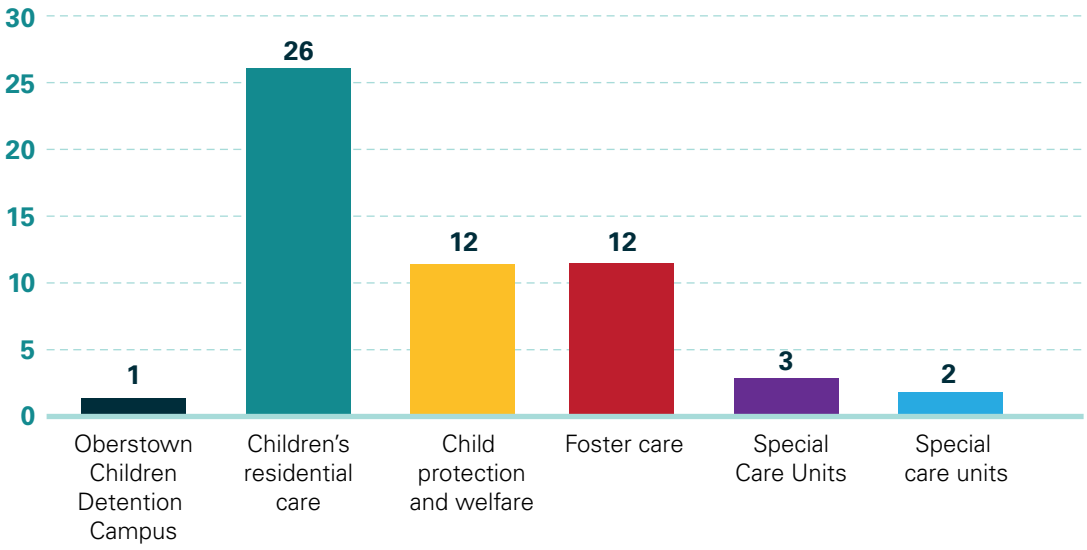
Monitoring activity

Regulatory activity carried out by the Children's Team in 2021 included:

- Inspections of 26 statutory residential centres for children against the *National Standards for Children's Residential Centres*, one of which was unannounced, with a short-notice announcement provided to the remaining centres. Twenty-four of these were full inspections, one was a follow up and one focused on specific risks.
- Three announced inspections of special care units took place, which included the renewal of registration of all three units during 2021. This was the first renewal process carried out since special care units were first registered in 2018. These inspections monitored ongoing compliance with the Health Act 2007 (Care and Welfare of Children in Special Care Units) 2017 and the Health Act 2007 (Registration of Designated Centres) (Special Care Units) 2017.
- Six announced inspections of statutory foster care were carried out as part of a thematic programme focusing on assessing the efficacy of governance arrangements across foster care services and the impact these arrangements have for children in receipt of foster care.
- Five announced inspections were carried out of non-statutory foster care services to examine management arrangements, safeguarding and child protection, and the recruitment, assessment, approval, supervision, training and review arrangements in place for foster carers.
- One annual announced inspection was carried out of Oberstown Children Detention Campus.
- Seven child protection and welfare inspections were carried out which focused on the child protection notification system (CPNS). Children who are assessed by Tusla as being most at risk are placed on the CPNS. The inspections examined the management of children on the system and the governance of the service.
- Two thematic announced inspections of a child protection and welfare service were completed in 2021. One of these inspections became a risk-based inspection and is included in the number below. This programme concluded in 2021 and focused on improving the management of referrals from screening and preliminary enquiry to safety planning and the completion of initial assessments.
- Four risk-based child protection and welfare inspections were carried out during 2021. These inspections were all announced and focused on Tusla's management of child protection concerns, the assessment of these concerns, safety planning and the governance of the service.

- Two risk-based inspections of service areas were completed. These inspections focused on specific risks in both child protection and welfare and foster care services in these areas. One area had a further follow-up risk-based foster care inspection which focused on care planning, safeguarding, visits to children, the support and supervision of foster carers, the foster care committee and the management of the foster care service.

Figure 19 - Inspections of children's services in 2021



During 2021, we:

- received 30 notifications of serious incidents from Tusla. Tusla is required to notify HIQA of deaths and serious incidents involving children in care and children known to its child protection and welfare service. All information received was assessed and risk rated to inform our monitoring programme.
- received 11 National Review Panel reports relating to serious incidents and deaths involving children in care and or children known to the child protection and welfare service.
- received 79 pieces of unsolicited information from children who use services, their families, foster carers, staff and members of the public, compared to 71 pieces of information received in 2020. Of the 79 pieces of information received, 38 (48%) related to child protection and welfare services, 26 (33%) related to foster care services, five (6%) related to children's statutory residential centres, eight (10%) related to special care units and two (3%) related to Oberstown Children Detention Campus. All information received was used to inform our monitoring programme.
- received 161 notifications from special care units, including 100 monitoring notifications, seven registration notifications and 54 others.

Figure 20 - Regulatory notifications received from special care units in 2021

In addition to the above inspections, our regulatory programme also included the following:

- An external advisory group, made up of representatives from key stakeholders, was established in early 2021 to input into the development of an inspection methodology for a thematic programme on the governance of foster care services. A guidance and assessment judgment framework was subsequently published in March 2021.
- Publication of an overview report on inspections of foster care services 2019-2020. This overview report incorporated findings from phase two of the HIQA foster care inspection programme, focused on the arrangements in place for the assessment of need for children in care, and the care planning and review process, including preparation and planning for leaving care, matching carers with children and safeguarding. It was published in September 2021.
- Publication of an overview report on inspections under our child protection and welfare thematic programme 2019-2021. This report was published in November 2021, outlining the key findings from a quality improvement programme of inspections of 12 Tusla child protection and welfare services. These inspections focused on defined points along a pathway in child protection and welfare services provided by Tusla; from the point of initial contact or reporting of a concern to Tusla through to the completion of an initial assessment.

- Due to the impact of the cyberattack on Tusla services and the ongoing COVID-19 pandemic, inspections of child protection and welfare and foster care services were confined to risk-based inspections in January and from May to the end of July 2021. We continued with the quality assurance process set up in 2020, with the majority of services being contacted regularly by inspectors until October 2021. As routine inspections of child protection and foster care services resumed, quality assurance calls ceased for these services. This process remains in place for children's residential care and Oberstown Children Detention Campus. Services are contacted by phone to provide support and monitor their preparedness for an outbreak of COVID-19, and its potential impact on the service delivery to children.
- An assessment judgment framework and guidance in relation to the inspection of Oberstown Children Detention Campus was published in September 2021. These documents reflect the new methodology for the inspection of this service against the rules contained in the *Oberstown Children's Rights Framework*, which replaced the *Standards and Criteria for Children Detention Schools (2008)*.

Stakeholder engagement

During 2021, while the COVID-19 pandemic impacted some stakeholder engagement opportunities, we continued to engage with children, external agencies services and service providers. We are committed to promoting and reflecting the voice of children and young people in our work.

In total, across all services, inspectors consulted with 195 children either directly, over the phone or by way of a questionnaire. Of the 195 children, 63 were children in residential care, 51 were in foster care, 36 were involved with child protection services, 34 were in detention and 11 were in special care. Inspectors also spoke with parents and foster carers as part of our inspection activity.

Listening to children's voices during inspections enables us to capture children's experiences of their care, and understand better the impact of the governance of these services on these experiences. A particular focus of participation of children and young people in our work is to capture how they are involved in decision-making on issues that affect them. Such decision-making is enshrined in the Irish Constitution and Article 12 of the United Nations Convention on the Rights of the Child (UN, 1989), ratified by Ireland in 1992.

During 2021, the Chief Inspector and the Head of Programme for Children's Services met with the Assistant Secretary, Child Policy and Tusla Governance Division of the Department of Children, Equality, Disability, Integration and Youth to exchange relevant updates and exchange information on actual or potential risk across the sector; and discuss progress on regulatory developments.

Throughout 2021, we held regular meetings with the CEO of Tusla and members of Tusla's senior management team to share information on topics such as regulatory developments, risks, practice issues and service delivery.

Other stakeholders we engaged with in 2021 included:

- the Chairperson of the Board and Campus Director of Oberstown Children Detention Campus
- the CEO of EPIC (Empowering People in Care)
- the CEO of Irish Foster Carers Association (IFCA)
- the Department of Education
- Children's Ombudsman's Office.

4.1.4 Healthcare regulation and monitoring

Currently in the healthcare setting, HIQA is responsible for monitoring compliance against national standards under the Health Act 2007 (as amended) to improve the quality of care to people using services. For example, in public acute hospitals and rehabilitation and community healthcare services. HIQA also has a remit to conduct statutory investigations into services where there are potential serious patient safety concerns impacting on the health and welfare of patients. In addition, HIQA is the Competent Authority in Ireland with responsibility for regulating medical exposure to ionising radiation.

HIQA is also in the process of preparing to take on a number of new responsibilities and commitments that have been set out in the current Programme for Government. These include the:

- Patient Safety (Notifiable Patient Safety Incidents) Bill 2019
- Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill (2018)
- monitoring of International Protection Accommodation Services (formerly referred to as direct provision).

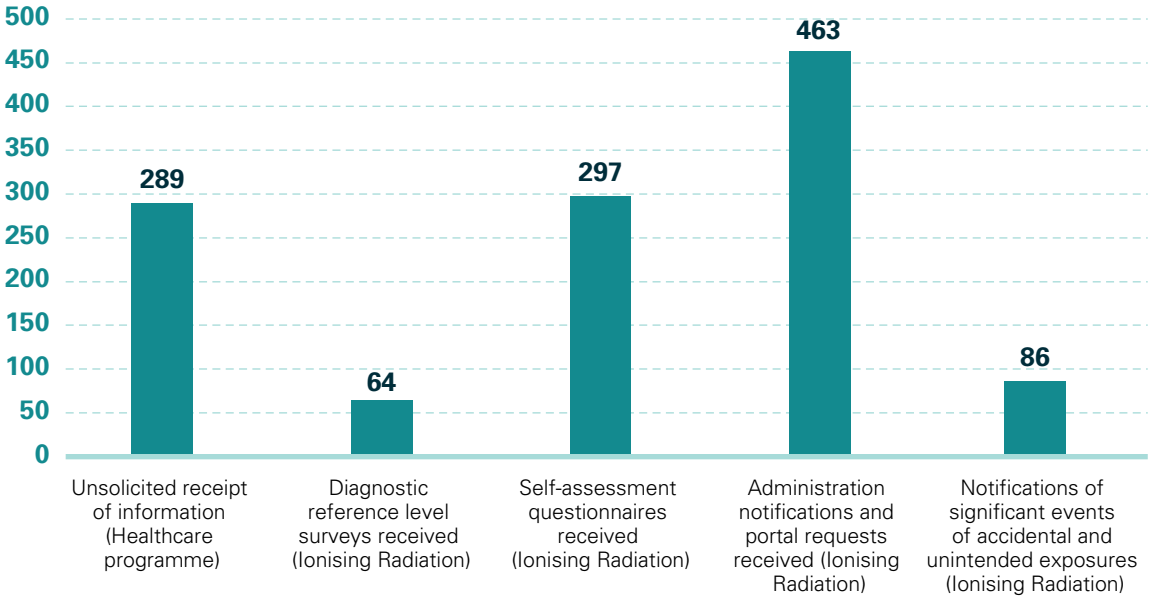
The commencements of the Patient Safety Bill and the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill (2018) represents a significant expansion of HIQA's current remit in healthcare services in Ireland. These pieces of legislation, once enacted, will place a statutory responsibility on HIQA to monitor private healthcare facilities against national standards, to receive and respond where necessary to notifiable patient safety incidents, and to regulate post-mortem practices that fall outside of the coroner's process.

During 2021, HIQA continued to engage with relevant colleagues in the Department of Health to prepare for these new functions. We also completed a substantial body of work to revise our approach to monitoring against the *National Standards for Safer Better Healthcare* which will be launched in early 2022. This new approach will be used for a number of years as we assume a broader monitoring remit under the Patient Safety Bill. It will involve both a 'Core Assessment' against 11 national standards, and the ability to conduct risk-based inspections against one or more of the full suite of 45 national standards if needed, using a comprehensive assessment and judgment framework against these standards. This approach will be finalised and published in early 2022.

During the course of the year, we also began engagement with the Department of Children, Equality, Disability, Integration and Youth to prepare for the taking on of new responsibilities on a temporary basis for monitoring international protection accommodation services. It is intended that HIQA will assume this new statutory responsibility in late 2022. We will fully engage with all relevant stakeholders as it prepares to begin inspecting such services over the course of 2022.

In order to prepare for the breadth of upcoming changes, a new Healthcare Regulation Directorate was established within HIQA during 2021. This organisational restructuring represents an important step in working to meet the requirements arising from an extension of HIQA's legal functions in the regulation and monitoring of healthcare across the public, private and voluntary sectors.

Figure 21 - Monitoring of healthcare services in 2021



4.1.4.1 Medical exposure to ionising radiation

In 2021, HIQA conducted 32 inspections of public and private hospitals and facilities as part of our role in regulating medical exposure to ionising radiation. Medical exposure to ionising radiation is when radiation is used as part of diagnosis, such as an X-ray or CT scan, for medical research purposes or the use of radiotherapy as part of cancer treatment at a hospital. The inspections carried out were prioritised based on risk in a range of services, including dental practices and hospitals carrying out diagnostic imaging and radiotherapy.

Overall, most services inspected were found to provide a safe service and high levels of compliance were evident. However, many services required improvement to meet the requirements of the regulations, which represent basic safety standards for medical exposure to ionising radiation.

The governance and management of services is underpinned by key regulations assessed as part of the monitoring programme. Overall, most services inspected were found to be compliant or partially compliant in relation to governance; however, for many services this was an area requiring improvement. This is a trend continuing from 2020.

While the governance arrangements in place varies greatly depending on the scale of radiation services being provided, the regulations require that a clear allocation of responsibilities for the protection of people using services must be in place. For example, there is a responsibility on each service provider to engage a medical physics expert to support the service. In sectors with a relatively low radiological risk, such as dental services, the required involvement of such professionals was found to be limited; however, their engagement is necessary nonetheless to ensure the safe provision of services.

Further to the inspection of services carrying out medical exposure to ionising radiation, HIQA has commenced issuing self-assessment questionnaires to assess baseline regulatory compliance related to radiation protection. This self-assessment questionnaire is a tool that allows services to self-appraise their level of compliance with the regulations and helps to identify any possible risks or perceived gaps in practice. HIQA continued this monitoring of services throughout 2021, with 297 self-assessment questionnaires received from dental services.

In addition, HIQA received the following notifications:

- 463 administrative notifications of medical exposure to ionising radiation were received in 2021. These included changes of service details, declarations of new undertakings and requests to access HIQA's Provider Portal.
- 86 notifications of accidental and unintended exposures to ionising radiation. These notifications and subsequent follow-up reports were assessed and used to inform the regulatory programme.

Overview report of lessons learned from receipt of statutory notifications of accidental and unintended exposures 2020

In 2021, HIQA published its annual overview report of lessons learned from receipt of statutory notifications of accidental and unintended exposures to ionising radiation in 2020. This report provides an overview of the findings from these notifications and shares learnings from the investigations of these incidents. We received notifications from computed tomography (CT), nuclear medicine, general radiography, fluoroscopy, mammography, interventional cardiology and radiotherapy services.

The number of notifications increased from the previous year which potentially suggests a more open and positive patient safety culture. The increase in reporting is a positive indicator, particularly in the context of the unprecedented additional challenges faced by undertakings during the COVID-19 pandemic. The most common error reported to HIQA involved medical exposures to the wrong service user, which accounted for 34% of all notifications reported. Notifications from the modalities of interventional cardiology, mammography, and fluoroscopy were also received for the first time. There were no reported significant events from the dental or dual-energy X-ray absorptiometry (DXA) services. However, in these areas, the dose of radiation involved would generally fall below the threshold for a significant event and therefore low levels of reporting would be expected given the current criteria.

Other functions fulfilled as Competent Authority for medical exposure to ionising radiation on behalf of the State

As the Competent Authority for medical exposure to ionising radiation, HIQA is required to fulfil a number of roles which complement the regulation of services through inspection and monitoring to improve the quality and safety of services. A number of these functions were progressed in 2021 as outlined below.

- As part of the competent authority function to review national diagnostic reference levels (DRLs) or typical doses service users should receive as part of their diagnosis, we published our first national review of general radiography, mammography and DXA scanning imaging doses in 2021. Updated national DRLs for general radiography and mammography procedures were determined and national DXA DRLs were produced for the first time in Ireland. When comparing new national DRL data for general radiography and mammography to the previous study conducted in 2010 by the HSE, we found reductions in reference doses ranging from 2-27% for all medical imaging procedures reviewed. This new national data allows service providers to compare representative service user doses to national DRL figures, identify medical radiological procedures that require review and put corrective actions in place where needed.
- In 2021, HIQA commenced a review of fluoroscopy and interventional radiology and cardiology imaging doses. This required extensive stakeholder engagement to develop a clinically appropriate national catalogue of common fluoroscopy and interventional radiology and cardiology imaging procedures. The diagnostic reference level survey tool was received by 64 undertakings and review of responses commenced in Q4 of 2021. The results of this survey will be published later in 2022 following the review and assessment of individual responses.

4.1.4.2 Healthcare monitoring

Due to the acute pressures of COVID-19 in the healthcare sector during the year, HIQA prioritised a significant review of gynaecology services at Letterkenny University Hospital to ensure that services had improved following prior significant service failures.

In addition to the above, we received information that was used to further inform and support our monitoring activities of healthcare services in 2021.

- In 2021, HIQA received 301 pieces of unsolicited information in relation to healthcare services. This information was reviewed and any potential non-compliance with national standards was followed up with the provider to ensure that risk issues were addressed and that services were improved where necessary.

Review of the governance arrangements of gynaecology services at Letterkenny University Hospital

In October, HIQA published the findings of a review of the governance arrangements of gynaecology services at Letterkenny University. The review aimed to determine the effectiveness and sustainability of the governance and oversight arrangements in place at national HSE, hospital group and hospital levels to assure and ensure the delivery of high-quality gynaecology services at the hospital. The review was carried out under Section 8 of the Health Act 2007.

HIQA found that Letterkenny University Hospital and Saolta University Health Care Group were significantly resourced with both funding and staffing to make improvements to gynaecology services at the hospital. The hospital group had introduced revised governance and accountability arrangements to enhance and strengthen governance and oversight of the gynaecology services. Some changes and initiatives had also been introduced to improve the quality, safety and reliability of gynaecology services at Letterkenny University Hospital. These included the introduction of:

- a new ambulatory (outpatient) gynaecology service
- revised procedures for the referral and triage of referrals to the hospital's gynaecology services
- set timelines for the timely review and diagnosis of women referred to the hospital with post-menopausal bleeding.

However, despite these improvements, HIQA found weaknesses in the revised governance and oversight arrangements. Letterkenny University Hospital failed to meet national HSE and hospital group timelines for the review, testing and diagnosis of some women referred with post-menopausal bleeding. The hospital group had failed to identify cases where non-adherence to timelines had occurred. This was of significant concern to HIQA and was raised with the hospital group. The hospital struggled to recruit and retain medical, nursing and midwifery, and administrative staff which presented a risk to patient safety. The ambulatory gynaecology service was not fully established and the number of women that could be managed in this service fell short of that estimated by national HSE.

HIQA was not assured of the effectiveness of the revised governance structures and oversight arrangements introduced at the hospital or Saolta University Health Care Group. Further improvements are needed to ensure the quality of the services and safety of women accessing gynaecology services at Letterkenny University Hospital, and HIQA continues to monitor progress in efforts to address these issues at hospital and hospital group level.

Overview report of the monitoring and regulation of healthcare services in 2020

In August, we published our overview report of the monitoring and regulation of healthcare services in 2020. This report provided an analysis of our monitoring work across healthcare services against the backdrop of the COVID-19 pandemic. The report identified good levels of compliance with national standards across a number of services. Nonetheless, the report also identified how insufficient resources, poor infrastructure and inadequate physical environments were, in some instances, significantly preventing the effective implementation of national standards.

4.1.5 Supports for services

COVID-19 supports for services

Throughout 2021, HIQA continued to actively monitor the developing COVID-19 situation in the context of health and social care services. Registered providers continued to use the COVID-19-specific notification which facilitated submission of daily updates on the status of suspected and confirmed cases of COVID-19 among residents and staff to the Chief Inspector. This provided important information which was used on a daily basis to identify designated centres that were struggling or had the potential to run into problems. Our inspection teams liaised closely with the HSE to ensure support for these centres was available as required.

We developed a guidance and assessment framework for risk inspections focused on Regulation 27, focusing on infection prevention and control, for designated centres for older people and for people with disabilities. The framework aims to support providers to ensure that procedures, consistent with the *National Standards for infection prevention and control in community services* (2018) are implemented in their service. Six webinars on the framework were attended by over 1,900 staff and providers of these designated centres.

Throughout 2021, the CEO, as a member of NPHET and the Chief Inspector were in contact with officials in the Department of Health, the HSE and other stakeholders to ensure effective lines of communication in terms of reporting and monitoring outbreaks and their impacts, as well as escalating concerns around PPE or staff shortages in centres, and advice or support for infection control.

Nursing Home Expert Panel Implementation Oversight Team

The COVID-19 Nursing Home Expert Panel report was published in August 2020. It contains 86 recommendations grouped into 15 thematic areas. Each recommendation has an associated timeline for implementation. HIQA is represented as part of the membership of the report's Implementation Oversight Team, which is chaired by the Department of Health.

Of the 86 recommendations, 31 include HIQA as either a lead organisation or with a compliance oversight role for its implementation. To date, on behalf of the Department of Health, we have facilitated four surveys, three related to the recommendations for which the provider is responsible and one staffing survey. We also inputted into each progress report produced by the Department of Health as required.

A significant number of COVID-19 Nursing Home Expert Panel recommendations require changes to the Health Act 2007 (as amended) and or statutory regulations. HIQA is represented on a bi-lateral group chaired by the Department of Health examining the changes required as a result of the report.

HIQA continues to work with the Department of Health to progress regulatory reform of the primary legislation regulations for designated centres for older people and for people with disabilities. A paper submitted to the Minister for Health in June 2020 on *Suggested interim amendments to the Health Act 2007 as amended and the regulations for designated centres for older people and adults and children with a disability* is also before this group for consideration.

Regulatory notices

In 2021, providers were reminded through regulatory notices about the importance of their preparedness and contingency plans, other notices issued related to the cyberattack, registration updates and changes to the HIQA Provider Portal.

Guidance for providers

Fire Safety Handbook – A guide for registered providers and staff

In February 2021, the Chief Inspector published a Fire Safety Handbook to help providers and staff of designated centres which offer residential facilities for older adults, children and people with disabilities to meet their fire safety obligations.

The potential impact from fire is greatly increased if providers do not mitigate against fire risk, and do not have suitable fire prevention and oversight measures in place in their centre. The handbook aims to help all providers to:

- comply with their legal obligations
- develop, implement and sustain a fire safety programme
- develop a strong fire safety culture in designated centres
- drive quality improvement.

The handbook also directs providers to relevant regulations and national standards, which should also be considered when developing a fire safety culture in a designated centre.

The handbook has four key themes that are central to developing a fire safety culture in a designated centre: governance and management; risk management; diverse care and support needs of residents; and staff knowledge. Focusing on these areas, in conjunction with all regulations, will help providers to develop a fire safety culture in their centre and improve the safety of life for people living there.

Approximately 1,500 providers and staff attended webinars aimed at supporting them in using the handbook to improve fire safety in their centres.

Are you ready for assessment of the application to register: Guidance and checklist

In August 2021, we published a guidance and checklist aimed at supporting new and existing providers to determine if their centre is ready for the assessment and decision on their application to register in advance of submitting the application.

This guidance and checklist will support providers who are applying to register a new centre, take over an existing centre or increase the footprint of an existing centre.

4.1.6 Regulatory research

The need for regulatory reform

In February 2021, we published a paper calling for reform to health and social care regulations. The report summarises HIQA's experience of regulating social care services over the past 12 years and outlines the changes we believe are required to make regulation fit for purpose into the future.

This paper outlines some key components of regulatory reform that need attention, such as:

- consideration to be given for the development of a comprehensive, integrated social care policy that considers social care in its totality alongside Sláintecare
- a comprehensive review of the current regulations pertaining to social care services in Ireland, and the establishment of a regular review process
- the reform of the Health Act 2007 to take account of the changing landscape in health and social care services

- the introduction of regulation into other forms of care that are currently unregulated and whose service users may be vulnerable
- a framework that makes a clear distinction between the purchaser and provider of services along with clear governance and accountability arrangements.

HIQA's recommendations serve to complement the objectives set out in Sláintecare by furthering the commitment to delivering person-centred care in the right place and at the right time for all.

Regulation of homecare

In December 2021, we published three papers calling for immediate reform, including the introduction of regulation, of Ireland's homecare services.

The papers set out that homecare is an essential, and increasingly in demand, service which allows people to receive health, social and personal care within their home. In line with the vision of the Sláintecare Programme, we believe now is an opportune time to take a different approach to the funding, procurement and delivery of all health and social care services, including homecare services.

As shown in the paper, most people in Ireland would prefer to age and receive care in their own home. However, we found that homecare operates in a complex environment with many influencing factors such as funding, availability and geography. The research found the current homecare system is not sustainable and is not meeting the needs of people, with some vulnerable people unable to avail of support in their home. Furthermore, homecare services are not currently regulated to establish and ensure their quality and safety.

HIQA has, over the last number of years, advocated that the homecare sector needs a complete overhaul given the uneven distribution of homecare services and the absence of a statutory footing. We have called for a full 'root and branch' review of homecare to be undertaken before legislation is drafted, that will involve engagement with all key stakeholders, at all levels across the sector. We have also called for the development of homecare standards and regulations that should incorporate the principles of a human rights-based approach; safety and wellbeing, responsiveness, and accountability — which will work together to achieve person-centred care and support.

LENS Project (Learning from Statutory Notifications in Social Care)

In 2019, HIQA was awarded €250,000 in funding from the Health Research Board under the Secondary Data Analysis Project Grant. This project aimed to learn from the statutory notifications HIQA received from designated centres.

Since 2021, the Database of Statutory Notifications from Social Care is available on our website. The data were primarily retrieved from HIQA's IT system and supplemented with additional data from designated centres' statement of purpose documents. Other variables were generated by combining or editing existing data. The database is updated in April of each year for the previous year's notifications. The database has been made publicly available to promote secondary analyses of the data that may inform policy, practice and innovation in the care for older persons and people with disabilities. The data has been used for a number of academic publications to date (see Appendix 8 for more information).

In March 2021, we held a webinar to provide information on the development of the open access database, relating to:

- the project overview and development of the database
- accessing and using the database
- descriptive analyses of statutory notifications
- current practice in the aftermath of current events.

4.2 Health technology assessment and evidence synthesis

HIQA's Corporate Plan 2019-2021 includes the following two strategic objectives:

- To produce high-quality health technology assessments (HTAs) and other evidence synthesis to inform major health-policy and health-service decisions, including national clinical guidelines and national clinical audit.
- To expand and consolidate capacity to conduct and use evidence synthesis and knowledge generation both in HIQA and across the health system.

Under the Health Act 2007, HIQA has a statutory role to evaluate the clinical and cost-effectiveness of health technologies and to provide advice to the Minister for Health and the HSE in this regard. This is called HTA, and it informs investment decisions in health and social care. We also conduct evidence synthesis to support the development of national clinical guidelines and national clinical audit, as well as to inform the development of health policy. We develop national HTA guidelines to inform the production of timely, consistent and reliable assessments that are relevant to the needs of the people using health and social care services.

In 2020, HIQA also took on a key role in providing evidence synthesis and evidence-based advice to inform public health decision-making in relation to COVID-19; this support has continued in 2021. HIQA also established a new HTA function in relation to ionising radiation in 2021.

4.2.1 Health technology assessment (HTA)

The choice of which HTAs are undertaken by HIQA is key to ensuring that we fulfil our role of supporting evidence-based decisions on the efficient delivery of national health services. In April 2021, a request for HTA topics was sent to the Department of Health and the HSE. Ten topics were scoped in accordance with the standard operating procedure for scoping topics as per the HTA prioritisation process.

We completed a desktop review and liaison with the relevant requestors to gather information relating to the description of the technology and its likely use, its potential clinical and economic impact, related decision-making and policy impact. We then summarised the recommended approach to HTA which was provided for consideration by the Prioritisation Advisory Group. The Prioritisation Advisory Group comprises two representatives of the Department of Health, two from the HSE, and two patient representatives.

The group rated the topics relative to each other using four main prioritisation criteria: clinical impact, economic impact, relevance of this technology in the context of national health policy initiatives, and clear link to decision-making in regard to the introduction of this technology and a reasonable assumption that a HTA could directly contribute to aiding the decision-making process.

Given the available resources, existing commitments and estimated resources required to undertake each HTA and the relevant time frame for decision-making, the HTA work programme for 2021 and 2022 was developed and approved by the Board of HIQA.

As a result, the following assessments were commenced in 2021 and are due for completion in 2022:

- **Varicella vaccination**

  The Department of Health has requested a HTA to determine the clinical effectiveness, safety, cost-effectiveness, budget impact, organisational and ethical aspects of a national programme of childhood vaccination against varicella-zoster (chicken pox).

- **A HPV vaccination mop-up programme**

  HIQA has been asked by the Department of Health to determine the likely demand for a human papillomavirus virus (HPV) vaccination mop-up programme for those who did not avail of the schools-based vaccination programme when originally offered. The budget impact and organisational implications will also be assessed.

- **Repatriation of haematopoietic stem cell transplants**

  Following a request from the HSE, HIQA is undertaking an assessment of the repatriation of haematopoietic stem cell transplants (HSCT). There is a single paediatric HSCT centre in Ireland, located in Children's Health Ireland (CHI) at Crumlin, equipped with a four-bed, purpose-built inpatient transplant unit. The assessment will consider the clinical need and budget impact, organisational and ethical aspects of extending paediatric HSCT services in Ireland to include patients currently treated abroad.

HTA of metabolic surgery for people with type 2 diabetes and obesity

Following a request from the HSE, we commenced a HTA of including metabolic surgery services as part of the National Clinical Programme for Diabetes. Bariatric surgery, initially developed for the treatment of obesity, has been shown to result in additional benefits beyond weight loss for the treatment of type 2 diabetes, such as improvements in glycaemic control leading to the coining of the term 'metabolic surgery'.

The HTA aims to establish the clinical and cost-effectiveness of metabolic surgery services in Ireland. In addition, it will estimate the budget impact of introducing a metabolic surgery programme and assess the organisational and resource implications of such a service. An expert advisory group comprising representatives from key stakeholder groups has been convened to provide advice and guidance over the course of the HTA.

The HTA will be finalised in 2022 and provided as advice to the HSE to inform a decision on whether or not to implement a metabolic surgery programme in Ireland.

HTA of birth cohort testing for hepatitis C

In 2019, HIQA commenced a HTA of offering testing for the hepatitis C virus (HCV) to people in Ireland born between 1965 and 1985. The HTA was prioritised following publication of an Irish National Clinical Guideline for Hepatitis C Screening, which was quality assured by the National Clinical Effectiveness Committee and endorsed by the Minister for Health in 2017. The guideline included a conditional recommendation to offer one-off HCV testing to people in Ireland born between 1965 and 1985 (that is, birth cohort testing) subject to the outcome of a full HTA.

In Ireland, HCV testing is routinely offered to people with known risk factors for infection (for example, people who have ever injected unprescribed or illicit drugs, people on renal dialysis) and people that have symptoms of chronic HCV infection. Chronic HCV infection is most common in people born between 1965 and 1985 in Ireland. Birth cohort testing would test everyone born between these two dates, therefore being more likely to identify and treat people with undiagnosed chronic HCV infection before they develop serious liver-related complications. It would not impact access to existing risk-based approaches for detecting HCV infection or the treatment of people identified through risk-based testing.

As part of the HTA, we assessed the epidemiology of HCV in Ireland and reviewed the diagnostic accuracy of tests for diagnosing chronic HCV infection, in addition to the safety and effectiveness of therapies to treat chronic HCV infection. We also undertook systematic reviews of the diagnostic accuracy of laboratory-based tests using dried blood spot samples and the cost-effectiveness of population-based testing strategies for identifying people with undiagnosed chronic HCV infection. An economic model was developed to estimate the cost-effectiveness and budget impact of the potential introduction of birth cohort testing in Ireland. Finally, we analysed the organisational and ethical implications of the proposed introduction of birth cohort testing.

The draft HTA was made available for a six-week public consultation period, allowing members of the public and stakeholder organisations to provide feedback.

The HTA was supported by an Expert Advisory Group with representation from the Department of Health, the National Hepatitis C Treatment Programme, the National Virus Reference Laboratory, the National Programme for Pathology, the Health Protection Surveillance Centre, clinicians with specialist expertise in infectious diseases, the National Screening Service, the National Centre for Pharmacoeconomics, the Irish College of General Practitioners, relevant patient advocacy groups and methodological experts.

The HTA found that birth cohort testing for HCV in Ireland would be a cost-effective use of resources, but would require a significant upfront investment. Given substantial uncertainty regarding the prevalence of undiagnosed chronic HCV infection in the 1965 to 1985 birth cohort and the logistical challenges posed by a potential birth cohort testing programme, we advised that consideration should be given to an initial pilot programme.

The HTA was approved by the HIQA Board and submitted to the Minister for Health for consideration.

4.2.2 National Screening Advisory Committee (NSAC) – Evidence synthesis support

The National Screening Advisory Committee (NSAC) was established in 2019 following a recommendation of the 2018 Scoping Inquiry into the CervicalCheck Screening Programme. NSAC is an independent advisory committee that advises the Minister for Health and Department of Health on new proposals for and revisions to population-based screening programmes. Since 2020, HIQA has undertaken evidence synthesis and provided evidence-based advice to NSAC on behalf of the Minister for Health. This support has involved both assessments of new and existing population-based screening programmes and reviews of processes (such as prioritisiation and decision-making approaches, or the development of ethical frameworks) used to inform policy-making on screening.

Extended Interval Screening of the Diabetic RetinaScreen Programme in Ireland

In February 2021, we published a scoping report which provided an overview of the evidence for extending the screening interval for diabetic retinopathy from one to two years for those at low risk of diabetic retinopathy progression.

Diabetic retinopathy is a microvascular complication of diabetes mellitus and is a common cause of vision impairment and sight loss. The screening programmes can prevent sight-threatening diabetic retinopathy through the timely detection and treatment of cases. It had been proposed that, in line with international practice, screening intervals of every two years could be introduced for those at low risk of retinopathy progression and who had demonstrated compliance with the programme.

Supported by the evidence from our scoping report, NSAC made a recommendation to the Minister for Health for the screening interval to be extended from one to two years for individuals at low risk of retinopathy progression who have demonstrated compliance with the programme. This change to the screening programme was implemented in 2021.

Review of processes in use to inform the expansion of newborn bloodspot screening programmes

This review was requested by NSAC to help inform the development of their processes for the assessment of conditions being considered for inclusion in Ireland's National Newborn Bloodspot Screening Programme (NNBSP). The NNBSP delivers newborn bloodspot screening (NBS), also known as the 'heel prick test', which is completed in the first 72 to 120 hours of life. Currently in Ireland, eight conditions are screened for within NBS, with a ninth condition undergoing implementation.

HIQA undertook a comprehensive review of countries recognised as having described policy-making processes in place for their newborn bloodspot screening programmes. Following review of the literature, nine countries were identified and a thorough review of academic literature and relevant policy documents associated with these countries was conducted. The report summarised a number of elements relevant to decision-making on the expansion of NBS programmes. Elements of interest included: (i) the range of conditions screened for in international NBS programmes; (ii) the processes for condition proposal, prioritisation and selection for evidence review; (iii) the decision-making processes leading to the inclusion of a condition in international NBS programmes; and (iv) the role of emerging technology in NBS programme expansion. A multidisciplinary Expert Advisory Group was convened to consider the evidence outlined and provide expert input to the report.

This report noted that, when considering expansion of a screening programme, important ethical, legal and social implications must be taken into account; including the perspectives of a broad range of stakeholders, such as, the child, their family, scientists, healthcare professionals, and public health professionals. Furthermore, the resources required to expand the programme should be considered at an early stage. The report advised NSAC that an explicit, structured approach to each aspect of policy-making on this topic should be prepared to ensure consistency and transparency into the future. This report was presented to NSAC on 20 May 2021 and published on www.hiqa.ie.

Review of international ethics frameworks in the context of screening

In 2021, NSAC began development of an ethics framework to support its evaluations and deliberations in relation to population-based screening programmes in Ireland. In May 2021, NSAC requested HIQA to assist in the development of this ethics framework by performing a scoping review of best practice related to this topic.

HIQA performed an international review of ethics frameworks used in policy-making in the context of screening. Sources for the review included bodies with responsibility for screening policy-making, public health agencies, national ethics bodies, and international agencies. While considerable variation was found in the content and structure of the frameworks identified, consistencies were noted in the ethical principles and procedural values that are considered. Several frameworks highlighted the need to consider the relevance and relative importance of values or principles within different contexts of screening (for example, adult versus child programmes), and the possibility that some values and principles may conflict with each other. Furthermore, as public health decisions related to screening are taken at the population or community level, the values and principles that guide these decisions differ from those that guide traditional clinical decision-making. Therefore, it was considered important to balance the consideration of the benefits and harms of screening as they relate to the overall population and for the individual.

This project was supported by an Expert Advisory Group with relevant expertise. The report was presented to NSAC on 21 October 2021.

HTA of the addition of severe combined immunodeficiency (SCID) to the National Newborn Bloodspot Screening Programme

Severe combined immunodeficiency (SCID) is a group of rare, inherited immune system disorders, characterised by the absence, or significantly reduced number, of T cells. Ireland has a comparatively high prevalence of Adenosine Deaminase Deficiency SCID (ADA-SCID), a specific form of SCID, relative to other countries. In September 2021, at the request of NSAC, HIQA agreed to undertake a HTA of the addition of SCID to the National Newborn Bloodspot Screening Programme.

A two-phase process to evidence synthesis was adopted. In the first phase, evidence synthesis will include description of the technology, epidemiology of SCID, and an assessment of the clinical effectiveness and safety of T cell receptor excision circles-based screening for SCID. The findings will be submitted to NSAC for consideration. At NSAC's request, a second phase may be undertaken to assess the economic, organisational, social, ethical and legal implications of introducing TREC-based screening for SCID in Ireland.

A multidisciplinary expert advisory group will be convened by HIQA to provide advice during the course of the HTA.

4.2.3 HRB-CICER – National clinical guideline support

In 2016, HIQA was awarded a contract for €2.25 million by the Health Research Board (HRB) to establish the HRB Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER). A no-cost extension was approved for HRB-CICER in December 2021, extending the work programme until April 2023. HIQA's main collaborator is the HRB Centre for Primary Care Research (HRB-CPCR) in the Royal College of Surgeons in Ireland (RCSI).

HRB-CICER aims to deliver a high-quality evidence base with regard to systematic review of clinical and cost-effectiveness and budget impact analysis to support the development of evidence-based recommendations in national clinical guidelines and national clinical audits. These guidelines and audits are quality assured by the National Clinical Effectiveness Committee (NCEC) and mandated by the Minister for Health for implementation by the HSE. The collaboration also provides training in evidence synthesis and advises the NCEC on improvements in methodological developments in evidence generation, and on research gaps in the evidence base and how they may be best addressed.

We also provide support to the NCEC through membership of the committee and by assisting with the prioritisation and appraisal of submitted guidelines. In 2021, HIQA provided expert input to NCEC appraisal and prioritisation teams for the following guidelines:

- Diagnosis, Staging and Treatment of Gestational Trophoblastic Disease, National Clinical Guideline
- Unexpected Intraoperative Life-threatening Haemorrhage, National Clinical Guideline
- Stop Smoking, National Clinical Guideline.

National clinical guideline on chronic obstructive pulmonary disease

We supported the development of a national clinical guideline for the treatment and management of chronic obstructive pulmonary disease (COPD) in adults. We carried out a systematic review of economic literature and conducted a budget impact analysis to estimate the costs of implementing the clinical recommendations. The guideline was launched in November 2021.

National clinical guideline on sepsis management for adults (including maternity)

HRB-CICER supported the development of a national clinical guideline for the management of sepsis for adults, including during maternity. We provided methodological support to the guideline development group at all stages. The guideline was launched in September 2021.

Guideline development

We also provided the following to guideline development groups in 2021:

- a systematic review of clinical and economic literature on interventions to improve hand hygiene adherence to support the healthcare-acquired infection guideline
- a systematic review of clinical and economic literature on single patient room accommodation compared to multi-bed rooms in acute settings to support the development of the healthcare-acquired infection guideline
- a budget impact analysis of the implementation of the stop smoking national clinical guideline
- a budget impact analysis of the intraoperative massive haemorrhage guideline.

In 2021, work began on:

- a systematic review of international guideline update processes to inform revisions to the NCEC processes for updating the national clinical guidelines.

Health Research Board Emerging Investigator Award

HIQA is a co-applicant on the Health Research Board Emerging Investigator Award (EIA) led by Dr Barbara Clyne, HRB-CICER and RCSI, entitled *Evidence synthesis and translation of findings for national clinical guideline development: addressing the needs and preferences of guideline development groups*. This research aims to support clinical guideline development processes underlying the work conducted by HRB-CICER by developing a 'toolkit' for evidence producers and end users. This toolkit will support:

- optimal selection of evidence synthesis methods
- communication of the findings of evidence synthesis and
- translation of research evidence into recommendations.
- a Delphi study on optimal selection of evidence synthesis methods: ethical approval has been received and the questionnaire has been finalised
- applying for ethical approval to co-develop and pilot test prototype modes of communicating findings of evidence summaries.

Health Research Board Collaborative Doctoral Award

HIQA is a co-applicant on the Health Research Board Collaborative Doctoral Award led by Professor Susan Smith, RCSI, which funds a programme entitled *Managing complex multimorbidity in primary care: a multidisciplinary doctoral training programme*. The programme includes a collaboration with HIQA to evaluate the costs of adhering to clinical guidelines falling on patients with complex multimorbidity and their carers, an area under researched to date.

During 2021, work commenced on a survey which will be administered by Behaviours and Attitudes on 'How do people with multimorbidity prioritise their healthcare when unable to afford healthcare costs: a choice experiment'. One systematic review was completed and published, and one paper examining the association between multimorbidity and healthcare expenditure in older adults was submitted for peer-review publication.

4.2.4 Evidence for Policy

Our Evidence for Policy Team was established in 2018 following a request from the National Patient Safety Office (NPSO) in the Department of Health. The team is responsible for the effective implementation of evidence synthesis programmes to deliver high-quality research to support policy development by the Department of Health.

Economic burden of antimicrobial resistance: An analysis of additional costs associated with resistant infections

At the request of the Department of Health, we undertook an analysis of the hospital costs associated with antimicrobial resistance (AMR) in 2019, which was published in 2021. This work, part funded by the Health Research Board, supported Ireland's First National Action Plan (iNAP) on Antimicrobial Resistance. A multidisciplinary Expert Advisory Group was convened to advise HIQA during the course of the study.

AMR occurs when micro-organisms adapt over time and no longer respond to antimicrobials. When micro-organisms become resistant to antimicrobials, infections become more difficult and more expensive to treat. AMR presents a significant threat to public health globally, as it is associated with substantial levels of mortality and morbidity. The financial cost of treating resistant infections places a significant burden on society, as patients infected with drug-resistant micro-organisms are more likely to remain in hospital for a longer period of time, have poorer outcomes and be unable to work.

Ireland's National Action Plan (iNAP) on Antimicrobial Resistance (2017-2020) included a strategic intervention to undertake an economic analysis of AMR. This aimed to estimate the current costs associated with select antimicrobial-resistant micro-organisms of public health concern in the public acute hospital setting in Ireland.

We carried out a literature review to inform an economic assessment of AMR. The subsequent analysis estimated the costs associated with eight selected antimicrobial-resistant bacteria of public health concern. We found that over 4,700 of these resistant bacterial infections occurred across 50 public acute hospitals in Ireland in 2019. The study estimated that AMR associated with these bacteria cost the health service an additional €12 million in extra hospital bed days in 2019, while these resistant infections resulted in about 215 deaths and almost 5,000 disability-adjusted life years, or years of full health lost. The study will inform understanding of the economic costs associated with AMR in Ireland and has informed the development of the second National Action Plan (2021-2025), iNAP 2.

4.2.5 COVID-19 evidence synthesis and advice

The evidence and information relating to COVID-19 continues to rapidly evolve since its emergence in December 2019. HIQA began to provide evidence synthesis to support the national public health response to the COVID-19 pandemic in March 2020 at the request of the Department of Health.

A COVID-19 Evidence Synthesis Team was established to provide evidence synthesis to support the work of the National Public Health Emergency Team (NPHET), its sub-groups and other groups in the Department of Health and HSE working on the public health response. In September 2020, HIQA commenced providing evidence-based advice to NPHET on behalf of the Minister for Health. The advice is informed by evidence synthesis undertaken across all relevant domains of HTA and health services research. A COVID-19 Expert Advisory Group (EAG) was established to provide expert interpretation of the relevant evidence and inform the development of advice to NPHET. The EAG comprises nominated representatives from the relevant clinical and public health stakeholder groups, patient representation and methodological expertise.

In 2021, we produced a range of evidence syntheses, some of which were regularly updated. These included: five reviews of public health guidance (nine versions in total), 13 evidence summaries (22 separate versions), five facilitated discussions covering three individual topics, two pieces of analysis or modelling (two separate updates), a regularly updated database of international public health guidance (56 updates) and reviews of policy measures to limit the spread of COVID-19 (updated 33 times).

The reports compiled in response to specific requests from NPHET, the Department of Health, National Immunisation Advisory Committee (NIAC), HSE Antimicrobial Resistance and Infection Control (AMRIC) team and Health Protection Surveillance Centre (HPSC) in 2021 included:

- evidence summaries:
  - Public health guidance for community and healthcare settings in the context of COVID-19
  - Interventions in an ambulatory setting to prevent progression to severe disease in patients with COVID-19
  - Review of measures to support those in self-isolation or restriction of movements
  - Duration of protective immunity (protection from reinfection) following SARS-CoV-2 infection
  - Groups in vaccine allocation group nine - those aged 18-64 years living or working in crowded conditions
  - Policies relating to healthcare personnel who do not avail of COVID-19 vaccination
  - Mandatory home quarantine and post-travel testing
  - Public health measures to limit SARS-CoV-2 transmission at mass gatherings
  - COVID-19 - Interventions and health-related factors that prevent infection or minimise progression to severe disease
  - Interventions that prevent infection or minimise progression of COVID-19
  - Rapid antigen testing of asymptomatic individuals
  - Duration of immunity post vaccination
  - Rolling review of the evidence in relation to the Omicron (B.1.1.529) variant
- facilitated discussions
  - Derogation of vaccinated healthcare workers
  - Reducing the minimum age for mask wearing requirements and recommendations in COVID-19
  - Respirator mask use by persons who are at higher risk from COVID-19

- international reviews of public health measures and strategies
  - Antigen testing in asymptomatic individuals in community settings
  - Public health measures and strategies to limit the spread of COVID-19
  - Face masks and physical distancing
  - Approaches to Personal Protective Equipment (PPE) modelling
  - Rolling review of International Public Health Guidance in relation to the Omicron variant (B.1.1.529)
- epidemiological analysis and modelling
  - Rapid Antigen Diagnostic Tests in meat processing plants
  - Factors associated with outbreaks of SARS-CoV-2 in nursing homes
- database of international public health measures provided to the Department of Health and HPSC three times per week until 10 February 2021 and weekly thereafter
- international reviews of public health measures provided to the Department of Health and HPSC, including reviews of public health guidance:
  - for residential care facilities in the context of COVID-19
  - on protective measures for vulnerable groups in the context of COVID-19.

Eight manuscripts from this work have been accepted for publication in academic journals. A peer-reviewed publication 'SARS-CoV-2 detection, viral load and infectivity over the course of an infection' was awarded the Overall Winner award at the HSE Open Access Awards 2021.

We have also contributed to a number of expert groups responding to the pandemic. Our Director of HTA, Dr Máirín Ryan, is a member of NPHET; while our Chief Scientist, Dr Conor Teljeur, and Dr Ryan, are members of NPHET's Irish Expert Modelling Advisory Group. Our Deputy Director of HTA, Dr Patricia Harrington, is a member of the HSE Rapid Antigen Diagnostic Testing working group.

Dr Ryan also chaired NPHET's SARS-CoV-2 Surveillance & Whole Genome Sequencing (WGS) Working Group. The group made recommendations to NPHET on a national WGS surveillance programme which was duly established as a key component of the public health response to COVID-19.

HIQA made a series of presentations to the National Immunisation Advisory Committee (NIAC) on our evidence synthesis on the duration of immunity to COVID-19 vaccines. This research informed the recommendations from NIAC with regard to use of booster doses of COVID-19 vaccine.

4.2.6 Generic justification of ionising radiation

Directive 2013/59/Euratom (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) was transposed into Irish law on 8 January 2019. Under the regulations, HIQA has responsibility for the generic justification of new types of practices involving medical exposure to ionising radiation as well as the review of existing practices under certain circumstances. We also have responsibility for the specific justification of ionising radiation performed as part of a health screening programme or individual health assessment and to publish guidelines in relation to the screening of asymptomatic individuals outside of existing national health screening programmes. To fulfil our statutory responsibilities in relation to generic justification, HIQA established a new ionising radiation function within our HTA Directorate in 2021. Work on the processes underpinning the function have commenced.

4.2.7 Stakeholder engagement

National and international networks

In 2021, HIQA contributed to a number of advisory groups and networks run by external stakeholders. These included the Technology Review Group of the HSE National Cancer Control Programme, the Technology Review Group of the HSE Rare Diseases Programme, the SPHeRE Steering Group, the HSE Community Health Schemes (Medicines) Open Data Project Governance Committee and the Department of Health's Health System Performance Assessment Stakeholder Group.

Last year, we entered into a collaboration with the HSE National Health Library and Knowledge Service. HSE librarians provided technical support to HIQA's evidence synthesis team to support the response to COVID-19. This support was formalised in 2021 with HSE librarians continuing to provide technical support to HIQA's librarian, as needed.

We partnered with the Department of Public Health in the Mid-West to co-host a Clinical Leadership in Public Health Medicine fellow from July 2021 to July 2022. This is one of a series of post-specialist registrar training fellowships under the auspices of the Royal College of Physicians of Ireland and funded by the HSE to facilitate access to specialist training, in this case advanced evidence synthesis skills.

In 2019, we signed a memorandum of understanding (MoU) between national health technology assessment (HTA) bodies in Scotland, Wales and Ireland. The MoU established a collaborative approach to the identification and assessment of new health technologies between the three organisations. Collaboration has included HIQA team members acting as dedicated reviewers for assessments produced by the other member agencies.

A collaborative panel discussion was delivered by HIQA, Health Technology Wales, the Scottish Health Technology Group and other international health technology agencies (including the Swedish Agency for Health Technology and the Canadian Agency for Drugs and Technologies in Health), at the Health Technology Assessment international (HTAi) conference in 2021. The topic of the panel discussion was "Embedding Impact Evaluation in Health Technology Assessment: Successes and Challenges".

In 2021, we collaborated with AGENAS, the Italian national HTA agency. AGENAS is funding one of its senior health economists to work in HIQA on an 18-month fellowship. The fellowship, which commenced in October 2021, will provide a unique opportunity for skills transfer and information exchange between the two agencies.

HIQA is a member of both HTAi and the International Network of Agencies for Health Technology Assessment (INAHTA). These international collaborations allow us to share research and collaborate on and co-produce evidence reviews on health technologies.

HIQA has been nominated by the Department of Health to represent Ireland in the European Network for Health Technology Assessment (EUnetHTA) since 2008. EUnetHTA was a collaboration of over 80 HTA organisations from all 28 European Union (EU) member states, Norway and Switzerland between 2008 and 2020. It aimed to bring about effective and sustainable HTA collaboration that creates added value at European, national and regional levels. A series of Joint Actions were undertaken to foster interagency cooperation, improve HTA output and avoid duplication of effort. HIQA was an active participant in EUnetHTA contributing to several joint outputs, including relative effectiveness assessments and HTA guidelines, as well as participating in the EUnetHTA Executive Board from 2014 to 2021. This work has informed the development of the EU Health Technology Assessment (HTA) Regulation which was formally adopted in December 2021. The regulation replaces the current system based on the voluntary network of national authorities (HTA Network) and the EU-funded project-based cooperation (Joint Actions EUnetHTA) with a permanent framework for joint work. It will apply from January 2025. The new framework covers joint clinical assessments, joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation. HIQA will play an active part in the implementation of the new framework.

HIQA is also a founding member of the Heads of Agencies Group, a network of health technology assessment agencies across the EU. The group's main objectives are as follows:

- to support the development of the basis for joint work on all HTA activities at EU level within the framework of the EU HTA Regulation once it comes into force
- to support the preparation of national systems and capacities for the adoption of the HTA Regulation
- to support the joint work performed at the technical and scientific level by HTA bodies across Europe
- to advise policy-makers and relevant EU and national institutions on matters regarding HTA, particularly cooperation in HTA.

HIQA has collaborated with the European Centre for Disease Prevention and Control on the Systematic review of the efficacy, effectiveness and safety of newer and enhanced seasonal influenza vaccines. Five manuscripts based on this research were submitted for publication in a peer reviewed journal in 2021.

A presentation was completed to the EU/EEA National Immunisation Technical Advisory Groups (NITAG) collaboration on 10 June 2021. We also established national and international academic collaborations, for example through the HRB Emerging Investigator Award project, and engaged with ISPOR through attendance at roundtable discussions and meetings.

Evidence Synthesis Ireland

We collaborate on the Evidence Synthesis Ireland initiative led by Professor Declan Devane, National University of Ireland Galway (NUIG), which aims to strengthen Ireland's capabilities in evidence synthesis to promote evidence-informed health decision-making. Evidence Synthesis Ireland is funded by the HRB and the Public Health Agency, Northern Ireland. HIQA is one of four placement sites for successful applicants to undertake training in systematic review skills.

The Director of HTA is a member of the International Advisory Board for Evidence Synthesis Ireland.

Conferences

During 2021, members our HTA teams participated in and presented their research work at a number of conferences (see Appendix 7).

The Director of HTA, Dr Máirín Ryan, was invited to give a plenary presentation at the ISPOR 2021 Annual Meeting examining the role of health economics and HTA in the assessment of public health interventions with a particular focus on assessment of interventions in the context of a pandemic response.

Dr Ryan was also invited to present to the Irish Society of Clinical Microbiologists on HIQA's evidence synthesis work to support the public health response during the COVID-19 pandemic.

4.3 Health and social care standards

Working in conjunction with a wide range of stakeholders, we aim to improve the quality and safety of health and social care services by setting national standards and developing implementation support tools. Standards promote practice that is up to date, evidence based, effective and consistent. Standards help the people who provide health and social care services to identify strengths and highlight areas that may need improvement. National standards show people what safe, high-quality care should look like and what to expect from a service. When national standards are finalised, we also develop additional support materials to help health and social care services and staff to understand and implement them in practice.

4.3.1 New Standards Development Framework: a principles-based approach

We published the *Standards Development Framework: a principles-based approach* in September 2021. Following a review of international evidence, we developed this framework to set out how HIQA will develop national standards into the future. The new framework follows a principles-based approach for future national standards for health and social care services. These principles will be used as HIQA's standards development framework, replacing the eight-theme framework which HIQA has used to develop standards since 2012.

Based on this work and engagement with key stakeholders, four principles emerged, underpinned by the core concept of person-centred care and support. The principles are: a human rights-based approach, safety and wellbeing, responsiveness and accountability. This framework places the person receiving care and support at the core of everything, with each of the principles working together to achieve person-centred care and support. Within the framework, person-centred care and support is not viewed as a principle in itself, rather it is an approach to care.

Standards developed with this framework will describe how service providers can achieve safe, high-quality and integrated person-centred care and support for people accessing the relevant health and social care services. The framework puts the person receiving care and support at the core of everything and services should work together to achieve the best possible outcomes for them.

The draft principles were tested in practice in the development of the Draft National Standards for Children's Social Services in 2021. As part of the standards development process, we held a public consultation on these draft standards and on the principles underpinning them. Overall, the four principles were positively received. The principles were finalised and will be used as the framework for the development of all national standards by HIQA, including any tools and resources developed to support their implementation, irrespective of the setting or service type. This will not affect national standards already published, which continue to be fit-for-purpose and will remain in place unless a decision is made, in line with HIQA's prioritisation process, to review and update them. Any such decision to review or update existing standards will be informed by consultation with stakeholders.

4.3.2 Building capacity and capability in our health and social care services

Standards promote practice that is up to date, evidence based, effective and consistent. Implementation support tools, such as e-learning modules, assist service providers and staff to understand and implement national standards. They help to build capacity, and to ensure there is sustained quality improvement within services. In 2021, we placed additional focus on supporting the implementation of national standards through the development of e-learning modules, in accordance with HIQA's Corporate Plan 2019–2021. This work helps to improve understanding and implementation of standards and to bring about better outcomes for people using services, in line with our corporate objectives.

In 2021, there was significant engagement with stakeholders in the form of public consultations, focus groups and one-to-one meetings to inform the development of standards and support tools. Going forward, we will continue to develop support tools to assist services to build capacity among health and social care staff. We will continue to work with staff and people with experience of using health and social care services to develop evidence-based national standards and support materials, and to identify additional support tools to assist in the implementation of national standards.

A human rights-based approach in health and social care

In 2019, we published *Guidance on a Human Rights-based Approach in Health and Social Care Services* in conjunction with Safeguarding Ireland. To further support health and social care staff to understand and apply a human rights-based approach in their work, we launched an e-learning course on HSELanD (the HSE's learning and development website) as a series of modules between March and May 2021. The *Applying a Human Rights-Based Approach in Health and Social Care: Putting National Standards into Practice* course consists of four modules:

- Module 1: Introduction to Human Rights in Health and Social Care
- Module 2: Role of Good Communication in upholding Human Rights
- Module 3: Putting People at the Centre of Decision-Making
- Module 4: Positive Risk-taking.

The course builds upon the guidance to further support staff to understand and implement a human rights-based approach in their work. In addition to promoting and supporting good practice in this area, the course aims to address knowledge and skills gaps that were identified through extensive stakeholder engagement during the guidance development process. It contains practical scenarios describing real-life examples of good and poor practice, self-reflection questions and links to additional resources to extend learning. Each module can be completed separately and the learner receives a certificate of completion at the end of each module.

By the end of 2021, on HSELanD:

- 15,212 people had completed Module 1
- 12,571 had completed Module 2
- 9,870 had completed Module 3
- 8,376 had completed Module 4.

Total completions of the rights-based care modules in 2021 is 46,029.

We included an online evaluation form at the end of each module to gather feedback on the module and assess its impact. At the end of 2021, 4,290 evaluation surveys had been completed. For each of the four modules, 99% of people said the module had given them a better understanding of the topic and 96% would recommend the module to a colleague. For Module 1, 75% of people intended to change their practice having completed the module and for Modules 2, 3 and 4, 82% intended to change their practice. Due to the level of interest in the course, all e-learning modules were also made available on HIQA's website from June 2021.

In addition, we developed a video animation for people using services to raise awareness of what they should expect from a health or social care service that is committed to respecting, protecting and promoting their human rights.

We also engaged with representatives from the Galway Advocacy Council, a self-advocacy group in the Brothers of Charity in Galway, to create a video explaining what being at the centre of decision-making means to them.

Infection prevention and control

In August 2020, we launched an e-learning module to support health and social care staff to implement the *National Standards for infection prevention and control in community services*. The module is an important resource for front-line staff working in health and social care services, demonstrating how they can practically implement the standards in their day-to-day work. The module is available on both the HIQA website and HSELanD.

In 2021, 16,170 people completed the module. Our online evaluation form has been completed by 6,760 people. 94% of people said the course gave them a better understanding of what the national standards look like in practice, 79% intend to change their practice having completed the course and 95% would recommend the course to a colleague.

Adult safeguarding

The *National Standards for Adult Safeguarding*, jointly developed with the Mental Health Commission (MHC), were published in 2019. In November 2020, we launched an e-learning module to support people who work in health and social care services to implement these standards in their service. In 2021, 9,962 people completed the module.

An online evaluation form on the module was completed by 2,606 people, the majority of whom are front-line staff working in health and social care services. Over half of respondents (53%) worked in residential settings, with the other 47% of respondents coming from a wide variety of community and acute services. Based on these evaluations, 99% of people said the course gave them a better understanding of what the national standards look like in practice, 78% intended to change their practice having completed the course, and 85% would recommend the course to a colleague.

Tools to support advocacy in nursing homes

Following the impact of COVID-19 in nursing homes in Ireland, the COVID-19 Nursing Homes Expert Panel Report was published in August 2020. The report highlights the psychological impact of the lockdown and the social isolation of nursing home residents, and contains a range of recommendations including the need to highlight and promote independent advocacy services available to residents.

The report also highlights that the rights of residents in terms of dignity, freedom, choice and equality need to be respected and at the forefront of policy going forward.

In response to these recommendations, we are developing an e-learning module on advocacy to support the implementation of the report, the *National Standards for Adult Safeguarding,* and the *Guidance on Human Rights-Based Approach in Health and Social Care Services.*

The e-learning module will aim to enable health and social care staff to support the people they care for to advocate for themselves and access advocacy services. It aims to improve knowledge and understanding of advocacy among health and social care staff and the role of each staff member in advocacy.

4.3.3 National standards

Overarching National Standards for the Care and Support of Children using Health and Social Care Services

Together with the Mental Health Commission (MHC), we are developing a set of overarching national standards for all health and social care services providing care and support to children. This includes disability services, mental health services, hospital services, general practitioners (GPs), primary care services and children's social services. The overarching standards aim to support services to work together in an integrated way to deliver high-quality, safe, consistent and coordinated care and support to children using these services. The standards will set out what outcomes a child should expect and what a service needs to do to achieve these outcomes.

To inform the development of the draft standards, we engaged extensively with a wide range of stakeholders with experience of health and social care services. In 2021, we conducted 39 focus groups and three telephone consultations, meeting with 217 children, young people, families, advocates and staff. We held two meetings of the Children's Reference Group[11] and one meeting of the Advisory Group, in addition to holding individual stakeholder meetings with senior representatives across the health and social care sector.

In September and October 2021, HIQA and the MHC undertook a six-week public consultation to gather feedback on the draft standards, receiving 58 responses from a wide range of organisations and individuals including Tusla, the National Disability Authority, the Office of the HSE Nursing and Midwifery Services Director, An Garda Síochána, front-line services and people with experience of services.

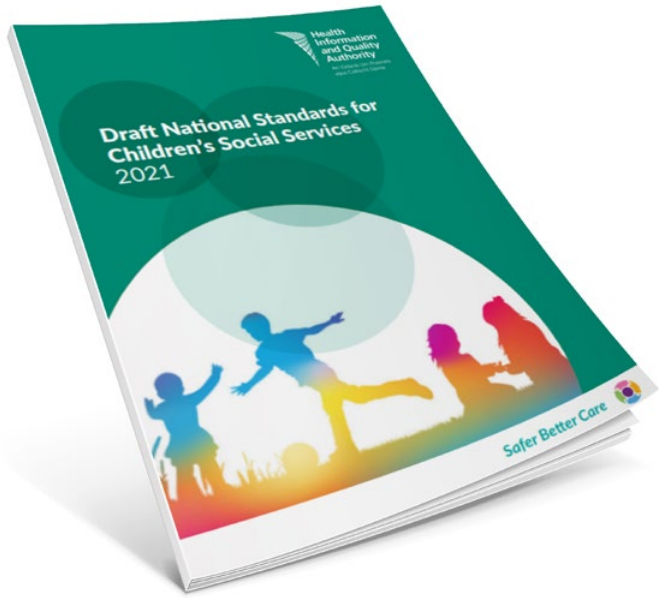
11 The Children's Reference Group is comprised of young people and family members with experience of using a range of health and social care services for children. The group gives insight into the issues that are important to children and families using services, so that this is reflected in the content of the standards.

Feedback from the public consultation has been incorporated into the draft standards where relevant and in early 2022, the revised draft standards will be presented to a final meeting of the Advisory Group and Children's Reference Group before being finalised and submitted for Ministerial approval.

It is envisaged that the overarching standards will act as a framework to inform the development of future standards and implementation support tools for health and social care services working with children. HIQA and the MHC are committed to developing materials and tools to support health and social care services to put these standards into practice. To this end, we have explored barriers and facilitators to implementation and what would help services and staff to apply the standards in their services. In addition, we held three focus groups with members of the Advisory Group to explore these issues in greater depth. In 2022, HIQA and the MHC will build on this work to identify and commence the development of implementation support tools that are likely to have the greatest impact for the health and social care sector.

National Standards for Children's Social Services

We have completed the development of draft *National Standards for Children's Social Services*, which were submitted for Ministerial approval in December 2021. These standards cover all children's social services, from the point of a child's referral to a service until they transfer to another service or are discharged. The national standards aim to drive improvements in the quality and safety of care for all children, and support a rights-based approach to the provision of care and support for children who are at risk in the community or who are living away from their families in the care of the State, regardless of their needs or stage of development.



In 2021, we held a six-week public consultation on the Draft National Standards for Children's Social Services to gather feedback on the content and structure, as well as the four principles underpinning the standards. The consultation received 81 responses from a range of stakeholders with experience of children's social services, including responses from statutory bodies, service providers, advocacy bodies and individuals. In addition we held a series of 10 focus groups with 56 participants, including children and young people, families, advocates, and staff. Feedback from the written responses and the focus groups were incorporated into the standards, where relevant.

Throughout the development of the standards we asked stakeholders what was needed to support services and staff to implement the standards in their work settings, for example any additional tools and resources required to support the standards in practice. Respondents provided a wide range of suggestions in this area. Additionally, we held three focus groups with members of the Advisory Group to explore this topic, gathering rich information to inform the process. Using the findings gathered throughout the standards development process, HIQA is developing support tools. This work will continue throughout 2022.

National Standards for Homecare and Support Services

It is widely recognised that the majority of people wish to be cared for in their own homes for as long as possible. Future demographic challenges, trends towards increasingly complex care being provided in the home, and the need to focus on a human rights-based approach that facilitates autonomy and choice, underline the need for quality home support services. HIQA recognises the importance of the quality and safety of home support services to allow people to remain in their own homes for longer. As such, HIQA is developing national standards for organisations who provide homecare and support services in Ireland, to complement the primary legislation and regulations currently being developed by the Government.

These standards, based on evidence and stakeholder input, will aim to promote progressive quality improvements in homecare and support services and give a shared voice to the expectations of the public, people using services, service providers and staff.

In 2021, we commenced an evidence review to inform these standards. The evidence review summarises international, national and academic evidence to identify characteristics of good person-centred practices in homecare and support services, where people experience safe, high-quality outcomes from their care and support. During the development of this review, we met with international colleagues from six countries to learn from their experiences of developing standards and regulating homecare and support services.

A crucial element throughout the development of any set of standards is engagement and consultation with a range of stakeholders to ensure the standards are fit-for-purpose, implementable and will contribute to the improvement of relevant health and social care services in Ireland. The following stakeholder engagement took place to inform the development of the national standards:

- A public scoping consultation was undertaken in September 2021 receiving 182 responses from a wide range of stakeholders.
- Between October and December 2021, 22 online meetings and focus groups were conducted with 122 stakeholders.

Online focus group conducted in December 2021 with members of the HIQA Standards Team meeting Independent Living Movement Ireland to inform the development of the Draft National Standards for Homecare and Support Services, clockwise from top left Michelle Williams (HIQA), James Cawley, Judy Gannon (HIQA) and Shelly Gaynor.

- An advisory group has been convened for the development of Draft National Standards for Homecare and Support Services, comprising 18 members including representation from Department of Health, HSE, service users, service providers and advocacy bodies. The first meeting of this group took place in November 2021.

In 2022, in line with the standards development process, we will continue to engage widely with people using homecare and support services, their families and other key stakeholders through focus groups, online meetings and discussions. A public consultation will be held in mid-2022, following which the standards will be finalised and go through HIQA's internal approval process in preparation for submitting them for Ministerial approval.

Influences on the implementation of health and social care standards in health and social care services

To promote evidence-based practice and to inform the work of our Standards Team, a PhD student has been sponsored by HIQA to undertake research on 'Influences on the Implementation of Health and Social Care Standards in Health and Social Care Services.' The PhD is being undertaken in collaboration with University College Cork and the SPHeRE Programme.

This research aims to support and enhance the implementation of health and social care Standards by identifying and describing the enablers and the barriers to implementation. It will then identify implementation support tools to leverage the enablers and overcome the barriers to implementing standards in health and social care services.

The research will contribute towards developing an innovative implementation framework that can be applied to future standards projects and will also support the broader implementation of standards in health and social care in Ireland.

During 2021, the following progress was made:

- Definitions of health and social care standards used internationally; a narrative review. A preliminary version of the findings was published as an abstract by the National Institute of Health Sciences, Research Bulletin, while a full version has been submitted for publication to an academic journal.
- A systematic review on enablers and barriers to implementation of standards is complete and will be submitted to an academic journal for publication in 2022.
- 14 focus groups and interviews with 38 participants were undertaken in 2021 to explore experiences with implementation of standards in Irish health and social care services.

4.3.4 Stakeholder engagement

Throughout the year, we continued to engage with stakeholders beyond the development of each set of national standards and supporting documentation. We participate in the European Social Network (ESN) whose mission is to advance the exchange of knowledge in public social services in partnership with health, education, housing, employment and social inclusion, to benefit people and communities through improved policy and practice. Over the past number of years we have presented our work on ensuring a participatory approach to the development of standards, as well as their work on supporting staff to implement a human rights-based approach in community care at the annual European Social Services conference.

We are represented on the steering group of the Ireland-Northern Ireland Implementation Network. The network brings together senior policy-makers, service providers, managers, practitioners and researchers in an all-island capacity to promote learning about implementation.

4.4 Health information

We work in three areas to support the national health information or eHealth agenda. These include:

- providing evidence to inform national health information policy
- developing national standards and guidance
- reviewing against national standards.

Working collaboratively with key stakeholders, we gather national and international evidence on best practice. We consult with experts, stakeholders, service providers and service users. We develop recommendations, national standards and guidance to support the eHealth agenda in Ireland. In addition, we assess compliance of national health information systems with national standards. The aim is to ensure there is quality data and information to support individual care, planning and management of services, policy-making and research.

4.4.1 Evidence to inform national health information policy

Position paper on the Need for Reform of Ireland's Health Information System

In our paper on *The Need for Reform of Ireland's Health Information System*, we highlighted the need for reform of Ireland's health information system in order to achieve the Sláintecare vision of an integrated healthcare service.

Several national strategies have shown the need for reform to ensure a secure, well-governed and well-resourced health information system. The COVID-19 pandemic further highlighted the need for timely availability of information and the cyberattack on the HSE health information systems in 2021 demonstrated the critical role that the health information system plays in the front-line delivery of care.

Our paper identifies areas of good practice and shortcomings that exist regarding health information in Ireland, and makes recommendations to inform policy and the strategic direction.

We made recommendations on reform and emphasised three core enablers as being the foundation of a robust health information system — a national health information strategy, strong governance and leadership to ensure accountability of our national health information system that is underpinned by legislation. Without these core enablers, a well-functioning health information system is difficult to achieve. Additional recommendations were made in relation to workforce, standards and health information infrastructure needed to establish an effective and efficient national health information system.

The paper and a series of videos on the need for reform are available on www.hiqa.ie.

Recommendations on the ICT enablement of older people's services

To address the increasingly complex needs of an ageing population, the Irish health system is undergoing a major transformation to a population-based, integrated care model. Information communication technology (ICT) is recognised as a key enabler.

These challenges have intensified under COVID-19, and following the recommendation from the COVID-19 Nursing Homes Expert Panel for the accelerated implementation of an integrated IT system for older people, we are developing recommendations on ICT enablement of older people's services.

These recommendations will provide an overview of work ongoing and, informed by best practice internationally, will outline measures to support the successful ICT enablement of older people's services. To date, we have engaged with experts in eight countries to gather international evidence and undertake extensive engagement with local stakeholders. In addition, a special advisory group was convened with members drawn from 32 stakeholder organisations and programmes to advise on the national situation and the overall recommendations. We published a review of ICT enablement of older persons services in October 2021 which collates best practices and lessons learned from these programmes in eight jurisdictions. The findings will inform the development of HIQA's recommendations on ICT enablement of older persons' services in Ireland.

Recommendations on a model for the collection, use and sharing of health information in Ireland

In 2021, we continued to develop recommendations on a model for the collection, use and sharing of health information in Ireland. To inform these recommendations, we undertook a national public engagement on the collection, use and sharing of health information in Ireland.

In September 2021, we published three reports on the findings of Ireland's first National Public Engagement on Health Information. The public engagement was conducted by HIQA in partnership with the Department of Health and the HSE. People were asked to share their views through a national telephone survey and in-depth focus groups.

The focus groups were held to ensure the voices of special interests groups were included. These focus groups were held with the public, patient representatives, addiction service users, mental health service users, homeless service users, members of the Traveller community, disability service users, sexual health service users, 16-17 year olds, and migrant community representatives. Overall, over 1,300 people told us their views during the focus groups and survey, stating that they are happy for information about their health to be collected, used and shared electronically; however, they want to know that access to, and security of, the information will be protected.

Health Information and Quality Authority
An tÚdarás um Fhaisnéis agus Cáilíocht Sláinte

An Roinn Sláinte
Department of Health

HSE

National Public Engagement on Health Information

1,313 people

told us their views on the collection, use and sharing of their health information

Survey: 1,228 people

Focus groups: 85 people

Use of health information for direct patient care

97%

think it is important that a hospital doctor has access to accurate health information.

90%

trust GPs to keep their information safe and secure and to share only relevant information.

71%

would like to know what information will be shared between the GP and hospital.

"I see multiple specialists over four different hospitals in three different counties, so I need them all to be able to look at what the other one has written"

A full report, technical report, and response document were published. The reports detailed the survey and focus groups undertaken with members of the public. Three knowledge sharing resources were also published; an anonymised data file from the national public engagement survey, an infographic and an animation of the key findings.

The findings were used to inform the recommendations on a model for the collection, use and sharing of personal health information. The Department of Health and HSE will also use the findings to develop national policy and strategy on eHealth in Ireland.

To progress the recommendations development, in November 2021, we published an *Evidence synthesis: Recommendations on a consent model for the collection, use and sharing of health information in Ireland*. We also published *Draft recommendations on a consent model for the collection, use and sharing of health information in Ireland* for public consultation. Following extensive engagement, the paper included 10 draft recommendations outlining the situations when consent is, and is not, required for the use of personal information in health and social care, as well as the need to establish legislative and governance structures, and technical and operational capabilities to support a consent model. It also defines key health information concepts and outlines the need for significant public engagement in this area.

The public consultation ran for seven weeks from November 2021 until January 2022 and submissions were received from members of the public and from key organisations and stakeholders across Ireland. In addition, a focus group on the draft recommendations was held with health professionals in December 2021, as well as four focus groups with members of the public which were held online in collaboration with The Irish Platform for Patient Organisations, Science and Industry (IPPOSI). A series of targeted consultation meetings with key stakeholders also took place.

The public consultation and focus group findings will inform the final recommendations on a model for the collection, use and sharing of health information in Ireland. This public consultation has initiated a national conversation on the importance of ensuring that individuals are informed about how their information might be used, as well as the choices they have about this.

Recommendations on health information modelling

In 2020, we commenced the development of recommendation on health information modelling in Ireland. In the context of healthcare, an information model identifies the information that can be included when collecting and sharing clinical and administrative information. It allows key stakeholders, including clinicians, to identify the common categories of information that can be grouped together in a logical way (known as concepts) — such as patient, medications, diagnosis — and which computer systems need to support. Our recommendations on a national information model for health information in Ireland will support the collection, use and sharing of information across health information systems, including national data collections (patient registries), and will be finalised in 2022. In 2021, we published a *Best Practice Review of Health Information Modelling* which outlines the approach to information modelling that countries have taken, the governance structures in place to support information modelling activities and the international standards used to implement models.

Recommendations on a national health and social care portal for Ireland

In 2021, we commenced a project to develop recommendations on the implementation of a national portal for health and social care in Ireland. This project will result in a set of recommendations to the Minister for Health on the sharing of information with patients in a national portal for health and social care. To date, we have engaged extensively with experts from local and international organisations to inform the development of evidence syntheses. This evidence will then inform the recommendations.

Development of personalised knowledge graphs for use in a patient portal to support caring for older persons

To promote evidence-based practice and to inform our work, a PhD student has been funded to undertake their doctoral studies while working within HIQA. The PhD is being undertaken in collaboration with Trinity College, Dublin.

The title of this PhD research is 'Development of personalised knowledge graphs for use in a patient portal to support caring for older persons'. Knowledge graphs consist of data and importantly relationships between data. They provide structure for data and facilitate combining data from multiple sources so it can be used in applications, for example in patient portals.

The outputs from this PhD research will contribute towards developing patient portals in Ireland.

Progress in 2021 included:

- Modelling temporal data in the knowledge graphs: A systematic review protocol published in HRB Open Research
- Development of a framework to assess the quality of data sources in healthcare settings was has been accepted for publication by the Journal of the American Medical Informatics Association, and will be published in early 2022.

4.4.2 Developing national standards and guidance

Developed guidance and digital learning tools to support the national data collections and data quality

In 2021, we revised HIQA's e-learning modules on how to improve data quality in health and social care services. The modules highlight the importance of high-quality data in health and social care services. The first module provides an 'Introduction to Data Quality' and the second module is on 'Developing a Data Quality Framework'. The module on an 'Introduction to Data Quality' highlights the importance of high-quality data and explains how everyone working in health and social care has a role to play in driving improvements in the quality of data in their service. It also emphasises how data can impact on the quality and safety of care of people who use health and social care services.

In November 2021, 'Introduction to Data Quality' was made available on HSELanD.

The second module was launched in early 2022. 'Developing a data quality framework' introduces the concept of a data quality framework and how it can be used to drive improvement in health and social care.

4.4.3 Reviewing against national standards

Review programme of compliance of national data collections with information management standards

In 2021, we continued to review compliance of national data collections with information management standards. The review programme aims to drive quality improvement in information management standards in all major national health and social care data collections within the HSE.

In May 2021, HIQA published a review of information management practices for the National Incident Management System (NIMS) within the HSE. NIMS is the national information system for reporting and managing incidents across the HSE and HSE-funded services in Ireland. It is one of the HSE's most important health information systems and is used for patient safety monitoring and learning by the HSE, and for risk management, litigation and claims by the State Claims Agency (SCA).

The review made 10 key recommendations in order to improve information management practices for NIMS within the HSE. We identified a number of shortcomings in relation to the joint governance arrangements between the HSE and the SCA, and the need for an effective governance, leadership and management model to be put in place to support NIMS. Furthermore, although there was evidence of good work undertaken in relation to data quality, there was a need for the HSE, with support from the SCA, to develop an overarching data quality framework. It also highlighted good practices in a number of areas including information governance and use of information. However, roles and responsibilities for areas of information governance for NIMS within the HSE — such as information security, data quality, data protection and the secondary use of information — also needed to be clarified.

In 2021, we commenced a review to assess compliance with information management standards for national waiting list data within the HSE. We have engaged with key stakeholders within HSE Acute and Community Operations and within the National Treatment Purchase Fund. We also carried out two acute hospital site visits to gather evidence for the review.

4.4.4 Stakeholder engagement

Engagement with external committees and initiatives

Engagement with external committees and initiatives in 2021 included:

- **International Network for Innovation in Regulation and Supervision of Care (SINC) Group.** SINC is an informal group which members drawn from health and social care regulators across Europe and beyond. Our Health Information Quality Manager and Health Information Technical Standards Manager sit on the group. Sweden, England, Denmark, Norway, Scotland, Ireland, Portugal, Finland, Singapore, Netherlands are currently participating.
- **National Standards Authority of Ireland's (NSAI's) Health Informatics Standards Consultative Committee TC 21 (HISC).** The NSAI, through the HISC, participates in the work of International Standards Organisation (ISO) TC 215 Health Informatics Committee and European Committee for Standardization (CEN) TC 251 Health Informatics Committee. Health informatics standards currently under development by CEN and ISO are discussed and formal responses are agreed. In addition, the committee regularly provides responses to consultation on health information standards in Ireland.
- **X-eHealth.** The X-eHealth project is an EU project which aims to lay the foundations to advance the integration of eHealth services features already in place for the European Cross Border sharing of patient summary information and electronic prescriptions. The X-eHealth project is developing functional and technical specifications for discharge summaries and for the revision of the existing patient summary to include rare diseases.
- **SNOMED CT Governance Board.** A SNOMED CT Governance Board has been established to provide strategic advice and oversight on the implementation of SNOMED CT in Ireland. A strategy has been agreed covering 2021-2023. The Board is chaired by Dr Kevin O'Carroll, our Technical Standards Manager. The Enterprise Architecture function of the Office of the Chief Information Officer in the HSE is where Ireland's National Release Centre has been established and is responsible and has the delegated authority to licence the SNOMED CT Irish Edition and derivatives.
- **DASSL (Data Access, Storage, Sharing and Linkage) Proof of Concept Project Stakeholder Group.** The DASSL model aims to facilitate the safe and secure linkage and analysis of health and related data in Ireland, with a view to supporting healthcare research and policy decisions. The Irish Centre for High-End Computing has been funded by the Health Research Board to develop a proof-of-concept technical infrastructure to support this model. HIQA is represented on this stakeholder group to provide expert advice in relation to this proof of concept model.

- **HSE National Health and Social Care Data Dictionary Governance Group.** HIQA is a member of this group to provide advice in relation to the strategic direction and governance of this project.
- **EU Joint Action 'Towards the European Health Data Space'.** HIQA is a member as a stakeholder in Work Package 4 – Policy Forum and a member of the overarching stakeholder forum.

Panel workshop at the 14th European Public Health Conference

On 11 November 2021, a panel workshop was facilitated at the 14th European Public Health Conference 2021 on the challenges of developing a consent model for health information in a changing digital world.

The session was chaired by Dr Barbara Foley, our Health Information Manager.

Our Research Officer, Dr Sarah Jane Flaherty, presented the findings of our National Public Engagement on Health Information in Ireland. She also spoke about how these findings are being used to inform HIQA's draft recommendations on a consent model of health information in Ireland.

Michelle Mackie, Head of Qualitative Research and Engagement with Ipsos MORI in England, presented on the important role that public engagement plays in building public trust in data use. Madis Tiik, former CEO of the Estonian eHealth Foundation, provided insight into the factors that have been fundamental in achieving strategic goals in relation to eHealth and establishing Estonia as a leader in this area.

A panel discussion was then facilitated by HIQA to discuss the importance of ensuring data ownership and access rights were considered in the development of a consent model. Questions from the audience focused on the issue of trust, which prompted a discussion on the role of public engagement to build trust and the value of creating a transparent system where there is a clear understanding of how health information is collected, used and shared.

4.5 National Care Experience Programme

The National Care Experience Programme seeks to improve the quality of health and social care services in Ireland by asking people about their experiences of care and acting on their feedback. The National Care Experience Programme is a joint initiative by HIQA, the Health Service Executive (HSE) and the Department of Health.

The National Care Experience Programme has a suite of surveys that capture the experiences of people using our services. The Programme implements surveys which aim to learn from people's feedback about the care received in health and social care services to find out what is working well, and what needs to be improved.

A National Care Experience Programme Survey Hub is available on www.yourexperience.ie to provide support, guidance, information and resources to assist providers to develop, conduct and analyse their own surveys, and act upon the findings.

4.5.1 National Inpatient Experience Survey

In 2021, we adapted the survey model and questionnaire of the National Inpatient Experience Survey for use during the COVID-19 pandemic. Adaptations of the National Inpatient Experience Survey questionnaire were informed by a review of the literature and engagement with national stakeholders and the international patient experience community. A series of new questions were included to address specific aspects of inpatient experiences during the pandemic that were not captured by the existing survey, such as staff communication while wearing personal protective equipment (PPE) and contact with family and friends given visitor restrictions. The new questions were cognitively tested with four patient representatives to ensure clarity and understanding. The National Inpatient Experience Survey 2021 presented an important opportunity for patients to provide feedback on their experiences of care during the pandemic. As a result of the cyberattack on the HSE IT systems in May 2021, the survey month was postponed from May to September 2021. The findings from the survey and quality improvement plans will be published in 2022.

4.5.2 National Nursing Home Experience Survey

In 2021, we continued development of the National Nursing Home Experience Survey, with a view to surveying nursing home residents and their designated representatives (such as a family member or friend) in 2022. We held four calls with international experts, including from the Netherlands, Australia, the US and Canada, to obtain greater insights into the survey model and methodology used to conduct nursing home experience surveys in other countries. As part of our stakeholder engagement, we ran 10 information sessions to inform nursing homes of the survey and ask for their feedback. To determine the most important areas of experience to be included in the survey, we held eight focus groups with 60 participants, including nursing home residents and their families, healthcare professionals, managers and service providers, policy-makers, researchers and advocacy organisations. In order to identify the most important questions for inclusion in the survey, we conducted two rounds of Delphi studies[12] with 25 participants, including designated representatives of nursing home residents, healthcare professionals and managers, policy-makers, researchers and advocacy organisations. We cognitively tested[13] the newly developed survey questionnaires (one for nursing home residents, one for designated representatives) with four nursing home residents and four designated representatives, in order to assess the clarity and appropriateness of the questions and response options. We also published an International Review of Nursing Home Experience Surveys.

The National Nursing Home Experience Survey will be the first national survey to provide an opportunity for nursing home residents to describe their lived experiences of nursing home care in Ireland. The findings of this national survey will drive improvements in nursing home care provision, acknowledging what is working well and also identifying areas where improvements are needed. The findings will also be used to inform national policies, regulatory programmes and standards.

4.5.3 National End of Life Survey

In 2021, we continued to develop the National End of Life Survey, with a view to surveying bereaved relatives in 2022. To identify the most important areas of experience to be included in the survey, we held 11 focus groups with 68 participants, including bereaved families, healthcare professionals, managers and service providers, policy-makers, researchers and advocacy organisations.

12 A Delphi study is a consensus-building technique used to refine the selection of questions to be included in each survey questionnaire.

13 Cognitive testing involves exploring how participants interpret and understand survey questions and response options.

In order to ascertain the most important questions for inclusion in the survey, we conducted two rounds of Delphi studies with 82 participants, including bereaved families, healthcare professionals and managers, policy-makers, researchers and advocacy organisations. We cognitively tested the newly-developed questionnaire with eight bereaved relatives, in order to assess the clarity and appropriateness of the questions and response options. We held six information sessions to inform key stakeholders of the survey and the areas of care that would be captured, which were attended by 129 people. We also published an International Review of National End of Life Surveys.

The National End of Life Survey will provide an opportunity for bereaved relatives, including the closest relatives or friends of those who have died, to tell us about the experience of end-of-life care from their perspective. This will be the first time that Ireland will hear about the experience of care in a person's last months of life. The findings of the survey will be used to improve care services and to inform regulation, national policies and standards.

4.5.4 National Maternity Bereavement Experience Survey

Work continues to develop the National Maternity Bereavement Experience Survey, which will provide an opportunity for parents who experienced a second trimester miscarriage, a stillborn infant or the early neonatal death of a baby to describe their experience of care.

In 2021, we held six information sessions with key stakeholders and presented at three forums, reaching a total of 309 stakeholders. To identify the most important areas of experience to be included in the survey, we held 10 focus groups and one individual meeting with 60 participants, including bereaved parents, healthcare professionals, managers and service providers, policy-makers, researchers and advocacy organisations. In order to determine the most important questions for inclusion in the survey, we conducted two rounds of Delphi studies with 120 participants, including bereaved parents, healthcare professionals and managers, policy-makers, researchers and advocacy organisations. We cognitively tested the newly developed questionnaire with eight bereaved parents, in order to assess the clarity and appropriateness of the questions and response options. We also published an International Review of Maternity Bereavement Experience Surveys and a Scoping Review of Early Pregnancy Loss in Ireland.

The National Maternity Bereavement Experience Survey will be the first national survey of maternity bereavement experiences in Ireland. The feedback that parents provide will be used to acknowledge areas of good experience and identify areas needing improvement. The findings will be used to improve care services and to inform regulation, national policies and standards.

4.5.5 Survey Hub

In 2020, we launched a Survey Hub to provide expertise and skills and to support greater engagement with national and international stakeholders. In 2021, we continued to the develop research, academic and international partnerships and links with key stakeholders to build capacity and understanding of people's experiences of health and social care services. We continued to engage with professional bodies and educational institutions to support and demonstrate use of the National Care Experience Programme survey findings. We supported four student work placements from three universities:

- Two undergraduate medical students from University College Dublin
- One undergraduate public health student from University College Cork
- One postgraduate masters in applied social research student from Trinity College Dublin.

We published a report on secondary analysis of the responses to the 2017 and 2018 National Inpatient Experience Survey, which presented the results of an in-depth secondary analysis of free-text survey responses. This analysis was conducted in partnership with a team based at the Insight Centre for Data Analytics at the National University of Ireland, Galway.

The National Disability Authority published a report on the Experiences of Women with Disabilities in their Journey through Maternity Services in Ireland, using data from the National Maternity Experience Survey.

We worked with researchers and academics at Maynooth University on a successful grant application for funding from the Health Research Board under the Secondary Data Analysis Projects (SDAP 2021) funding scheme, with co-applicants from the HSE, Department of Health, and patient representatives. The grant will support a project involving a detailed analysis of over 70,000 free-text comments received in response to our surveys, as well as development of a tool that will facilitate more efficient and standardised analysis of qualitative data received in response to future surveys. The project is led by Professor Adegboyega Ojo at Maynooth University, with support from co-applicants Dr Conor Foley and Dr Daniela Rohde from the National Care Experience Programme.

Furthermore, in 2021 we presented four posters and gave three oral presentations at national and international conferences. We continued to engage and collaborate with our international networks in 2021 and Picker Institute Europe to inform and support all of our surveys.

4.5.6 Let's Talk Care Experience podcast

We launched a new podcast series, Let's Talk Care Experience, in November 2021. The podcast discusses all aspects of people's experiences using Ireland's health and social care services. It features people who use services, staff within services, as well as leading health and social care experts.

In Episode 1, we discuss the importance of listening to the voice of patients with Paul Reid, HSE CEO; Phelim Quinn, HIQA CEO; Karen Greene, Deputy Chief Nursing Officer in the Department of Health; and Phyllis MacNamara, patient representative on the Saolta University Health Care Group Board.

In Episode 2, we talk about the impact of food and nutrition on patients' experience with Jennifer Feighan, CEO of the Irish Nutrition and Dietetic Institute, and Laura Brennan, Senior Dietitian in St James's Hospital.

Listen at www.yourexperience.ie or wherever you get your podcasts from.

4.6 Operations, Communications and Stakeholder Engagement and Information Division

4.6.1 Operations

Financial management

Throughout 2021, HIQA continued to manage its financial resources in line with good practice and all relevant governance requirements. The use of planning and ongoing financial management enabled HIQA to use its resources efficiently and effectively.

HIQA's internal financial controls were audited during the year by our internal audit provider. No material concerns were identified. Improvements were made to the financial management system that processes financial transactions and provides management information to support decision-making.

HIQA's annual accounts for 2021 were submitted to the Comptroller and Auditor General in accordance with the timescales set out in the Health Act 2007.

Health and safety

HIQA remains strongly committed to the protection of the health and safety of all employees. It has a comprehensive suite of health and safety related policies and procedures and training programmes in place.

During the year, the ongoing pandemic required continued focus on the risks that this created to the health and safety of employees. All required precautions were taken to protect the small numbers of staff who were required to attend our offices. Staff who had to carry out inspection activities were provided with training, guidance and PPE in line with public health guidance.

COVID-19 continued to impact on our activities and key training modules were customised to facilitate in class and remote participation. This ensured compliance with legislation and gave employees skills and knowledge to protect their own health and safety.

There was one reportable incident to the Health and Safety Authority during the year.

Human resources

The Human Resources (HR) Team continued to provide support to all employees during the continued remote working arrangements. This included responding to changing Government and public health guidance at different stages of the pandemic.

We continued to deliver a number of strategic human resources and organisational development initiatives, as set out below.

Health and wellbeing

The health and wellbeing agenda continued as a key focus with a number of initiatives adapted to the remote environment. These included the hosting of regular webinars, in partnership with our Employee Assistance Programme provider, organised in response to identified needs.

Learning and development

HIQA offers an extensive range of supports to all staff to develop competencies across the organisation and to support the delivery of its functions and strategic goals. This includes development of soft skills, technical training and provision of support to participate in relevant academic programmes

HIQA continued the development of its management development programmes including developing and delivering a 'Management Fundamentals' training programme for early career or new managers and a 'Leading with Impact' programme for experienced managers and individual contributors.

In 2021, HIQA was awarded the highest level of accreditation for the Excellence Through People award — Ireland's only national human resource management quality standard dedicated to the role of people and their impact on business — by the National Standards Authority of Ireland.

Management

The continued development of the HR Business Partner model played a key role in supporting managers and staff to work remotely and ensure any issues or concerns were managed appropriately. We worked closely with management to support workforce planning and change associated with the planned commencements of a range of new functions.

Ongoing change management support was delivered to various projects across the organisation including work on digital and data transformation projects.

Organisation design

To ensure that HIQA is best positioned to meet its future needs and those of its employees, a project on a model for future working was progressed in 2021 to enable more flexible working arrangements in the organisation going forward.

Furthermore, an organisational restructure project was commenced to ensure that the structure in place supports the organisation to deliver its functions, with strong internal supports.

Talent management

Recruitment processes continued to be developed to support remote working and remote recruitment during a period of significant growth and change for the organisation. We supported and progressed the recruitment and appointment of a number of key senior roles, including a new CEO, Chief Inspector of Social Services and Director of Healthcare Regulation. A succession plan was developed to mitigate the risks that vacancies in critical roles will not be filled satisfactorily within an acceptable time frame.

4.6.2 Information Division

Our Information Division supported the organisation in 2021, through providing ongoing technical and ICT support to staff, enabling and maintaining regulatory and business systems, remote working, and preparing for a new suite of technologies.

2021 laid the foundation for HIQA's Digital and Data Transformation Strategy. This will allow HIQA to be proactive in the provision of services, and to manage increased demand. We assessed current processes and ran a pilot project to create the foundation for an agile software methodology and toolkit. These initiatives introduced a new way of working for the Information Division to collaborate with business and other stakeholders to deliver on this strategy.

During the year, we extended the roll out of HIQA's project management methodology, including formal PRINCE2 accreditation across the organisation. This training will support delivery of a range of projects enabling the implementation of key strategic, operational and legislative requirements across HIQA. These projects were delivered as part of our Digital and Data Transformation Strategy and key business initiatives. A multidisciplinary team conducted an open competitive dialogue procurement to implement a strategic regulatory solution which will meet the current and future business needs of HIQA. We worked closely with our Regulation Directorate to lean business processes ahead of implementing this new strategic system.

Throughout 2021, we also provided deskside and system support. We handled over 1,300 support queries on our internal regulatory system. We received an 8% increase in support tickets to our Service Desk in 2021, while achieving a 95% customer satisfaction rating. During the year, we further strengthened security measures by implementing 24/7 security monitoring services and delivered additional security upgrades on HIQA's systems.

4.6.3 Communications and stakeholder engagement

Our Communications and Stakeholder Engagement Team supported HIQA's work throughout the year. The team is responsible for communicating and engaging with the public and a wide range of stakeholders including the Government and opposition, media, health and social care services, people using services and employees. The team manages the organisation's publications, media relations, website, social media accounts, graphic design, internal communications and complaints.

In 2021, this work included publishing:

- **68** documents on our work in evidence synthesis, health information, regulation, and standards and guidance development
- **1,536** inspection reports
- **60** press releases
- **97** publication statements
- **6** issues of external newsletter, HIQA News
- **12** issues of staff e-zine.

Our website, www.hiqa.ie, received over 1 million page views during the year.

We received and responded to 29 parliamentary questions in 2021.

During the year, HIQA made submissions to a number of other organisations' public consultations, including on:

- the Children and Young People's Participation in Decision-Making, 2015-2020
- the National Action Plan on Antimicrobial Resistance
- Rotunda Hospital's Strategic Plan 2022-2026
- the future development of the Hospital In-Patient Enquiry (HIPE) system.

4.6.4 Quality, risk and compliance

Our Quality, Risk and Compliance Team supported HIQA staff throughout the year. This included implementing a new corporate performance and risk reporting software system across the organisation in line with the commitments set out in our strategy. The team also provided risk management and quality improvement training to staff which was conducted remotely in line with public health guidance. An internal audit programme for 2021 was completed, while a gap analysis of our quality management system was conducted with a view to achieving external accreditation in the future.

5 Annual financial statements

HIQA Board membership

Name	Role
Pat O Mahony	Chairperson
James Kiely	Board Member
Caroline Spillane	Board Member
Paula Kilbane	Board Member
Michael Rigby	Board Member
Tony McNamara	Board Member
Lynsey Perdisatt	Board Member
Bernadette Costello	Board Member
Martin Higgins	Board Member
Martin O Halloran	Board Member
Marion Meany	Board Member
Daniel McConnell	Board Member

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Dublin 2
D02 KV6

Statement on Internal Control

1. Scope of responsibility

On behalf of the Health Information and Quality Authority (HIQA) I acknowledge the Board's responsibility for ensuring that an effective system of internal control is maintained and operated. This responsibility takes account of the requirements of the Code of Practice for the Governance of State Bodies 2016, and adherence to HIQA's own Code of Governance.

2. Purpose of the system of internal control

The system of internal control is designed to manage risk to a tolerable level rather than to eliminate it. The system can therefore only provide reasonable, and not absolute, assurance that assets are safeguarded, transactions authorised and properly recorded and that material errors or irregularities are either prevented or detected in a timely way.

The system of internal control, which accords with guidance issued by the Department of Public Expenditure and Reform, has been in place in HIQA for the year ended 31 December 2021 and up to the date of approval of the financial statements.

3. Capacity to Handle Risk

HIQA has an Audit, Risk and Governance Committee comprising three Board members and one external member with financial expertise. The Committee met six times during 2021.

HIQA has outsourced its internal audit function to an independent professional firm who conduct a programme of work agreed with the Audit, Risk and Governance Committee and the Board.

A risk management policy and procedure has been approved by the Board, which sets out HIQA's risk appetite, the risk management processes in place, and the roles and responsibilities of staff in relation to risk. This policy has been issued to all staff who are expected to work within HIQA's risk management policies, to alert management on emerging risks and control weaknesses, and assume responsibility for risks and controls within their own area of work.

4. Risk and control framework

HIQA has implemented a risk management system which identifies and reports key risks and the management actions being taken to address and, to the extent possible, to mitigate those risks.

A risk register is in place which identifies the key risks facing HIQA. Risks have been identified, evaluated and graded according to their significance, and are regularly reviewed as appropriate by various levels within the organisation including management, the Audit, Risk and Governance Committee, other committees of the Board and the Board. These assessments are used to plan and allocate resources to ensure risks are managed to an acceptable level.

Statement on Internal Control *(continued)*

The risk register details the controls and actions needed to mitigate risks and responsibility for operation of controls assigned to specific staff. I confirm that a control environment containing the following elements, is in place:

- procedures for all key business processes have been documented,
- financial responsibilities have been assigned at management level with corresponding accountability,
- there is an appropriate budgeting system with an annual budget which is kept under review by senior management,
- there are systems aimed at ensuring the security of the information and communication technology systems,
- there are systems in place to safeguard assets.

Throughout 2021, in line with public health advice and government policy, most of HIQA's staff continued to work from home. HIQA had established systems and controls that facilitate dispersed and remote working. Potential security and control threats were monitored and addressed on an ongoing basis. HIQA has been able to continue its operations without disruption and with minimal changes to its risk and control processes.

5. Ongoing monitoring and review

Formal procedures have been established for monitoring control processes and control deficiencies are communicated to those responsible for taking corrective action, to management and to the Board, where relevant, in a timely way. I confirm that the following ongoing monitoring systems are in place:

- key risks and related controls have been identified and processes have been put in place to monitor the operation of those key controls and report any identified deficiencies
- reporting arrangements have been established at all levels where responsibility for financial management has been assigned, and
- there are regular reviews by senior management of periodic and annual performance and financial reports which indicate performance against budgets and forecasts.

6. Procurement

I confirm that HIQA has procedures in place to ensure compliance with current procurement rules and guidelines and during 2021, with the following exceptions.

Statement on Internal Control *(continued)*

(a) On 14 May 2021, the Health Service Executive was subjected to a serious cyber-attack, through the criminal infiltration of its IT systems. Given the critical risks identified HIQA immediately took steps to strengthen its security stance and introduced additional security measures. HIQA contracted with an external provider to put in place a Monitoring Detection and Response solution, with the capability to record system-level behaviours, using them to detect suspicious events, investigate and block malicious activity, and remediate affected systems. This involved expenditure of €149k in 2021. This contract will expire in Q1 2022 when this service will be subject to a procurement process.

(b) In 2021 HIQA incurred €106K of expenditure on executive search fees. The expenditure was incurred on filling HIQA's Chief Executive Officer and two vacancies on the Executive Management Team. In the interests of speed and efficiency, it was decided on foot of documented business justifications, that the agency previously procured to fill the vacant CEO role was also contracted to fill the two other roles. All of this work concluded in 2021.

(c) The contract procured for professional recruitment system and services expired on 21 August 2021. Pending review a recruitment processes, HIQA continued to use these services to the end of 2021. The value of these services received after date of contract expiration was €45k.

7. Review of effectiveness

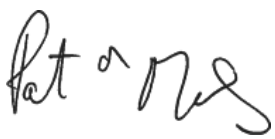
I confirm that HIQA has procedures to monitor the effectiveness of its risk management and control procedures. HIQA's monitoring and review of the effectiveness of the system of internal control is informed by the work of the internal and external auditors, the Audit, Risk and Governance Committee and senior management within HIQA who are responsible for the development and maintenance of the internal control framework.

I confirm that the Board conducted an annual review of the effectiveness of the internal controls for 2021.

8. Internal control issues

No weakness in internal control were identified in relation to 2020 that require disclosure in the financial statements.

On behalf of the Board,



Pat O'Mahony
Chairperson

Date: 19 April 2022

Governance Statement and Board Members' Report

1. Governance

The Board of the Health Information and Quality Authority (HIQA) was established under the Health Act 2007. The functions of the Board are set out in Section 8 of the Act. The Board is accountable to the Minister for Health and is responsible for ensuring good governance. The Board performs this task by setting strategic objectives and targets and taking strategic decisions on all key business issues. The regular day-to-day management, control and direction of HIQA are the responsibility of the Chief Executive and the senior management team.

The Chief Executive and the senior management team follow the broad strategic direction set by the Board, and ensure that all Board members have a clear understanding of the key activities and decisions related to the entity, and of any significant risks as they arise. The Chief Executive acts as a direct liaison between the Board and management of HIQA.

2. Board responsibilities

The work and responsibilities of the Board are set out in HIQA's Code of Governance which also contains the matters specifically reserved for Board decision. Standing items considered by the Board include:

- declaration of interests,
- reports from committees,
- financial reports and management accounts,
- performance reports, and
- reserved matters as arise.

Section 35 of the Health Act requires the Board of HIQA to keep, in such form as may be approved by the Minister for Health with consent of the Minister for Public Expenditure and Reform, all proper and usual accounts of money received and expended by it.

In preparing these financial statements, the Board of HIQA is required to:

- select suitable accounting policies and apply them consistently,
- make judgments and estimates that are reasonable and prudent,
- prepare the financial statements on a going concern basis unless it is inappropriate to presume that it will continue in operation, and
- state whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements.

Governance Statement and Board Members' Report
(continued)

The Board is responsible for keeping adequate accounting records which disclose, with reasonable accuracy at any time, its financial position and enables it to ensure that the financial statements comply with Section 35 of the Health Act 2007. The Board is responsible for approving the annual business plan and budget. Evaluation of HIQA's performance against the annual business plan and budget is carried out on an ongoing basis.

The Board is also responsible for safeguarding its assets and taking reasonable steps for the prevention and detection of fraud and other irregularities. The Board considers that the financial statements of HIQA give a true and fair view of the financial performance and the financial position of HIQA at 31 December 2021.

3. Board structure

The Board consists of a Chairperson and eleven ordinary members, all of whom are appointed by the Minister for Health.

Name	Role	Tenure commenced	Tenure expires
Pat O'Mahony	Chairperson of the Board	03/10/2018	02/10/2023
Paula Kilbane	Board Member	29/07/2015 30/09/2020	28/07/2020 29/09/2025
James Kiely	Board Member	26/02/2018	25/02/2023
Caroline Spillane	Board Member	26/02/2018	25/02/2023
Lynsey Perdisatt	Board Member	02/09/2019	01/09/2024
Tony McNamara	Board Member	02/09/2019	01/09/2024
Michael Rigby	Board Member	02/09/2019	01/09/2024
Bernadette Costello	Board Member	28/02/2020	27/02/2025
Martin Higgins	Board Member	01/06/2021	25/02/2023
Martin O Halloran	Board Member	01/06/2021	31/05/2026
Daniel McConnell	Board Member	01/06/2021	31/05/2026
Marion Meany	Board Member	01/06/2021	31/05/2026

Governance Statement and Board Members' Report
(continued)

4. Committees of the Board

The Board has established four committees, as follows:

a) **Audit Risk and Governance Committee:** The role of the Audit Risk and Governance Committee is to support the Board in relation to its responsibilities for issues of risk, control and governance and associated assurance. The Committee is independent from the financial management of the organisation. In particular the Committee ensures that the internal control systems including audit activities are monitored actively and independently. The Committee reports to the Board after each meeting, and formally in writing annually. An external independent person is also a member of the Committee.

b) **Resource Oversight Committee:** This committee monitors the resource requirements of HIQA to ensure that they are aligned with HIQA's corporate strategy including oversight of resource related risks. In addition, it oversees managerial performance.

c) **Regulation Committee:** This committee oversees the effectiveness, governance, compliance and controls around the delivery of HIQA's regulatory functions.

d) **Standards, Information, Research and Technology Committee:** This committee oversees the governance arrangements, including compliance and controls, for the functions of standards development, health information and health technology assessment functions.

Governance Statement and Board Members' Report
(continued)

5. Schedule of attendance, fees and expenses for Board members and external committee members

A schedule of attendance at Board and Committee meetings in 2021 is set out below, including the fees and vouched expenses paid to each member:

(a) Current Board Members

	Statutory Board meeting	Extra Board meetings	Audit, Risk and Governance Committee	Regulation Committee	Standards, Information Research and Technology Committee	Resource Oversight Committee	Fees	Vouched expenses
Number of meetings	**6**	**6**	**6**	**4**	**5**	**6**		**-**
Pat O'Mahony	6 of 6	6 of 6	N/A	N/A	N/A	6 of 6	€11,970	-
James Kiely	6 of 6	6 of 6	N/A	4 of 4	3 of 5	5 of 6	€7,695	-
Caroline Spillane	5 of 6	3 of 6	6 of 6	N/A	N/A	N/A	€7,695	-
Paula Kilbane	6 of 6	6 of 6	N/A	N/A	5 of 5	N/A	€7,695	-
Michael Rigby	6 of 6	5 of 6	N/A	4 of 4	5 of 5	N/A	€7,695	-
Tony McNamara	4 of 6	5 of 6	2 of 2	4 of 4	4 of 5	N/A	€7,695	-
Lynsey Perdisatt[1]	6 of 6	4 of 6	3 of 3	N/A	N/A	6 of 6	€4,489	-
Bernadette Costello	6 of 6	6 of 6	6 of 6	N/A	N/A	6 of 6	€7,695	-
Martin Higgins[2]	2 of 3	3 of 4	2 of 3	N/A	N/A	1 of 3	€4,489	-
Martin O Halloran[3]	3 of 3	4 of 4	N/A	2 of 2	2 of 3	N/A	€4,489	-
Danny McConnell[4]	2 of 3	4 of 4	N/A	N/A	N/A	3 of 3	€4,489	-
Marion Meany[5]	3 of 3	4 of 4	N/A	2 of 2	2 of 3	N/A	€4,489	-
Total							**€80,585**	-

1 Resigned from ARGC on 01/06/21

2 Appointed to Board on 01/06/2021

3 Appointed to Board on 01/06/2021

4 Appointed to Board on 01/06/2021

5 Appointed to Board on 01/06/2021

Governance Statement and Board Members' Report
(continued)

(b) External Audit, Risk and Governance Committee Members

Dónall Curtin was appointed as an external committee member to HIQA's Audit, Risk and Governance Committee on 29/02/2020 and has attended six of the six Audit, Risk and Governance Committee meetings during 2021. Fees of €2,565 were paid to him in 2021. No expenses were paid to him in 2021.

Fees were paid to Board members at the approved standard rates for the periods involved.
Fees are not paid to Board members employed in the public service, under the 'One Salary One Person Principle' directive, issued by the Department of Public Expenditure and Reform. As a result, one of HIQA's Board members (Lynsey Perdisatt), was not in receipt of fees until 08 June 2021, when she took up employment outside of public sector and has been in receipt of fees since that date.

6. Disclosures required by Code of Practice for the Governance of State Bodies

The Board is responsible for ensuring that HIQA has complied with the requirements of the Code of Practice for the Governance of State Bodies 2016. The following disclosures are required by the Code.

6.1 Employee Short Term Benefits

Employee short-term benefits in excess of €60,000 are set out in note 6 of the Annual Financial Statements.

6.2 Consultancy Costs

Consultancy costs include costs of external expert analysis and advice to management which contributes to decision making or policy direction. It excludes outsourced 'business as usual' functions

	2021 €	2020 €
Consultancy		
Legal advice	69,545	73,265
Human resources	55,653	3,354
Governance and strategy	466,797	54,029
Digital and data transformation	702,490	648,179
Total consultancy	**1,294,485**	**778,827**

Governance Statement and Board Members' Report
(continued)

	2021	2020
	€	€
Consultancy costs charged to capital account*	600,729	587,954
Consultancy costs charged to the Income and Expenditure and Retained Revenue Reserves**	693,756	190,873
Total	**1,294,485**	**778,827**

*Included in Statement of Capital Income and Expenditure

**Included in Professional Services in the Income and Expenditure Statement

6.3 Legal Costs and Settlements

	2021	2020
	€	€
Legal fees – legal proceedings (Note 1)	185,770	174,160
Legal Settlement (Note 2)	-	(40,000)
Total	**185,770**	**134,160**

Note 1

The table provides details of expenditure in the reporting period in relation to a range of legal proceedings. It includes two disputes with public sector organisations that were either heard or are pending a hearing in court. This does not include expenditure incurred in relation to general legal advice received by HIQA which is disclosed in consultancy services above.

Note 2

Included in legal proceedings is a receipt of €40,000 in settlement of HIQA legal costs associated with a Judicial Review, for which party to party costs were awarded to HIQA against the applicant in 2019.

Governance Statement and Board Members' Report
(continued)

6.4 Travel and Subsistence Expenditure

Travel and Subsistence Expenditure is categorised as per note 8 of the Annual Financial Statements.

6.5 Hospitality

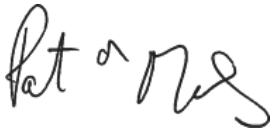
The Income and Expenditure and Retained Revenue Reserves Statement includes the following hospitality expenditure:

	2021	2020
	€	€
Board and Staff Hospitality	4,686	1,231
Total	**4,686**	**1,231**

7. Statement of compliance

The Board has adopted the Code of Practice for the Governance of State Bodies 2016 and put procedures in place to ensure compliance with the Code. HIQA was in full compliance with the Code of Practice for the Governance of State Bodies for 2021.

On behalf of the Board,



Signed:

Pat O'Mahony Date: 19 April 2022
Chairperson

Signed:

Bernadette Costello Date: 19 April 2022
Board Member

Comptroller and Auditor General Report

Report for presentation to the Houses of the Oireachtas Health Information and Quality Authority

Qualified opinion on financial statements

I have audited the financial statements of the Health Information and Quality Authority for the year ended 31 December 2021 as required under the provisions of section 35 of the Health Act 2007. The financial statements have been prepared in accordance with Financial Reporting Standard (FRS) 102 — *The Financial Reporting Standard applicable in the UK and the Republic of Ireland and comprise*

- the statement of income and expenditure and retained revenue reserves
- the statement of capital income and expenditure
- the statement of financial position
- the statement of cash flows and
- the related notes, including a summary of significant accounting policies.

In my opinion, except for the non-compliance with the requirements of FRS 102 in relation to retirement benefit entitlements referred to below, the financial statements give a true and fair view of the assets, liabilities and financial position of the Health Information and Quality Authority at 31 December 2021 and of its income and expenditure for 2021 in accordance with FRS 102.

Basis for qualified opinion on financial statements

In compliance with the directions of the Minister for Health, the Health Information and Quality Authority accounts for the costs of retirement benefit entitlements only as they become payable. This does not comply with FRS 102 which requires that the financial statements recognise the full cost of retirement benefit entitlements earned in the period and the accrued liability at the reporting date. The effect of the non-compliance on the Health Information and Quality Authority's financial statements for 2021 has not been quantified.

I conducted my audit of the financial statements in accordance with the International Standards on Auditing (ISAs) as promulgated by the International Organisation of Supreme Audit Institutions. My responsibilities under those standards are described in the appendix to this report. I am independent of the Health Information and Quality Authority and have fulfilled my other ethical responsibilities in accordance with the standards.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Comptroller and Auditor General Report *(continued)*

Report on information other than the financial statements, and on other matters

The Health Information and Quality Authority has presented certain other information together with the financial statements. This comprises the annual report, the statement on internal control and the governance statement and board members' report. My responsibilities to report in relation to such information, and on certain other matters upon which I report by exception, are described in the appendix to this report.

I have nothing to report in that regard.

John Crean
For and on behalf of the
Comptroller and Auditor General

6 May 2022

Comptroller and Auditor General Report *(continued)*

Responsibilities of Board members

As detailed in the governance statement and Board members' report the Board members are responsible for

- the preparation of financial statements in the form prescribed under section 35 of Health Act 2007
- ensuring that the financial statements give a true and fair view in accordance with FRS 102
- ensuring the regularity of transactions
- assessing whether the use of the going concern basis of accounting is appropriate, and
- such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

Responsibilities of the Comptroller and Auditor General

I am required under section 35 of the Health Act 2007 to audit the financial statements of the Health Information and Quality Authority and to report thereon to the Houses of the Oireachtas.

My objective in carrying out the audit is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement due to fraud or error. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with the ISAs, I exercise professional judgment and maintain professional scepticism throughout the audit. In doing so,

- I identify and assess the risks of material misstatement of the financial statements whether due to fraud or error; design and perform audit procedures responsive to those risks; and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

Comptroller and Auditor General Report *(continued)*

- I obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal controls.
- I evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures.
- I conclude on the appropriateness of the use of the going concern basis of accounting and, based on the audit evidence obtained, on whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Health Information and Quality Authority's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my report. However, future events or conditions may cause the Health Information and Quality Authority to cease to continue as a going concern.
- I evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

I report by exception if, in my opinion,

- I have not received all the information and explanations I required for my audit, or
- the accounting records were not sufficient to permit the financial statements to be readily and properly audited, or
- the financial statements are not in agreement with the accounting records.

Comptroller and Auditor General Report *(continued)*

Information other than the financial statements

My opinion on the financial statements does not cover the other information presented with those statements, and I do not express any form of assurance conclusion thereon.

In connection with my audit of the financial statements, I am required under the ISAs to read the other information presented and, in doing so, consider whether the other information is materially inconsistent with the financial statements or with knowledge obtained during the audit, or if it otherwise appears to be materially misstated. If, based on the work I have performed, I conclude that there is a material misstatement of this other information, I am required to report that fact.

Reporting on other matters

My audit is conducted by reference to the special considerations which attach to State bodies in relation to their management and operation. I report if I identify material matters relating to the manner in which public business has been conducted.

I seek to obtain evidence about the regularity of financial transactions in the course of audit. I report if I identify any material instance where public money has not been applied for the purposes intended or where transactions did not conform to the authorities governing them.

Statement of Income and Expenditure and Retained Revenue Reserves

For the year ended 31 December 2021

	Notes	2021 €	2020 €
Income			
Department of Health (Vote 38, E1)		19,369,000	17,269,000
Annual and registration fees	2	7,108,240	7,250,687
Other income	3	4,358,298	1,541,888
		30,835,538	**26,061,575**
Expenditure			
Staff costs	4	23,087,156	19,888,956
Travel and subsistence	8	456,239	422,235
Professional fees	9	1,213,039	*663,726
Publication expenses		51,966	41,153
Support costs	10	3,402,537	*2,390,181
Establishment expenses	11	2,116,703	2,269,857
		30,327,640	**25,651,108**
Surplus/(Deficit) for the year		507,898	410,467
Surplus as at 1 January		1,542,220	1,131,753
Surplus at 31 December		**2,050,118**	**1,542,220**

*For comparative purposes, 2020 expenditure of €24,509 for facilitation and coaching services has been reclassified to staff training and development in Support costs (Note 9 and note 10).

The Statement of Income and Expenditure and Retained Revenue Reserves includes all gains and losses recognised in the year with the exception of depreciation and amortisation which are included in the Statement of Capital Income and Expenditure.

The Statement of Cash Flows and Notes 1 to 19 form part of these financial statements.

On behalf of the Health Information and Quality Authority,

Signed:

Pat O'Mahony
Chairperson

Date: 19 April 2022

Signed:

Angela Fitzgerald
Chief Executive

Date: 19 April 2022

Statement of Capital Income and Expenditure

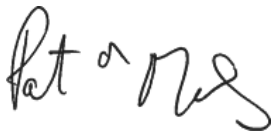
For the year ended 31 December 2021

	Notes	2021 €	2020 €
Income			
Department of Health (Vote 38, L)	15	2,427,907	2,052,108
Amortisation of Capital Fund Account	15	1,657,952	1,240,474
		4,085,859	**3,292,582**
Expenditure			
Fixtures and fittings	12	17,110	15,343
Computer equipment	12	1,810,068	1,448,811
Non capital expenditure	15	600,729	587,954
Depreciation	12	1,657,952	1,240,474
		4,085,859	**3,292,582**
Surplus/(Deficit) for the Year		**-**	**-**
Opening (deficit)/surplus		-	-
Surplus/(Deficit) for Year		**-**	**-**

The Statement of Income and Expenditure and Retained Revenue Reserves includes all gains and losses recognised in the year with the exception of depreciation and amortisation which are included in the Statement of Capital Income and Expenditure.

The Statement of Cash Flows and Notes 1 to 19 form part of these financial statements.

On behalf of the Health Information and Quality Authority,

Signed: 

Pat O'Mahony
Chairperson

Date: 19 April 2022

Signed: 

Angela Fitzgerald
Chief Executive

Date: 19 April 2022

Statement of Financial Position

As at 31 December 2021

	Notes	2021 €	2020 €
Fixed Assets			
Tangible Assets	12	2,960,706	2,791,480
Current Assets			
Receivables	13	1,194,198	1,221,454
Cash and cash equivalents		3,228,679	2,073,259
		4,422,877	3,294,713
Less Current Liabilities			
Payables falling due within one year	14	(2,372,759)	(1,752,493)
Net Current Assets		**2,050,118**	**1,542,220**
Total Assets less Current Liabilities		**5, 010,824**	**4,333,700**
Capital and Reserves			
Revenue Reserves		2,050,118	1,542,220
Capital Account	15	2,960,706	2,791,480
		5,010,824	**4,333,700**

The Statement of Cash Flows and Notes 1 to 19 form part of these financial statements.

On behalf of the Health Information and Quality Authority,

Signed:

Pat O'Mahony
Chairperson

Date: 19 April 2022

Signed:

Angela Fitzgerald
Chief Executive

Date: 19 April 2022

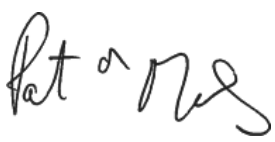
Statement of Cash Flows

For the year ended 31 December 2021

Reconciliation of Operating Surplus to Net Funds Inflow from Operating Activities

	2021 €	2020 €
Operating Surplus	507,898	410,467
Decrease in receivables	27,256	184,490
Increase in payables and accruals	620,266	262,994
Interest received	(81)	(124)
Net Cash Flow from Operating Activities	**1,155,339**	**857,827**
Cash Flows from Investing Activities		
Purchase of fixed assets	1,804,158	1,609,113
Non capital expenditure	489,414	625,823
Capital grants received	(2,293,572)	(2,234,936)
Net Cash Flows from Investing Activities	**-**	**-**
Cash Flows from Financing Activities		
Interest received	81	124
Net Cash Flows from Financing Activities	**81**	**124**
Net Increase in Cash and Cash Equivalents	**1,155,420**	**857,951**
Cash and cash equivalents at 1 January	2,073,259	1,215,308
Cash and Cash Equivalents at 31 December	**3,228,679**	**2,073,259**

On behalf of the Health Information and Quality Authority,

Signed: 

Pat O'Mahony
Chairperson

Date: 19 April 2022

Signed: 

Angela Fitzgerald
Chief Executive

Date: 19 April 2022

Notes to the Financial Statements

For the year ended 31 December 2021

1. Accounting Policies

1. (a) General Information

The basis of accounting and significant accounting policies adopted are set out below. They have all been applied consistently throughout the year and for the preceding year.

1. (b) Statement of Compliance

The financial statements of HIQA for the year ended 31 December 2021 have been prepared in accordance with FRS102 (the financial reporting standard applicable in the UK and Ireland), as modified by the directions of the Minister for Health in relation to superannuation. In compliance with the directions of the Minister for Health, HIQA accounts for the costs of superannuation entitlements only as they become payable (see (k) and (l)). This basis of accounting does not comply with FRS102, which requires such costs to be recognised in the year in which entitlement is earned.

1. (c) Basis of Preparation

The financial statements are prepared under the accruals method of accounting and under the historical cost convention in the form approved by the Minister for Health with the concurrence of the Minister for Public Expenditure and Reform, in accordance with Section 35 of the Health Act 2007.

The following accounting policies have been applied consistently in dealing with items which are considered material in relation to HIQA's financial statements.

1. (d) Income

(i) Oireachtas grants

The amount brought to account in the Statement of Income and Expenditure and Retained Revenue Reserves represents the actual grants received in the accounting grants in respect of approved capital expenditure are accounted for in the Capital Income and Expenditure account on an accrual basis.

(ii) Annual fee income

Annual fees from providers of Designated Centres for Older Persons are recognised three times every year in accordance Health Act 2007 Registration of Designated Centres for Older People (Regulations 2009 (S.I. 245 of 2009) and, Health Act 2007 Registration of Designated Centres for Older People) (Amendment) Regulations 2013 (S.I. 493 of 2013).

Notes to the Financial Statements

For the year ended 31 December 2021

Annual fees from providers of Designated Centres for Persons with Disabilities are recognised three times every year in accordance with Health Act 2007 Registration of Designated Centres for Persons (Children and Adults) with Disabilities Regulation 2013 (S.I. 366 of 2013).

(iii) Application to register or vary fees

Applications to register or vary fees are recognised on receipt of the relevant fee, in accordance with Statutory Instrument 245 of 2009, Health Act 2007 (Registration of Designated Centres for Older People) Regulations 2009 and Statutory Instrument 366 of 2013, Health Act 2007 (Registration of Designated Centres for Persons (Children and Adults) with Disabilities) Regulation 2013.

(iv) Other grants

Other grants, such as EU project funded grants are recognised on an accrual basis.

1. (e) Employee - short-term benefits

Short term benefits such as holiday pay are recognised as an expense in the year and benefits that are accrued at year-end are included in the payables figure in the Statement of Financial Position.

1. (f) Receivables

Receivables are recognised at fair value, less a provision for doubtful debts. The provision for doubtful debts is a specific provision and is established when there is objective evidence HIQA will not be able to collect all amounts owed to it. All movements in the provision for doubtful debts are recognised in the Statement of Income and Expenditure and Retained Revenue Reserves.

Annual fee debt is only written off on the basis of management assessment of the probability of non-collection and the cost of collection versus the debt outstanding. All amounts for debt written off are recognised in the Statement of Income and Expenditure and Retained Revenue Reserves.

Notes to the Financial Statements

For the year ended 31 December 2021

1. (g) Operating lease

Rental expenditure under operating leases is recognised in the Statement of Income and Expenditure and Retained Revenue Reserves over the life of the lease. Expenditure is recognised on a straight line basis over the lease period. Any lease incentives are released over the life of the lease.

1. (h) Capital funding

HIQA's fixed assets are funded from a combination of capital grants and allocations from current revenue. Funding sourced from grants is transferred to a capital account which is amortised in line with the depreciation of the related assets. Capital grants in respect of approved expenditure are accounted for in the Capital Income and Expenditure Statement on an accrual basis. Expenditure funded from capital funding that does not result in the creation of an asset is expensed to the Capital Income and Expenditure Statement on an accruals basis.

1. (i) Property, computer software, plant and equipment and depreciation

Property, computer software, plant and equipment are stated at cost less accumulated depreciation, adjusted for any provision for impairment. Depreciation is provided on all property, computer software and equipment, plant and equipment at rates estimated to write off the cost less estimated residual value of each asset on a straight line basis over their estimated useful lives, as follows:

- Leasehold interest — Life of the lease
- Furniture and fittings — 20%
- Computer software and equipment — 33.33%
- Cloud based computer software and equipment are written off over the life of the contract

Asset acquisitions, regardless of the source of funds, are capitalised with the exception of assets funded from revenue (non-capital) grants with a value below the following threshold:

- Equipment or furniture and fittings — - Less than €3,809
- Computer software or ICT equipment — - Less than €1,270

Notes to the Financial Statements

For the year ended 31 December 2021

Residual value represents the estimated amount which would currently be obtained from disposal of an asset, after deducting the estimated costs of disposal, if the asset were already of an age and in the condition expected at the end of its useful life. If there is objective evidence of impairment of the value of an asset, an impairment loss is recognised in the Statement of Capital Income and Expenditure and Retained Revenue Reserves.

1. (j) Intangible Assets

Intangible assets comprise software acquired by HIQA. The external costs of software licences and development are capitalised where it can be separately identified as software for use by HIQA and where it is expected to convey business benefits for a number of future years. Research costs are written off as incurred.

1. (k) Superannuation

In accordance with Section 27 of the Health Act 2007, HIQA has established a superannuation scheme which has been approved by the Department of Health.

The scheme is a defined benefit superannuation scheme for employees. No provision has been made in respect of benefits payable. Contributions from employees who are members of the scheme are credited to the Statement of Income and Expenditure and Retained Revenue Reserves when received. Pension payments under the scheme are charged to the Statement of Income and Expenditure and Retained Revenue Reserves when paid. By direction of the Minister for Health, no provision has been made in respect of benefits payable in future years.

1. (l) Single public service pension scheme

All new entrants into the public sector with effect from 1 January 2013 are members of the single public service pension scheme, where all employee pension deductions are paid to the Department of Public Expenditure and Reform. Pension payments under the scheme are charged to the Statement of Income and Expenditure and Retained Revenue Reserves when paid. By direction of the Minister for Health, no provision has been made in respect of benefits payable in future years.

Notes to the Financial Statements

For the year ended 31 December 2021

1. (m) Critical accounting judgments and estimates

The preparation of the financial statements requires management to make judgments, estimates and assumptions that affect the amounts reported for assets and liabilities as at the statement of financial position date and the amounts reported for revenues and expenses during the year. However, the nature of estimation means that actual outcomes could differ from these estimates. The following judgment has had the most significant effect on amounts recognised in the financial statements:

Depreciation and residual values

HIQA has reviewed the asset lives and associated residual values of all fixed assets, and in particular the useful economic life and residual values of fixtures and fittings, and have concluded that assets lives and residual values are appropriate.

2. Annual and Registration Fee Income

	2021	2020
	€	€
Annual fees	6,669,740	6,798,237
Registration fees	438,500	452,450
	7,108,240	**7,250,687**

Notes to the Financial Statements
For the year ended 31 December 2021

3. Other Income

	2021	2020
	€	€
Department of Health:		
- Nursing Home Expert Panel Grant	2,707,406	-
- National Screening Advisory Committee	290,915	237,123
Superannuation contributions	567,428	459,039
EU and other grants	46,375	38,546
Mental Health Commission	32,636	3,764
European Centre for Disease Prevention and Control	-	21,914
Health Research Board grants	344,383	451,318
Health Service Executive - National Care Experience Program	369,004	330,000
Interest received	81	124
Miscellaneous income	70	60
Total	**4,358,298**	**1,541,888**

4. Staff Costs

	2021	2020
	€	€
Wages and salaries	18,238,858	16,108,962
Pensions	1,402,179	850,689
Agency staff	1,482,993	1,225,227
Board members' fees	80,584	75,178
Employers' pay related social insurance	1,882,542	1,628,900
Total	**23,087,156**	**19,888,956**

Additional superannuation contributions of €551,749 (2020, €509,387) were deducted from staff salaries and remitted to the Department of Health.

Superannuation contributions of €404,031 (2020 €384,928) were deducted from staff members of the Single Public Service Pension Scheme salaries and remitted to the Department of Public Expenditure and Reform.

Notes to the Financial Statements
For the year ended 31 December 2021

5. Remuneration

5. (a) Aggregate Employee Benefits

	2021 €	2020 €
Employee short-term benefits	18,238,858	16,108,962
Outstanding annual leave entitlement	158,264	220,889
Employer's contribution to social welfare	1,882,542	1,628,900
	20,279,664	**17,958,751**

The total number of staff employed, whole time equivalents, at year end was 320 (2020, 264)

5. (b) Short-term Benefits

	2021 €	2020 €
Basic pay	18,238,858	16,108,962
	18,238,858	**16,108,962**

5. (c) Key Management Personnel

Management personnel consist of the Chief Executive, the Director of Health Technology Assessment and Deputy Chief Executive, the Director of Regulation (until her retirement in August 2021), the Director of Healthcare (appointed October 2021), the Chief Inspector of Social Services (appointed September 2021), the Director of Health Information and Standards, and the Acting Chief Operations Officer. The total value of short term benefits for key management personnel is set out below:

	2021 €	2020 €
Chief Executive Officer	163,327	160,524
Other Key Management Personnel	604,974	550,372
	768,301	**710,896**

Notes to the Financial Statements
For the year ended 31 December 2021

This does not include the value of retirement benefits earned in the period. The Chief Executive and the other key management personnel are members of HIQA's pension scheme and their entitlements in that regard do not extend beyond the terms of the model public service pension scheme.

HIQA's key management personnel were reimbursed €7,460 (2020, €7,683) for travel, subsistence and other expenses incurred while carrying out their duties.

Details of fees earned and expenses reimbursed to members of the Board are set out in the Governance Statement and Board Members' Report.

6. Employee Short-Term Benefits

Employees' short-term benefits in excess of €60,000 are categorised into the following bands:

Employee benefits	**2021 Number**	**2020 Number**
€60,001 - €70,000	80	86
€70,001 - €80,000	33	35
€80,001 - €90,000	19	13
€90,001 - €100,000	12	9
€100,001 - €110,000	5	5
€110,001 - €120,000	4	0
€120,001 - €130,000	0	0
€130,001 - €140,000	0	0
€140,001 - €150,000	0	2
€150,001 - €160,000	1	2
€160,001 - €170,000	2	0

Total employer pension contributions paid during the year was nil (2020, nil).
For the purposes of this disclosure, short-term employee benefits in relation to services rendered during the reporting period include salary, overtime allowances and other payments made on behalf of the employee, but exclude employer's Pay Related Social Insurance.

Notes to the Financial Statements
For the year ended 31 December 2021

7. Average Headcount

	2021	2020
Regulation	-	170
Chief Inspector	164	-
Healthcare	19	-
Health Technology Assessment	18	14
Health Information and Standards	33	26
Support staff	60	51
	294	**261**

As at 31 December, HIQA employed 320 whole time equivalent staff (2020, 264). During 2021 HIQA spilt its Regulation Directorate into Chief Inspector and Healthcare Directorates.

8. Travel and Subsistence

	2021	2020
	€	€
Domestic		
Board	-	932
Employees	454,757	413,218
International		
Employees	1,307	4,999
External professional services*	175	3,086
	456,239	**422,235**

Board travel and subsistence includes €0 paid directly to Board members (2020, €592). The balance of €0 (2020, €340) relates to expenditure paid by HIQA on behalf of the Board members in relation to hotel accommodation. Where hotel accommodation was provided by HIQA, no subsistence was claimed by the Board member.

*This cost relates to travel and subsistence costs which were incurred by HIQA as part of the contractual cost associated with the receipt of certain professional services.

Notes to the Financial Statements
For the year ended 31 December 2021

9. Professional Fees

	2021 €	2020 €
Legal advice	255,314	207,425
ICT professional services and consultancy	207,797	229,978
Strategic Human Resource Development	358,775	27,167
Financial Management Development	31,488	18,634
Standards development and health technology assessments	57,140	7,949
Corporate plan stakeholder engagement	36,048	-
Organisational development	-	77,469
Market Oversight Research	31,376	-
Human resources information system	246	3,030
Estate Services	72,735	30,589
Staff survey	23,063	-
Data Protection Services	17,318	-
External accreditations	10,593	3,176
Pension support services	36,710	8,926
Procurement services	8,377	5,218
Website review	-	10,164
Board risk and governance workshop	-	(4,365)
Contract Management Policy Development	-	8,228
Human Resources consultancy	55,653	3,354
Other	10,406	1,784
Total professional services	**1,213,039**	***638,726**

* For comparative purposes, 2020 expenditure of €24,509 for facilitation and coaching services has been reclassified to staff training and development in Support costs.

Notes to the Financial Statements
For the year ended 31 December 2021

10. Support costs

	2021	2020
	€	€
Recruitment	458,612	144,075
Staff training and development	593,869	*378,481
Advisory membership and subscriptions	69,590	131,506
Telephone	162,539	144,080
IT support and supplies	1,884,837	1,402,367
Cloud Services	39,302	-
Internal audit	61,483	78,551
External audit	17,300	17,000
Postage and stationery	95,947	75,882
Media monitoring	8,491	7,890
Couriers	4,492	7,663
Prompt payment interest and charges	3,908	1,652
Bank charges	2,167	1,034
Total	**3,402,537**	**2,390,181**

Notes to the Financial Statements
For the year ended 31 December 2021

11. Establishment Expenses

	2021 €	2020 €
Rent	1,250,834	1,342,149
Building leases-rent free reserves	57,790	-
Building service charge	206,191	202,031
Insurance	35,033	(1,147)
Repairs and maintenance	109,009	278,502
Meeting room hire	625	1,386
Stakeholder events and catering	7,705	15,306
Light and heat	151,435	129,729
Cleaning and refuse	123,267	155,522
Security	150,751	129,852
Record retention and storage	2,851	2,920
Health and safety	21,212	13,607
Total	**2,116,703**	**2,269,857**

Notes to the Financial Statements
For the year ended 31 December 2021

12. Fixed assets

	Leasehold interest	Fixtures and fittings	Computer equipment	Total
	€	€	€	€
Cost or valuation				
Balance at 1 January 2021	2,067,364	745,160	6,481,015	9,293,539
Additions	-	17,110	1,810,068	1,827,178
Disposals	-	(146)	(187,778)	(187,924)
Cost or valuation at 31 December 2021	2,067,364	762,124	8,103,305	10,932,793
Accumulated depreciation				
Balance at 1 January 2021	1,218,942	679,751	4,603,366	6,502,059
Depreciation charge for the period	109,126	23,495	1,525,331	1,657,952
Accumulated depreciation on disposal	-	(146)	(187,778)	(187,924)
Accumulated depreciation at 31 December 2021	1,328,068	703,100	5,940,919	7,972,087
Net book value at 31 December 2021	**739,296**	**59,024**	**2,162,386**	**2,960,706**
Net book value at 31 December 2020	**848,422**	**65,409**	**1,877,649**	**2,791,480**

Notes to the Financial Statements
For the year ended 31 December 2021

13. Receivables

	2021 €	2020 €
Annual fee receivables	-	244
Prepayments	760,834	581,631
Department of Health – Capital Grants receivable	339,412	205,077
Project Debtors	4,173	390,944
Payroll Receivables	52,295	9,524
Other Receivables	37,484	24,034
	1,194,198	**1,221,454**

14. Payables (amounts falling due within one year)

	2021 €	2020 €
Payables	215,786	65,251
Prepaid income	41,774	48,949
Prepaid project income	304,704	231,261
Trade accruals	915,712	642,785
Payroll deductions	678,729	543,358
Holiday pay accrual	158,264	220,889
Building Leases-rent free reserves	57,790	-
	2,372,759	**1,752,493**

Notes to the Financial Statements
For the year ended 31 December 2021

15. Capital Account

	2021 €	2020 €
Opening balance at 1 January	2,791,480	2,567,845
Movement for period		
Expenditure from capital and ICT programme grant	2,427,907	2,052,108
Non capital expenditure (Note 1)	(600,729)	(587,954)
Disposals	(187,924)	(72,552)
Amount amortised in line with depreciation for the period	(1,657,952)	(1,240,474)
Accumulated depreciation on disposals	187,924	72,507
Balance at 31 December	**2,960,706**	**2,791,480**

Note 1

Non capital expenditure relates to expenditure on professional fees, which have not met the FRS 102 definition of a fixed asset.

16. Capital Commitments

	2021 €	2020 €
Contracted for	544,466	100,262
	544,466	**100,262**

Notes to the Financial Statements
For the year ended 31 December 2021

17. Leasehold Commitments

HIQA is currently occupying three leased premises (Cork, Dublin and Galway). In all cases the lease agreement is between the landlord and the Office of Public Works.

The lease in respect of City Gate, Mahon, Cork was entered into in 2008 for a term of 20 years and one month. The annual rent payable is €388,941. As a result of agreements entered into as part of the decentralisation programme, this rent is paid by The Office of Public Works and is not recouped from HIQA.

The lease in relation to Smithfield in Dublin was entered into 2008 for a 20-year term. The annual rent payable is €1,383,012.

The lease in relation to Headford Road in Galway was entered into on 01 February 2016 for a 10-year term. The annual rent payable is €20,151.

HIQA commenced a 20 year lease for a premises at Building 2000, City Gate Mahon, Cork on 01 November 2021. The lease is subject to a rent review every five years and includes a rent free period from 01 November 2021 to 31 March 2022. This six month rent free period is amortised over the life of the lease. In 2021 the effective cost of this lease was €33,100. The annual effective cost of the lease is €201,354.

As at 31 December 2021, HIQA had the following future minimum lease payment for each of the following periods:

Within one year	€201,354
Between two to five years	€805,416
After five years	€2,987,212

HIQA commenced a 15 year lease for a premises at One Central, Forester Street, Galway on 19 November 2021. The lease is subject to a rent review every five years and includes a rent free period from 19 November 2021 to 31 July 2022 and a further three months' rent free for the first quarter of the second term of the lease. This twelve month rent free period is amortised over the life of the lease. In 2021 the effective cost of this lease was €24,690. The annual effective cost of the lease is €214,570.

As at 31 December 2021, HIQA had the following future minimum lease payment for each of the following periods:

Within one year	€214,570
Between two to five years	€858,278
After five years	€2,121,006

Notes to the Financial Statements
For the year ended 31 December 2021

18. Board Members' Interests

The Authority has procedures for dealing with conflicts of interest, in accordance with guidelines issued by the Department of Public Expenditure and Reform.

19. Approval of Financial Statements

These financial statements were approved by the Board on 19 April 2022.

Appendices

Appendix 1: **Annual protected disclosures report**

Under section 22 of the Protected Disclosures Act 2014 each public body is required to publish an annual report outlining the number of protected disclosures received in the previous year and the action taken (if any). This report must not result in the identification of persons making a protected disclosure.

The Minister for Public Expenditure and Reform has, under Section 7(2) of the Protected Disclosures Act 2014, prescribed the Chief Executive Officer of HIQA as an appropriate recipient of disclosures of relevant wrongdoings relating to all matters relating to the standards of safety and care of persons receiving health and social care services in the public and voluntary healthcare sectors and social care services in the case of the private healthcare sector, as provided for by the Health Act 2007. Any such disclosures made can only be dealt with in a way that is consistent with, and appropriate to the role, statutory rights and duties of HIQA.

This report covers the period of 1 January to 31 December 2021.

In 2021, 23 disclosures received were assessed under the Protected Disclosures Act 2014. This information was logged and risk-assessed and in each case used to inform the most appropriate intervention by HIQA as a regulator of health and social care services and in compliance with its duties under the Protected Disclosures Act 2014. Twenty of these have been closed out and three remain under regulatory review.

One protected disclosure was received internally in 2021, but was later withdrawn.

Further information on making a protected disclosure to the CEO as a prescribed person under the Protected Disclosures Act 2014 can be found on the HIQA website here.

Appendix 2: **Service Charter**

HIQA has developed a Service Charter and Action plan for the purpose of providing information to people engaging with our services on the level of service they can expect from us. The Charter sets out our commitment to engaging with our stakeholders in line with the principles of quality customer service for customers and clients of the public service. We have published progress on implementing our Service Charter action plan in 2021 on www.hiqa.ie.

Appendix 3: **Freedom of Information report**

HIQA received a total of 153 Freedom of Information (FOI) requests in 2021, carrying over five from 2020. These figures represent a 45% increase in FOI requests to HIQA compared to 2020 and a 105% increase compared to 2019. Further details on these requests are provided in the tables below.

2021 FOI Requests	
Brought forward from 2020	5
Received 2021	153
Total Requests Handled	**158**
Brought forward into 2022	7
Closed in 2021	151

2021 Closure Breakdown	
Granted	21
Part Granted	65
Refused	31
Transferred	1
Withdrawn	20
Dealt with outside FOI	13

The Freedom of Information requests received in 2021 related to records from across HIQA's areas of responsibility. Some of the most common types of requests were in regard to correspondence of the CEO; evidence synthesis in relation to the COVID-19 pandemic, correspondence with individual nursing homes related to the COVID-19 pandemic and unsolicited information received by HIQA.

Furthermore, HIQA carried out refresher training for a number of decision-makers during 2021, while a number of new decision-makers were appointed and received training.

Non-personal FOI requests, including the decisions issued and records that were released under FOI, can be viewed on HIQA's website here.

Appendix 4: Energy consumption

HIQA continues to work to meet its obligations to reduce its impact on our natural resources and the planet.

Under the optimising Power@Work programme introduced by the Office of Public Works (OPW) to meet the targets set out by Government, we have cut our overall energy consumption by 35%.

Description	Electricity	Gas	Total
Benchmark Year	728,242	608,769	1,337,011
Previous 12 Months	328,991	544,662	873,653
% Difference	-54.8%	-10.5%	-34.7%

Energy Performance (Dec 2021) vs Benchmark Year

To ensure HIQA is in a position to meet the carbon reduction target of 51% by 2030, we have completed an independent energy audit and are analysing the findings to identify road maps to further reductions.

Compared the base year of 2010, the carbon emissions over the last 12 months have reduced by 40%.

Monthly comparison data shows that the December 2021 CO2 emissions are 51% lower (19 tonnes) than in December 2010.

Description	Electricity	Gas	Total
Benchmark Year	236	125	361
Previous 12 Months	106.76	111.49	218.25
% Difference	-54.8%	-10.5%	-39.5%

Annualised tonnes of C02 emitted 2021

Appendix 5: **Complaints management**

HIQA welcomes comments, suggestions and complaints about its performance and conduct in the discharge of its statutory duties and responsibilities. This feedback may come from service providers, patients, carers, relatives, private and voluntary organisations, statutory agencies and the general public. HIQA welcomes all feedback and regards complaints as opportunities to review practice and procedures, and identify areas for improvement. We also wish to resolve complaints in an effective and timely manner, and use an early resolution approach to complaints wherever possible.

During 2021, 10 complaints were received by HIQA. Four complaints related to our work in nursing homes, three related to our work in disability services, while three related to other areas of HIQA's role or services.

All complaints were dealt with in accordance with the stages and timelines in our policy.

Appendix 6: Irish Human Rights and Equality Commission Act 2014

The Irish Human Rights and Equality Commission Act 2014 Section 42 places an obligation on all public bodies to uphold the public sector duty to protect human rights, promote equality and eliminate discrimination. HIQA is compliant with its public sector duty under the Act; however, the organisation is ambitious in this regard and wishes to develop its human rights approach further.

In 2020, HIQA carried out a review of how it promotes equality and protects human rights in all its activities.

HIQA's human resources function supports equality of opportunity in its recruitment processes, the development of a competency framework and in its learning and development opportunities. It has fair procedures in place and promotes equality in its grievance policy and dignity at work processes as well as its equality policy.

The protection of rights and promotion of equality is a central tenet of HIQA's regulatory functions. In 2021, we worked to amplify the voice of adults and children who use regulated and monitored services and provide more information on human rights. HIQA has advocated to the Department of Health for amendments to the Health Act 2007 and its regulations which will strengthen its approach in this regard.

HIQA's new Corporate Plan 2022-2024 places a significant focus on human rights, outlining a core value of:

- **Promoting and protecting human rights:** We will work to promote human rights as well as identifying, challenging and reporting on breaches of rights in health and social care services.

Appendix 7: Conferences and lectures

During 2021, HIQA employees presented the organisation's work at a number of virtual conferences and events, including:

- 7th Annual SPHeRE Network Conference
- Trinity Health and Education International Research Conference
- 18th Annual Psychology, Health and Medicine Conference
- European Implementation Collaborative conference
- Implementation Science workshops for the Ireland and Northern Ireland Network on Implementation Science
- European Social Services Conference
- International Society for Quality in Health Care International Conference
- National Child Protection and Welfare Social Work Conference
- Social Care Ireland Annual Conference
- National Women & Infants Health Programme Virtual Conference Series
- 14th European Public Health Conference
- UCD School of Medicine Summer Student Research Awards
- Health Technology Assessment international (HTAi) Annual Meeting 2021
- G-I-N (Guidelines International Network)
- Impact of Covid-19 Amongst Cancer Patients and Survivors from an economic and social perspective panel
- Society for Medical Decision Making 43rd Annual North American Meeting
- International Network of HTA Agencies
- International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
- Health Tech Ireland Association Conference 2021
- Irish Society of Clinical Microbiologists Annual Meeting 2021
- Health Summit 2021
- Pushing the Boundaries of Costs and Outcome analysis of Medical Technologies (COMED) Conference 2021
- Royal College of Surgeons in Ireland ISPOR Student Chapter
- Masters in Pharmaceutical Medicine, Trinity College Dublin
- Masters in Health Economics, National University of Ireland Galway
- SPHeRE PhD programme
- Masters in Health Informatics, University College Dublin
- Masters in Public Health, University College Cork
- Masters in Healthcare Infection, Trinity College Dublin
- Social Care Degree programme, IT Sligo
- Bachelor of Arts Social Care, Technical University Dublin

Appendix 8: **Academic publications**

- Broderick N, Fawsitt CG, Tyner B, Larkin J, McCarthy M, Walsh KA, O'Neill M, Ryan M. COVID-19 Public Health Guidance Database. European Journal of Public Health. 2021 Oct;31(Supplement_3):ckab164-738.
- Broderick N, Walsh K, O'Brien K, Smith S, Harrington P, O'Neill M, Ryan M, Fawsitt C. 2022. POSC124 Economic Burden of Antimicrobial Resistance: An Analysis of the Additional Bed Day Costs Associated with Treating Resistant Infections in Ireland. Value in Health, 25(1), p.S111.
- Cardwell K, O'Murchu E, Byrne P, Broderick N, O'Neill SM, Walsh K, Smith SM, Harrington P, Ryan M, O'Neill M. Pharmacological interventions to prevent COVID-19 disease: a rapid review. Rev *Med Virol*. 2021 Sep 28:e2299. Available from: https://onlinelibrary.wiley.com/doi/pdf/10.1002/rmv.2299
- Cardwell K, O'Neill SM, Tyner B, Broderick N, O'Brien K, Smith SM, Harrington P, Ryan M, O'Neill M. A rapid review of measures to support people in isolation or quarantine during the Covid-19 pandemic and the effectiveness of such measures. *Reviews in Medical Virology* 2021: e2244. Available from: https://onlinelibrary.wiley.com/doi/10.1002/rmv.2244
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