Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

ANNUAL REPORT 2016

Safer Better Care

Foreword by the Chairperson

Brian McEnery
Chairperson

Throughout 2016, the Health Information and Quality Authority continued to deliver on its commitment to play a significant role and contribution in ensuring that the Irish health and social care system is safe and of high quality, and that the experience of everyone who uses these services progressively improves.

During 2016, we advanced our key activities of regulation and the oversight of services, setting standards and providing strategic advice to Government and national provider organisations. HIQA published and began to implement our Corporate Plan 2016 – 2018. This plan identifies HIQA's priorities over the next three years, and describes the outcomes that we intend to achieve and the activities to be undertaken to deliver on these outcomes.

Our Corporate Plan for 2016 – 2018 builds upon the achievements of our previous corporate plan and takes into consideration our experience of applying our functions across the health and social care system.

Developing the Irish health information landscape is critical for improvement within the health and social care system. During 2016, in collaboration with our stakeholders, we developed a range of evidence-based health information standards, continued with the development of a national patient experience survey and developed standards to advance the implementation of the eHealth Strategy. In addition, we began developing a framework for monitoring the national standards for the health identifier operator and national standards for health and social care data collections.

The desire to use health technology assessment (HTA) to inform decision-making continues to increase. In 2016, we undertook a number of system-wide HTAs, such as a HTA of smoking cessation interventions. We provided guidance on the use of HTA and evaluated the impact of our advice on Ireland's health policy and health service decision-making. We continued to support the work of the National Clinical Effectiveness Committee in optimising patient care.

In line with Government and service priorities, we developed a range of national standards, including national standards for maternity services. We also started development of the first standards of their kind to be developed through a collaborative project with the Mental Health Commission. These standards set out how patient safety incidents are reviewed across acute health and mental health services.

In regulating designated centres, HIQA continued its programmes of regulation in line with its legal mandate, enhancing internal systems and processes to help predict and respond to services that are failing or likely to fail. We continued to take a human rights-based approach to regulation and build upon thematic programmes of inspection in the areas of medication safety and dementia care.

Throughout 2016, HIQA carried out a comprehensive programme of inspection of children's social services. In addition, we commenced a review of the governance arrangements in place in the Child and Family Agency's child protection and welfare service, and reviewed the implementation of national guidance in relation to the Child and Family Agency's national review panel. This included scoping and developing regulatory approaches to an expanded range of children's services in conjunction with the Department of Children and Youth Affairs and the Child and Family Agency.

We expanded our monitoring programme in the prevention and control of Healthcare Associated Infections, and published an overview report of antimicrobial stewardship. Our review of nutrition and hydration in public acute hospitals continued and we carried out a programme of monitoring medication safety in public acute hospitals. In addition, we assessed progress made with recommendations made against our:

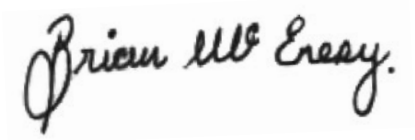
Review of pre-hospital emergency care services to ensure high quality in the assessment, diagnosis, clinical management and transporting of acutely ill patients to appropriate healthcare facilities.

Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise.

As an independent public body charged with driving high-quality and safe care for people using our health and social care services in Ireland, HIQA is responsible for delivering its mandate in an effective, cost-efficient manner.

I thank all the staff of HIQA for their hard work and commitment during 2016 and I thank the members of the Board for the advice and direction that they provide.

Together, we will carry on the task of promoting capacity, capability and confidence in the quality and safety of health and social care services in this country.



Brian McEnery
Chairperson

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Chapter 1: About the Health Information and Quality Authority

1.1 Introduction

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our 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 is the tenth annual report of HIQA's work since our establishment in 2007.

In 2016, we continued to regulate residential services for older people, children, and people with disabilities, to provide advice on decision-making and the assessment of new and existing health technologies, to advance the implementation of health information to improve outcomes for patients, and to provide quality and safety development opportunities that support the improvement of services.

HIQA published a new three-year corporate plan in 2016, *Corporate Plan 2016-2018*. The objectives outlined in this Corporate Plan shaped the work that we carried out in 2016 (See Chapter 3). This Annual Report sets out how we advanced these objectives and those from our 2016 Business Plan.

We continue to report publicly on the safety, quality and effectiveness of health and social care services. In so doing, HIQA enables the health and social care system to reduce the risk of harm and abuse to people who use services. We inform health policy and service-based decisions on investment and disinvestment. We also inform the public and service users about our activities. We share the learning from activities to ensure continuous improvement in the planning, management and delivery of services.

1.2 Our mandate and activities

HIQA was established almost 10 years ago to regulate Ireland's health and social care sector, to safeguard people and to improve the safety and quality of health and social care services. Our remit has grown substantially since then; however, our core activities remain the same.

Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation** – Registering and inspecting designated centres.
- **Monitoring Children's Services** – Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality** – Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** – Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information** – Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Our legal mandate

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

This Annual Report outlines the work of HIQA from 1 January to 31 December 2016, is presented 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 Annual Report of the Chief Inspector of Social Services as required by the Health Act 2007.

1.3 Mission statement and corporate values

HIQA exists to promote sustainable improvements, safeguard people using health and social care services and support informed decisions on how services are delivered. This mission guides and directs all of the activities of HIQA. Corporate values are intended to express what we believe is important, how we work and how we hope to be viewed by external stakeholders, as well as the ethos and approach which our staff are encouraged to observe. Our five corporate values are illustrated below.

HIQA's core values

- **Putting people first** – we put the needs and the voices of service users, and those providing the services, at the centre of all of our work.
- **Fair and objective** – we strive to be fair and objective in our dealings with people and organisations. We undertake our work without fear or favour.
- **Open and accountable** – we share information about the nature and outcomes of our work. We accept full responsibility for our actions.
- **Excellence and innovation** – we strive for excellence in our work. We seek continuous improvement through self-evaluation and innovation.
- **Working together** – we engage with people providing and people using the services in developing all aspects of our work.

Chapter 2: Governance and management

2.1 Our Board

The Board is the governing body of HIQA and was first established on 15 May 2007. 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 are recognised as having 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 2016 included:

Brian McEnery
Chairperson

Partner in BDO Accountants and Business Advisors. Global President of Association of Chartered Certified Accountants. Chartered Accountant Australia and New Zealand member. Board member of NAMA and Chairman of NAMA Audit Committee.

Sheila O'Malley

Former Chief Nursing Officer, Department of Health. Former President of An Bord Altranais agus Cnáimseachais na hÉireann/Nursing and Midwifery Board of Ireland.

Dr David Molony

GP and Occupational physician, founding member of Mallow Primary Healthcare Centre (MPHC), a trainer in the South West Vocational Training scheme, senior adjunct lecturer to GEMS Medical School in University of Limerick and a member of the national GP Committee of the Irish Medical Organisation.

Dr Una Geary

Consultant in Emergency Medicine at St James's Hospital, Dublin. Honorary lecturer in the School of Medicine, Trinity College Dublin.

Anne Carrigy

Former National Lead of Acute Hospital Services, HSE. Former President of An Bord Altranais agus Cnáimseachais na hÉireann/Nursing and Midwifery Board of Ireland.

Bairbre O'Neill

Barrister, practising in the area of civil litigation, with a particular emphasis on commercial litigation and judicial review.

Mary Fennessy

Formerly, head social worker at Lucena Child and Adolescent Mental Health Services. Board member and Commissioner of the Commission to Inquire into Child Abuse. Chairperson of Mountjoy Prison Visiting Committee and Health Committee Member of the Pharmaceutical Society of Ireland. Serves on a committee of the Health and Social Care Professionals Council regulatory body CORU.

Judith Foley

Acting Chief Education Officer, Education Department of An Bord Altranais agus Cnáimhseachais na hÉireann/ Nursing and Midwifery Board of Ireland.

Dr Paula Kilbane

Formerly 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.

Molly Buckley

Public health nurse. Vice Chairperson of the Irish Council for Social Housing and a director and chairperson of a number of national and international social inclusion organisations and projects.

Martin Sisk

Solicitor. Independent Non-Executive Director of the Interim Board of the Office of Government Procurement. Director of the Irish League of Credit Unions. Chairman of the Irish Auditing and Accounting Supervisory Authority.

Stephen O'Flaherty

Qualified accountant with the Association of Chartered Certified Accountants who worked with AIB Business Banking and is now a director with BDO.

The Board is responsible for the appropriate governance of the Health Information and Quality Authority. It ensures that HIQA has effective systems of internal control, statutory and operational compliance and risk management. These provide the essential elements of effective corporate governance and compliance.

The Health Act 2007 specifies that HIQA has a Code of Governance that includes an outline of its internal controls, including its procedures in relation to internal audit, risk management, public procurements and financial reporting. HIQA has set out its arrangements for implementing and maintaining adherence to the Code of Governance as part of its annual financial statements.

2.2 Board meetings

The Board is required under the Health Act 2007 to meet six times annually. Two additional Board meetings were held in 2016 for the purpose of progressing various significant matters (see Appendix 1 for the dates of these meetings).

2.3 Board committees

There are four Board committees with specific responsibilities to 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** assists the Board in its assessment of the effectiveness of the systems established by Management of HIQA by reviewing the comprehensiveness and reliability of internal controls, and assurances on governance, risk management, the control environment and the accuracy and completeness of the financial statements.
- **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 Organisational structure

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

The members of HIQA's Executive Management Team as at December 2016 include:

Phelim Quinn

Chief Executive

Dr Máirín Ryan

Director of Health Technology Assessment and Deputy Chief Executive

Mary Dunnion

Director of Regulation and Chief Inspector of Social Services

Rachel Flynn

Director of Health Information

Marie Kehoe-O'Sullivan

Director of Standards and Quality Improvement

Sean Angland

Acting Chief Operating Officer

The following table outlines how we carry out our core business.

The purpose of each functional Directorate

Regulation

Monitoring of acute health services, children's services and the registering and inspection of designated social care services in line with legal requirements. We will continue driving improvement in the quality and safety of services through thematic monitoring, and will continue to develop our approaches to regulation in line with emerging government policy and national and international principles of good regulation.

Standards and Quality Improvement

Actively supporting and enabling a culture of safety and quality improvement across and within the health and social care system; helping to build capability and capacity in the people providing services; developing national standards and guidance in consultation with stakeholders and the provision of quality improvement methodologies and tools; operating schemes aimed at ensuring safety and quality in the provision of services.

Health Information

Identifying and advising on health information deficiencies; establishing an information governance framework and setting standards for health information and health information systems; and evaluating and providing information on the provision of health and social services.

Health Technology Assessment

Informing national decision making on the use of resources in our health services, specifically through the assessment (and supporting the assessment) of the clinical and cost-effectiveness of health technologies, in order to support the best outcome for the patient.

Chapter 3: Strategic objectives and achievements

3.1 Strategic objectives

On 4 April 2016, HIQA published its Corporate Plan 2016–2018. The Corporate Plan sets out the framework and the objectives that enable us to meet existing and new obligations.

The plan was based on our experience of reviewing and investigating the health and social care system over the last nine years, and also on what we see as the current and future challenges facing this system in Ireland.

The Corporate Plan reflects HIQA's core values of putting people first, being fair and objective, focusing on excellence and innovation and being open and accountable. It outlines our priorities for the next three years to enable us to meet our strategic corporate objectives.

People have a right to expect safe, effective and high-quality care. HIQA envisions an informed health and social care system that delivers safer, higher quality care and support. HIQA will continue to be a central driving force in improvement towards this vision. This Corporate Plan aims to support the health and social care sector in the challenges it faces while ensuring that people using services remain at the heart of our work.

HIQA has five core activities aimed at achieving its strategic objectives. The strategic objectives are summarised below and are also illustrated in Appendix 2.

1. **Advise on the effective use of information in health and social care services.**
    - Over the next three years, HIQA will:
        - provide leadership in defining the health information landscape in Ireland by influencing policy and legislation through engaging with informed and interested parties and developing recommendations
        - contribute to the development of the foundations required to make possible eHealth in Ireland and support progress with rolling out the national eHealth strategy through developing technical and information standards
        - promote improvements in the quality of health information to underpin the delivery of safe care, informed decision-making, and monitoring, planning and regulation by HIQA.

2. Assess health technologies.

- Over the next three years, HIQA will:
  - produce high-quality health technology assessments (HTAs) targeted to inform major health policy and health service decisions
  - continue to build capacity to conduct and use HTA across the health system.

3. Set standards for health and social care services.

- Over the next three years, HIQA will:
  - work with those who fund, plan, provide and use services to identify and prioritise the areas within which HIQA will develop or revise standards and guidance
  - promote quality improvement in health and social care services in line with identified priorities.

4. Regulate health and social care services.

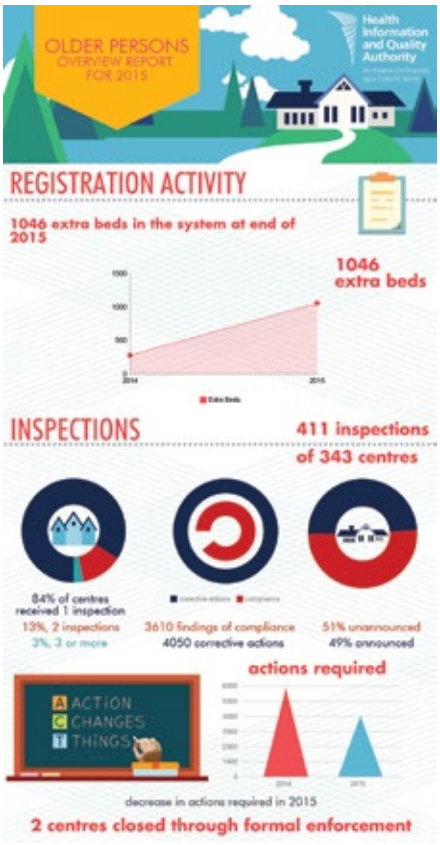
- Over the next three years, HIQA will:
  - carry out and develop its programmes of regulation in line with its legal mandate
  - take into account the transformation of the health and social care system, working with government to ensure our resources and processes meet the range of services (current and future) under HIQA's remit
  - use information to predict and respond more quickly to services that are failing or likely to fail.

5. Build transparent, constructive relationships to promote improvement

- Over the next three years, HIQA will:
  - maintain existing relationships and seek to develop new relationships that focus on improving the safety and quality of health and social care services
  - actively engage with the public and our stakeholders to communicate the work of HIQA, this includes publishing clear information in an accessible manner.

3.2 Summary of achievements from 1 January to 31 December 2016

- We carried out 750 inspections of designated centres for children and adults with disabilities in 2016. At the end of 2016, 701 designated centres for people with disabilities are registered with HIQA.
- We published the first overview report of disability regulation in 2016. The report showed how regulating disability services has led to the evolution of a cultural change in the sector.
- We carried out 608 inspections in designated centres for older people in 2016; with 107 of these focusing specifically on dementia care.
- We published our annual overview report on the regulation of designated centres for older people for 2015, highlighting that governance and leadership lays the foundations for the quality of care provided to residents.



Older persons overview infographic 2015

- We published revised *National Standards for Residential Care Settings for Older People in Ireland* which came into effect on 1 July 2016.
- We carried out 66 inspections in public acute hospitals, as part of our programme for monitoring against the *National Standards for the Prevention and Control of Healthcare Associated Infections* and *National Standards for Safer Better Healthcare*.
- We published a review of how public acute hospitals are protecting patients from the growing threat of antimicrobial resistance. We found that while progress has been made in larger hospitals in implementing best practice in managing and using antibiotics, the level of progress identified varied across the country, with some smaller hospitals not having safe and sustainable measures in place to protect patients.
- We found that one in four patients admitted to hospital are affected by malnutrition in our report on nutrition and hydration in public acute hospitals. We carried out 27 inspections under the theme of nutrition and hydration in public acute hospitals.
- We carried out 53 inspections of services provided to children in 2016.
- We commenced a review of the governance arrangements in place in the Child and Family Agency's (Tusla) child protection and welfare service to ensure a safe, timely and effective service is being delivered to meet the needs of children.
- We published an overview of our regulatory activity for children's services for 2015, which found inconsistency in the quality of children's services being provided across the country.
- We published *Supporting people's autonomy* guidance for providers of adult health and social care services to help services demonstrate how they show respect for human dignity, how they provide person-centred care, and how they ensure an informed consent process that values personal choice and decision-making.

- We launched *National Standards for Safer Better Maternity Services* on 21 December 2016.
- We published a number of documents for public consultation including;

  Draft revision of the national standards for the prevention and control of Healthcare Associated Infections in acute healthcare services

  Draft Information Management Standards for National Health and Social Care Data Collections

  Revision of the Draft National Standard Demographic Dataset and Guidance for use in health and social care settings in Ireland

  Draft National Standards for the Conduct of Reviews of Patient Safety Incidents.

- We supported a national roll-out of ePrescribing by holding a public consultation on a draft *National Standard for a Dispensing Note Dataset including a Clinical Document Architecture specification*.
- The 10 *Recommendations on the coordination of patient safety intelligence in Ireland* were published in January 2016 and include a proposal for a new model for coordinating patient safety intelligence in Ireland and the implementation and rollout of the national incident management system.
- We published an international review of, and draft information management standards for, national health and social care data collections to improve the quality of national health information and data, contributing to the delivery of safe and reliable healthcare.
- We commenced development work for the first ever National Patient Experience Survey to be conducted in Ireland in 2017.

National Patient Experience Survey

- A *Guide to Health Technology Assessment at HIQA* was published in October 2016.
- We signed a contract with the Health Research Board (HRB) to provide the evidence for clinical guidelines that are developed for the National Clinical Effectiveness Committee. The five-year contract, worth €2.25 million, will establish the HRB-Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER).

CEO Phelim Quinn and Leigh Gath, the Confidential Recipient,at the signing of a Memorandum of Understanding between HIQA and the Confidential Recipient

Phelim Quinn, CEO of HIQA and Dr Niall Muldoon, the Ombudsman for Children at the signing of the Memorandum of Understadning between HIQA and the Ombudsman for Children's Office on 24 October 2016

- We signed a number of Memorandums of Understanding throughout the year to facilitate the sharing of information with a number of organisations, including:
  - the Department of Health and Health Service Executive (HSE) to support development of the National Patient Experience Survey,
  - Leigh Gath, the Confidential Recipient,
  - the Ombudsman for Children's Office (OCO),
  - the Nursing and Midwifery Board of Ireland (NMBI).
- We appeared before the Joint Oireachtas Committee on Health in December 2016 to discuss the General Scheme of the Health Information and Patient Safety Bill.

Chapter 4: Activities by Directorate

This chapter of the Annual Report records the work that our Directorates carried out in 2016 to progress the strategic objectives outlined in HIQA's Corporate Plan 2016 - 2018.

4.1 Report of the Office of the Chief Inspector of Social Services (Regulation)

The Regulation Directorate within HIQA is responsible for regulating the quality and safety of specified health and social care services across Ireland.[1]

During 2016, the Directorate was restructured into the four separate pillars of regulation;

4.1.1 Designated centres for older people

4.1.2 Designated centres for people with disabilities

4.1.3 Healthcare

4.1.4 Children's services.

These pillars are supported by the Regulatory Practice Development and the Business Services teams.

We meet our strategic objectives through our regulatory activity by ensuring that care is improved, that people are safeguarded, that people are informed, and that we influence the way in which policy and service decisions are made.

The Regulation Directorate carry out three different types of inspections:

- Registration inspections to inform a decision in relation to an application to register.
- Monitoring inspections to monitor ongoing compliance with regulations and standards. A specific number of outcome areas are considered during these inspections.
- Thematic inspections to focus on specific areas; for example, dementia thematic inspections.

1 This section of the report constitutes the report of the Chief Inspector of Social Services and relates to our responsibilities to report on the activities of the office under Section 37 of the Health Act 2007.

As well as carrying out inspections, we receive, analyse and risk assess information from a range of sources. Additional information on the quality, safety and experience of residents is vital in the regulation of services. This includes notifications from providers relating to specific events set out in the regulations. Equally, residents, service users, relatives, staff, advocates or third parties who have direct contact with a resident or residents also submit information to HIQA through our Concerns team. All information is used to inform our assessment of compliance and risk within services, and further inform our monitoring and inspection programme.

4.1.1 Regulation of designated centres for older people

As of 31 December 2016, there were 580 active registered designated centres for older people, providing 30,396 registered beds. Figure 1 outlines a breakdown of the size of registered centres by bed number.

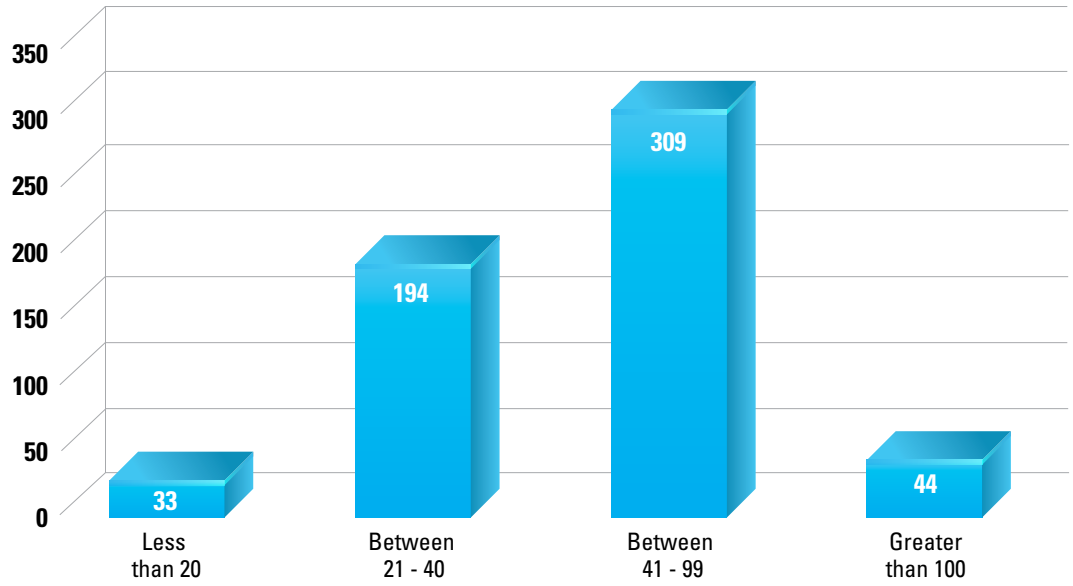


Figure 1: **Bed numbers in registered designated centres for older people, as of 31 December 2016**

Centres for older people include residential and residential centre-based respite services that are:

- privately operated nursing homes as defined by Health (Nursing Homes) Act, 1990 (private)
- operated by the Health Service Executive (HSE) (public)
- operated by HSE-funded bodies (voluntary).

The vast majority of residential services are provided by private providers, with the remainder being managed by the HSE and voluntary organisations. Figure 2 shows the number of centres operated under these arrangements.

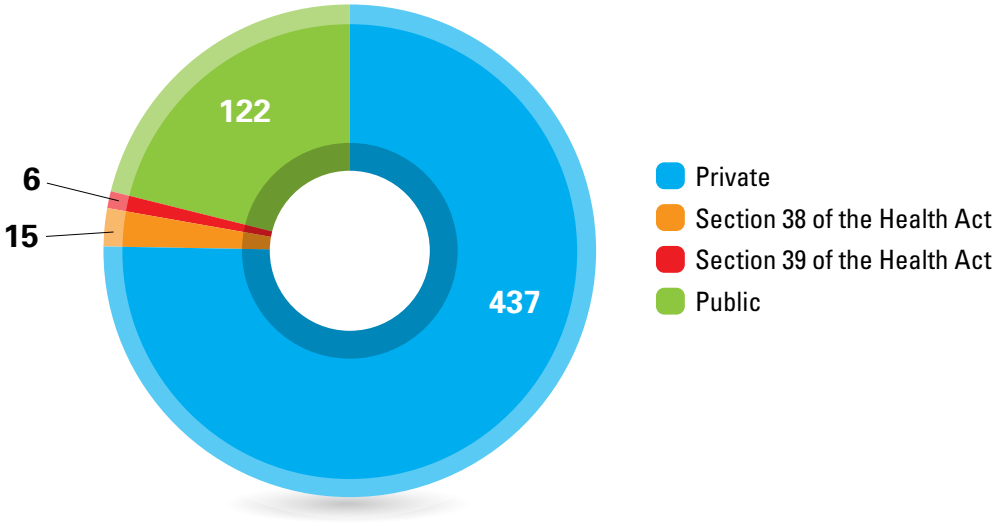


Figure 2: **Number and percentage of registered designated centres for older people (by provider type) by 31 December 2016** [2]

During 2016, the Older Persons' team carried out 608 inspections in 494 centres. While the majority of inspections were carried out to monitor compliance with the regulations and national standards[3], 170 inspections specifically focused on the area of dementia care. Figure 3 shows a breakdown of the types of inspection carried out in 2016.

The National Safeguarding Committee launched its Strategic Plan 2017-2021 to guide its work to safeguard vulnerable adults over the next five years. Pictured at the launch on 20 December 2016 in Dublin were HIQA CEO Phelim Quinn, Committee member; The Hon. Ms. Justice Mary Laffoy, Justice of the Supreme Court of Ireland, who launched the strategy; and Patricia Rickard-Clarke, the independent Chairperson of the Committee. For more information, see www.safeguardingcommittee.ie

2 Section 38 of the Health Act 2004 provides that the Health Service Executive (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 provides that the HSE can provide assistance to any person or body providing a similar service to the HSE.

3 Revised *National Standards for Residential Settings for Older People in Ireland* came into effect on 01 July 2016.

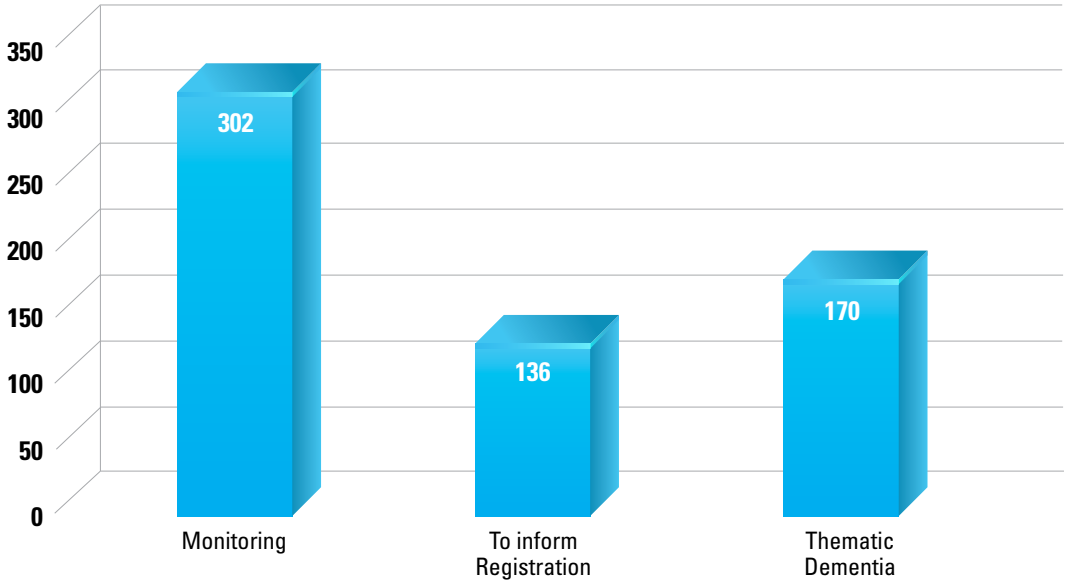


Figure 3: **Types of inspections carried out in 2016**

Of the 608 inspections completed, three out of four inspections (74%) were unannounced. Over one in four (26%) of these were announced inspections. While HIQA appreciates that unannounced inspections provide a perception of greater assurance to the public, announced inspections are used to enable review of information prior to inspection and greater participation of residents and relatives by letting them know when inspectors will be present in the service over a specific period of time.

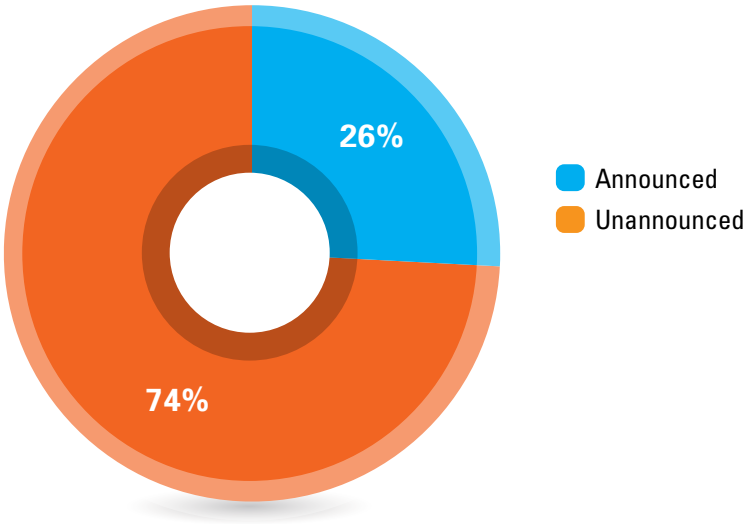


Figure 4: **Number of announced and unannounced inspections carried out in 2016**

The majority of centres (481) received two or less visits during 2016. However, 13 centres received three or more visits during the year. These included follow-up visits where areas requiring improvement were reviewed following an earlier inspection.

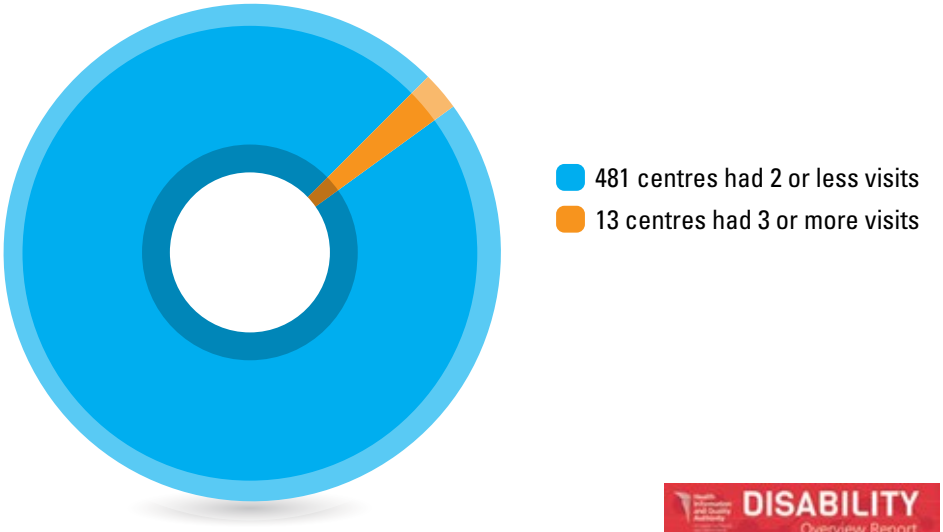


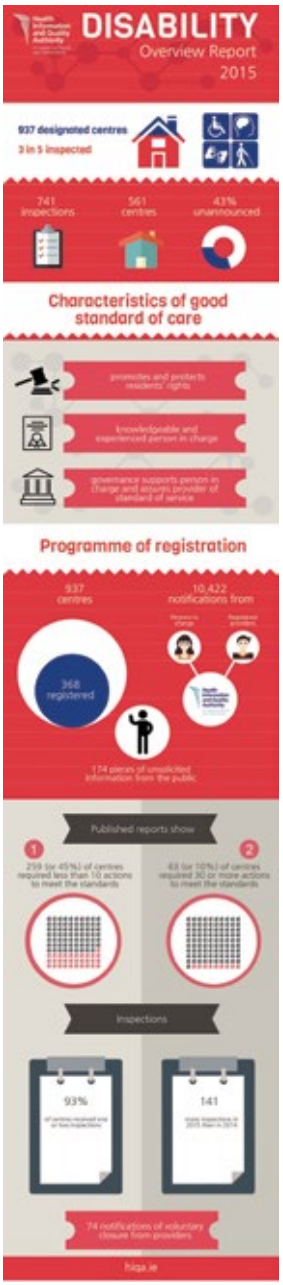
Figure 5: **The number of inspection visits per centre inspected in 2016**

4.1.2 Regulation of designated centres for people (adults and children) with disabilities

There are 1,055 centres currently providing services to adults and children with disabilities. While the vast majority of these designated centres provide services to adults or services to a mix of adults and children, 69 centres are specific to children with a disability.

The enactment of the Health (Amendment) Bill 2016 (Amendment of section 69 of Health Act 2007) in July 2016, extended the deadline for providers of residential services for persons with a disability to complete the registration process with HIQA by two years, to 31 October 2018.

At the end of 2016, 701 designated centres for people with disabilties are registered with HIQA. These 701 centres provide a total of 5,285 residential places. An additional 354 centres are deemed registered under section 69 of the Health Act 2007, but have yet to complete the registration process with HIQA.



Disability overview report infographic 2015

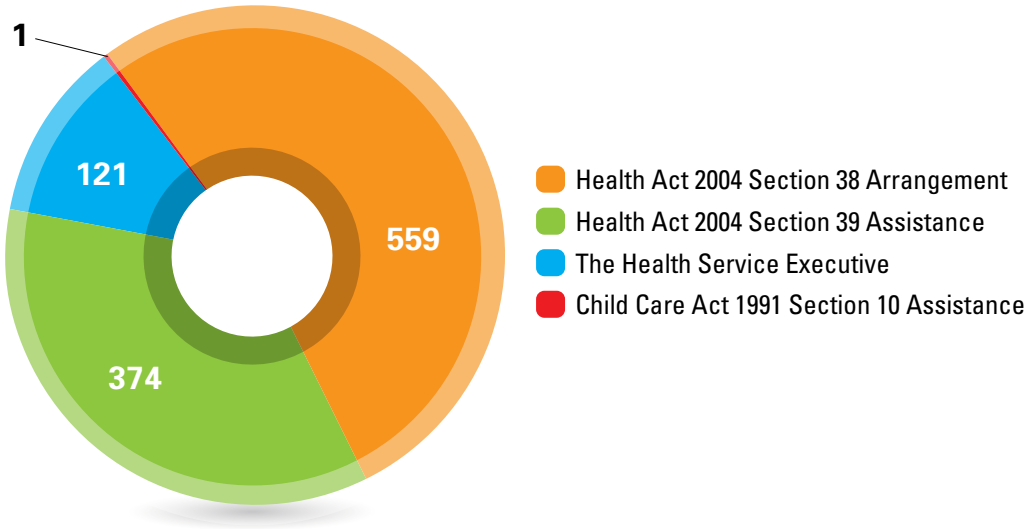


Figure 6: **Breakdown of providers of centres for people with disabilities**[4]

During 2016, 750 inspections of centres for people with disabilities were completed. These inspections took the form of either monitoring inspections, or inspections to inform a registration decision.

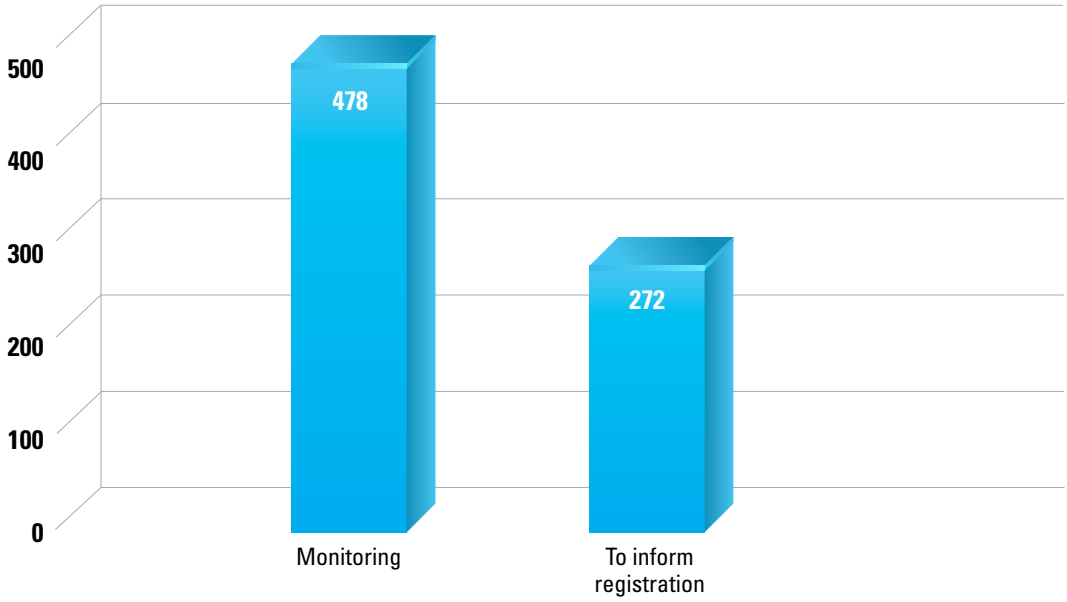


Figure 7: **Types of inspections carried out in 2016**

Of the 750 inspections completed, 42% were announced. This meant the provider knew the date that the inspectors would arrive. The remaining 58% were unannounced.

4 Section 38 of the Health Act 2004 provides that the Health Service Executive (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 provides that the HSE can provide assistance to any person or body providing a similar service to the HSE.

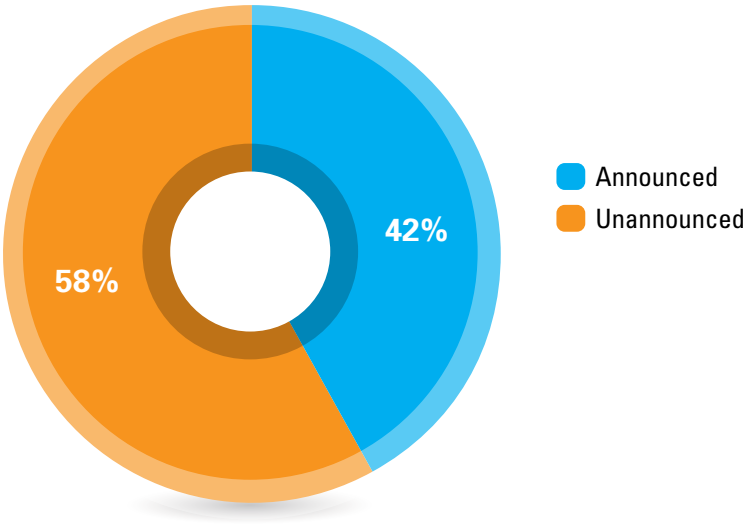


Figure 8: **Number of announced and unannounced inspections carried out in 2016**

Figure 9 shows that the majority of centres visited in 2016 did not require multiple follow-up inspections.

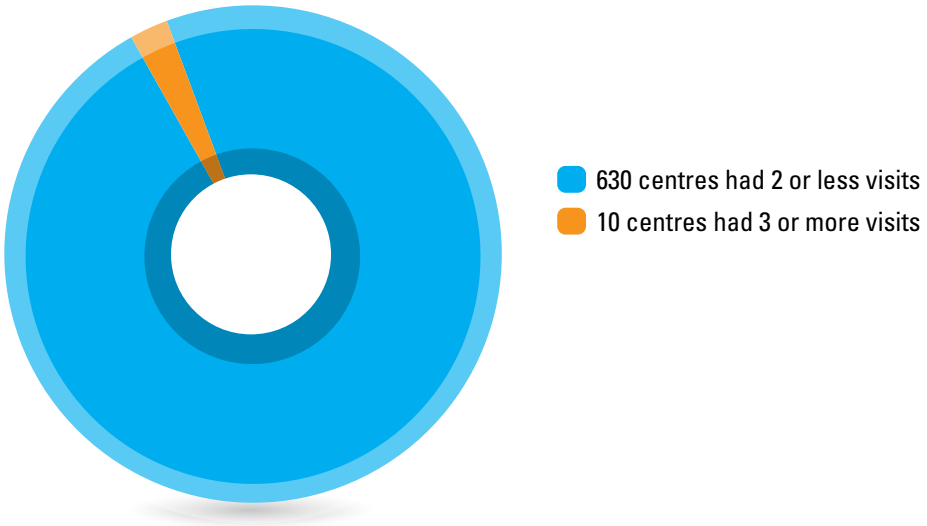


Figure 9: **The number of inspection visits per centre inspected in 2016**

4.1.3 Solicited (regulatory notifications) and unsolicited information received relating to designated centres for older people and people with disabilities

The receipt and assessment of information is a key monitoring activity. This information informs HIQA of the potential for adverse or potentially harmful events that have impacted or may impact on the health, safety and wellbeing of residents. All information received by HIQA is acknowledged, recorded, risk assessed and used to inform further monitoring activity, including inspection, as required.

The Health Act 2007 (Care and Welfare of Older People) Regulations (2013) requires providers and persons in charge of designated centres to notify us of specified events. As such, all designated centres for older people and people with disabilities are required to send notifications to HIQA. This includes changes to details relating to the information published on the HIQA register for the centre (registration notifications), and notifications in line with the care and welfare regulations (monitoring notifications).

During 2016, we received 24,124 notifications (Figure 10[5]). This included 10,931 monitoring notifications in line with the care and welfare regulations.

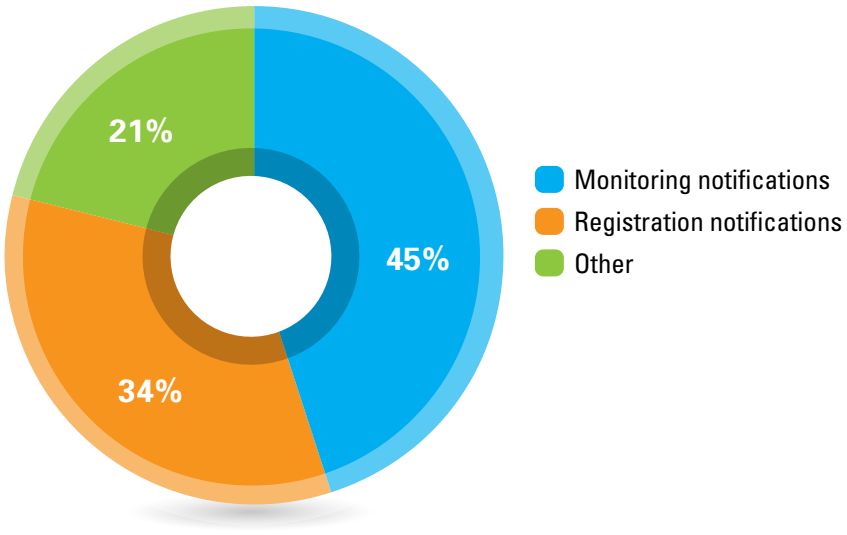


Figure 10: **Regulatory notifications by type**

5 Notifications classed as "Other" consist of annual returns of occupancy for disability centres operating under Section 69 of the Health Act, Quarterly Returns, Nil Returns.

Figure 11 breaks down further the types of notification received for centres for older people, while Figure 12 gives the detail for centres for people with disabilities.

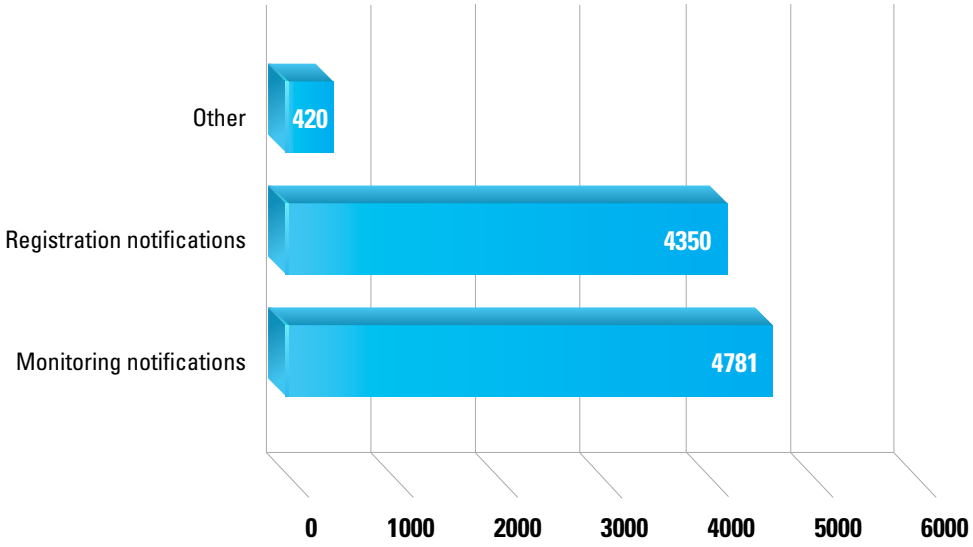


Figure 11: **Designated centres for older people regulatory notifications by type**

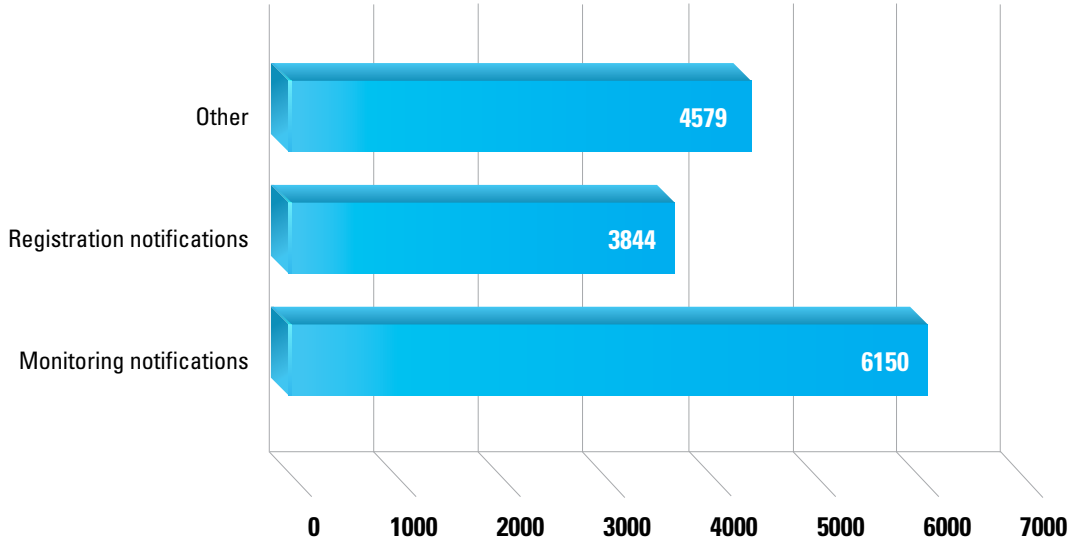


Figure 12: **Designated centres for people with disabilities regulatory notifications by type**

Our Concerns team received 945 pieces of unsolicited information during the year for designated centres for older people and people with disabilities. Unsolicited information is information provided to us by members of the public who have a concern or an issue with the care provided to residents. This information is used to support our inspection programme. All items of unsolicited information are risk rated and appropriate action is taken by HIQA. Figure 13 outlines the number of concerns received for centres for older people and people with disabilities.

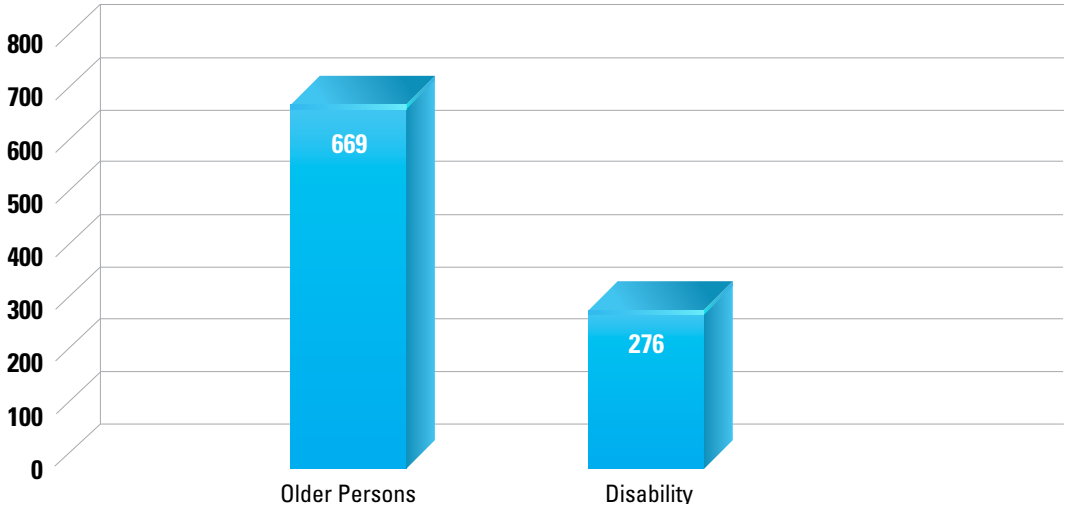


Figure 13: **Concerns by regulated sector**

4.1.4 Provision of an assurance programme of the quality and safety of defined healthcare services in Ireland

Under the Health Act 2007, HIQA is responsible for developing standards for the quality and safety of healthcare services and for monitoring compliance with those standards. Under the Act, we also have responsibility to investigate the safety, quality and standards of healthcare services if we believe that there is a serious risk to the health and welfare of patients. In 2016, this work involved the completion of 66 inspections. This included:

- 32 onsite monitoring assessments against the *National Standards for the Prevention and Control of Healthcare Associated Infections*, and publishing an overview report on our 2015 findings in this area.
- 27 inspections under the theme of nutrition and hydration as contained in the *National Standards for Safer Better Healthcare*, and publishing an overview report.
- A national review of antimicrobial stewardship in public acute hospitals under the *National Standards for the Prevention and Control of Healthcare Associated Infections*. Antimicrobial stewardship ensures best usage of antimicrobial medicines to treat and prevent infection. This in turn results in better patient outcomes, reduced antimicrobial resistance and reduced treatment costs.

Infection prevention and control overview infographic 2015

- Following support from an external advisory group and extensive stakeholder engagement, we devised a new monitoring programme for medication safety under the *National Standards for Safer Better Healthcare*. The new programme will see a phased approach for monitoring medication safety to encourage incremental improvement in the medication safety systems in place in public acute hospitals. The first phase will initially focus on the fundamental governance and structure requirements to support a medication safety programme. We published a guide to monitoring medication safety in public acute hospitals and completed seven inspections by the end of 2016. The first reports on medication safety will be published in early 2017.

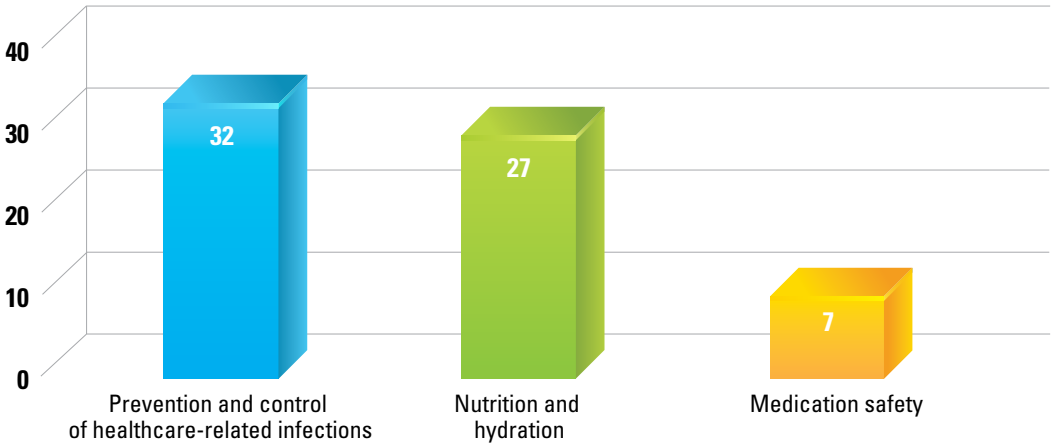
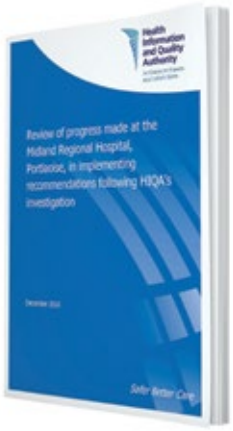


Figure 14: **Type of inspections carried out by the Healthcare team in 2016**

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

- A follow-up review to assess progress in addressing high-risk safety concerns identified in HIQA's previous report on pre-hospital emergency care. This review will be published in 2017.
- Assessment of progress on implementing the eight recommendations from HIQA's 2015 *Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise*. Our 2016 review found that maternity services at the hospital are now being provided in a safer and more sustainable way due to enhanced leadership, governance and management within the service, increased investment, and an improvement in the staff to birth ratio. However, many of the risks identified during the investigation in 2015 relating to general services, including critical care and emergency services for patients with any degree of seriousness or severity of illness or injury, remain unchanged. The review, *Review of progress made at the Midland Regional Hospital, Portlaoise,* in implementing recommendations following HIQA's investigation was published on 5 December 2016.



- Assessment of progress on implementing the recommendations from HIQA's 2014 *Review of pre-hospital emergency care services to ensure high quality in the assessment, diagnosis, clinical management and transporting of acutely ill patients to appropriate healthcare facilities*. This review will be published in 2017.
- Our Concerns team received 306 pieces of unsolicited information from the public during the year relating to healthcare services. This information is used to further support our monitoring programme.

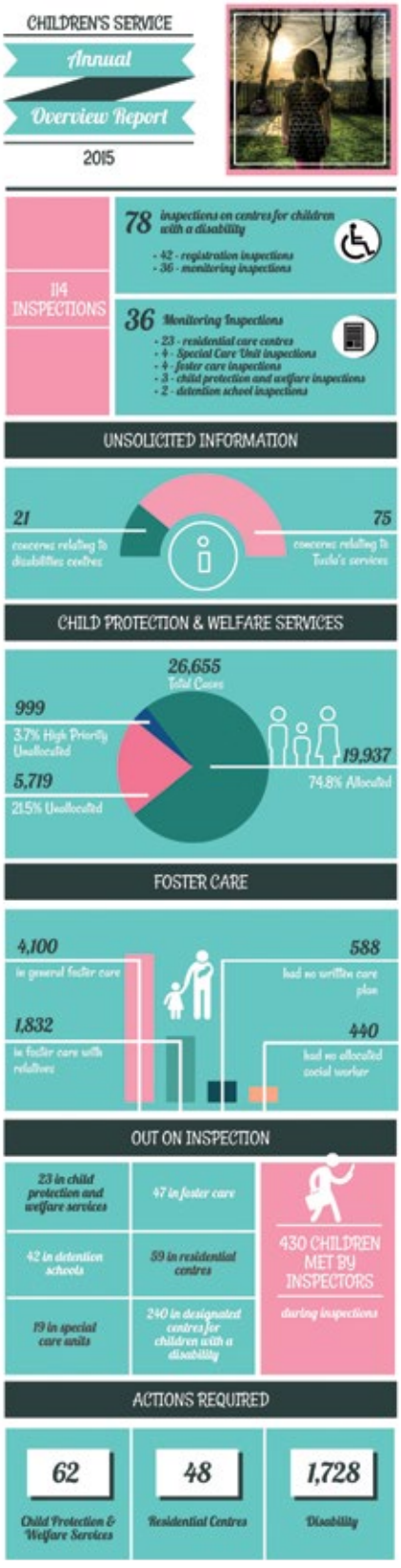
4.1.5 Provision of an assurance and regulation programme of the quality and safety of defined children's health and social care services in Ireland.

Our national Children's team monitor and inspect a range of services provided to children by statutory and non-statutory providers. These services include:

- Children's residential centres (statutory)
- Special care units
- Children's detention school
- Child protection and welfare services
- Foster care services (statutory and private).

Each service has its own statutory framework that gives authority to HIQA to monitor and inspect the service, using standards and, or regulations which set out what is expected from that service. Regulatory activity carried out by the Children's team during 2016 included:

- 40 inspections were carried out in all 35 statutory residential centres for children. Thirty of these inspections were full inspections against all of the standards, and 10 inspections were follow-up inspections to assess the progress made since previous inspections in 2016.
- Seven inspections were carried out in foster care services; three in private foster care services and four in statutory foster care services.
- Child protection and welfare inspections were carried out in three Child and Family Agency (Tusla) service areas. This completed the first cycle of inspections of child protection and welfare services in all 17 service areas, which commenced in November 2012.
- Annual inspections in each of the country's three special care units.
- Received and assessed 83 pieces of unsolicited information from staff, children who use services, and members of the public. We also received 44 notifications from Tusla. Tusla is required to notify HIQA of deaths and serious incidents involving children in care and children known to the child protection and welfare service. All information received is used to further support our monitoring programme.



Children's services overview infographic 2015

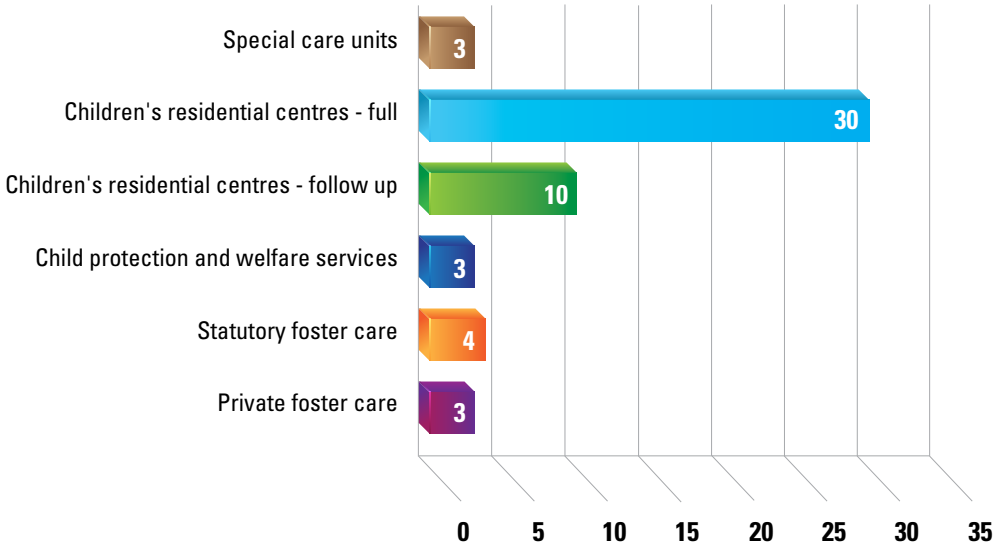


Figure 15: **Types of inspections carried out by our Children's team in 2016**

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

- We carried out a review of the work of the National Review Panel, which investigates serious incidents, including deaths of children in care and known to the child protection system. The review was carried out against the principles outlined in the Guidance for the Child and Family Agency on the Operation of The National Review Panel 2014.
- We commenced a review of the governance arrangements in place in the Child and Family Agency's (Tusla's) child protection and welfare service to ensure a safe, timely and effective service.
- We worked with the Department of Children and Youth Affairs to plan the transfer of the registration and inspection function for non-statutory children's residential centres from Tusla to HIQA.
- In light of the external review of Oberstown Children Detention Campus announced by the Minister for Children and Youth Affairs and the Chair of the Board of Management, we took the decision to defer an inspection of the campus to early 2017.
- We published an overview of our regulatory activity for children's services for 2015, which found an inconsistency in the quality of children's services being provided across the country.

4.1.6 Regulatory Practice Development and Business Services

The inspection activity carried out by the Regulation Directorate is supported by two teams, the Regulatory Practice Development and Business Services teams.

The work of the Regulatory Practice Development Unit is to coordinate the development of regulatory practice and methodological approaches within the Regulation Directorate. It facilitates associated training, professional development, and mentorship to support the delivery of confident and competent regulatory practice.

The Business Services team provides operational and administrative support to the Directorate by applying process improvement and project management methodologies.

During 2016, the Regulatory Practice Development and Business Services teams continued a project to review and improve the processes and procedures used by the inspection teams in their regulatory work.

During 2016, this project involved:

- The revision of tools used as part of our inspections. We carried out pilot inspections in a number of older people's and disability centres to assist with this review. The pilot providers involved had responded to an expression of interest issued to all designated centres.
- As part of the pilot we worked with residents on proposed revisions to the resident questionnaires, which allow us to take feedback from people who use social care services.
- The inclusion of registered providers in reviewing our quality improvement questionnaires to better assist us to evaluate the experience of the people we interact with as part of our regulatory activity. This engagement occurred as part of a series of stakeholder events involving representatives from over 100 designated centres.
- The launch of registration notification and application forms in 2016. These were supported by guidance for providers and a number of provider road shows to explain the changes.
- The extension of the provider's portal to providers of designated centres for people with disabilities. This allows regulatory notification information to be submitted online.
- In March 2016, we launched a revised submissions policy outlining in what circumstances a provider can make a submission in relation to a regulatory judgement made in an inspection report.

4.2 Health Technology Assessment

4.2.1 Background

The Health Act 2007 gave HIQA a statutory role to evaluate the clinical and cost-effectiveness of health technologies, and to provide advice to the Minister for Health and the Health Service Executive (HSE). To this end, the Health Technology Assessment (HTA) Directorate undertakes a range of work to support and inform healthcare decision-making, and to enable safe and effective national health policies and health service decisions that are patient-focused and achieve best value for the resources available.

The Directorate has developed a suite of national HTA guidelines that inform the production of timely, consistent and reliable assessments that are relevant to the needs of our stakeholders. The Directorate also has a central role in capacity development in HTA through its work with the National Clinical Effectiveness Committee, and its participation in a range of national and international activities and publications.

4.2.2 HTAs undertaken in 2016

HTA of smoking cessation interventions

Following a request from the Department of Health's National Tobacco Control Advisor, HIQA commenced work on a HTA to examine the clinical and cost-effectiveness of smoking cessation interventions in January 2016. The HTA aimed to inform decisions regarding the best possible use of interventions for quitting smoking in the general population to ensure maximum benefit from the funding available. In addition, the effectiveness of interventions in pregnant women and in those attending secondary mental health services was assessed.

The HSE currently funds a wide range of pharmacological (such as nicotine replacement therapy, bupropion and varenicline) and behavioural interventions (such as internet-based support, telephone-based support, individual and group behavioural support). Monotherapy and combinations of these treatments were assessed in addition to other interventions that are not currently funded (such as e-cigarettes).

A systematic review and network meta-analysis was carried out to summarise the available evidence on the clinical effectiveness of smoking cessation interventions among a general population of adult smokers (313 studies), users of secondary mental health services (10 studies), and pregnant women (137 studies). For the general population, interventions were broadly classified as pharmacotherapy or behavioural interventions and a network meta-analysis was carried out. All pharmacological interventions were found to be more clinically effective compared to a control of 'do nothing'.

Varenicline was found to be the most effective single therapy (over 2.5 times more effective), while varenicline used in combination with NRT was the most effective dual therapy (over 3.5 times more effective). E-cigarettes were found to be twice as effective as the control of doing nothing.

Evidence shows that all behavioural therapies were more effective than an alternative of 'do nothing', but there was a large variation in how behavioural interventions were defined and delivered. This often resulted in differing treatment effects. However, the effectiveness of pharmacological interventions is improved by an average of 18% when provided alongside behavioural therapy.

The published evidence for smoking cessation treatments among specific subgroups of the population is more limited. Among pregnant women, behavioural support interventions such as counselling, health education and the use of financial incentives can significantly improve quit outcomes during pregnancy. There are few published clinical trials in relation to smoking cessation treatments in those attending secondary mental health services, possibly because of the difficulty recruiting patients in this setting, particularly amongst the seriously mentally ill. Although there is a lack of data on the relative effectiveness of different smoking cessation interventions for people attending secondary mental health services, high-intensity programmes combining pharmacotherapy and behavioural support have been shown to improve quit outcomes in this group.

A cost-effectiveness analysis found that all smoking cessation interventions are cost-effective when compared with unassisted quitting. E-cigarettes and use of varenicline and NRT in combination provide the best value for money based on currently available information. However, the estimates of effect for e-cigarettes are based on pooling two small trials, and as such there is a high level of uncertainty surrounding both the clinical and cost-effectiveness of this intervention. There is also considerable uncertainty about the long-term health effects of e-cigarette use, along with concerns that their widespread promotion by health professionals could normalise nicotine consumption or act as a gateway to using tobacco for new generations of people who have never previously smoked. The assessment found that maximising the uptake of varenicline and NRT was the best possible strategy for improving quit rates. This would also be associated with significant additional drug expenditure and increases in demand for GP and nurse prescribing services. The draft HTA will be published for public consultation in early January 2017.

HTA of HPV testing as the primary screening method for the prevention of cervical cancer

Following a request from the National Screening Service, HIQA commenced work in December 2015 on a HTA to examine the clinical and cost-effectiveness of primary human papillomavirus (HPV) testing for cervical screening. This evidence will inform decisions in relation to potential changes to the existing cervical screening programme. Work on this assessment continued throughout 2016.

Cervical cancer is a rare outcome associated with persistent infection with 'oncogenic genotypes' of human papillomavirus (HPV). Infection with HPV is a necessary pre-requisite for the development of cervical cancer. Primary prevention through HPV vaccination and secondary prevention through cervical screening are two complementary approaches to the prevention of cervical cancer. The aim of a cervical screening programme is to reduce the incidence, morbidity and mortality from cervical cancer.

The HTA assessed primary HPV testing followed by five triage strategies using various combinations of liquid based cytology (LBC), HPV partial genotyping for HPV 16/18 and molecular biomarkers ($p16^{INK4a}$/Ki-67). In addition, a change to a five year screening interval, assessment of strategies by age and extending the screening age to 65 were also assessed. In total, 32 strategies were evaluated in the context of both vaccinated and unvaccinated women.

An economic model specific to the Irish setting was developed with expertise on cervical cancer modelling sought from UMIT, the German University for Health Sciences. A decision analysis model was built to compare the costs and benefits associated with HPV primary testing and five alternate triaging strategies with the current strategy (LBC primary test followed by HPV triage). The results of the cost-utility analysis will be reported as a cost per quality-adjusted life year (QALY) gained for each potential cervical screening strategy.

4.2.3 Research published in 2016

Cochrane review of left atrial appendage occlusion for the prevention of stroke in people with atrial fibrillation

Following a successful grant application by a HTA team member, work commenced on a Cochrane review protocol to assess left atrial appendage occlusion for the prevention of stroke in people with atrial fibrillation. Atrial fibrillation is a cardiac arrhythmia that causes ineffective contraction of the atrial and ventricular chambers of the heart, leading to stasis of blood in the atria. This may result in clot formation in the left atrial appendage; if the clot embolises to the brain then a stroke can occur. Closure of the left atrial appendage and excluding it from circulation is carried out using a range of approaches; including percutaneous catheter-based closure systems which were developed to minimise the invasive nature of open surgical approaches.

The protocol aims to assess the clinical effectiveness and safety of left atrial appendage closure compared with oral anticoagulation for preventing stroke in people with non-valvular atrial fibrillation.

The protocol was submitted in June 2016 detailing the proposed review aims and methods. It was published in the Cochrane database of systematic reviews in October 2016; see the journal publications section below for details.

International and national journal publications

Murphy LA, Teljeur C, Moran PS, Harrington P, Ryan M, Williams D, Foley DP and Smith SM. Left atrial appendage closure versus oral anticoagulation for preventing stroke in people with atrial fibrillation. The Cochrane database of systematic reviews. 2016, Issue 10. Art. No.: CD012385.

Moran PS, Teljeur C, Ryan M and Smith SM. Systematic screening for the detection of atrial fibrillation. The Cochrane database of systematic reviews. 2016 Jun 3; (6) Art. No.:CD009586.

Moran PS, Teljeur C, Harrington P, Smith SM, Smyth B, Harbison J, Normand C and Ryan M. Cost-Effectiveness of a National Opportunistic Screening Program for Atrial Fibrillation in Ireland. Value in Health. 2016 Dec;19(8):985-995.

Murphy LA, Harrington P, Taylor SJC, Teljeur C, Smith SM, Pinnock H and Ryan M. Clinical-effectiveness of self-management interventions in chronic obstructive pulmonary disease: An overview of reviews. Chronic Respiratory Disease, 2016. In Press.

Teljeur C, Moran PS, Walshe S, Smith SM, Cianci F, Murphy L, Harrington P and Ryan M. Systematic Review or Meta-analysis. Economic evaluation of chronic disease self-management for people with diabetes: a systematic review. Diabetic Medicine. 2016; In Press.

R Glynn, P Harrington, M O'Neill, and M Ryan. Utilisation and temporal trends for elective orthopaedic surgery in Ireland. Article in Irish Journal of Medical Science. 185:530-530, December 2016.

National conference abstracts

Murphy LA, Teljeur C, Moran PS, Williams D, Foley DP, Harrington P, Ryan M and Smith SM. Cochrane review protocol on left atrial appendage closure versus oral anticoagulation for preventing stroke in people with atrial fibrillation. 11th Annual All-Ireland Cochrane Conference, Queen's University Belfast.

4.2.4 Summary of other activities during 2016

Impact of HTA Report (2016)

HTA is a resource-intensive activity which involves gathering and synthesising evidence across a wide range of domains. Given the substantial capacity required to complete a HTA, it is important to consider the impact of HTA activity. This allows us to determine whether assessments are being used as intended, to identify opportunities for improvement in all areas including format, content and dissemination of HTA, to better support decision-making. In 2016, we assessed the impact of three HTAs published by HIQA in 2015 (a national screening programme for atrial fibrillation in primary care; a selective BCG vaccination programme; and, chronic disease self-management support interventions) under four themes:

1. internal processes,
2. relevance of activity,
3. value of activity,
4. and communication of activity.

Several tools were used for evaluation including, expert advisory group and decision-maker questionnaires, HTA downloads as a proxy of report uptake, time frames for completion of a HTA, a breakdown of team hours spent working on HTAs, adherence to our HTA quality assurance framework and readability scores.

Our impact assessments showed that stakeholder feedback was predominantly positive and indicated that projects were carried out to a high standard and the findings were based on appropriate evidence and analysis. Responses from decision-makers indicated that the HTAs were useful in the decision-making process, even if final decisions had not yet been made. Areas for improvement included low questionnaire response rates, and recommendations for improving HTAs were made. In addition, the nature of HTA reports is that their language can be very technical; alternative methods of also catering to lay readers were recommended in the final report.

The final report was submitted to HIQA's Board.

National HTA guidelines

HIQA has developed a suite of national HTA guidelines to promote the production of assessments that are timely, reliable, consistent and relevant to the needs of decision-makers and key stakeholders. In consultation with the HTA Scientific Advisory Group, (which includes broad representation from key stakeholders in healthcare in Ireland) this suite of guidelines is updated and added to as necessary. It was agreed that a guide providing an overview of heath technology assessment in HIQA should be developed in 2016. No updates to existing HTA guidelines were required in 2016. A guidelines update plan was discussed and agreed by the HTA group for the updates required in 2017.

A *Guide to Health Technology Assessment at HIQA* was completed in 2016. This guide explains what information is considered in a HTA and how that information is used to produce advice to ensure that investment and disinvestment decisions are well informed and evidence based. It also outlines what the outcomes of the HTA process are and how HTA is used in decision-making. The Guide is intended to be useful for all stakeholders, ranging from members of expert advisory groups convened to advise HIQA on specific HTAs, to members of the general public who are interested to learn more about HTA and how it is used in the Irish healthcare system. The guidance was developed in consultation with HIQA's HTA Scientific Advisory Group.

The guide was published in October 2016.

National Clinical Effectiveness Committee

In 2010, the Minister for Health established the National Clinical Effectiveness Committee (NCEC) to provide a framework for national endorsement of clinical guidelines and audit to optimise patient care within the Irish health system, both public and private.

As part of ongoing capacity development in the field of HTA, HIQA continues to provide support to the NCEC through its membership of the Committee. We assist with the prioritisation and appraisal of submitted guidelines, and provide technical support directly to clinical guideline developers seeking national endorsement for their guidelines.

As part of the NCEC training programme, HIQA delivered economic training sessions for both the NCEC and guideline developers. We also provided direct support to the developers of one clinical guideline mandated by the Minister, seven other guideline development groups and to one audit governance committee mandated by the Minister. These included: NEWS update (mandated), Hepatitis C Screening, Type 1 Diabetes in Adults, Emergency Medicine Early Warning System, Care of the Dying Adult Guideline, Lung, Colon and Rectal Cancer Guidelines and Major Trauma Audit (mandated).

Pictured at the HRB-CICER launch were (L-R) Dr Máirín Ryan from HIQA; Dr Graham Love, Chief Executive of the HRB; Professor Susan Smith from the RCSI; and Dr Karen Ryan, Chairperson of the National Clinical Effectiveness Committee

HRB-CICER grant application and award

Following a competitive grant application process, 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 (CICER). HRB-CICER will support Guideline Developers in developing evidence-based recommendations. The aim of HRB-CICER is to deliver a high-quality evidence base with regard to systematic review of clinical-effectiveness, systematic review of cost-effectiveness and budget impact analysis to support the development of National Clinical Guidelines and National Clinical Audits. National Clinical Guidelines and National Clinical Audits are quality assured by the National Clinical Effectiveness Committee (NCEC) and mandated by the Minister for Health for implementation by the HSE. In addition, the collaboration will provide training in evidence synthesis and will advise NCEC on improvements in methodological developments in evidence generation, and on research gaps with regard to the evidence base and how best they may be addressed. The 16 member co-applicant and collaborator team represents a broad range of disciplines with extensive experience in systematic reviewing, statistical analysis, health economic and budget impact analysis, clinical guideline and standards development, and related academic expertise in clinical research and practice, research methodology, statistics, psychology and education.

HIQA's main collaborator is the HRB Centre for Primary Care Research (HRB-CPCRin the Royal College of Surgeons in Ireland (RCSI). Led by Professor Tom Fahey and Professor Susan Smith, it has a strong track record in this area.

Collaborators from RCSI and National University of Ireland (NUI) Maynooth will provide expertise in systematic reviewing, in particular for more complex review methodology around diagnostic accuracy, risk prediction, meta-regression and qualitative synthesis. RCSI will provide senior-level information scientist expertise through Chief Librarian Kate Kelly. Other collaborators include Professor Michael Barry, National Centre for Pharmacoeconomics; Professor Marianne Klemp, Norwegian Knowledge Centre; Prof Mike Drummond, University of York, who chaired one of NICE's Guideline Review Groups for 10 years and contributed to development of NICE processes; Professor Michael Turner, Clinical Lead of the National Programme for Obstetrics and Gynaecology; and Professor Aine Carroll, Director of Clinical Strategy and Programmes, HSE.

Building capacity and capability in health technology assessment

HIQA has continued to engage with external stakeholders and to provide training and education opportunities in HTA to support the development of national expertise in the conduct and interpretation of HTA.

Support and training opportunities of varying intensity were provided to a broad range of stakeholders including work placements for public health doctors, external stakeholder training (patient representatives, NCEC-related, undergraduate, postgraduate, specialist registrars in public health and other), collaboration with colleagues from the RCSI, University of Limerick and NUI Galway on academic projects, and through training and education support for members of the HTA team to build on their expertise.

A newly recruited HTA analyst started work in the HTA directorate in June 2016. The analyst was successful in obtaining a place on the Structured Population and Health-services Research Education (SPHeRE) PhD programme, which will run for four years.

Stakeholder engagement

Stakeholder engagement throughout the HTA process is essential to deliver a high-quality, timely and relevant HTA that informs decision-making and translates into improved, equitable care for patients. Strategically for the HTA directorate, stakeholder engagement during the HTA process can also give credibility to our HTAs, and ensure our stakeholders are invested throughout. It can optimise our HTA process by ensuring its accuracy and allow for an early warning system and learning during the HTA process. Stakeholder engagement is also a control in our risk register to ensure we prioritise the right HTAs, meet decision-makers' needs and adequately engage for optimal results and transparency.

Through its engagement with a diverse range of stakeholders, HIQA incorporates the skills, experience and opinions of external stakeholders to inform priorities for the ongoing HTA programme of work, and to facilitate and inform projects that are underway.

The three assessments worked on in 2016 were each supported by a specifically convened expert advisory group that comprised representation from key stakeholders including policymakers, service providers, clinicians, patient groups and national and international HTA experts. The CICER grant application involved collaboration with national and international experts in HTA and a range of other disciplines. The Cochrane protocol involved collaboration with clinical experts, Cochrane experts and the Cochrane Stroke group.

We are preparing to hold a public consultation, to elicit the views of our stakeholders, on the HTA of smoking cessation interventions in early 2017.

We aim to continuously improve our engagement with stakeholders. We have developed an action plan for stakeholder engagement within the HTA Directorate over the next three years. Essentially, this plan aims to document key stakeholders and current engagement processes, and identify areas for improvement using relevant evidence. This plan falls under HIQA's Stakeholder Engagement Strategy.

The Directorate also contributed to a number of advisory groups and networks run by external stakeholders including the Technology Review Group of the National Cancer Control Programme, the HSE HTA Working Group, the National Trauma Steering Group, and the Central Statistics Office (CSO) and Department of Health Project Board for the national System of Health Accounts. Such stakeholder engagement when combined with ongoing horizon scanning helps to inform the HTA prioritisation process by identifying potential high priority topics for the work plan in a timely manner.

The work of the Directorate was also informed during 2016 by its Scientific Advisory Group (comprising broad representation from key stakeholders in healthcare in Ireland as well as methodological experts from the field of HTA).

4.2.5 International networks

European Network for Health Technology Assessment (EUnetHTA)

EUnetHTA, the European network of HTA is a collaboration of 79 HTA organisations from all 28 EU member states, Norway and Switzerland. EUnetHTA is currently in receipt of €20 million, over a four-year period, from the European Commission and member states to fund harmonisation of HTA methodology and joint production of HTA. HIQA has been nominated by the Department of Health to represent Ireland in EUnetHTA since 2008. This organisation aims to realise an effective and sustainable HTA collaboration that brings added value at European, national and regional level. A series of Joint Actions have been undertaken to foster inter-agency cooperation, improve HTA output and avoid duplication of effort. This work has also informed the establishment of a permanent Europe-wide network of HTA agencies.

HIQA's Dr Máirín Ryan at the European Commission-EUnetHTA forum entitled "European Cooperation on HTA: what's next?" shortly after being appointed as Chair. Also pictured are Xavier Prats Monné, Director-General for Health and Food Safety of the European Commission, and Wim Goettsch, Director of EUnetHTA

In October 2016, the Director of HTA in HIQA, Dr Máirín Ryan, was elected as Chair of the EUnetHTA Assembly. The Assembly is responsible for setting strategy and monitoring attainment of objectives by EUnetHTA. Dr Ryan will act as Chair of EUnetHTA for a period of two years and is a member of the EUnetHTA Executive Board. HIQA contributed extensively to planning for the third Joint Action to support European HTA collaboration 2016 to 2019, and is participating actively in four of the work packages.

Dr Máirín Ryan was invited to participate in a panel discussion at the EUnetHTA Forum entitled "European Cooperation on HTA: What's next?" in Brussels in October 2016.

Health Technology Assessment Network (HTAN)

Ireland is represented by HIQA's Director of HTA on the Health Technology Assessment Network (HTAN). This is a permanent network of HTA agencies which was established by the European Commission with an objective to foster sustained strategic and scientific collaboration in HTA across the EU. The Director was invited to join a European Commission Expert Group on assessing the impact of a sustainable mechanism for EU co-operation in HTA from 2020 onwards.

Other international collaborations

In order to increase its capacity to efficiently produce high-quality HTA, HIQA continues to engage with other HTA agencies and build on existing relationships. Examples include cooperation between agencies in sharing ongoing and completed assessments so as to minimise duplication of effort.

Expertise on cervical cancer modelling was sought from UMIT, the German University for Health Sciences, and the HTA was also informed by work from the Belgian Health Care Knowledge Centre (KCE). The HTA on smoking cessation was informed by several Cochrane reviews. Members of other HTA agencies have also acted as peer reviewers for HIQA assessments and as international HTA experts on Expert Advisory Groups convened by HIQA.

HIQA is a member of both Health Technology Assessment international (HTAi) and the International Network of Agencies for Health Technology Assessment (INAHTA). The latter facilitates international exchange of information to facilitate adaptation of HTA for local application.

The Director of HTA presented at the EuroNet MRPH winter meeting in collaboration with the Faculty of Public Health Medicine. The presentation was titled "Leadership in public health: using evidence to drive improvements in healthcare". A webinar was prepared and delivered to the EURORDIS multi-national alliance of patient organisations for rare diseases. Entitled "Introduction to HTA", this was co-presented with international HTA colleagues. Lectures were provided to undergraduate and postgraduate courses in Trinity College. A guest lecture was given in the Department of Economics at NUI Galway on Systematic reviews and evidence synthesis in HTA.

4.2.6 Research ethics

It is envisioned that HIQA will take on a new role of Supervisory Body of research ethics committees, under the Health Information and Patient Safety Bill. During 2016, we continued with our internal preparations for the new function, as described in the Revised General Scheme of this Bill which was published on the website of the Department of Health in November 2015.

The legislation related to clinical trials on medicinal products for human use is changing dramatically at European level. During 2016, we continued our participation in the working groups of the European Commission and the European Medicines Agency which are preparing to implement the new legislation. We have also been working with the Department of Health as they prepare for implementing new legislation on clinical trials of medicinal products at a national level, along with the Health Products Regulatory Authority and other national stakeholders.

4.3 Health Information Directorate

4.3.1 Background

Under section (8)(1)(k) of the Health Act 2007, HIQA has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving its quality, and filling-in gaps where information is needed but is not currently available.

The Health Information Directorate seeks to improve patient safety and quality of care by developing standards, recommendations and guidelines in health information. These include standards for definitions, sharing information, ensuring the governance and privacy of information, and optimising the use, coverage and quality of information. We continue to monitor trends in other countries to ensure that we are using effective methodologies to inform and improve patient safety and quality of care.

Information on the availability, accessibility, effectiveness and efficiency of our health services is fundamental to a reliable and safe healthcare system. Having good information and using it well are the keys to good decision-making and lead to improved services at operational and planning levels.

The Health Information Directorate is responsible for analysing the existing quality and coverage of health information, identifying gaps, and making recommendations to fill those gaps. We set standard definitions for information to ensure meaningful comparability and to help avoid duplication of effort. Equally important are standards that support the ability of health information systems to communicate and facilitate efficient sharing of health information.

Rachel Flynn, Director of Health Information presenting to Joint Committee on Health on 14 December 2016

In addition to the function set out in the Health Act 2007, the Health Information Directorate is responsible for delivering and advancing the use of information in HIQA through its business intelligence function, and also through implementing the National Patient Experience Survey Programme.

4.3.2 Strategic Objectives for Health Information

Within our Corporate Plan 2016–2018 our objectives include the following;

- provide leadership in defining the health information landscape in Ireland by influencing policy and legislation through engaging with informed and interested parties and developing recommendations
- contribute to the development of the foundations required to make possible eHealth in Ireland and support progress with rolling out the national eHealth strategy, through developing technical and information standards
- promote improvements in the quality of health information to underpin the delivery of safe care, informed decision-making, and monitoring, planning and regulation by HIQA.

The following sets out what has been achieved in 2016 to advance these corporate objectives.

4.3.3 Influencing policy and legislation

Joint Oireachtas Committee on Health

Phelim Quinn, CEO, Mary Dunnion, Director of Regulation and Chief Inspector of Social Services and Rachel Flynn, Director of Health Information, appeared before the Joint Oireachtas Committee on Health in December 2016 to discuss the General Scheme of Health Information and Patient Safety Bill. This is a critical piece of legislation which will establish the legal framework to enable HIQA to fulfil its statutory obligations in relation to health information, amongst other functions.

Under this Bill, the Health Information Directorate will have a formalised role in setting standards on 'prescribed data matching programmes' and 'prescribed health information resources', and will also monitor compliance with these standards, as laid out in the General Scheme. HIQA's role will also extend to the private sector as regards setting standards for management of health data by private health services.

Recommendations on the coordination of patient safety intelligence in Ireland

The Health Information Directorate developed 10 *Recommendations on the coordination of patient safety intelligence in Ireland*. The recommendations were published in January 2016 and include a proposal for a new model for coordinating patient safety intelligence in Ireland and the implementation and rollout of the national incident management system.

These recommendations, in addition to the *Recommendations for a more integrated approach to national health and social care data collections in Ireland* published in 2014, continue to inform national health information policy. The Health Information Directorate continues to work closely with the Department of Health to implement both sets of recommendations.

4.3.4 Standards development

National health and social care data collections

International review of national health and social care data collections

The Health Information Directorate published an international review of national health and social care data collections in July 2016. The review found that having national health and social care data collections with quality data leads to improvements in the quality of care patients receive, and better informs national policy and research. The review considered health and social care data collections in Australia, Canada, England, New Zealand and Scotland. The review focused on governance and management structures in place for national collections, data quality arrangements, standards, guidelines, and monitoring and regulatory approaches. A core finding of the review was that having one central organisation that governs either all or most of the national collections is instrumental in ensuring the quality of a data collection. The countries reviewed consistently monitor the quality of their data, use health information standards and benefit from having unique health identifier numbers in place. Findings from the international review informed the development of information management standards for national health and social care data collections.

Information management standards for national health and social care data collections

Information management standards for national health and social care data collections were developed in line with HIQA's standards development process, and significant stakeholder engagement was undertaken to inform the content of the standards. An advisory group of experts and key stakeholders was convened to provide advice and guidance on the development of the standards. HIQA also carried out a nine-week public consultation of the draft standards between July and September 2016, allowing interested parties to submit their views and feedback on the standards. The feedback from the public consultation was analysed, considered and used to inform the finalised standards. A Statement of Outcomes report following the consultation will be published alongside the final standards.

The standards were approved by the HIQA Board in November 2016 and submitted to the Minister for Health for approval in December 2016. When implemented, the standards will improve the quality of national health information and data, contributing to the delivery of safe and reliable healthcare.

HIQA is currently developing a structured programme of assessing compliance with the information management standards for national data collections, within its legislative remit.

Technical standards

International Review of National Summary Care Records

A review of international evidence and best practice concluded that using a central, secure record of people's medical history can help to improve patient care and safety by giving healthcare professionals timely access to relevant patient information to guide care and treatment, such as in an emergency department or a pharmacy.

The international review, published in August 2016, considered summary care records in regions that are strong leaders in delivering eHealth initiatives; the UK (England, Scotland, Northern Ireland and Wales), Australia, New Zealand and The Netherlands. Evidence showed that a summary care record is usually created automatically from existing records. It is usually held in a central national location, accessed on a secure network, and contains key elements such as a patient's name, address, age, allergies, current medications and diagnoses.

In each country reviewed, common information in the summary care records included patient's details, medications and allergies. Also, the main source of information that was used to generate the summary care records came from primary care, specifically from family doctors.

This review aimed to inform how a national summary care record could be developed in Ireland and will help inform implementing such a record here. Areas such as governance, evaluation of their use and appropriate patient permission models to share information will need to be considered.

The international review showed improved patient experience, patient safety and the effectiveness of patient care. The quality of care that patients receive can be improved by timely access to relevant records.

National Standard for a Procedure Dataset

In 2016, we finalised the *National Standard for a Procedure Dataset including a Clinical Document Architecture specification*. This national standard was developed to standardise how procedures are recorded and to facilitate easier sharing of information within and between health and social care services.

This standard is part of a suite of standards that HIQA has developed to support standardising patient summaries, and it complements the work undertaken in the international review of patient summaries. A five-week, targeted consultation was held in September to October 2016 to inform development of this standard.

Standardised patient summaries can increase patient safety as they facilitate effective and accurate exchange of information, and support improved communication between healthcare providers. They can also support continuity of care as patient summaries are intended to help clinicians to access key information when emergency care is being provided.

Information about procedures is a key section of the patient summary. This standard defines a minimum dataset for a procedure and defines a Clinical Document Architecture (CDA) specification based on the dataset. The final standard, will standardise how a procedure is recorded in a structured way and can facilitate easier sharing of information within and between health and social care services.

Standard for a Dispensing Note Dataset

ePrescribing has been identified as a key priority for Ireland in the National eHealth Strategy (2013).[6] Multiple standards are required to enable the roll-out of ePrescribing nationally. HIQA has previously undertaken work in this area, including a data model for prescribed medications and an ePrescribing standard developed in 2015.

In 2016, we developed a *National Standard for a Dispensing Note Dataset including a Clinical Document Architecture specification* to support the sharing of information on the medications supplied by a dispensing pharmacist to the patient when they fulfil a prescription. This standard defines a minimum dataset of medication or medications dispensed to a patient in a community pharmacy for use in a summary care record. A five-week, targeted consultation was held in September to October 2016 to inform development of this standard.

ePrescribing standards reduce medication prescription and transcription errors, leading to increased quality and efficiency, and safer health services for patients. Medication error is one of the most common adverse events in Irish healthcare, with medication safety incidents accounting for up to 8% of clinical incidents reported to the State Claims Agency. ePrescribing gives health providers an important tool to safely and efficiently manage patients' medications. The standard supports the electronic sharing of information regarding medications dispensed to a patient, and provides a mechanism for safely exchanging this information in electronic documents.

6 Department of Health. *eHealth Strategy for Ireland*. 2013. Available online from: http://www.dohc.ie/publications/eHealth_Strategy_2013.html

4.3.5 Promote improvements in the quality of health information

National data collections

Programme for assessing compliance with information management standards for national health and social care data collections

During 2016, HIQA completed the development of a framework for monitoring compliance with the information management standards for national health and social care data collections. An Assessment and Judgement Framework was prepared to support how the national collections will be assessed against the standards. This was developed in line with HIQA's Monitoring Approach.

A self-assessment tool for national collections was also developed and trialled in three national collections. The tool will enable national collections to determine the extent to which they meet the requirements of the national standards. It will highlight areas where action is required or where improvements are needed, and will also inform the scheduling of assessments by HIQA. Feedback was sought from each of the three trial sites and the self-assessment tool will be amended before it is finalised for use in 2017.

4.3.6 National Patient Experience Survey Programme

The first of its kind in Ireland, the National Patient Experience Survey is a nationwide survey which will ask adult patients about their recent experience in an acute hospital. The results of the survey will help improve the safety and quality of services provided to patients, inform healthcare standards and help shape future healthcare policies.

National Patient Experience Survey Programme team

Patrick Lynch, National Director of Quality Assurance and Verification, HSE; Phelim Quinn, Chief Executive Officer, (HIQA) and Dr. Kathleen MacLellan, Director of the National Patient Safety Office, Department of Health

Due to commence in 2017, the National Patient Experience Survey is a collaboration between HIQA, the Health Service Executive (HSE) and the Department of Health. The partnership approach was formalised with the signing of a Memorandum of Understanding on 3 October 2016.

During 2016, a governance structure was established. Oversight and management of risks of the project is provided by the National Patient Experience Survey Steering Group. It is chaired by the CEO of HIQA and comprises members from HIQA, the Department of Health, the HSE and Patient Focus.

The National Patient Experience Survey Advisory Group provides advice and guidance on the design and development of the model and methodology for the Survey Programme. Advisory Group membership comprises the three partner organisations, patient representatives and subject matter experts.

The National Patient Experience Survey Delivery Group is the working group responsible for delivering the project, with membership comprising the three partner organisations.

The scope of the survey is defined as being all patients aged 18 years and over, who have spent a minimum of one night in a public acute hospital, and have been discharged during May 2017. A target population of approximately 27,000, across 41 acute hospitals is expected. A survey tool was developed using evidence-based methodologies. A validated international question set was purchased from Picker International, comprising 189 questions. Eight focus groups were held in locations around Ireland to test the questions in an Irish context. Six focus groups were patient led, and a Statement of Outcomes was written to provide an outline of the results. The remaining two focus groups were held with data users.[7]

7 'Data users' refers to individuals who work with data (healthcare or other) on a regular basis.

Following the focus groups, a Delphi Study was conducted on the library of 189 questions, to reduce the number of questions to a core of 60, with an additional 40 ranked in order of preference. Sixty participants, including 10 patient representatives took part in this group. The findings of the Delphi Study will be published on www.patientexperience.ie in early 2017.

Picker International were consulted in relation to the proposed final survey questions, given their extensive experience. In addition, they provided advice and guidance in relation to statistical significance at hospital group and hospital level.

The National Patient Experience Survey Programme team has commissioned a Privacy Impact Assessment from an independent third party. In addition, the survey attained ethical approval from the Royal College of Physicians Ireland in December 2016.

Communications tools have been developed, to inform the public of the key messages of the importance of taking part and how the information will be used. These include information leaflets and a website, www.patientexperience.ie. Continual and frequent stakeholder engagement took place throughout the year, including a presentation at the National Patient Safety Conference in December 2016.

The National Patient Experience Survey will be launched and implemented during 2017, and the findings, both at a national, hospital group and hospital level, will be published in 2017.

4.3.7 Business intelligence

Business intelligence is central to HIQA in providing an analytical basis to inform our regulatory operations. Delivery of the actions associated with our Business Intelligence Strategy 2015-2017 was one of HIQA's prioritised objectives in our 2016 Business Plan. Business intelligence provides operational data to support inspections, reviews and investigations which underpin the regulatory interactions between HIQA and the services that it regulates. The development of robust risk-based regulatory systems and processes allows HIQA to prioritise and target our regulatory interventions efficiently and effectively.

The Business intelligence team works to ensure that the maximum benefit is derived from all its available information channels, optimising existing information, combining it with relevant external data sources to maximise the benefit and availability of information in order to inform and improve HIQA's regulatory and quality assurance programmes and outcomes.

The Business Intelligence Strategy defines 27 milestones to be achieved within a three-year period. In 2016, we completed 10 milestones, with another seven in progress.

The milestones achieved related to:

- governance of business intelligence within HIQA,
- integration of business intelligence within business processes,
- enhancing the use of internally created data and information and externally sourced datasets,
- providing tools and resources for the effective and timely delivery of high-quality information to the business functions.

4.4 Standards and Quality Improvement Directorate

4.4.1 Background

During the year, the Standards and Quality Improvement Directorate actively supported and enabled a culture of patient safety and quality improvement across and within the health and social care system.

We promoted quality and safety by developing national standards and guidance for health and social care services in consultation with stakeholders. We also hosted the graduation of the final year of participants of a programme to build capacity in quality improvement methodologies and tools for front line staff. We also identified end-of-life care in nursing homes as a strategic quality improvement initiative, and supported this work at our regional awareness sessions on the revised *National Standards for Residential Care Settings for Older People in Ireland, 2016*.

4.4.2 National standards: development and review

National Standards for Residential Care Settings for Older People

The revised *National Standards for Residential Care Settings for Older People in Ireland*, 2016 were approved by the Minister for Health in the first quarter of 2016. The revised standards were published on 3 May 2016. In preparation for monitoring against the standards, the Standards and Quality Improvement Directorate and Regulation's Older Persons' team conducted four regional awareness sessions on the standards in June 2016. Monitoring against these standards commenced on 1 July 2016.

National Standards for the Prevention and Control of Healthcare Associated Infections

Work continued on the revision of the *National Standards for the Prevention and Control of Healthcare Associated Infections*. Due to the contextual differences within primary and community care facilities, the Standards Advisory Group determined that these standards should be for acute healthcare services only.

These draft standards are a revision of the 2009 *National Standards for the Prevention and Control of Healthcare Associated Infections*, and incorporate learning from HIQA's programme of inspections against these standards across Irish hospitals. The *draft National Standards for the Prevention and Control of Healthcare Associated Infections* were published on 10 October 2016 for an eight-week public consultation. The revised *National Standards for the Prevention and Control of Healthcare Associated Infections* in acute healthcare facilities will be finalised and submitted to the Minister for Health in early 2017.

National Standards for Safer Better Maternity Services

We continued to develop the *National Standards for Safer Better Maternity Services* in 2016. The standards cover eight themes of care including, person-centred care and support, and better health and wellbeing, to improve outcomes for women and their babies. The standards were informed by the Standards Advisory Group, focus groups with service users and frontline staff, and an eight-week public consultation, held from March to May 2016. The final standards were approved by the Minister for Health and launched at Dublin Castle on 21 December 2016.

National Standards for the Conduct of Reviews of Patient Safety Incidents

We continued to develop National Standards for the Conduct of Reviews of Patient Safety Incidents in 2016. This was the first time that standards were jointly developed by HIQA and the Mental Health Commission. The standards set out how patient safety incidents are reviewed across acute health and mental health services. The standards were informed by a Standards Advisory Group made up of a diverse range of interested and informed parties, including service users, healthcare (including mental health) professionals, and representatives from the Department of Health, the Health Service Executive (HSE), the State Claims Agency, the Office of the Ombudsman and the Private Hospitals Association of Ireland. HIQA and the Mental Health Commission also undertook a series of focus groups with service users, front-line staff and management involved in patient safety incidents. Draft standards were published for a six-week public consultation in September 2016. The final standards will be completed in 2017.

National Standards for Safer Better Maternity Services launch: Phelim Quinn, HIQA CEO; Simon Harris TD, Minister for Health; and Brian McEnery, Chairperson of HIQA Board

4.4.3 Guidance to support implementation of national standards

HIQA continued to develop guidance documents for health and social care services in 2016 to help service providers to understand and adopt national standards. These provide a common understanding and language for service users, patients and service providers on how the national standards apply across all health and social care services. They also help people working in health and social care services to understand how to achieve compliance with HIQA's standards.

We completed work on *Supporting people's autonomy: a guidance document*, which we published and launched in February 2016. This document was written to help providers of adult health and social care services to promote and support individuals' autonomy, choice and decision-making in the care setting.

In 2016, HIQA continued to work on an ongoing process of review and engagement with relevant interested parties to update our guidance and to identify areas which may require more specific guidance.

We circulated over 500 copies of our guidance documents at national conferences throughout the year.

4.5 Operations

HIQA's Operations team seek to ensure that HIQA has effective systems, infrastructure and processes in place to facilitate the efficient delivery of business plan objectives. In 2016, we continued to strengthen and develop these functions.

4.5.1 Human Resources

The Human Resources team supports employee relations, policy development, recruitment, payroll and pensions, performance management and organisational development. It does this through working in partnership with managers and staff and through the provision of professional expertise, projects policies and processes.

Human Resources led the recruitment of 37 permanent positions within HIQA in 2016. It also recruited a number of agency staff to provide additional support in a temporary capacity. The team provided induction and mentoring support programmes to all new staff members.

Organisational learning and development initiatives continued across HIQA. This is an important contributor to developing and improving organisational and personal performance. A wide range of programmes were delivered in 2016, including a 360 degree development programme for senior staff members, 'Train the Trainer' development programmes, and change management facilitated sessions with key teams across the organisation. Work continued with staff to identify and deliver core learning and development programmes in strategic areas.

During 2016, there was significant focus on implementing the Human Resources Information System (HRIS). This will provide a platform to facilitate the replacement of manual processes with an integrated database and automated workflows. This will be followed by a progressive roll out of further modules and functionality in 2017.

We committed to promoting a working environment that takes account of the needs of individuals, while meeting the needs of the organisation. Human Resources completed a comprehensive review of policies, procedures and practices relating to flexible working in 2016, and introduced changes and enhancements in line with current best practice.

4.5.2 Financial management

Throughout 2016, HIQA continued to manage its financial resources in line with governance requirements. Annual fees were collected on time, and the use of budgeting and ongoing forecasting enabled secure management of actual expenditure against planned and available resources.

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

HIQA's annual accounts for 2016 were submitted to the Comptroller and Auditor General in accordance with the timescales set out in the Health Act 2007.

4.5.3 Quality management

HIQA's Quality function was formally established in 2016, and work commenced on the organisation's quality management system (QMS). A gap analysis was carried out and an action plan was developed to further improve and standardise the organisation's work processes. As part of the QMS development, an in-house quality assessment function was established and a number of quality assessments were carried out. A review of information governance practices also commenced in 2016, with improvements identified. Progress has also been made on the further development of our internal document management system.

4.5.4 Information systems

HIQA continued to successfully deliver the goals of its eStrategy which was revised and updated in 2016. The governance and oversight of this work was carried out by the Information System Board chaired by HIQA's CEO Phelim Quinn. HIQA's enterprise information system was further enhanced throughout 2016, adding additional functionality and improvements to better support regulatory activity.

A continuous improvement programme for HIQA's infrastructure progressed in 2016. Key systems were upgraded, including major communication and collaborative solutions. These upgrades improved efficiency and performance, while also increasing overall reliability.

A number of initiatives were undertaken throughout the year to strengthen HIQA's ICT security. These included new security systems and external reviews of HIQA's security; leading to subsequent remediation work were necessary. This work is ongoing and further enhancements will be rolled out in the coming year.

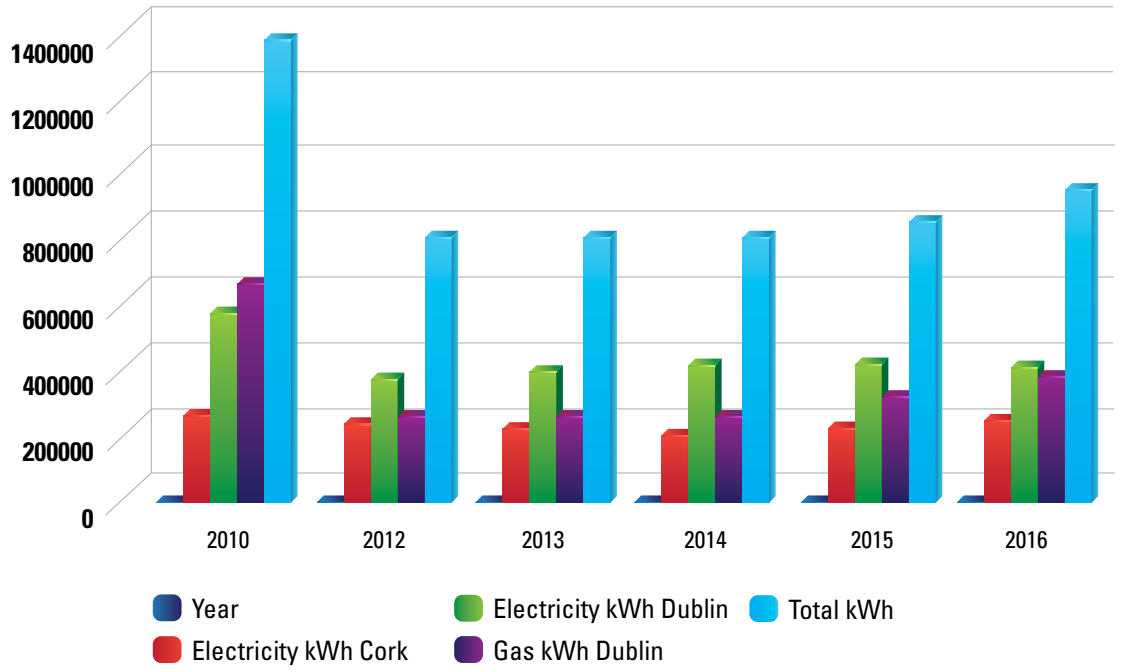
During the year, HIQA commissioned a strategic readiness review of its technical teams, including ICT support and development groups, Business intelligence and Business support functions. This review looked at how these teams are aligned with each other and if they are correctly structured to best support HIQA to deliver on its remit. This review will be used to inform the reorganisation of the technical support teams in the coming year to ensure they are best positioned to support achieving business plan objectives.

4.5.5 Energy consumption

HIQA continue to play an active part in the 'Optimising Power @ Work' programme run by the Office of Public Works. Once again, we achieved very good results due to the ongoing efforts of all staff. HIQA consumed a total of 883641 kWh of energy in 2016. This consisted of:

1. 192500 kWh of electricity in our head office in Mahon, Cork
2. 349971 kWh of electricity in our Dublin Regional Office
3. 341170 kWh of fossil fuels in our Dublin Regional Office

In total, HIQA achieved a 31.8% reduction in its energy consumption in the Dublin office and a 10.5% reduction in the Head Office in Cork when compared to the baseline figure which was established in 2010 which is in excess of the targets set under the National Energy Efficiency Action Plan. Under this initiative, the Public Sector were challenged to achieve a verifiable 33% reduction in its energy consumption by the year 2020.



4.5.6 Health and safety

HIQA remains committed to protecting the safety, health and welfare of all employees and visitors in our offices. We continue to invest resources in our Health and Safety programme which enables colleagues to actively participate in the management of their own health and safety. The Safety Management System was revised and updated in 2016. New safety representatives were elected and joined the Health and Safety Committee, and safety training continued to be rolled out to ensure that health and safety is at the forefront of our activities. There was one reportable accident in 2016.

4.5.7 Facilities

HIQA's regulatory remit covers services provided across all 26 counties in the state. To enhance the organisation's capacity, a decision was taken to acquire a small office in Galway that allows HIQA to operate more effectively in the west of the country. This office complements the larger offices in Cork and in Dublin. Working with the Office of Public Works, a suitable space was identified and fit-out works were completed by the end of January 2016. The office was opened on 1 February 2016.

4.5.8 Planning

We published our Corporate Plan 2016-2018 in April 2016, following extensive stakeholder consultation. This plan articulates the core strategic objectives that HIQA aims to achieve over the next three year period. HIQA's Corporate Plan is underpinned by an annual Business Plan. The Business Plan is aligned with the Corporate Plan, and sets out the business objectives to be delivered in 2016, the first year of the three-year corporate planning cycle. Both the Corporate Plan and Business Plan were approved by the Minister for Health during the year.

Business planning for 2017 began in early September 2016. A draft business plan will be sent for consideration by the Minister for Health within 30 days of receipt of HIQA's financial determination for 2017.

4.6 Communications and Stakeholder Engagement

4.6.1 Background

HIQA communicates with the public and our wide range of stakeholders on a regular basis. The Communications and Stakeholder Engagement team provide timely and accurate information to the public, while maintaining an independent and impartial voice.

All reports and recommendations published during 2016 applied HIQA's core values of openness and transparency. We continued to work with the media and other stakeholders to ensure information on our work is reported accurately and appropriately, and the public are informed and facilitated to access and understand what we do.

4.6.2 Functions

The Communications and Stakeholder Engagement team deliver eight functions to meet HIQA's communications needs. These are:

- press and media relations
- managing and publishing publications
- stakeholder engagement and consultation
- public and parliamentary affairs
- management of our online channels
- internal communications
- Freedom of Information
- management of complaints.

4.6.3 Press and media relations

Throughout 2016, the Communications and Stakeholder Engagement team continued to communicate HIQA's key messages. HIQA's work was reported by international, national and local media organisations across print, broadcast and online publications. We worked with the media to ensure that our message reached audiences in a timely and accurate manner.

Thirty press releases on HIQA's work were issued during 2016. These included significant media events such as the publication of the *Report of the review of nutrition and hydration care in public acute hospitals*, and a review of progress at Midland Regional Hospital, Portlaoise, National Standards for Safer Better Maternity Services, CEO Phelim Quinn speaking on safeguarding at the National Federation of Voluntary Bodies' national conference, and the signing of memorandums of understanding.

We issued 48 publication statements to accompany the publication of inspection reports on health and social care services.

We recorded an average of 380 news stories every month directly related to our work. This amounted to over 4,500 news reports on HIQA's work during 2016.

4.6.4 Publishing and publication management

HIQA is committed to promoting the use of plain English in all our publications. During 2016, we provided in-house report writing and plain English training to 24 of our personnel.

We publish our reports and publications on our website www.hiqa.ie, where they can be easily downloaded. We produced several of our publications in easy-to-read versions. We also designed infographics for a number of our publications to make them more accessible.

We remain committed to ensuring that information is published on the website in a timely manner.

In 2016, we published 35 publications. This includes standards, annual reports and guidance documents, as well as our newsletter and speaking notes from major national events. Over 1,300 inspection reports were published on our website in 2016.

Type of report	Total number published
Healthcare	42
Children (excluding disability)	46
Disability (including children)	700
Nursing homes	575
Total	**1,363**

4.6.5 Stakeholder engagement and consultation

We continued to liaise with stakeholders, including the general public, patients, residents, service providers and advocacy groups. Our priority is to be responsive to the needs of those who use health and social care services.

Engaging the public in consultations is an important part of HIQA's work. In 2016, we held seven public consultations before finalising a number of national standards. During consultation, interested parties were invited to submit their views and feedback on the draft standards. These views informed the final standards which were then approved by the HIQA Board.

- *Revision of the Draft National Standard Demographic Dataset and Guidance for use in health and social care settings in Ireland*
- *Draft National Standards for Safer Better Maternity Services*

Phelim Quinn speaking at the MacGill Summer School on 21 July 2016 (Photo Donegal County Council)

- *Draft Information Management Standards for National Health and Social Care Data Collections*
- *Draft National Standard for eDispensing datasets and Clinical Document Architecture*
- *Draft National Standard for Procedures datasets and Clinical Document Architecture*
- *Draft National Standards for the Conduct of Reviews of Patient Safety Incidents*
- *Draft revision of the national standards for the prevention and control of Healthcare Associated Infections in acute healthcare services.*

We also contributed to a number of consultations organised by other organisations and public bodies, such as, eHealth's public consultation on a Privacy Impact Assessment for the Individual Health Identifier.

Throughout 2016 HIQA accepted invites to attend a number of conferences across the country to address stakeholders. HIQA's CEO Phelim Quinn prepared a number of presentations, such as his address to the MacGill Summer School in Glenties, Co. Donegal on 21 July 2016, and to the Irish Nurses and Midwives Organisation and the Royal College of Midwives NI's All-Ireland Annual Midwifery Conference in October 2016.

During the year, we continued to publish our newsletter for our stakeholders and the public, HIQA News, containing information from our various teams. In 2016, we published five issues and had an average of 2,823 subscribers.

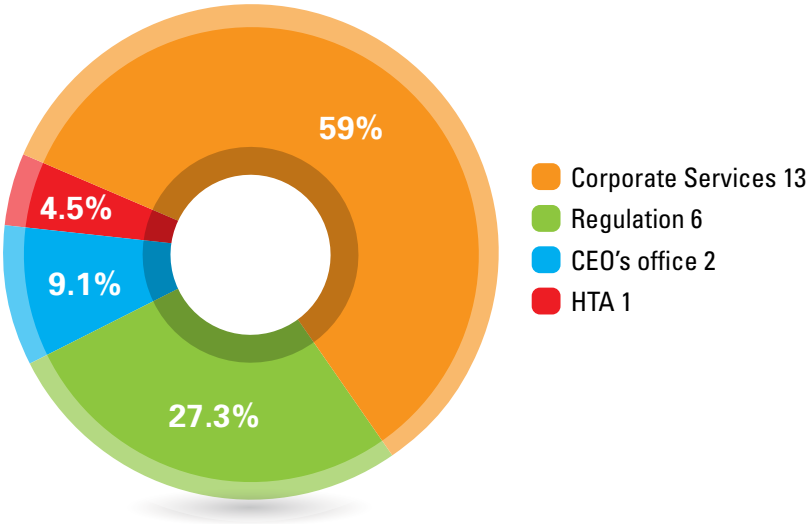
4.6.6 Public and parliamentary affairs

Through our public and parliamentary affairs function, HIQA is accountable to the Government and the Houses of the Oireachtas, ensuring that accurate and up-to-date information is provided in a timely manner. We are proactive and responsive in providing detailed information to political queries in a timely manner.

We communicate directly with Government departments, the Joint Committee on Health, the Joint Committee on Children and Youth Affairs, the Committee on the Future of Healthcare, and with relevant spokespersons.

We received and responded to 22 parliamentary questions last year. Parliamentary questions serve an important purpose in ensuring that HIQA's work is accountable, understood, and accurately and fairly reported.

Parliamentary questions answered by HIQA related to:



All questions were responded to on time. We also replied to two formal information requests from the Department of Health on issues relating to regulation. The range of questions asked from across the political groupings within the Oireachtas demonstrates general engagement by elected representatives with our work. We engage with Oireachtas Health, Older People, Disability and Children spokespersons on an ongoing basis. More generally, HIQA regularly receives queries directly from public representatives and their offices.

We made two submissions in 2016 to assist the work of public bodies. Based on our experience of the health and social care system, HIQA made a submission to the Committee on the Future of Healthcare setting out our vision for the future of health and social care in Ireland. We also made a submission on the Department of Health's Statement of Strategy 2016 – 2019.

Furthermore, HIQA's Chief Executive, Phelim Quinn; Director of Regulation and Chief Inspector of Social Services, Mary Dunnion; and Director of Health Information, Rachel Flynn, appeared before the Joint Health Committee on 14 December 2016 as part of the process of pre-legislative scrutiny on the General Scheme of the Health Information and Patient Safety Bill.

4.6.7 Online communications

The Communications and Stakeholder Engagement team manage all online channels including our website, intranet and social media sites such as our Twitter and Facebook pages.

Our website continues to be an important source of information for our stakeholders and the general public. During the year, work continued on the major redevelopment of the website. The new website will be launched in the first quarter of 2017.

The four most popular sections of www.hiqa.ie were the homepage, our latest inspection reports section, our disability services inspection reports and our careers page.

The number of publication downloads from our website increased by 6% during 2016. The four most popular documents downloaded from our website were:

- *Revised National Standards for Residential Care Settings for Older People in Ireland, 2016*
- *National Standards for Safer Better Healthcare*
- *National Standards for Residential Services for Children and Adults with Disabilities*
- *Annual overview report on the regulation of designated centres for older people - 2015*

Download of the *National Standards for Safer Better Healthcare* increased by 50% in 2016. During 2016, the number of visits to our website from mobile devices, including phones and tablets, continued to grow grew by 25%.

In 2016, we continued to use social media to engage with our stakeholders including our Facebook page, our Twitter account and LinkedIn page. Our interactions and connections on social media work to build a community interested in the work of HIQA and seek input from stakeholders. Our number of followers on social media networks increased in 2016. HIQA's number of followers on Twitter grew by 48% and our Facebook page increased its number of followers by 22%.

Phelim Quinn presenting at the All-Ireland Annual Midwifery Conference (Photo Lisa Moyles)

Our number of connections on LinkedIn increased by 24% in 2016.

Our Youtube channel received 9,647 views in 2016, an increase of 6%. Our short messaging service (SMS) continued to notify our 548 subscribers of updates on our work. The number of SMS subscribers increased by 14% in 2016.

4.6.8 Internal communications

We maintain and support internal communication across HIQA. Regular staff meetings and our intranet were the primary sources of internal communication about HIQA's activities, and staff were kept updated on all changes and developments within the organisation. Daily news updates are circulated to all staff and Board members. The monthly, internal staff e-zine is used to inform staff about all aspects of work across the organisation.

4.6.9 Freedom of Information

HIQA received a total of 52 Freedom of Information (FOI) requests in 2016 and carried five requests over from 2015. Of this total of 57 requests, 11 were granted, 23 were part-granted, nine were refused, seven were handled outside of the FOI process or withdrawn, six were transferred to another government agency and one was carried over into 2017.

All requests were responded to in accordance with the requirements of the Freedom of Information Act 2014. HIQA increased the number of its FOI decision-makers through the provision of appropriate training.

4.6.10 Complaints

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, 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.

A new Complaints Policy was approved by the Board in March 2016 and has been implemented. During 2016, 12 complaints were received by HIQA, all of which were dealt with in accordance with the policy and the agreed timelines.

4.7 Chief Executive's Office

4.7.1 Background

The Chief Executive's Office provides oversight, direction and support to enable HIQA to deliver its objectives within a governance framework. This includes providing effective support for the Board and its committees so that the key functions of strategy and monitoring performance are delivered in manner that ensures that HIQA meets its statutory requirements.

4.7.2 Board and committee meetings

The Board held eight meetings during 2016. Six meetings were statutorily required and two additional meetings were scheduled to progress specific items of business without undue delay.

Board committees

During 2016, the Board reconfigured the structure and remit of its Board committees to optimise and streamline the work of the committees. Board committees assist and support the Board by providing more detailed oversight in core areas relating to the functions and operations of HIQA.

There are four committees of the Board. These are as follows:

- **Regulation Committee** oversees the effectiveness, governance, compliance and controls around the delivery of HIQA's regulatory functions. This committee met four times throughout 2016.
- **Audit, Risk and Governance Committee** assists the Board in its assessment of the effectiveness of the systems established by Management of HIQA by reviewing the comprehensiveness and reliability of internal controls, and assurances on governance, risk management, the control environment and the accuracy and completeness of the financial statements. This committee met six times during 2016.

Mary Griffin, Chief Executive of the NMBI, and Phelim Quinn, Chief Executive of HIQA, at the signing of a Memorandum of Understanding between the two organisations

- **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. This committee met twice during 2016.
- **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. This committee met three times in 2016.

4.7.3 Corporate governance

The Board of HIQA is responsible for HIQA's system of internal control and for annually reviewing the effectiveness of the internal controls, including financial, operational, 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 as follows:

- Internal audit work
- Audit by Comptroller and Auditor General
- Risk management
- Review of financial controls
- Review of financial statements.

In addition, a process is in place where 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 to the Board at each meeting of the Board. The Board Committees report to the Board.

Code of Business Conduct

Procedures are in place to ensure that HIQA is:

- Compliant with the Ethics in Public Office legislation
- Managing occasions where conflicts of interest may arise
- Ensuring that Board members understand their responsibilities and confirm in writing that understanding.

Chapter 5: Financial statements

The summarised financial information that is set out in this report does not constitute the Health Information and Quality Authority's accounts for the period ended 31 December 2016 as required by Section 35 (4) of the Health Act 2007.

The information here is derived from draft accounts because, at the time of publishing this Annual Report, these accounts have not been audited by the Comptroller and Auditor General and therefore cannot be finalised by HIQA.

Summarised income and expenditure account for HIQA year ended 31 December 2016:

Income	€'000
Department of Health and Children	11,550
Annual fees and registration fees	6,844
Other income	15
Total income	**18,409**

Expenditure	€'000
Professional fees	629
Staff costs	13,626
Travel and subsistence	805
Dissemination	107
Support and establishment	2,723
Total expenditure	**17,890**
Excess of income over expenditure	519
Opening reserves	322
Closing reserves	**841**

The full accounts for the period ended 31 December 2016, as well as the Comptroller and Auditor General's certificate for the accounts, will be published on www.hiqa.ie when the audited accounts are available.

Appendix 1: Board activity and attendance in 2016

According to the Health Act 2007, the Board shall hold such meetings as are necessary for the performance of its functions but in each year shall meet at least once every two months. The six scheduled meetings are listed below together with the attendance of each Board member.

Attendance of the six regular and statutorily required Board meetings 2016

Regular Board meetings 2016	20 Jan 2016	16 Mar 2016	25 May 2016	06 July 2016	21 Sept 2016	30 Nov 2016	Individual attendance record for regular Board meetings
Brian McEnery	YES	YES	YES	YES	YES	YES	6 out of 6
David Molony	YES	YES	YES	YES	YES	YES	6 out of 6
Sheila O'Malley	YES	YES	YES	YES	YES	YES	6 out of 6
Una Geary	YES	YES	YES	YES	YES	YES	6 out of 6
Anne Carrigy	NO	YES	NO	YES	YES	YES	4 out of 6
Bairbre O'Neill	YES	YES	YES	NO (mat leave)	NO (mat leave)	YES	4 out of 6
Mary Fennessy	YES	YES	YES	YES	YES	YES	6 out of 6
Judith Foley	NO	YES	YES	YES	NO	YES	4 out of 6
Stephen O'Flaherty	NO	YES	YES	YES	YES	YES	5 out of 6
Paula Kilbane	YES	YES	YES	YES	YES	NO	5 out of 6
Martin Sisk	YES	YES	YES	YES	YES	YES	6 out of 6
Molly Buckley	YES	YES	YES	YES	YES	YES	6 out of 6
Total attendance per Board meeting	9 out of 12	12 out of 12	11 out of 12	11 out of 12	10 out of 12	11 out of 12	

In addition to the statutory required number of Board meetings as laid out in the Health Act 2007, the Board of HIQA held two additional meetings to progress the functions of HIQA.

Attendance of the extraordinary Board meetings in 2016

Additional Board meetings 2015	27 April 2016	15 Dec 2016	Individual attendance record for additional Board meetings
Brian McEnery	YES	YES	2 OUT OF 2
David Molony	YES	YES	2 OUT OF 2
Sheila O'Malley	YES	YES	2 OUT OF 2
Una Geary	NO	YES	1 OUT OF 2
Anne Carrigy	YES	NO	1 OUT OF 2
Bairbre O'Neill	YES	NO	1 OUT OF 2
Mary Fennessy	YES	YES	2 OUT OF 2
Judith Foley	YES	NO	1 OUT OF 2
Stephen O'Flaherty	YES	YES	2 OUT OF 2
Paula Kilbane	NO	YES	1 OUT OF 2
Martin Sisk	YES	NO	1 OUT OF 2
Molly Buckley	NO	YES	1 OUT OF 2
Total attendance per Board meeting	9 out of 12	8 out of 12	

Appendix 2: **Strategy Map 2016 - 2018**

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

Appendix 3: Annual Report of the Health Information and Quality Authority required under the Protected Disclosures Act 2014

Section 22 of the Protected Disclosures Act 2014 requires the publication of a report each year relating to the number of protected disclosures made in the preceding year and any actions taken in response to such disclosures.

The Minister for Public Expenditure and Reform has, under section 7 (2) of the Protected Disclosures Act 2014, prescribed the Chief Executive of the Health Information and Quality Authority 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 health care sectors and social care services in the case of the private health care 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.

HIQA has a process for handling items of concern disclosed to it. In 2016, 1,334 items of concern were disclosed to HIQA .These disclosures were made by staff, people who use services, and the general public. 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.

One disclosure as defined by the Protected Disclosures Act 2014 was made by a number of staff to HIQA's Designated Recipient during 2016. The matter was referred to the Chief Executive Officer for investigation.

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

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